Dear Colleagues:

I cordially invite you to attend SOT’s 51st Annual Meeting, March 11–15, 2012, at the Moscone Convention Center in San Francisco, California. The SOT Annual Meeting is the forum to showcase toxicology’s novel discoveries. For the science of toxicology, this five-day event is the culmination of a year’s worth of achievements in research and education.

The Annual Meeting also affords attendees the opportunity to learn about the latest scientific achievements from myriad experts in the field of toxicology. The SOT thematic program provides participants with a unique opportunity to deepen their knowledge in topical areas and interact with leaders in their respective disciplines. Opportunities abound for members to meet other scientists they have never met and to network with friends and colleagues. The Annual Meeting also offers a chance to pause and pay tribute to those scientists who have distinguished themselves in their field of expertise and are the recipients of the Society’s most prestigious awards. Finally, SOT attendees can take advantage of the ToxExpo, which is the world's largest exposition of its kind, offering a comprehensive marketplace for product information and cutting-edge technology.

The SOT Annual Meeting is the premier event that the Society hosts every year to meet the needs of the entire toxicology community. More important, the Annual Meeting goes a long way toward fulfilling the SOT strategy of building for the future of toxicology, highlighting the significant scientific achievements, and broadening the awareness of these accomplishments and their potential impact. I urge you to join us for this event. Help us to make the SOT 51st Annual Meeting an event to remember.

Sincerely,

Jon C. Cook, PhD, ATS, DABT
2011–2012 SOT President
# Preliminary Program

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**Registration Express**

Register by January 27, 2012, with full payment and you’ll receive your name badge and tickets in the mail before the meeting.

*up-to-date information at [www.toxicology.org](http://www.toxicology.org)*
Dear Colleagues,

On behalf of the Scientific Program Committee and the Society of Toxicology, I would like to invite you to join us at our 51st Annual Meeting to be held from March 11–15, 2012, at the Moscone Convention Center in San Francisco, California.

As always, it is our goal to construct a program that reflects the best science as well as the breadth of interests among the SOT membership. We believe that the 2012 Symposia, Roundtables, Workshops, and other special sessions are timely and highly informative and span the entire spectrum of topics to meet the diversity of our membership.

We are anticipating a high level of member involvement in carrying forward the celebration of our most recent anniversary into the Society’s 51st meeting. At this time, the Society has confirmed the participation of Dr. Leroy Hood as the Plenary Opening Lecturer. Dr. Hood is a renowned scientist and pioneer in systems biology and medicine. While at Caltech, Dr. Hood, along with his colleagues, developed the DNA sequencer and synthesizer and the protein synthesizer and sequencer—four instruments that paved the way for the successful mapping of the human genome. These and many other contributions, including the concept of the 4Ps, has foreshadowed his receiving this year’s prestigious Russ Prize, awarded by the Academy of Engineering (2011).

In addition to regular programming, this year’s scientific program has been crafted to highlight five scientific themes of topical interest. These themes and their objectives are available online. The thematic approach continues to allow us the opportunity to gain depth of analysis and reflection on timely topics of relevance to toxicologists and position the meeting participants to effectively develop strategies for active involvement in these areas.

San Francisco is one of the top tourist destinations in the United States; famous for scenic beauty, cultural attractions, diverse communities, and world-class cuisine. San Francisco’s landmarks include the Golden Gate Bridge, cable cars, Fisherman’s Wharf, Alcatraz, Chinatown, Union Square, and North Beach.

Located at the edge of the city’s dynamic South of Market district, the Moscone Convention Center is just four blocks from Union Square, the City’s vibrant shopping district and the Powell Street cable car station to Nob Hill, Chinatown, and Fisherman’s Wharf. Bay Area Rapid Transit system (BART) and Muni Metro stations are within two blocks. Whatever your taste buds desire, there’s a creative culinary answer waiting for you on every corner.

In addition to the 2,700+ abstracts to be presented during the Annual Meeting, interested participants are welcome to submit late-breaking/grace period abstracts from December 12, 2011, through January 20, 2012. Abstracts accepted during this final submission phase will be programmed into poster sessions that will be presented on Thursday, March 15, and will not be included in the printed copy of The Toxicologist. Late-breaking/grace period abstracts should be submitted online at www.toxicology.org. We look forward to welcoming you to San Francisco, California.

Warmest Regards,

William Slikker Jr., PhD, ATS
SOT Vice President and Scientific Program Committee Chairperson, 2011–2012
Preliminary Program Content Reference

Maximize the value of your Annual Meeting attendance by familiarizing yourself with this reference guide for the Preliminary Program.

Preliminary Program Overview

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<td>Scientific Program Overview (pages 4–7)</td>
<td>This reference lists the Annual Meeting sessions and their scheduled dates and times, including Symposia, Workshops, and Roundtables, special lectures, and Platform and Poster Presentations. Please note that detailed information for many of these sessions will not be available until the final Program is published.</td>
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<tr>
<td>Thematic Session Index (pages 8–9)</td>
<td>Each of the Annual Meeting sessions highlighted within the five themes are listed. The list of sessions is preceded by a brief description of each theme. Throughout the Preliminary Program, each of the scientific sessions tracked within a theme is identified by a 🎉 symbol, including Continuing Education (CE) courses. For the 51st Annual Meeting the Society will highlight 54 Thematic Sessions and CE courses.</td>
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<td>Special Events (pages 38–50)</td>
<td>The Award pages announce your colleagues who have been awarded a prestigious SOT award in recognition of their accomplishments in the field of toxicology. The 51st Annual Meeting Recognition and Social Events details are provided. The Regional Chapter, Special Interest Group, and Specialty Section reception schedules are included in this section. The Student Events listing including the Student/Postdoc Scholar Mixer, and In Vitro Toxicology Lecture and Luncheon are listed. This section also highlights several scientific and career development sessions of particular interest to the SOT Student and Postdoctoral membership. A special highlight in this section includes the Educational Outreach initiatives undertaken each year at the Annual Meeting, including the Undergraduate Education Program.</td>
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<td>Continuing Education Courses (pages 52–60)</td>
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<td>Featured Sessions (pages 63–66)</td>
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<td>Scientific Sessions (pages 69–111)</td>
<td>The Preliminary Program layout is similar to that of the final Program. Specifically, this section lists the scientific sessions in date, time, and alphabetical order beginning with Symposia, Workshop, Roundtable, Informational, Education-Career Development, and finally the Regional Interest sessions.</td>
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<td>Exhibits (pages 113–120)</td>
<td>ToxExpo is the profession’s largest trade show and best resource for the latest information in technology, equipment, and services. This section contains the current list of exhibiting companies and Exhibitor Hosted sessions.</td>
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Scientific Session Types

**Education-Career Development Sessions (80 minutes)**—Sessions that provide tools and resources to toxicologists that will enhance their professional and scientific development (page 108).

**Exhibitor Hosted Sessions (60 minutes)**—Informative sessions developed by an exhibiting company (page 116).

**Featured Sessions (50–60 minutes)**—Keynote and other special lectures (page 63).

**Informational Sessions (80 minutes)**—These present the latest science in toxicology or other learning opportunities that address the professional interests and needs of toxicologists in the areas of career development, general information, and planned scientific activities and are not based on the outcome of scientific research (page 104).

**Platform Sessions (165 minutes)**—Oral presentations that cover new areas, concepts, or data (see details in the final Program).

**Poster Sessions (180–210* minutes)**—Topics specific presentations that cover new areas, concepts, or data (see details in the final Program).

**Regional Interest Sessions (165 minutes)**—Central topics of relevance that describe public health and/or ecological problems related to the region (page 110).

**Roundtable Sessions (80 minutes)**—These provide an overview of controversial subjects, followed by questions and discussion (page 100).

**Symposium Sessions (165 minutes)**—Cutting-edge science, emphasizing new areas, concepts, and data (page 69).

**Thematic Sessions and CE Target Areas (75–225 minutes)**—Timely topics of relevance to toxicology in informal interactive presentations with ample time for discussion (page 86).

*Poster sessions that occur on Monday morning will be programmed for 180 minutes. The remaining poster sessions, including those on Monday afternoon, will be programmed for 210 minutes.*

Use the new mobile applications or the online Itinerary Planner to plan your schedule to make the most of your time at the Annual Meeting (available in January). See pages 24 and 35 for more details.
**Scientific Program Overview**

### Sunday, March 11

#### Drug Metabolism

**Xenobiotic metabolism** (e.g., metabolic enzymes and drug transporters) is central to chemical disposition, and this field has made considerable advances in recent years. The application of advanced *in silico* technologies to more accurately predict compound fate, the incorporation of systems biology and ‘omics approaches to understand the impact of chemicals in an organism, and the identification of new gene product families that contribute to drug disposition may be presented.

**Noncoding RNAs and Their Role in Biology and Toxicology**

Small, medium, and long noncoding RNAs have been identified in many species including humans. Their functions are still not fully understood, but they are becoming increasingly recognized as important factors in physiology, xenobiotic sensitivity, and disease. This target area encourages presentations that will provide in-depth instruction on noncoding RNAs, including what they are and how they function, their effects on xenobiotic sensitivity and disposition, their importance in disease risks and phenotypes, and their relevance to toxicological research.

#### 7:00 AM–7:45 AM

**SUNRISE CONTINUING EDUCATION COURSE**

1. Alternative *In Vitro* Toxicology Testing for the 21st Century

#### 8:15 AM–12:00 Noon

**MORNING CONTINUING EDUCATION COURSES**

2. Applications of Biomarkers in the Assessment of Health and Disease
3. Basic Embryology and Developmental Toxicity Testing
5. Frontiers and Applications in Predictive Toxicology: *In Silico* Methods for Risk Assessment, Toxicology, and Metabolism
6. Overview and Application of the WHO/IPCS Harmonized Guidance for Immunotoxicity Risk Assessment for Chemicals
7. Stem Cells in Toxicology

#### 1:15 PM–5:00 PM

**AFTERNOON CONTINUING EDUCATION COURSES**

8. Concepts of Green Chemistry and Its Role in the Identification and Design of Safer Chemicals and Products
9. Innate Immunity and Its Relevance to Toxicology
10. MicroRNAs in Biology and Toxicology
11. Regulatory Sciences: Preclinical Drug Development from Small Molecules to Biologics
12. Specialized Techniques for Dose-Response Assessment and Risk Assessment of Chemical Mixtures
13. The Use of Physiologically-Based Pharmacokinetic Modeling to Inform Early Life Sensitivity to Chemical Toxicity

#### THEMATIC APPROACH

**Aberrant Gene Expression in Toxicity and Disease—Epigenetics and microRNAs**

Over the past decade, considerable effort has been expended in demonstrating that gene expression is altered in disease states and following exposure to pharmaceuticals and environmental agents. In many cases, the endpoint of interest has been mRNA levels; however, to more fully understand the etiology of disease, especially the timing and the role of toxicity in pathogenesis, it may be important to investigate the mechanisms that govern mRNA expression. Increasing evidence suggests that microRNAs may play a significant role in determining expression patterns, frequently in a highly temporal and tissue-dependent manner. Furthermore, epigenetic variables such as DNA methylation and histone modifications can influence gene expression in an inheritable fashion.

**Characterizing Toxic Modes of Action and Pathways to Toxicity**

Toxicants induce their effects via interactions with biological targets, triggering a cascade of key events that culminate in adverse health conditions. In keeping with contemporary, post-genome concepts, identification and integration of mechanisms of chemically-induced biological activity to develop more predictive models of *in vivo* biological response are being accomplished by using *in vitro* biochemical and cell-based assays.

**Clinical Toxicology from Bedside to the Bench and Back**

The overarching aim of clinical toxicology is to provide direction and insight from the clinical setting to drive discoveries in the research laboratory that will have meaningful consequences for the individual patient. Insights from the emergency department or the intensive care unit, for the acutely ill patient, as well as other clinical situations such as poison centers and occupational and environmental medical toxicology clinics, can provide direction for additional and complementary fundamental and translational studies.

**Influence of Global Climate Change on Environmental Health Issues**

It is expected that climate change will have potentially adverse effects on human health through several mechanisms such as extreme weather events, water level rises, malnutrition increase, ecosystem services impact, and spread of disease. For toxicologists, it will be important to study and predict the nature of adverse effects and the types of pollutant that will have their health effects altered by climate change and the magnitude of those alterations in order to minimize adverse public health effects. Temperature increases may synergize air pollution-mediated increases in deaths due to respiratory and cardiovascular effects. The effect of temperature increases on susceptibility to air and water pollution is a poorly understood area of concern, as are the impacts on ecosystems.

**Regulatory Science: Bridging the Gap between Discovery and Product Availability**

Recent breakthroughs in science and technology have the potential to transform our ability to prevent, diagnose, and treat disease. These developments will result in moving treatment strategies towards approaches that are tailored or personalized to individual patients, thus maximizing the benefit of treatments while decreasing their safety risks. Green chemistry initiatives are promoting the development of sound scientific screening strategies to support the design of better performing chemical products and manufacturing processes that minimize the use and generation of hazardous substances and pose lower risks to humans and the environment. Together, these approaches show how regulatory science is providing the pathway for better chemistries and products by developing new tools, standards, and approaches to assess safety, efficacy, and performance.
Monday, March 12
8:00 AM–9:00 AM
PLENARY OPENING LECTURE
Systems Medicine, Systems Toxicology, Transformational Technologies and the Revolution from Reactive to Proactive (P4) Medicine
Lecturer: Leroy Hood, Institute of Systems Biology

9:15 AM–12:00 Noon
SYMPOSIUM SESSIONS
• Dietary Supplement Adulteration and Impact on Human Health
• DNA Damage Responses and Repair
• The Thick and Thin of Nuclear Receptors and Nrf2 in Diabetes and Obesity
• Toxicological Considerations of Epigenetic Targets in Product Development

WORKSHOP SESSIONS
• Alternative Approaches to the Safety Assessment of Natural Ingredients and Extracts in Cosmetics
• High-Throughput In Vitro Toxicity Testing: A Midcourse Assessment of Predictive Accuracy for In Vivo Endpoints and Use in Decision-Making
• The Epididymis—The Forgotten Target of Toxicants
• Therapeutic Immunomodulation and Cancer Risk: Science, Risk Assessment, and Risk Communication

PLATFORM SESSIONS
• Biological Modeling: Addressing Disease States, Defining Age Differences, and Evaluating Uncertainty
• Hypersensitivity Methods
• Mechanisms of Carcinogenesis
• Nanotoxicology: Nanogold or Nanosilver

9:30 AM–12:30 PM
POSTER SESSIONS
• Cardiovascular Toxicity I
• Data Integration and Decision Support Systems
• Epidemiology: Assessments and Approaches
• Fukushima Radiation Toxicity and Global Toxicology Issues
• Inhalants and Cardiopulmonary: Particulates and Chemical Agents
• Liver
• Medical Devices
• Nanotoxicology: Environmental Toxicology, Zebrafish, and Nanoparticles
• Receptors and Toxicity
• Risk Assessment: Case-specific Characterizations
• Risk Assessment: New Applications and Analyses
• Safety Evaluation: Non-pharmaceuticals
• Toxicity of Mixtures

12:00 PM–1:30 PM
INFORMATIONAL SESSIONS
• Global Health and Environmental Impacts of E-Waste Recycling
• NIEHS Centers for Nanotechnology Health Implications Research: Building the Scientific Foundation for Evaluating Public Health Impacts of Engineered Nanomaterials

12:30 PM–1:20 PM
MERIT AWARD LECTURE
Lecturer: Curtis D. Klaassen, University of Kansas Medical Center

1:00 PM–4:30 PM
POSTER SESSIONS
• Alternatives to Mammalian Models II
• Biological Modeling: Predictive PBPK Dosimetry Structures and Pharmacokinetic Data
• Biomarkers of Organ Damage by Drugs and Xenobiotics
• Children’s Health and Juvenile Toxicity
• Computational Toxicology: Sequences, Systems, and Strategies
• Developmental Basis of Adult Disease
• DNA Damage and Repair
• Hypersensitivity and Autoimmunity
• Inflammation: Biochemical/Molecular Mechanisms
• Inflammation in Disease
• Liver and Model Systems
• Nanotoxicology: Nanoparticles I
• Pharmaceuticals
• Skin Toxicology

2:00 PM–4:45 PM
SYMPOSIUM SESSIONS
• 21st Century Validation Strategies—One Size No Longer Fits All
• Breast Cancer As a Multifactorial Disease: Interaction of Genetics, Life Stage, and the Environment
• Evaluation of Ocular Safety in the Development of New Drugs
• Molecular Basis for Prevention of Cardiotoxicity
• Nanoparticles for Drug Delivery: Interactions with the Immune System
• Toxic Cell Death: Signaling Pathways, Cross-Talk, and High-Throughput Analysis

WORKSHOP SESSION
• Concepts Critical to the Next Generation of Human Health and Ecological Risk Assessment

REGIONAL INTEREST SESSION
• Bridging the Green Chemistry Gap between Product Discovery and Availability

PLATFORM SESSIONS
• Ecotoxicology and Sentinel Animals
• Exposure Assessment: Biological and Probabilistic Approaches to Monitoring, Modeling, and Predictions
• Inhalants and Cardiopulmonary: Pollutants and Irritants

4:30 PM–5:50 PM
SOT/EUROTOX DEBATE
Comparative Hazards: Chemicals in the Environment Are the Largest Risk to Human Health

Tuesday, March 13
7:00 AM–7:50 AM
LEADING EDGE IN BASIC SCIENCE AWARD LECTURE
Lecturer: Myung-Haing Cho, Seoul National University

8:00 AM–9:00 AM
KEYNOTE MEDICAL RESEARCH COUNCIL (MRC) LECTURE
Role of microRNAs in Control of Gene Expression in Human Physiology and Pathology
Lecturer: Witold Filipowicz, Friedrich Miescher Institute for Biomedical Research

9:00 AM–11:45 AM
SYMPOSIUM SESSIONS
• An Intelligent Reproductive and Developmental Testing Paradigm for the 21st Century
• Cross-Species Analysis of Toxicogenomics Data: Approaches for Assessing Differences in Sensitivity and Conservation of Mode of Action
• Development of Biosimilar Products: Overview of Standards and Regulations
• The Role of Danger Signals in the Development of Chemical Sensitization by Environmental and Occupational Agents

WORKSHOP SESSIONS
• Assessing the Bioavailability and Risk from Metal-Contaminated Soils and Dusts
• State of the Science and the Future for the Predictive Power of In Vitro and In Vivo Models for Nanomaterials Toxicity Testing
• Sufficient Similarity of Whole Representative Mixtures or a Relative Potency Factor Approach: Polycyclic Aromatic Hydrocarbons As a Case Study

REGIONAL INTEREST SESSION
• What’s the Buzz: Bee Health and California’s Agricultural Industry

PLATFORM SESSIONS
• Acetaminophen Toxicity: Mechanistic and Translational Aspects
• Cardiovascular Toxicity of Nanoparticles
• Emerging Methodologies for Genotoxicity Assessment
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<td>- Improving Chemical Safety Assessment through Harmonization: Why, How, and When?</td>
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<td>- Nonclinical and Clinical Applications of Translational Organ-Based Imaging</td>
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<td>- Novel Topics in Environmental Polycyclic Aromatic Hydrocarbon Metabolism Leading to Carcinogenesis</td>
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<td>- Nonclinical Safety Assessment of Dual-Targeting Biotherapeutics</td>
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<td>- The Allergenicity and Immunomodulatory Effect of Food Substances</td>
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<td>- The Toxicological Impact of Metals, Crude Oil, and Chemical Dispersants from the Gulf of Mexico Oil Crisis on Human and Wildlife Health</td>
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<td><strong>4:30 PM–5:50 PM</strong></td>
<td><strong>WORKSHOP SESSIONS</strong></td>
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<td>- Caught in the Act: Free Radical Detection and Implications in Pathways to Toxicity</td>
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<td>- Chelation Therapy: A Focus on the Risks and Benefits</td>
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<td>- Cooperative Epidemiology and Toxicology Research: HEI’s National Particle Component Toxicity (NPACT) Initiative</td>
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<td><strong>4:30 PM–5:50 PM</strong></td>
<td><strong>PLATFORM SESSIONS</strong></td>
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<td>- Progress in Developing New Biomarkers of Drug-Induced Liver Injury (DILI): What You Don’t Know Can Hurt You</td>
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<td>- Biomarkers: Signature Applications and Network Analyses</td>
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<td>- Chemical and Biological Weapons: Agents and Countermeasures</td>
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<td>- Nanotoxicology: Carbon Nanotubes and Nanofibers</td>
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**SOT’s 51st Annual Meeting**
<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
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<tbody>
<tr>
<td>9:30 AM–4:30 PM</td>
<td>RESEARCH FUNDING SESSION &lt;ul&gt;&lt;li&gt;Research Funding Resource Room&lt;/li&gt;&lt;/ul&gt;</td>
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<tr>
<td>12:00 Noon–1:20 PM</td>
<td>ROUNDTABLE SESSIONS  &lt;ul&gt;&lt;li&gt;Scientific, Regulatory, and Public Perspectives on the Credibility and Use of Alternative Toxicological Test Methods in a Legislative Framework&lt;/li&gt;&lt;li&gt;The Future of Toxicology Education: Outcomes of the Toxicology Educational Summit&lt;/li&gt;&lt;/ul&gt;</td>
</tr>
<tr>
<td>4:30 PM–5:50 PM</td>
<td>INFORMATIONAL SESSIONS  &lt;ul&gt;&lt;li&gt;Evolution and Implementation of Combined Chemical Exposure Methods: International Perspectives&lt;/li&gt;&lt;li&gt;Proposition 65: Twenty-Five Years of Implementing California’s Unique and Far-Reaching Law Regulating Organic and Metallic Carcinogens and Developmental/Reproductive Toxins&lt;/li&gt;&lt;/ul&gt;</td>
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Thursday, March 15

7:30 AM–8:50 AM

ISSUES SESSION

Building for the Future: Strategic Initiatives for the SOT Endowment Fund

8:30 AM–12:00 noon

POSTER SESSION

- Carcinogenesis

9:00 AM–11:45 AM

SYMPOSIUM SESSIONS  
- Advances in Bridging Nonclinical Cardiovascular Data to the Clinic
- Emerging Evidence for Novel Noncholinergic Mechanisms of Organophosphate-Induced Neurotoxicity
- Emerging Mechanistic Targets in Lung Injury Induced by Combustion-Generated Particles
- Realizing the Vision of 21st Century Toxicity Testing: Genetic Approaches to Pathway Analysis

WORKSHOP SESSIONS

- Challenges and Opportunities in Evaluating Protein Allergenicity across Biotechnology Industries
- Chemical Standardization of Botanical Medicines for Safe and Effective Use As Therapeutic Agents

1:00 PM–2:00 PM

TOXEXPO TIME

- Alternatives to Mammalian Models in Skin Sensitization
- Computational Toxicology: Predicting Hepatotoxicity
- Inhalants and Cardiopulmonary: Particulates
- Risk Analysis: New Derivations and Updated Debates
2012 SESSIONS:
THEMATIC APPROACH

Aberrant Gene Expression in Toxicity and Disease—Epigenetics and microRNAs

Over the past decade, considerable effort has been expended in demonstrating that gene expression is altered in disease states and following exposure to pharmaceuticals and environmental agents. In many cases, the endpoint of interest has been mRNA levels; however, to more fully understand the etiology of disease, especially the timing and the role of toxicity in pathogenesis, it may be important to investigate the mechanisms that govern mRNA expression. Increasing evidence suggests that microRNAs may play a significant role in determining expression patterns, frequently in a highly temporal- and tissue-dependent manner. Accordingly, microRNAs are also being studied as highly specific biomarkers of target organ injury. Epigenetic variables such as DNA methylation and histone modifications can influence gene expression in an inheritable fashion. Furthermore, there is growing interest in discovering chemical/biological modulators of epigenetic targets for disease intervention, yet little is currently known regarding the potential toxicological consequences of such modulation.

Characterizing Toxic Modes of Action and Pathways to Toxicity

Toxicants induce their effects via interactions with biological targets, triggering a cascade of key events that culminate in adverse health conditions. Knowledge of the temporal- and dose-dependency determinants of the key events defined through laboratory animal and in vitro studies, coupled in context with consideration of their relevance to the human mode of action and target context, will improve the accuracy and scientific basis for risk and safety assessments. In keeping with contemporary, post-genome concepts, identification and integration of mechanisms of chemically induced biological activity to develop more predictive models of in vivo biological response are being accomplished by using in vitro biochemical- and cell-based assays. Pathways of toxicity are being identified with the use of results from these medium- and high-throughput assays integrated with in silico techniques for data extraction, biologically-based dose response, and virtual tissue modeling.

The Scientific Program Committee has developed a slate of timely and highly informative Symposium Sessions, Workshop Sessions, Roundtable Sessions, and other special sessions that span the spectrum of topics of interest to our diverse membership.

The 2012 scientific themes listed here illustrate the core contributions toxicology makes to these areas, and the sessions that will be highlighted within these themes are indicated.

- Applications of Biomarkers in the Assessment of Health and Disease—Continuing Education Course (AM02)
- Circulating microRNAs: A New Class of Biomarkers for Tissue-Specific Toxicity—Symposium Session
- Epigenetic and miRNA Regulations in Carcinogenesis: Toxicological Implications—Symposium Session
- Mechanisms of Carcinogenesis—Platform Session
- MicroRNAs in Biology and Toxicology—Continuing Education Course (PM10)
- Toxicological Considerations of Epigenetic Targets in Product Development—Symposium Session
- New Visions in Toxicology: Lysosomes—Roles in Disease, Toxicity, and Drug Development—Symposium Session
- Novel Topics in Environmental Polycyclic Aromatic Hydrocarbon Metabolism Leading to Carcinogenesis—Workshop Session
- Nrf2—Poster Session
- Oxidative Injury—Poster Session
- Pharmaceutical Safety Assessment: Methods and Mechanisms—Poster Session
- Pharmaceutical Safety Assessment: Novel Therapeutics and Preclinical Safety Assessment—Poster Session
- Realizing the Vision of 21st Century Toxicity Testing: Genetic Approaches to Pathway Analysis—Symposium Session
- Receptors and Toxicity—Poster Session
- State of the Science and the Future for the Predictive Power of In Vitro and In Vivo Models for Nanomaterials Toxicity Testing—Workshop Session
- The Epididymis—The Forgotten Target of Toxicants—Workshop Session
- The Thick and Thin of Nuclear Receptors and Nrf2 in Diabetes and Obesity—Symposium Session
- Toxic Cell Death: Signaling Pathways, Cross-Talk, and High-Throughput Analysis—Symposium Session

2012 SESSIONS:
THEMATIC APPROACH

The Scientific Program Committee has developed a slate of timely and highly informative Symposium Sessions, Workshop Sessions, Roundtable Sessions, and other special sessions that span the spectrum of topics of interest to our diverse membership.

- Aberrant Gene Expression in Toxicity and Disease—Epigenetics and microRNAs
- Characterizing Toxic Modes of Action and Pathways to Toxicity

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Clinical Toxicology from Bedside to the Bench and Back

The overarching aim of clinical toxicology is to provide direction and insight from the clinical setting to drive discoveries in the research laboratory that will have meaningful consequences for the individual patient. Insights from the emergency department or the intensive care unit, for the acutely ill patient, as well as other clinical situations such as poison centers and occupational and environmental medical toxicology clinics, can provide direction for additional and complementary fundamental and translational studies. By working together around a set of clinically relevant issues it will be possible to demonstrate the deep and important connection between clinical care and fundamental research, and emphasize the potential for improved clinical trial design and individual health outcome.

• Advances in Bridging Nonclinical Cardiovascular Data to the Clinic—Symposium Session
• Chelation Therapy: A Focus on the Risks and Benefits—Workshop Session
• Dietary Supplement Adulteration and Impact on Human Health—Symposium Session
• Muscle Toxicity—Current Challenges in Translatable Biomarkers—Workshop Session
• Nonclinical and Clinical Applications of Translational Organ-Based Imaging—Workshop Session
• Progress in Developing New Biomarkers of Drug-Induced Liver Injury (DILI): What You Don’t Know Can Hurt You—Workshop Session

Influence of Global Climate Change on Environmental Health Issues

It is expected that climate change will have potentially adverse effects on human health through several mechanisms such as extreme weather events, water level rises, malnutrition increase, ecosystem services impact, and spread of disease. For toxicologists, it will be important to study and predict the nature of adverse effects and the types of pollutant, that will have their health effects altered by climate change and the magnitude of those alterations in order to minimize adverse public health effects. Droughts and floods can have effects through mobilization of carcinogens from agricultural soils and drinking water. Temperature increases may synergize air pollution, mediated increases in deaths due to respiratory and cardiovascular effects. The effect of temperature increases on susceptibility to air and water pollution is a poorly understood area of concern, as are the impacts on ecosystems. Ecosystem services and other ecological evaluations may serve to identify important pathways.

• Emerging Mechanistic Targets in Lung Injury Induced by Combustion-Generated Particles—Symposium Session

Regulatory Science: Bridging the Gap between Discovery and Product Availability

Recent breakthroughs in science and technology—ranging from sequencing of the human genome to advances in the application of nanotechnology to new medical products—have the potential to transform our ability to prevent, diagnose, and treat disease. These developments will result in moving treatment strategies toward approaches that are tailored or personalized to individual patients, thus maximizing the benefit of treatments while decreasing their safety risks. Similarly, advances in research and information technologies are enabling us to more efficiently identify microbial pathogens, track food contamination outbreaks, and determine where foods and other products are produced or manufactured, how they are transported, where they go and, who uses them. These tools also can play an important role in protecting human health by enabling more comprehensive countermeasure strategies, especially in the face of emerging pandemics or chemical and biological threats. Green chemistry initiatives are promoting the development of tools to support the design of better performing chemical products and manufacturing processes that minimize the use and generation of hazardous substances and pose lower risks to humans and the environment. Together, these approaches show how regulatory science is providing the pathway for better chemistries and products by developing new tools, standards, and approaches to assess safety, efficacy, and performance.

• 21st Century Validation Strategies—One Size No Longer Fits All—Symposium Session
• Advancing Food Safety in a Global Marketplace—Workshop Session
• Bridging the Green Chemistry Gap between Product Discovery and Availability—Regional Interest Session
• Challenges and Opportunities in Evaluating Protein Allergenicity across Biotechnology Industries—Workshop Session
• Concepts Critical to the Next Generation of Human Health and Ecological Risk Assessment—Workshop Session
• Concepts of Green Chemistry and Its Role in the Identification and Design of Safer Chemicals and Products—Continuing Education Course (PM08)
• Development of Biosimilar Products: Overview of Standards and Regulations—Symposium Session
• Evolving the EPA Endocrine Disruptor Screening Program: From Using High-Throughput Screening Assays for Prioritization to Reducing Reliance on Whole-Animal Tests—Roundtable Session
• Frontiers and Applications in Predictive Toxicology: In Silico Methods for Risk Assessment, Toxicology, and Metabolism—Continuing Education Course (AM05)
• High-Throughput In Vitro Toxicity Testing: A Midcourse Assessment of Predictive Accuracy for In Vivo Endpoints and Use in Decision-Making—Workshop Session
• Improving Chemical Safety Assessment through Harmonization: Why, How, and When?—Roundtable Session
• Overview and Application of the WHO-IPCS Harmonized Guidance for Immunotoxicity Risk Assessment for Chemicals—Continuing Education Course (AM06)
• Regulatory Sciences: Preclinical Drug Development from Small Molecules to Biologics—Continuing Education Course (PM11)
• Scientific, Regulatory, and Public Perspectives on the Credibility and Use of Alternative Toxicological Test Methods in a Legislative Framework—Roundtable Session
### SOT Affiliates

<table>
<thead>
<tr>
<th>Abbott Laboratories</th>
<th>Abbott Park, Illinois</th>
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<tr>
<td>Absorption Systems</td>
<td>Exton, Pennsylvania</td>
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<td>Alcon Research Ltd.</td>
<td>Fort Worth, Texas</td>
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<td>American Chemistry Council</td>
<td>Arlington, Virginia</td>
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<td>American Petroleum Institute</td>
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<td>Ani Lytics, Inc.</td>
<td>Gaithersburg, Maryland</td>
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<td>AstraZeneca R&amp;D</td>
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<td>The DuPont Haskell Global Centers for Health and Environmental Sciences</td>
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<td>Eli Lilly and Company</td>
<td>Indianapolis, Indiana</td>
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<td>GlaxoSmithKline</td>
<td>King of Prussia, Pennsylvania</td>
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<td>Research Triangle Park, North Carolina</td>
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<td>Morristown, New Jersey</td>
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<td>Syngenta Crop Protection, Inc.</td>
<td>Greensboro, North Carolina</td>
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<td>Toxicology Excellence for Risk Assessment (TERA)</td>
<td>Cincinnati, Ohio</td>
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<td>WIL Research Company, Inc.</td>
<td>Ashland, Ohio</td>
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If your organization is interested in participating in the SOT Affiliate program, please contact Marcia Lawson at marcia@toxicology.org.
Your Invitation to Attend

The Society of Toxicology (SOT) 51st Annual Meeting is the largest toxicology meeting and exhibition in the world, with an expected attendance of more than 7,500 scientists from academia, government, and industry from various countries around the globe. From the Plenary Opening and featured lectures to the wide range of scientific sessions and Continuing Education courses, the Annual Meeting offers an unparalleled depth of analysis on relevant toxicological issues. From basic to advanced topical issues, the thematic approach provides each attendee an opportunity to learn about emerging fields. Whether you are speaking in or chairing a session, honoring a colleague as the recipient of an SOT award, or collaborating with your peers at an SOT event, this meeting has something for every attendee. Plenary speakers include Dr. Leroy Hood (Institute for Systems Biology, Seattle, Washington) and Witold Filipowicz (Friedrich Miescher Institute for Biomedical Research, Basel, Switzerland).

You will want to attend because...

Cutting-Edge Science and Innovative Perspectives: The SOT Annual Meeting provides the most complete and in-depth coverage of toxicology. The SOT Scientific Program Committee is charged with creating a thought-provoking and dynamic program that captures all the latest scientific advances that have occurred during the past 12 months. The Committee reviews more than 2,700 abstracts to come up with a final program that is highly relevant, multidimensional, and comprehensive in scope.

Depth of Analysis: Five scientific themes will allow attendees to gain depth of analysis:

- Aberrant Gene Expression in Toxicity and Disease—Epigenetics and microRNAs
- Characterizing Toxic Modes of Action and Pathways to Toxicity
- Influence of Global Climate Change on Environmental Health Issues
- Clinical Toxicology from Bedside to the Bench and Back
- Regulatory Science: Bridging the Gap between Discovery and Product Availability

The Continuing Education Courses highlight two additional target areas:

- Drug Metabolism
- Noncoding RNAs and Their Role in Biology and Toxicology

Untold Networking Opportunities: The five days that attendees participate in the SOT Annual Meeting offer a wide range of networking opportunities for everyone. In a congenial and welcoming atmosphere, Annual Meeting attendees can join in deliberations about the latest scientific research, meet old friends during the receptions and luncheons, make new friends while visiting the ToxExpo, or attend one of the many scientific sessions throughout the week.

ToxExpo—A Great Opportunity for Exhibitors

We’ve Got the Numbers You Want

We are expecting to attract more than 7,500 scientists and industry professionals to attend SOT’s 51st Annual Meeting and ToxExpo. What better opportunity to...

- meet face-to-face,
- build relationships with new prospects, and
- network with other exhibiting companies.

New Faces/New Leads Every Year

Research shows that 55% of the professional toxicologists who will attend the 2012 Annual Meeting and ToxExpo did not attend the 2011 Meeting in Washington, DC.

Online Marketplace at ToxExpo.com

ToxExpo exhibitors are listed online year around to increase your visibility and exposure to your target audience. It’s a rich resource for all the services and products toxicologists need throughout the year.

ToxExpo Time!

In addition to the standard Exhibit Hall hours and poster presentation times, one hour of dedicated ToxExpo Time has been allotted in the scientific program for attendees to visit with exhibitors. ToxExpo Time will take place on Wednesday, March 14, from 1:00 pm–2:00 pm.

For more information on exhibiting at the largest toxicology trade show in the world, please visit ToxExpo.com, or contact Liz Kasabian at 703.438.3115 ext. 1454, email at sot_exhibits@toxicology.org.
SOT Annual Meeting

A Global Audience: The Annual Meeting and ToxExpo attract not only a broad attendance from the United States, but also from the global community, with over 20% international attendees. Scientists from as far away as Australia, China, and Egypt come to the United States to participate in this event, exchanging lessons learned and sharing scientific findings and novel approaches with other toxicologists.

Value: The SOT Annual Meeting is cost-effective, with low registration fees, minimal travel to San Francisco, California, for many, inexpensive high-quality Continuing Education Courses, and exposure to the very latest advances in science. International attendees benefit from the good exchange rate.

Why Attend ToxExpo?
ToxExpo is the profession’s largest trade show of its kind anywhere. Attendees and exhibitors from around the globe gather to exchange ideas and debut cutting-edge products, services, and technologies. Toxicologists and industry professionals have the unparalleled opportunity to gain first-hand knowledge on the latest advances from more than 360 exhibitors.

The following are the exhibit hours for the 2012 ToxExpo:

- Monday .......................... 9:00 AM–4:30 PM
- Tuesday ............................. 8:30 AM–4:30 PM
- Wednesday ...................... 8:30 AM–4:30 PM

ToxExpo Time!—In addition to the standard Exhibit Hall hours and poster presentation times, one hour of dedicated ToxExpo Time has been allotted in the scientific program for attendees to visit with exhibitors. ToxExpo Time will take place on Wednesday, March 14, from 1:00 pm–2:00 pm.

ToxExpo is available all year. Visit www.ToxExpo.com for the latest in toxicology-related products and services. The website offers access 24/7, 365 days per year, to resources for toxicologists worldwide. ToxExpo is a valuable tool for the policy-maker, scientist, student, or anyone who is looking for the best that toxicology has to offer.

An Invitation to International Attendees
The Society of Toxicology invites scientists from around the world to attend its 51st Annual Meeting, March 11–15, 2012. Please note that individual invitations are not required for attendance at meetings of the Society of Toxicology. Since the meetings are open scientific events, SOT invites all interested persons to attend.

Visa Information
If your travels require a visa, the United States is advising visa applicants to apply at least three to four months in advance of their travel date. To increase security for citizens and visitors, the United States has updated its policies for visas. We request that you contact the United States Consulate/Embassy and Currency Exchange in your own country regarding documentation and necessary information for your visit to the United States.

If for visa purposes you need a formal invitation letter, you may request an invitation by sending your name, address, and fax number to the SOT Registration Department. If you have been accepted to make a presentation at the meeting, please include the name and date of your presentation. You will need to make your own hotel reservations and register for the meeting. If you need assistance, please contact the SOT Registration Department at tel: 703.438.3115, fax: 703.438.3113, or email: sothq@toxicology.org.

Here are some sources of information to help you obtain a visa:

- http://travel.state.gov/visa
A website designed with you in mind about current visa policies and procedures.
Accessibility for Persons with Disabilities

The Moscone Convention Center and most of the SOT hotels are accessible to persons with disabilities. If you require special services, please mark the appropriate box on the Annual Meeting Registration Form.

LSA Interpretation Services
800.305.9673
www.lsaweb.com

Language Services Associates is a nationwide full-service firm providing translators and interpreters in 180 languages.

Wheelchair and Scooter Rentals:
ITC Medical
415.387.7100

Mobility Equipment Inc.
415.564.2098

Scooter Rentals:
Scoot Around
888.441.7575
www.scootaround.com

If you require more information about accessibility, please contact Heidi Prange at SOT Headquarters: 703.438.3115 ext. 1424.

Attire

The official attire for the Annual Meeting is business casual. No coat or tie is required! We encourage you to bring comfortable clothing and shoes. Because meeting rooms may seem cold, please bring a sweater or jacket and/or dress in layers.

Badge

Annual Meeting attendees who register by January 27, 2012, will receive badges and registration materials in the mail. Attendees who already have their 2012 Annual Meeting badges do not need to stand in the registration line. If you have registered by the meeting date and have NOT received your badge by mail, or need a replacement badge, go to the “BADGE PICK UP ONLY” registration counter to pick up your badge. You will be asked to show a photo ID.

If you have not registered for the meeting before you arrive in San Francisco, please complete the on-site Registration Form found at the kiosks in the registration area and proceed to the appropriate registration line.

All attendees should stop by the registration area to pick up their registration materials (page 30).

Child Care Services

Child care services will not be provided during the Annual Meeting. Arrangements may be made by contacting the concierge desk at your hotel. To ensure safety, children are not permitted in session rooms, the Exhibit Hall, or the poster area.

Climate

San Francisco has a mild climate. The typical temperature range for March is an average low of 51°F/10°C and an average high of 64°F/17°C. For an up-to-date, detailed weather forecast, visit the National Weather Service Forecast Office at www.wrh.noaa.gov/mtr.
General Information

First Aid and Security

If an emergency should occur while at the Moscone Convention Center, proceed directly to the nearest house phone, located throughout the facility and in most meeting rooms, and dial 511 for security. You will be connected directly to the 24-hour manned security department at the Convention Center. From your cell phone, dial 415.974.4021, which will connect directly to security.

A First Aid room will be located near Room 106 and is accessible from the corridor, inside the hall, and from the loading dock.

The First Aid Administrator will be on duty:

- Sunday ..................7:00 AM–8:00 PM
- Monday .................7:00 AM–6:00 PM
- Tuesday ..................7:00 AM–6:00 PM
- Wednesday ...........7:00 AM–6:00 PM
- Thursday ...............7:00 AM–5:00 PM

Please note that in accordance with regulations, the First Aid Administrator is not permitted to dispense any medication.

Global Gallery of Toxicology

Societies of toxicology from around the world are invited to participate in the “Global Gallery of Toxicology.” Now in its second year, posters showcasing the formation, key accomplishments, strategic initiatives, and current and future activities of these sister societies will be prominently displayed during the meeting. SOT and these societies aim to increase the reliance of international decision makers on the science of toxicology to advance human health and disease prevention. For more information, please contact Renee Maisel at renee@toxicology.org by January 5, 2012.

Green in San Francisco

Named one of the top 10 “green cities” in the United States by The Green Guide, and the second greenest United States city according to Popular Science, San Francisco was cited as a city that puts transit first and dedicates more than 17 percent of its 47 square miles to parks and open space.

The Moscone Convention Center has been setting the recycling standard for convention centers for more than a decade, diverting nearly two million pounds of materials from landfills each year. The Moscone Convention Center offers high performance windows and lighting; mechanical systems that exceed Title 24 Energy Efficiency standards; a full-time air quality technician on staff, and one of the nation’s largest municipally-owned solar generation installations. The solar component consists of a solar electrical system capable of producing enough power for 550 homes annually. Over the project’s lifetime, it will reduce emissions of carbon dioxide by 34,000 tons, or the equivalent of removing 7,000 cars from Bay Area roads for one year.

Over half of San Francisco’s taxi fleet is composed of hybrid or compressed natural gas vehicles. Many San Francisco hotels have implemented eco-friendly practices such as the towel and linen reuse program; 100 percent nonsmoking policy; recycling program for guests; use of compact fluorescent lights instead of incandescent bulbs; and the use of nontoxic cleaning products by housekeeping staff. In addition, many of the hotels compost food waste and have installed devices that power down heating and cooling when guestrooms are not occupied.

AT&T Park is the first major league baseball stadium to use solar panels. The Diamond Vision scoreboard will use 78 percent less energy than the ballpark’s original scoreboard.

Nine farmers’ markets operate in the city including the renowned Ferry Plaza Farmers Market, operated by The Center for Urban Education about Sustainable Agriculture (CUESA).

Guest/Spouse Hospitality Room

The SOT Guest/Spouse Hospitality Room provides guest participants (nonscientists) with a place to meet and socialize with other guests. To visit the Hospitality Room, guests must register for the Annual Meeting with the person they are accompanying. Guests will not have access to the scientific sessions or the Exhibit Hall. Please remember to wear your badge to all SOT events. The Guest/Spouse Hospitality Room will be located in the Marriott Marquis.
Housing Information

You may make your housing reservations through the online reservation system, Experient, found on the SOT Annual Meeting website.

The Society of Toxicology has reserved and arranged for SOT Annual Meeting attendee discounted room rates at various San Francisco hotels—known as the SOT hotel block. This block includes discounted room rates at many premier hotel chains.

SOT depends on the Annual Meeting revenue to fund other programs throughout the year and to keep future registration fees low. Please assist the Society by making your hotel reservation through Experient.

Room Sharing Program

The Society is pleased to provide a Room Sharing Program to those registered for the Annual Meeting. It is available to each meeting registrant who voluntarily enrolls in the program and accepts the terms of the legal disclaimer. This program allows SOT Annual Meeting Registrants to identify others with whom a room might be shared. Access this option from the Annual Meeting section of the SOT website.

Hotel Reservation Information

The deadline date for new housing reservations is February 3, 2012. Between February 4 and February 13, hotels will be downloading their lists and no changes can be made. After February 13, you may call the hotels directly to make any changes to reservations.

For information regarding your hotel room reservation on-site, please visit the SOT Housing Desk, located in, the SOT registration area of the Moscone Convention Center.

You may also make a reservation by the following method(s):
- Fax: 301.694.5124
  (International and Domestic)
- Mail: Experient/SOT
  PO Box 4088
  Frederick, MD 21705
  United States
- Toll-Free: 800.424.5256 (USA)
  Tel: 847.996.5881 (International)

Hours of Operation:
8:00 AM–5:00 PM (CST)
Monday–Friday

Confirmations

Hotel confirmations will be emailed, faxed, or mailed to you from Experient once your reservation has been booked. You will not receive a confirmation from your hotel. If you do not receive confirmation within two weeks, please call Experient at 800.424.5256 USA; 847.996.5881 International.

Changes and Cancellations

The deadline date for new reservations is Friday, February 3, 2012. Between February 4 and February 13, hotels will be downloading their lists and no changes can be made. After February 13, you may call the hotels directly to make any changes to reservations. Please ask the hotel to send you a new email or fax confirmation showing the new change. All cancellations made within 72 hours prior to the day of arrival will be charged the first night’s room and tax by the hotel. Early departures are subject to penalty fees set by the hotel.

For best availability and immediate confirmation, make your hotel reservation via Internet or telephone. Faxed and mailed housing requests will take longer to process and your hotel selections may become unavailable.

Society of Toxicology
K–12 Outreach Event
March 10, 2012 • 10:30 AM–4:30 PM
The Lawrence Hall of Science • University of California, Berkeley

What Do Snow White, Romeo and Juliet, and the Madhatter Have in Common?...Toxicology!

The Education Committee K–12 Subcommittee, in conjunction with the Northern California Regional Chapter, is hosting special activities at the Lawrence Hall of Science so that visitors are engaged in activities related to toxicology and explore toxicology careers.

Volunteer to Assist!
Bring your Family!

Check the SOT Annual Meeting website “Special Events: Education and Outreach” tab for more information.
## General Information

### Hotel Accommodations

<table>
<thead>
<tr>
<th>Hotel Name</th>
<th>Room Type</th>
<th>Address</th>
<th>Phone</th>
<th>Fax</th>
<th>Website</th>
<th>Club Program</th>
<th>Check-in Time</th>
<th>Check-out Time</th>
<th>Distance from Convention Center</th>
<th>Parking Price</th>
<th>Internet Access</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1) Hotel Abri</strong></td>
<td>$229 single/double</td>
<td>127 Ellis Street, San Francisco, CA 94102</td>
<td>415.392.8800</td>
<td>415.398.2650</td>
<td><a href="http://www.hotel-abri.com">www.hotel-abri.com</a></td>
<td>Club: Stash Rewards Program</td>
<td>3:00 PM</td>
<td>12:00 Noon</td>
<td>5 blocks from Convention Center</td>
<td>$35/day valet parking</td>
<td>Complimentary wireless Internet in lobby, complimentary wired Internet in guest rooms</td>
</tr>
<tr>
<td><strong>2) Courtyard by Marriott Downtown</strong></td>
<td>$229 single/double</td>
<td>299 Second Street, San Francisco, CA 94105</td>
<td>415.947.0700</td>
<td>415.947.0800</td>
<td><a href="http://www.marriott.com/sfocd">www.marriott.com/sfocd</a></td>
<td>Club: Marriott Rewards</td>
<td>3:00 PM</td>
<td>12:00 Noon</td>
<td>2 blocks from Convention Center</td>
<td>$51.30/day valet parking</td>
<td>Complimentary wireless Internet in lobby, complimentary wired Internet in guest rooms</td>
</tr>
<tr>
<td><strong>3) Grand Hyatt</strong></td>
<td>$239 single/double</td>
<td>345 Stockton Street, San Francisco, CA 94108</td>
<td>415.398.1234</td>
<td>415.391.1780</td>
<td><a href="http://www.grandsanfrancisco.hyatt.com">www.grandsanfrancisco.hyatt.com</a></td>
<td>Club: Hyatt Gold Passport</td>
<td>3:00 PM</td>
<td>12:00 Noon</td>
<td>4.5 blocks from Convention Center</td>
<td>$49/day valet parking, $32/day self parking</td>
<td>Wireless Internet in guest rooms is $9.99/day</td>
</tr>
<tr>
<td><strong>4) Handlery Union Square</strong></td>
<td>Historic $199, Premiere $239 single/double</td>
<td>351 Geary Street, San Francisco, CA 94102</td>
<td>415.781.7800</td>
<td>415.781.0269</td>
<td><a href="http://www.handlery.com/sf">www.handlery.com/sf</a></td>
<td>Club: Handlery Club</td>
<td>3:00 PM</td>
<td>12:00 Noon</td>
<td>5.5 blocks from Convention Center</td>
<td>$58/day valet parking</td>
<td>Wireless Internet in guest rooms is $9.99/day</td>
</tr>
<tr>
<td><strong>5) Hilton Union Square</strong></td>
<td>$229 single/double</td>
<td>333 O’Farrell Street, San Francisco, CA 94102</td>
<td>415.771.1400</td>
<td>415.771.6807</td>
<td><a href="http://www.sfmarriott.com">www.sfmarriott.com</a></td>
<td>Club: Hilton HHonors</td>
<td>3:00 PM</td>
<td>12:00 Noon</td>
<td>5 blocks from Convention Center</td>
<td>$49/day valet parking, $45/day self parking</td>
<td>Complimentary wireless Internet in lobby, wireless Internet in guest rooms is $12.95/day</td>
</tr>
<tr>
<td><strong>6) InterContinental</strong></td>
<td>$259 single/double</td>
<td>888 Howard Street, San Francisco, CA 94103</td>
<td>415.616.6500</td>
<td>415.616.6581</td>
<td><a href="http://www.intercontinentalsanfrancisco.com">www.intercontinentalsanfrancisco.com</a></td>
<td>Club: Priority Club Rewards</td>
<td>3:00 PM</td>
<td>12:00 Noon</td>
<td>1 block from Convention Center</td>
<td>$60/day valet parking</td>
<td>Complimentary wireless Internet in bar area, wireless Internet in guest rooms is $14.95/day</td>
</tr>
<tr>
<td><strong>7) Marriott Marquis</strong></td>
<td>$279 single/double</td>
<td>55 Fourth Street, San Francisco, CA 94103</td>
<td>415.442.6029</td>
<td>415.486.8101</td>
<td><a href="http://www.sfmarriott.com">www.sfmarriott.com</a></td>
<td>Club: Marriott Rewards</td>
<td>4:00 PM</td>
<td>12:00 Noon</td>
<td>1 block from Convention Center</td>
<td>$58.14/day valet parking</td>
<td>Complimentary wireless Internet in lobby, wireless Internet in guest rooms is $14.95/day</td>
</tr>
</tbody>
</table>

All hotel accommodations, rates, Internet access, and parking pricing are subject to change. Early departures are subject to penalty fees set by the hotels.

Although we understand that making your reservations outside of the SOT hotel block can sometimes be more economical, it decreases the money available to the Society to carry out its strategic goals and may cause the Society to have to pay attrition fees for unutilized hotel rooms. In addition, the Society is unable to assist you if you have any difficulties with your room reservation, such as the hotel over-booking or misplacing your reservation.

SOT depends on the Annual Meeting revenue (hotel room commissions and rebates) to fund other programs throughout the year and to keep future registration fees low. Please assist the Society by making your hotel room reservation through Experient.
General Information

8) Marriott Union Square

- $259 single/double
- 480 Sutter Street
- San Francisco, CA 94108
- Tel: 415.398.8900
- Fax: 415.989.8823
- Website: www.marriott.com/sfous

Club: Marriott Rewards
Check in: 4:00 PM
Check out: 12:00 Noon
5 blocks from Convention Center
$54.72/day valet parking
Complimentary wireless Internet in lobby,
wireless Internet in guest rooms is $12.95/day

9) Mosser Hotel

- $159 single/double
- 54 4th Street
- San Francisco, CA 94103
- Tel: 415.986.4400
- Fax: 415.495.7653
- Website: www.themosser.com

Club: None
Check in: 3:00 PM
Check out: 12:00 Noon
1 block from Convention Center
$43/day valet parking, $32/day self parking
Complimentary wireless Internet in lobby,
complimentary wireless Internet in guest rooms
Complimentary Breakfast

10) Palace Hotel

- $249 single/double
- 2 New Montgomery Street
- San Francisco, CA 94105
- Tel: 415.512.1111
- Fax: 415.543.0671
- Website: www.sfpalace.com

Club: SPG Starwood
Check in: 3:00 PM
Check out: 12:00 Noon
2 blocks from Convention Center
$48/day valet parking
Wireless Internet in guest rooms is $14.95/day

11) Pickwick Hotel

- $169 single/double
- 85 5th Street
- San Francisco, CA 94103
- Tel: 415.267.3940
- Website: www.thepickwickhotel.com

Club: None
Check in: 3:00 PM
Check out: 12:00 Noon
2 blocks from Convention Center
$32/day self parking
Complimentary wireless Internet in lobby,
complimentary wireless Internet in guest rooms

12) Villa Florence Hotel

- $219 single/double
- 225 Powell Street
- San Francisco, CA 94102
- Tel: 415.397.7700
- Fax: 415.397.1006
- Website: www.villaflorence.com

Club: Stash Rewards Program
Check in: 3:00 PM
Check out: 12:00 Noon
6 blocks from Convention Center
$40/day valet parking
Complimentary wireless Internet in lobby,
complimentary wireless Internet in guest rooms

13) Westin Market Street

- $285 single/double
- 50 Third Street
- San Francisco, CA 94103
- Tel: 415.974.6400
- Fax: 415.543.8268
- Website: www.westinsf.com

Club: SPG Starwood
Check in: 3:00 PM
Check out: 12:00 Noon
1.5 blocks from Convention Center
$48/day valet parking
Wireless Internet in guest rooms is $14.95/day

14) Westin St. Francis

- $259 single/double
- 335 Powell Street
- San Francisco, CA 94102
- Tel: 415.397.7000
- Fax: 415.774.0124
- Website: www.westinstfrancis.com

Club: SPG Starwood
Check in: 3:00 PM
Check out: 12:00 Noon
7 blocks from Convention Center
$57/day valet parking
Complimentary wireless Internet in lobby,
wired Internet in guest rooms is $14.95/day

Legend:

- Valet Parking
- Self Parking
- Fitness Center
- Swimming Pool
- Business Center
- In-Room Wireless
- In-Room Safe
- Gift Shop
- Complimentary Breakfast
- Restaurant
- AAA Rating
- Mobile Rating

All hotels have Internet access.
Hotel sales tax is currently 14%

up-to-date information at www.toxicology.org
General Information

Hotel Map

1. Hotel Abri
2. Courtyard by Marriott Downtown
3. Grand Hyatt
4. Handlery Union Square
5. Hilton Union Square
6. InterContinental
7. Marriott Marquis*  
   * SOT Headquarters Hotel
8. Marriott Union Square
9. Mosser Hotel
10. Palace Hotel
11. Pickwick Hotel
12. Villa Florence Hotel
13. Westin Market Street
14. Westin St. Francis

Moscone Convention Center  
South Building
## General Information

### Hotel Services

<table>
<thead>
<tr>
<th>Hotel Service</th>
<th>Hotel</th>
<th>Rewards Program</th>
<th>Blocks to Convention Center</th>
<th>Single/Double Rate</th>
<th>Restaurant</th>
<th>Complimentary Breakfast</th>
<th>Fitness Center</th>
<th>Indoor Pool</th>
<th>In-Room Wireless Internet</th>
<th>Room Service</th>
<th>Gift Shop</th>
<th>Overnight Self-Parking</th>
<th>Early Departure Fee</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Hotel Abri</td>
<td>Stash Rewards Programs</td>
<td>5 Blocks</td>
<td>$229</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2) Courtyard by Marriott Downtown</td>
<td>Marriott Rewards</td>
<td>2 Blocks</td>
<td>$229</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>3) Grand Hyatt</td>
<td>Hyatt Gold Passport</td>
<td>4.5 Blocks</td>
<td>$239</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
</tr>
<tr>
<td>4) Handlery Union Square</td>
<td>Handlery Club</td>
<td>5.5 Blocks</td>
<td>Historic $199 Premier $239</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>5) Hilton Union Square</td>
<td>Hilton HHonors</td>
<td>5 Blocks</td>
<td>$229</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>6) InterContinental</td>
<td>InterContinental Priority Club Rewards</td>
<td>1 Block</td>
<td>$259</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>7) Marriott Marquis*</td>
<td>Marriott Rewards</td>
<td>1 Block</td>
<td>$279</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>8) Marriott Union Square</td>
<td>Marriott Rewards</td>
<td>5 Blocks</td>
<td>$259</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>9) Mosser Hotel</td>
<td>None</td>
<td>1 Block</td>
<td>$159</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
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</tr>
<tr>
<td>10) Palace Hotel</td>
<td>Starwood</td>
<td>2 Blocks</td>
<td>$249</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>11) Pickwick Hotel</td>
<td>None</td>
<td>2 Blocks</td>
<td>$169</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
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<td>✓</td>
</tr>
<tr>
<td>12) Villa Florence Hotel</td>
<td>Stash Rewards Program</td>
<td>6 Blocks</td>
<td>$219</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>13) Westin Market Street</td>
<td>Starwood</td>
<td>1.5 Blocks</td>
<td>$285</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>14) Westin St. Francis</td>
<td>Starwood</td>
<td>7 Blocks</td>
<td>$259</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tr>
</tbody>
</table>

All hotel accommodations and rates may be subject to change.
Early departures are subject to penalty fees set by the hotels.
Internet access and parking pricing are subject to change.

up-to-date information at www.toxicology.org
General Information

Internet Access at the Convention Center
SOT knows the importance of staying connected to your daily activities while attending the Annual Meeting and provides several ways for you to access the Internet while at the Moscone Convention Center.

Computers with Internet Access/Email Center
SOT will provide computers you can use to access the Internet. These computers are available to attendees in the Email Center, located in the registration area.

Free Wireless Internet Access
Free wireless Internet access is available through open “Wi-Fi Zones” in designated areas in the Exhibit Hall that are clearly marked for laptop and handheld users.

Free wireless Internet is available in the common areas including the South Lobby, North/South Concourse, and Esplanade Ballroom Foyer. The network name is “moscone-free-wifi.” You will need to open a web browser and click the login button to be authenticated with the network. This free service is capable of supporting up to 50 users in each public space. Moscone Convention Center does not offer Internet for purchase by the attendee.

Luggage/Coat Check
For your convenience, a luggage/coat check will be available in the Moscone Convention Center. The luggage/coat check will be open Sunday, March 11 through Thursday, March 15. There will be a fee of $3 per item checked. Laptops, cameras, and other electronics will not be accepted.

Hours of operation:
Sunday ................... 8:00 AM–8:00 PM
Monday ................. 7:00 AM–6:00 PM
Tuesday ............... 7:00 AM–6:00 PM
Wednesday .......... 7:00 AM–6:00 PM
Thursday .......... 7:00 AM–12:00 Noon

Luggage/coat check hours are subject to change.

Media Support Services
The Society of Toxicology welcomes accredited representatives of media organizations. Journalists receive complimentary registration for all meeting sessions as well as media kits. Interviews can be arranged with Council, members, and speakers. A press room will be available for reporters. For more information about the program and room location, please contact:

Martha Lindauer
SOT Headquarters: 703.438.3115
Email: martha@toxicology.org

Meeting Requests: Hospitality Suites and Ancillary Meetings
All requests for hospitality suites and ancillary meetings must be approved by SOT Headquarters. To reserve a meeting room or hospitality suite, go to www.toxicology.org/ai/meet/ancillarymtg/ and complete the Ancillary Meeting Form online. Ancillary functions may be hosted only by SOT Affiliates, Exhibitors, or organizations affiliated with SOT. Hospitality suites and ancillary meeting spaces book quickly—submit your request now! Only meeting requests made by December 16, 2011, will be listed in the Annual Meeting Calendar and the Program.

Moscone Convention Center
The SOT 51st Annual Meeting and ToxExpo 2012 will be held at the Moscone Convention Center. Located at the edge of the city’s dynamic South of Market district, the Moscone Convention Center is just four blocks from Union Square, the city’s vibrant shopping district, and the Powell Street cable car to Nob Hill, Chinatown, and Fisherman’s Wharf. Bay Area Rapid Transit System (BART) and Muni Metro stations are within two blocks of the Moscone Convention Center. There also are over 100 restaurants within a seven-block radius.

Recording, Photography, and Cell Phone Policies
Each year, we welcome more than 7,500 attendees to the Society of Toxicology’s Annual Meeting and ToxExpo. With almost 3,000 presentations, this meeting is the largest international forum for toxicological research.

The Society does not permit photography or the electronic capture of scientific sessions in meeting rooms or the Exhibit Hall without the consent of the session chair and the presenter(s)/author(s). This policy also includes photographing colleagues against the backdrop of scientific posters on display without the express consent of the presenting author(s).

• Photographing exhibit booths is prohibited.
• Electronic capture of scientific sessions by any method is prohibited.
• All cell phones and electronic devices must be put on mute while attending scientific sessions.

December 16, 2011, will be listed in the Annual Meeting Calendar and the Program.
The policies adopted above will be enforced by the Society. Those individuals who do not comply will be asked to leave the session or Exhibit Hall floor. If you have any questions regarding these policies, please contact the SOT Headquarters Office.

San Francisco Area Activities

One of the nicest things about visiting San Francisco is that, although the city is “big” in terms of attractions and amenities, it is geographically small—only 49 square miles. Consequently, it is very easy to see and do a great many things in a short period of time.

It also is easy to spend weeks in San Francisco and still not experience everything the city has to offer. Here is a suggested list of the top 10 things not to miss in San Francisco, according to the San Francisco Travel Association:

1. The Golden Gate Bridge, the most famous bridge in the world, manages to impress even the most experienced travelers with its stunning 1.7-mile span. Approximately 120,000 automobiles drive across it every day. A pedestrian walkway also allows the crossing on foot, and bikes are allowed on the western side. The Golden Gate Bridge is said to be one of the most photographed things on Earth.

2. Cable cars have been transporting people around San Francisco since the late 19th century. The cars run on tracks and are moved by an underground cable on three routes. Their familiar bells can be heard ringing from blocks away. Tickets ($5) may be purchased at the cable car turnaround stations at the ends of each route. Each one-way ride will provide spectacular views of the city’s celebrated hills as well as exhilarating transportation (www.sf cablecar.com).

3. Alcatraz, the notorious former prison, is located on an island of the same name in the middle of San Francisco Bay. Some of the United States’ most notorious criminals were incarcerated there. Though several tried, no inmate ever made a successful escape from “The Rock.” The prison was closed in the 1960s and stories about Alcatraz are legendary. A visit to Alcatraz today is fascinating. Recorded cell-house tours are available, allowing visitors to learn about the prison as they explore the buildings and grounds. To reach the island, take an Alcatraz Cruises ferry from Pier 43. Advance reservations are recommended, 415.981.ROCK (7625) (www.alcatrazcruises.com).

4. Fisherman’s Wharf is also home to Pier 39, a festive waterfront marketplace that is one of the city’s most popular attractions. A community of California sea lions has taken up residence on the floats to the west of the pier and visitors line the nearby railing to watch their antics. From there it’s a short walk to the Wax Museum, Ripley’s Believe It or Not!, and the famous crab vendors selling walk-away crab and shrimp cocktails (www.sanfrancisco.travel/neighborhood/fishermans-wharf).

5. Union Square is the place for serious shoppers. Major department stores and the most exclusive designer boutiques line streets like Post, Sutter, Geary, Grant, Stockton, and Powell. The Westfield San Francisco Centre houses the largest Bloomingdale’s outside of New York and the second largest Nordstrom in the United States.

6. North Beach, the city’s Italian quarter, isn’t a beach at all. It’s a neighborhood of romantic European-style sidewalk cafes, restaurants, and shops centered near Washington Square along Columbus and Grant avenues. The beautiful Church of Saints Peter and Paul is a beloved landmark. Coit Tower atop Telegraph Hill offers a splendid vantage point for photos of the bridges and the Bay. Inside the tower, floor-to-ceiling murals painted in the 1930s depict scenes of early San Francisco.

7. The entrance to Chinatown at Grant Avenue and Bush Street is called the “Dragon’s Gate.” Inside are 24 blocks of hustle and bustle, most of it taking place along Grant Avenue, the oldest street in San Francisco. This city within a city is best explored on foot; exotic shops, renowned restaurants, food markets, temples, and small museums comprise its boundaries. Visitors can buy ancient potions from herb shops, relax and enjoy a dim sum lunch, or witness the making of fortune cookies.

8. Dining in San Francisco is an attraction in itself. Known as America’s best restaurant city, San Francisco chefs excel at combining the freshest local ingredients, authentic international flavors, and a touch of creative genius. Choose your cuisine—Chinese, Japanese, French, Italian, Spanish, Moroccan, Indian, Malaysian, Mexican, Greek, Russian, or “fusion,” a combination of any or all of these influences. There is a listing of restaurants within seven blocks of the Moscone Convention Center on the SOT Annual Meeting website (www.toxicology.org/am2012) or visit TasteSF at www.sanfrancisco.travel/taste for a list of San Francisco’s hottest restaurants, a calendar listing of food-related news and events, the history of San Francisco’s many food firsts, chef profiles, and Foodie 411, a weekly insider’s blog by Marcia “the tablehopper” Gagliardi.
9. Nightlife in San Francisco is a constantly changing scene. The “hottest” clubs currently are in the South of Market and Mission districts, with live and recorded rock and Latin music. Jazz, blues, swing, and “oldies” music can be found all over town. For a complete list of nightlife options, visit www.sanfrancisco.travel.

10. A visit to San Francisco would not be complete without a cultural experience. The city is home to internationally recognized symphony, opera, and ballet companies. Playwrights such as Sam Shepherd and Tom Stoppard introduce their works in San Francisco and avant-garde theatre and dance companies dot the city. The San Francisco Museum of Modern Art, the Asian Art Museum, the de Young Museum, the Palace of the Legion of Honor, and other museums and galleries are devoted to the finest of classical and contemporary arts. For a complete museum guide, visit www.sftravel.us/groups/sot.asp.

San Francisco Fun Facts

- Levi’s denim jeans were invented in San Francisco—gold miners needed durable clothes.
- Chinese fortune cookie were invented at the Japanese Tea Garden in San Francisco by Makato Hagiwara.
- It is here that the famous Irish coffee was invented.
- Z is for ZigZag—San Francisco is famous for its bendy streets. Vermont Avenue between 22nd and 23rd is “crookedest,” and Filbert between Hyde and Leavenworth is steepest at 31.5 degrees, but neither fact discourages tourists from flocking to Lombard Street’s seductive curves.
- At Angel Island, the Ellis Island of the West, 175,000 Chinese immigrants and Japanese “picture brides” once waited to enter the country. Poems of hope they carved into the walls are still visible at Immigration Station.
- Alcatraz means pelican in Spanish. The rocky pelican’s island was a military fort before it became a prison.
- In 1850, gold seekers abandoned over 600 vessels in the bay. Some became landfill, now lying beneath the Jackson Square Historic District where the city’s few surviving nineteenth century commercial buildings include Ghirardelli’s first chocolate factory.
- Sutro Baths was an extravagant public bathhouse built by the eccentric former mayor, Adolph Sutro, who is also known for building the Cliff House. The vestiges of Sutro Baths are located at Ocean Beach, where a massive crowd of 7,000 people once gathered on the occasion of its official opening.
- The computer mouse was invented in Silicon Valley and the picture of a rolling hill against a blue sky, which is the default wallpaper in Windows XP, was shot in the Napa Valley.

Satellite Meetings

Each year, SOT endorses several Satellite Meetings that are held in conjunction with the Annual Meeting. Satellite Meetings are organized around scientific topics related to toxicology and are scheduled at the end of the Society’s program. The 2012 Satellite Meetings will be held in and around the San Francisco area. Proposals for a Satellite Meeting should be sent by email to heidi@toxicology.org to the attention of William Slikker Jr., SOT Vice President and Scientific Program Committee Chair. Requests approved by December 16, 2011, will be published in the Program. All requests must be received by January 6, 2012.
**Scientific Poster Printing Services**

SOT is pleased to offer our poster presenters a convenient service through Shepard Exposition Services, the official general service contractor for the Annual Meeting. No need to worry about traveling with your poster or having your poster lost in shipping. Simply fill out the online form, email or upload your poster using the link provided, review and approve the final layout of your poster, and then pick up your poster on-site. Shepard will produce the materials for a reasonable price, which will include production, transportation, and storage for the show. It’s as simple as that! Please call 404.720.8666 or send an email to thand@shepardes.com for more information. Further information and the order form can also be found on the SOT website at www.toxicology.org/ai/meet/am2012/present.asp.

**Session Etiquette for Attendees**

Attendees are encouraged to ask questions following the presentations by speakers or at the direction of the moderator.

Given the importance of the scientific program to attendees and out of respect for the presenters, we ask that you adhere to the following rules of etiquette:

- Cell phones and other electronic devices should be set on mute.
- Electronic capture of scientific sessions by any method is prohibited.
- Children under the age of 15 are not allowed in the Exhibit Hall or in scientific sessions unless the session chair gives consent.

Session chairs are asked to enforce these policies and individuals who do not comply will be asked to leave the session.

Any items that are left behind in any of the rooms should be taken to the SOT Headquarters office.

If you have any questions regarding these policies, please contact the SOT Headquarters staff at the Registration Desk.

**SOT Pavilion**

Do you know all the resources available through SOT and where to find them? Stop by the SOT Pavilion to learn about SOT activities, membership benefits, strategic initiatives, and the Endowment. Learn about materials to support the discipline of toxicology and information on K–12 and public outreach. It is a one-stop shop for all your questions and member needs. The Pavilion is located in the Exhibit Hall, Booth 1700, and open the following hours:

- Monday ..................9:00 AM–4:30 PM
- Tuesday ..................8:30 AM–4:30 PM
- Wednesday ............8:30 AM–4:30 PM

**Sponsorship**

Annual Meeting sponsorship serves as visible evidence of an organization’s commitment to the Society’s mission of “creating a safer and healthier world by advancing the science of toxicology.” Moreover, sponsorship provides an opportunity for private, public, and not-for-profit organizations to increase overall awareness of their services and programs to SOT members and Annual Meeting attendees.

Sponsors are listed in publications related to the Annual Meeting, including the Preliminary Program, the Program, pre- and postmeeting newsletters, and the ToxExpo Directory. In addition, Annual Meeting Sponsors are listed on the SOT Annual Meeting website, an essential go-to source of information for all registrants. During the Annual Meeting, acknowledgment signs, which group sponsors by level of contribution, are displayed prominently at many of the SOT functions, as well as in the SOT presentations in all session rooms.

In appreciation for their support of the Society, sponsors at the Silver Level and above are invited to the SOT President’s Reception.

Five levels of sponsorship are available:

- Diamond ($10,000 or more)
- Platinum ($5,000–$9,999)
- Gold ($2,500–$4,999)
- Silver ($2,000–$2,499)
- Contributor ($1,000–$1,999)

In 2011, several new benefits were made available to Diamond Level Sponsors and will continue again this year. Please see www.toxicology.org for more details.
The Toxicologist and Annual Meeting Program

The Toxicologist: The Official Record of the 2012 Annual Meeting Abstracts

The Toxicologist is an important scientific resource, as it is the official compilation of all accepted abstracts for the 51st Annual Meeting of the Society of Toxicology. With over 2,700 abstracts for the meeting, this supplementary issue of Toxicological Sciences is a critical publication to access the latest findings in toxicology. A full version of The Toxicologist is available on the CD-ROM in the Program and includes the official Itinerary Planner. (This useful planner includes not only the full abstracts accepted for presentation, but all ancillary meetings, events, receptions, and SOT Committee, Task Force, and Component Group meetings.)

The Program: The Official Guide to the SOT 2012 Annual Meeting and ToxExpo

The Program is the official guide to all the activities of the 2012 Annual Meeting and ToxExpo. The Program includes detailed information on the scientific sessions including an overview for these sessions, with the exception of the poster and platform sessions. The Program includes the poster session schedule, and a map of the poster sessions, as well as an abstract overview of all the Continuing Education course offerings. The Program details the schedule of events by name and a listing of all the special events including 2012 award recipients, 2012 Honorary members, SOT Endowment Fund 2011 Award recipients, recognition and special events, and Regional Chapter, Special Interest Group, and Specialty Section meetings and receptions. In addition, the Program includes a general section that highlights tour, travel, hotel, registration, parking, and safety and security information. The complete listing of the ToxExpo exhibitors is provided along with the floor plan for the Exhibit Hall and a complete listing of Exhibit Hosted sessions.

- Copies of the Program and The Toxicologist on CD-ROM will be mailed to SOT members in the United States and Canada prior to the Annual Meeting.
- Copies of the Program and The Toxicologist on CD-ROM and Itinerary Planner will be mailed to non-SOT members who register on or before January 27.
- The Late-Breaking Abstract Supplement to The Toxicologist will not be mailed prior to the meeting and copies will be available on-site in the registration area and outside Gateway Ballroom, where the posters will be presented on March 15.
- Copies of the Program and The Toxicologist on CD-ROM with the Itinerary may be picked up on-site at the Moscone Convention Center registration area.
- A copy of the printed version of The Toxicologist may be preordered via the Registration Form or purchased on-site while supplies last for $20.

Note: Please bring your copy of the Program with you to the meeting.

Itinerary Planning Tool Enhancements

SOT is excited about the improved functionality of the online customizable Itinerary Planner. We invite you to use this tool to plan your Annual Meeting experience using iCal technology. New this year, the Itinerary Planner is available via a free mobile application. You’ll have all the functionality of the online Itinerary Planner delivered conveniently to your mobile phone, tablet, or iPad.

Choose the presentations, featured lectures, meetings, or special event functions you wish to add to your personal itinerary. After you’ve selected your schedule of sessions, you’ll be able to export this information to your default calendar program for reference using iCal. The downloaded information will contain specific details for these sessions or events such as date, time, and the location. Additionally, each presentation downloaded provides you with access to detailed abstract information, including authors, institutions, and the full abstract. Late-breaking and grace period abstracts will be available through the Itinerary Planner (online and mobile versions) in mid-February.

Look for more information to be made available in January on the SOT website.
Tours

SOT is proud to offer all attendees and their guests a wide range of tours to make your visit to San Francisco, more enjoyable. A tour desk will be located in the SOT Registration area of the Moscone Convention Center. Tour desk hours will be listed in the Program, or you may visit the Annual Meeting section of the SOT website for details.

Tour Registration

To register for tours, please visit the Key Events website at www.usahosts.com/eventregistration.asp?id=89. The website will provide you with real-time availability and immediate confirmations. The website is SSL encrypted and provides a secure payment platform. You also may fax, mail, or email your tour registration form, found on the SOT website. If you have any questions, please call Key Events at 415.695.8000 or email at sot@keyevents.com.

Register now to ensure your reservation for tours. On-site registration will be limited and will be accommodated on a space-available basis only.

- The registration deadline is February 13, 2012, for all tours, except February 1, 2012, for Alcatraz. Key Events reserves the right to cancel tours if minimums are not met.
- If a tour is cancelled due to insufficient registration, customers will be given the opportunity to either receive a full refund or to select another tour, if seating is available.
- Full payment to Key Events must accompany your registration form. All payments can be made in US dollars, VISA, MasterCard, American Express, checks, and cash (on-site sales only). Refunds will be made only if notice is received in writing to Key Events or faxed to 415.695.8010 by February 13, 2012, for all tours, except February 1, 2012, for Alcatraz. No refunds will be made after this date.
- No tickets will be issued in advance of the meeting. Tour guest names will be on a list at each coach for boarding.

Experience San Francisco: City Tour
Sunday, March 11, 2012
12:30 PM–4:30 PM
$28 per person
Minimum of 40 people

San Francisco is well-known as one of the world’s most charismatic and cosmopolitan cities. Her world famous landmarks and her hidden treasures are the highlights of this fascinating tour. Spectacular scenery, the city’s diverse cultures, and a wild and colorful past are brought to life through the dynamic narration of our knowledgeable guides. Enjoy lush parks, sparkling waterfronts, pristine shop windows, classic San Francisco landmarks, and unparalleled views, all while learning about the unique history of the City by the Bay. See the breathtaking sights that have helped make San Francisco the “number one city to visit” by Condé Nast Travel Magazine 18 years in a row.

Sights Visited May Include:
- Golden Gate Bridge and Vista Point
- The Cliff House and Ocean Beach
- Golden Gate Park
- Twin Peaks (weather permitting)
- Victorian Neighborhoods
- Fisherman’s Wharf and Pier 39
- North Beach
- Chinatown
- Union Square

Alcatraz: A Visit to “The Rock”
Monday, March 12, 2012
12:30 PM–4:30 PM
$64 per person
Minimum of 40 people

Please Note:
Registration deadline is February 1, 2012.

Alcatraz. The name alone sent a shudder down the spines of the nation’s most incorrigible criminals from the day it opened in 1934. It stripped Al Capone of his power, tamed “Machine Gun” Kelly into a model of decorum. It took the birds away from the Birdman of Alcatraz. The prison was closed in 1963 by Robert Kennedy and has become a once-in-a-lifetime experience for all those who visit this infamous island.

The tour includes a scenic ferry ride to this island, an optional short film detailing the island’s history, and an award-winning self-guided audio tour. These tapes were recorded not by actors, but actual guards and inmates who occupied this desolate penitentiary. Warm clothing and comfortable walking shoes are recommended. Following Alcatraz, time permitting, you will enjoy time to explore Pier 39, Fisherman’s Wharf, and make a visit to the world famous sea lions!
General Information

Over the Golden Gate Bridge: A Visit to Muir Woods and Sausalito
Tuesday, March 13, 2012
10:00 AM–2:00 PM
$59 per person
Minimum of 20 people
Venturing beyond the golden city of San Francisco, there lays a combination of lush vegetation, majestic wooded areas, hill-coated havens, and rugged coastline. The scenic beauty that is Northern California is best represented in Marin County. Found in Marin is a grove of ancient, mighty, giant redwoods. Muir Woods is the closest grove to San Francisco and one of Northern California’s most enchanting treasures. Coastal Redwoods are the world’s tallest living things—the loftiest tree in Muir Woods, if found in San Francisco Bay, would reach about 35 feet higher than the Golden Gate Bridge roadway. Muir Woods National monument is a 550-acre preserve of old growth coastal redwoods, some dating back over 1,000 years.

Two World-Class Museums: The California Academy of Sciences and The de Young
Wednesday, March 14, 2012
10:00 AM–2:00 PM
$78 per person
Minimum of 40 people
The California Academy of Sciences is the only place on the planet with an aquarium, a planetarium, a natural history museum, and a four-story rainforest all under one living roof. With its grand re-opening in September 2008, the museum not only houses amazing new exhibits, but the building itself is a “Green Dream.” Sustainable features include solar panels, radiant sub floor heating, water reclamation, and more, including the 2.5-acre living roof covered with native plants, making it the greenest museum in the world.

Founded in 1895, the de Young Museum has been an integral part of the city. Recently re-engineered, the state-of-the-art facility is constructed of warm, natural materials featuring a 144-foot tower that gently spirals from the ground floor with a public observation floor offering panoramic views of the entire Bay Area. The de Young museum features priceless collections of American art from the 17th through the 20th centuries, and art of the native Americas, Africa, and the Pacific. Its collection has more than 25,000 western and non-western works of art.

A Wine Country Adventure
Thursday, March 15, 2012
1:00 PM–7:00 PM
$109 per person
Minimum of 40 people
The Sonoma Valley features some of the best wines produced in California. Although it’s not as visited as the Napa Valley, it offers a slower more relaxed atmosphere. Rustic wineries can be found throughout the valley. Small and charming, they are like what Napa was prior to its rise in popularity. Today, you will be offered a taste of Sonoma Valley. Cool bay breezes, hot days, mild nights, and nutrient rich soil make for the ideal environment, and the rolling hills of Sonoma County provide the ideal backdrop for enjoying a relaxing day of tastings and tours.

Mixed in with the winery visits, you will head to the town of Sonoma. In this quaint historical town, you will enjoy time to explore the Square. Sonoma Square offers many boutique shops, with a various assortment of charming gifts, art, and boutique shops, a cheese factory, historical California mission, and more. And all these sites line a very scenic park with ducks, geese, and even wild chickens!

At the end of the day, you will have had the experience of distinctly different varietals from two different wineries in or around the same region.

Transportation

Air Transportation
Special Airfare Discounts
American Airlines
800.433.1790
www.aa.com
SOT Discount Code: 8932AX
American Airlines is offering a seven percent discount off the lowest applicable fare for attendees traveling to San Francisco for the SOT Annual Meeting. The discount is valid March 7–19, 2012. You may book your ticket at www.aa.com (no service fee applies); under the promotion code, type 8932AX to receive the discount.
General Information

You may also book your reservation by calling the AA Meeting Services Desk at 800.433.1790; however a service fee per ticket will apply. International attendees please contact the local AA reservations office and give them the code 8932AX.

**Delta Airlines**

800.328.1111  
www.delta.com  
SOT Discount Code: NM7UV

Delta Airlines is offering a two percent to ten percent discount off full/nonrestricted fares to San Francisco from the US/Canada. The discount is valid March 8–18, 2012. You may make reservations by calling the Meeting Services Desk at 800.328.1111 from anywhere in the United States or Canada and refer to the discount code NM7UV. Delta does not charge a reservation service fee. No discount applies if you book your ticket online at www.delta.com.

**Airport**

San Francisco International Airport (SFO) is located in San Francisco, California, 13 miles south of San Francisco, near the junction of Highways 101 and 380. The airport offers nonstop links with more than 31 international points on 30 international carriers. The Bay Area's largest airport connects nonstop with more than 71 cities in the United States on 18 domestic airlines. For up-to-the-minute departure and arrival information, airport maps and details on shopping, dining, cultural exhibitions, ground transport, and more, visit www.flysfo.com. SFO was voted “North America’s Best Airport” by passengers for its outstanding customer service and amenities.

At 2.5 million-square-feet, SFO’s International Terminal is equivalent to the size of 35 football fields and is the largest in the United States.

- **Taxicabs:** Depart from designated taxi zones located at the roadway center islands, on the Arrivals/Baggage Claim Level of all terminals.

Uniformed taxi coordinators are stationed at the taxi zones from 7:00 am to 1:00 am to assist passengers with questions or concerns.

Ramp accessible taxis are available. Please contact the taxi coordinator to request a ramp accessible taxi, or phone *1191 from any airport courtesy phone.

Approximate fares to San Francisco Downtown are $37 one way. Metered rates apply to all destinations and most cab companies accept credit cards as a form of payment. A $2 exit surcharge is included in all San Francisco taxicab meter fares for rides originating from San Francisco International Airport. By sharing a ride, up to five people can ride for the price of one person.

- **BART Rapid Rail:** BART is the fast, easy, inexpensive way to get to San Francisco and around the Bay Area. Trains arrive at the SFO International Terminal every 15 minutes and it takes just 30 minutes to downtown San Francisco. A one-way ticket from SFO to downtown is $8.10; find fares from the airport to any station by using the QuickPlanner.

The BART station at SFO is located in the International Terminal. It’s a short walk from United Airlines in Terminal 3 and a slightly longer walk from Terminal 1. You can also take the free AirTrain from both terminals directly to the BART station. Just follow the signs to AirTrain and board the Red Line train. When you arrive, take the escalator down to the departures level and walk straight ahead to the BART station. Terminals 1, 2, and 3 are approximately a one to three-minute AirTrain ride to the BART station.

International passengers should turn right when leaving customs, walk to the escalator, and go up to the departures level. Walk straight ahead and turn left at the art exhibit and you’ll see the station entrance.

**To/From Downtown San Francisco**

Board the Pittsburg/Bay Point train to one of four downtown San Francisco stations that are an easy walk or short cab ride to most San Francisco hotels. BART shares these stations with San Francisco Municipal Transportation Agency (MUNI), which can also take you throughout the city.

- **Civic Center:** Exit for Upper Market, Van Ness, the Castro, and Civic Center districts. Take the Market/7th Street exit for the Renoir Hotel.
- **Powell Street:** Use the Hallidie Plaza exit for the InterContinental, Parc 55, Hilton, Nikko, and Union Square hotels. Use the 4th Street exit for the Marriott and Moscone West.
- **Montgomery Street:** Financial District and Moscone North/South. Use the Market/3rd Street exit for Moscone Convention Center, W Hotel, Westin, The Palace, and Financial District and South of Market hotels.

**Getting Back to San Francisco International Airport**

Take any SFO-bound train from any downtown BART station. If you are going to SFO from another city it may be necessary to transfer to the SFO-bound train, which originates on the Pittsburg/Bay Point line. Check the BART System Map for transfer points.

Upon arriving at SFO, take the AirTrain Red Line from BART to Terminal 1, 2, or 3 for domestic flights. You can also walk to Terminal 1 or 3 in five to ten minutes. International terminal passengers should exit the train and walk to the front of the station. The international flight check-in counters are a very short walk from the BART station main entrance.

For more information about BART, visit their website at www.bart.gov.
Located in the ToxExpo Exhibit Hall, the SOT Pavilion is your place to connect and learn about SOT program, services, membership benefits, and more. Find out about the SOT Endowment Fund, Toxicological Sciences, SOT awards and sponsored awards and fellowships, ToXchange—the SOT member network, educational programs directed across the spectrum from K–12 to throughout the toxicology career, and everything taking place at the Annual Meeting. The SOT Pavilion is your place on the exhibit floor for all you want to learn about SOT and more. It’s a great place to connect, network, and discover what’s new.

SOT Pavilion Booth #1700

Find out how you can:

• Be an Advocate for Toxicology
• Participate in Your SOT Regional Chapter
• Choose a Special Interest Group
• Join a Specialty Section
• Connect through the SOT Website
• Use the SOT Job Bank—FREE!

• Actively Participate in ToXchange, the Private and Secure SOT Member Network
• Lead an SOT Committee or Activity
• Nominate and Apply for SOT Awards
• Partake in ToxExpo
General Information

Airport Ground Transportation

SuperShuttle
SuperShuttle provides ground transportation service between the San Francisco Airport and all major hotels in the downtown area. SOT attendees can receive discounts by going to www.supershuttle.com/sales/sot_am2012.html. The SOT discount one-way cost is $15. The discount is valid online only with travel dates between March 1–18, 2012. You do not have to have an advance reservation to ride SuperShuttle, but without a reservation, you will pay the full fare at the ticket counter.

ShareRide Transfers

- $2 off each way per passenger to/from SFO and downtown San Francisco.
- $3 off each way per passenger to/from Oakland (OAK) Airport and downtown San Francisco.
- $4 off each way per passenger to/from San Jose (SJC) Airport and downtown San Francisco.

Exclusive Vans (accommodates up to nine passengers traveling together) or ExecuCar (town car up to four passengers)

- $5 off each way per vehicle to/from SFO/OAK/SJC and downtown SF.

Parking

As a city-owned facility, the Moscone Convention Center provides information according to the city’s traffic management philosophy, which encourages the use of transit first. View the parking map to find a parking garage, or use the list below for reference. Please check with each location for cost information as it is subject to change.

Fifth and Mission Parking Garage
415.982.8522 ext. 18
833 Mission Street (between Fourth and Fifth Streets, adjacent to Moscone West)

Hearst Parking Center
415.989.4000
45 Third Street (entrance on Stevenson, 2 blocks from Moscone South/North)

Moscone Convention Center Garage
415.777.2782 (garage)
415.538.7888 (office)
255 Third Street (Folsom & Howard, across the street from Moscone South’s Esplanade Ballroom)

Museum Parc Garage
415.348.0304
300 Third Street (entrance on Third and on Folsom Streets)

Paramount Valet Parking
415.341.1410
680 Mission Street (separate entrance on Jessie Street, off Third, located 2 blocks from Moscone South and North)

Post Montgomery Center Garage
415.393.1500
161 Sutter Street (turn onto Sutter Street from Montgomery)

Sutter/Stockton Garage
415.982.7275
444 Stockton Street (second entrance on Bush between Stockton and Grant)

Please check the SOT Hotel Block and Information page for valet parking rates for your hotel.

SOT Ride Share

SOT is offering a Ride Sharing Program in conjunction with the Annual Meeting. For those who live close enough to the San Francisco area or those who do not wish to fly, you may want to consider the Ride Share Program. Avoid airport hassles by driving and make it easier for other scientists to attend by sharing rides. Students especially appreciate ways to make the meeting even more economical.

Once you have registered for the Annual Meeting, you can access the Ride Sharing Program. You can indicate whether you want to drive or be a passenger, and then see a list of others who have signed up. It will be up to you to match your plans with someone else who is registered, and then to remove your names when you have travel plans in place.

SOT Travel Agent—Carlson Wagonlit

Carlson Wagonlit is the official travel management firm for SOT’s 51st Annual Meeting. To take advantage of their services and savings, call toll-free 800.669.6024 Monday through Friday, 9:00 am–5:30 pm (Eastern Standard Time) and ask to speak to anyone on our SOT-dedicated team or email: Arlington.us@contactcwt.com. To obtain the maximum discounted fares, call at least 60 days prior to departure. Discounted fares are still obtainable up to 14 days in advance. Please note that Carlson Wagonlit charges a $42 service fee per ticket.

Before calling Carlson Wagonlit, please gather the following information:

- The desired dates of arrival to and departure from San Francisco
- Your home city or originating airport
- Your approximate time of departure from the originating airport
- The number of persons traveling (adults/children)
- Your method of payment, either credit card or check
- Your airline frequent flyer number(s)
- Your name as it appears on your ID and your date of birth

Identify yourself as a Society of Toxicology attendee. Carlson Wagonlit will find the best fare for you and email you an itinerary.

March 11, 2012
Day Light Saving Time
Starts in the United States, Canada, and Mexico
Registration

Registration for the Annual Meeting is available now. Register by January 27 to get the Early Bird Rate to avoid on-site registration lines and ensure that you receive your registration materials before the meeting. Registration is available online, via fax, or can be mailed to SOT Headquarters.

Online Registration
SOT members and non-members are invited to register for the 2012 SOT Annual Meeting using the SOT Online Registration system. The system is designed for those who will be paying their registration fee by credit card. Registration information can be accessed via the SOT website at www.toxicology.org/register. After registering, you will receive an electronic confirmation. If you do not, please send an email to jimd@toxicology.org.

Mail or Fax Registration
Registrants may fax or mail their registration payments using the Registration Form located on pages 31 and 33.

Please type or print clearly.
No phone registrations will be accepted.

Please send Registration Forms to:
SOT Registration
PO Box 91895
Washington, DC 20090-1895

or
SOT Headquarters
(Faxes require credit card payment)
Fax: 703.438.3113

Express packages must be mailed to:
SOT Headquarters Registration Dept.
1821 Michael Faraday Drive, Suite 300
Reston, VA 20190

Forms will be date-stamped as they arrive. This is your date of registration. Fax registrations will be accepted by SOT Headquarters only if a credit card number is clearly listed in the appropriate area.

NOTE: To prevent double-billing, if you are registering by fax, DO NOT mail your original Registration Form. SOT needs only one copy for processing. All mailed and faxed Registration Forms will be processed online by SOT staff.

Registration Materials
Badges and event tickets will be mailed in advance if you register by January 27, 2012. When you arrive at the Moscone Convention Center, please go to the registration area located in the South Lobby to pick up your registration materials that were not mailed (i.e., The Toxicologist on CD-ROM, the ToxExpo Directory, and other supplementary materials). You must present your 2012 Annual Meeting badge to obtain these items. The materials will be available in bins near the registration area.

If you have not already registered or have not received your badge when you arrive at the meeting, please go to the registration counters. NOTE: If you are registered and have your badge, you do not need to stand in the registration line.

Registration Guidelines

Payment
Registration Forms will be returned if not accompanied by one of the following methods of payment:
• Check (company or personal); United States Currency only. Please list all registrants on check memo or check stub
• Government Purchase Order. (Check must be drawn from the US Department of Treasury)
• Money Order
• Visa, MasterCard, Discover, Diner’s Club, or American Express

Registration Deadlines
• Early Bird Registration: January 27, 2012
• Standard Registration: February 17, 2012
• Final Registration after: February 17, 2012

DO NOT mail your Registration Form to SOT if it will arrive after March 7, 2012. SOT will accept Annual Meeting Registrations until March 7. After March 7, registrations not processed online will only be accepted on-site at the Annual Meeting. The online registration system will be open throughout the meeting and if you register online after March 7, 2012, you can easily pick up your badge at the “BADGE PICK UP ONLY” registration counter.

Registration Discount to Non-Members
Special offer to non-member 2012 Annual Meeting attendees: apply for membership by May 1, 2012, and if accepted, SOT will waive your 2012 dues.

Guest/Spouse Registration
The SOT Guest/Spouse Hospitality Room provides guest participants (nonscientists) with a place to meet and socialize with other guests. The room will be open Sunday through Thursday, and information on local attractions, rental cars, and tours will be available there.

Guests and spouses must be registered for the Annual Meeting to access the Hospitality Room. Guests must register with the person they are accompanying. Reminder: Guest registrants and children under the age of 15 are not permitted in the Exhibit Hall at any time or in scientific sessions unless consent is given by the session chair.

One-Day Registration
There is no reduced fee for one-day registration.

(continued on page 34)
## Registry Form (Part 1)

**SOT 51st Annual Meeting**  
**March 11–15, 2012**

(Required: Please check the appropriate box)

**PLEASE PRINT CLEARLY OR TYPE**

- [ ] SOT Member  - [ ] Non-Member  - Badge Name: ___________________________

**First Name/Middle Initial:** ___________________________  
**Last Name:** ___________________________  
**Professional Degree(s):** ___________________________

**Organization Name:** _____________________________________________________________________________

(Is this a new employer and/or new address? ______ Yes ______ No)

**Company (second line):** __________________________________________________________________________

**Department:** _______________________________________________________________________________

**Street Address:** _______________________________________________________________________________

**City/Region:** ___________________________  
**State/Prov:** ___________________________  
**Postal Code:** ___________________________  
**Country:** ___________________________

**Area Code/Phone Number:** ___________________________  
**Fax Number:** ___________________________

**Email Address:** _______________________________________________________________________________

**Special Accessibility Requirements:** ___________________________________________________________________________

If you are a Student or Postdoc registrant, please provide the following information:

- [ ] Postdoc  - [ ] Graduate Student  - [ ] Undergraduate Student (Fax or mail a copy of Student ID with the form)

**Institution:** _______________________________________________________________________________

**Advisor’s Name:** _____________________________________________________________________________

**Advisor’s Phone Number:** ___________________________  
**Advisor’s Email:** _____________________________________________________________________________

**REGISTRATION FEES:**

<table>
<thead>
<tr>
<th>Registration Type</th>
<th>Early Bird Registration (Received by Jan. 27)</th>
<th>Standard Registration (Jan. 28 to Feb. 17)</th>
<th>Final Registration (After Feb. 17*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOT Member</td>
<td>$300</td>
<td>$360</td>
<td>$420</td>
</tr>
<tr>
<td>Non-Member**</td>
<td>$600</td>
<td>$660</td>
<td>$720</td>
</tr>
<tr>
<td>SOT Retired/Emeritus Member</td>
<td>$70</td>
<td>$120</td>
<td>$170</td>
</tr>
<tr>
<td>Postdoctor SOT Member</td>
<td>$85</td>
<td>$135</td>
<td>$185</td>
</tr>
<tr>
<td>Postdoctor Non-Member**</td>
<td>$170</td>
<td>$220</td>
<td>$270</td>
</tr>
<tr>
<td>Graduate Student Member</td>
<td>$65</td>
<td>$115</td>
<td>$165</td>
</tr>
<tr>
<td>Graduate Student Non-Member**</td>
<td>$130</td>
<td>$180</td>
<td>$230</td>
</tr>
<tr>
<td>Undergraduate Student</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
</tbody>
</table>

(Copy of Student ID Required)

**SOT Affiliate** | $0 | $0 | $0 |

**Press** | $0 | $0 | $0 |

**Guest/Spouse (Non-Scientist)** | $70 | $85 | $100 |

**Guest/Spouse Name:** ___________________________

---

**METHOD OF PAYMENT:**

All registrations submitted by hard copy or fax will be processed on-line by SOT staff.

- [ ] Check or Money Order # ___________________________

**Government Purchase Order # ___________________________**  
**(US GOVERNMENT PO FORM MUST BE ATTACHED)**  
- [ ] American Express  - [ ] Diner’s Club  - [ ] Discover  - [ ] MasterCard  - [ ] Visa

**Credit Card #:** ___________________________  
**Cardholder’s Printed Name:** ___________________________  
**Expiration Date:** ___________________________

---

*After February 17, Final Registration rates apply. SOT will accept faxed Registration Forms until March 7. Online registration will be open until March 15. On-Site Registration Forms will be available at the Annual Meeting Registration Desk.

**Special offer to non-member 2012 Annual Meeting attendees: apply for membership by May 1, 2012, and if accepted, SOT will waive your 2012 dues.**
Founded in 1961, the Society of Toxicology (SOT) includes more than 7,000 members from nearly 60 countries worldwide. SOT members are drawn from academic institutions, industry, and government service, among others, and are active in myriad related fields and professions. All members partner with SOT in advancing science to enhance human, animal, and environmental health. You may apply to join the SOT at the following membership levels:

- **Student**—you must be enrolled in a graduate degree program related to toxicology.
- **Postdoctoral Fellow**—you must hold a PhD or other doctoral degree (e.g., MD, DVM) with an interest in toxicology and be under the direction of a research mentor.
- **Associate**—you must be engaged in continuing professional scientific activities in toxicology.
- **Full**—you must demonstrate a continuing professional interest in toxicology and have conducted and published original research and/or are generally recognized as expert in some phase of toxicology.

Apply for the level of membership that’s right for you! Please see the “Join SOT” section of the SOT website at www.toxicology.org/ms/join.asp for further information.

Undergraduate students may become SOT Undergraduate Student Affiliates.

**As an SOT member you can …**

- Communicate, Connect, and Collaborate with colleagues via ToXchange, the professional, secure SOT member network, and keep current at www.toxicology.org with member-only information
- Qualify for reduced SOT member rates for the SOT Annual Meeting, Continuing Education Courses, and Current Concepts in Toxicology topical meetings
- Receive SOT publications including the official journal of the SOT, Toxicological Sciences; the Toxicologist; the SOT newsletter, Communiqué, and the SOT Membership Directory
- Utilize Career Resources such as the SOT Job Bank and register for Mentor Match as a mentor or mentee
- Qualify for exclusive SOT member awards—-from Graduate Student Travel Support and Research Training to Postdoctoral Fellowships, Traveling Lectureships, SOT Awards, and more!

**Membership Fees:**

- Full Membership ............................................. $136
- Associate Membership ..................................... $136
- Postdoctoral Membership ................................ $35
- Student Membership ....................................... $20

*Members from Developing Countries are eligible for reduced dues.*

- Full Membership ............................................. $50
- Associate Membership ..................................... $50
- Postdoctoral Membership ................................ $10
- Student Membership ....................................... $10

Easy online membership application takes approximately 15 minutes to complete.
## CONTINUING EDUCATION COURSES:

- Yes, I would like to attend the following CE courses. (Only meeting registrants may enroll in a CE course.)

<table>
<thead>
<tr>
<th>AM #</th>
<th>PM #</th>
<th>Early Bird Registration (Received by Jan. 27)</th>
<th>Standard Registration (Jan. 28 to Feb. 17)</th>
<th>Final Registration (After Feb. 17)</th>
<th># of Courses</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOT Member/Affiliate</td>
<td>$150 each</td>
<td>$185 each</td>
<td>$220 each</td>
<td>x________</td>
<td>$________</td>
</tr>
<tr>
<td>SOT Retired/Emeritus Member</td>
<td>$110 each</td>
<td>$145 each</td>
<td>$180 each</td>
<td>x________</td>
<td>$________</td>
</tr>
<tr>
<td>Non-Member</td>
<td>$300 each</td>
<td>$335 each</td>
<td>$370 each</td>
<td>x________</td>
<td>$________</td>
</tr>
<tr>
<td>Postdoctoral (SOT Member/Non-Member)</td>
<td>$90 each</td>
<td>$125 each</td>
<td>$160 each</td>
<td>x________</td>
<td>$________</td>
</tr>
<tr>
<td>Graduate or Undergraduate Student (SOT Member/Non-Member)</td>
<td>$45 each</td>
<td>$80 each</td>
<td>$115 each</td>
<td>x________</td>
<td>$________</td>
</tr>
</tbody>
</table>

- Press | $0 each | $0 each | $0 each | x________ | $________ |

## STUDENT AND POSTDOCTORAL FUNCTIONS:

- Yes, I would like to attend the Sunrise Continuing Education Mini-Course (includes continental breakfast)

| SOT Member/Affiliate | $55 each | $90 each | $125 each | $________ |
| SOT Retired/Emeritus Member | $55 each | $90 each | $125 each | $________ |
| Non-Member | $75 each | $110 each | $145 each | $________ |
| Postdoctoral (SOT Member/Non-Member) | $55 each | $90 each | $125 each | $________ |
| Graduate or Undergraduate Student (SOT Member/Non-Member) | $25 each | $60 each | $95 each | $________ |

- Press | $0 each | $0 each | $0 each | $________ |

## OPTIONAL ABSTRACT MATERIAL:

- Yes, I want to publish my abstract in The Toxicologist on CD-ROM, as part of the Annual Meeting registration fee.

- Yes, I am a student or postdoc registrant and would like to attend the following CE courses. (Only meeting registrants may enroll in a CE course.)

### REGISTRANT—CIRCLE ALL THAT APPLY: (YOU MUST MAKE ONE SELECTION/CATEGORY)

- A. Type of Organization:
  - 1. Academia
  - 2. Government
  - 3. Military
  - 4. Private Industry
  - 5. Other

- B. Job Function:
  - 6. Analytical
  - 7. Financial/Purch.
  - 8. Health and Safety
  - 10. Mgmt/Corporate
  - 11. Mgmt/Facilities
  - 12. Mgmt/Personnel
  - 13. Marketing/Sales
  - 14. Quality Assurance
  - 15. Regulatory
  - 16. R&D/Admn.
  - 17. R&D/Operations

- C. Field of Work:
  - 18. R&D/Technical
  - 19. Teaching
  - 20. Other
  - 21. Biological Modeling
  - 22. Biotechnology
  - 23. Carcinogenesis
  - 24. Cardiovascular
  - 27. Dermal Tox.
  - 29. Epidemiology
  - 30. Ethical, Legal, and Social Issues
  - 31. Food Safety
  - 32. Genetic Tox.
  - 33. Immunotoxicology
  - 34. Infusion Tox.
  - 35. Inhalation Tox.
  - 36. In Vitro and Alt. Methods
  - 37. Mechanisms
  - 38. Medical Devices
  - 39. Metals
  - 40. Methods
  - 41. Mixtures
  - 42. Molecular Biology
  - 43. Mutagenicity
  - 44. Nanotoxicology
  - 45. Neurotoxicology
  - 46. Pathology
  - 47. Pharmacokinetics
  - 48. Pharmacology
  - 49. Occup. and Public Health
  - 50. Occul Tox.
  - 51. Risk Assessment
  - 52. Reg. and Safety Eval.
  - 54. Stem Cells
  - 55. General Tox.
  - 56. Other

- D. Product Interest:
  - 57. Publications
  - 58. Contract Services:
    - a. Analytical
    - b. Aquatic Tox.
    - c. Clinical Tox.
    - d. Computer
    - e. In Vitro Tox.
    - f. Metabolic Profile
    - g. Pathology
    - h. Preclinical Tox.
    - i. Quality Assurance
    - j. Wildlife Tox.

- E. Purchasing Responsibilities:
  - 61. a. I make purchasing decisions
  - b. I influence purchasing decisions
  - c. I do not participate in purchasing decisions

SOT will accept faxed Registration Forms until March 7. Online registration will be open until March 15. On-Line Registration Forms will be available at the Annual Meeting Registration Desk. There will be no refunds after February 17, 2012.
Registration

Tickets
Tickets are required for Continuing Education courses and some other events. If you have these events on your registration form, your tickets will be issued with your meeting badge. Annual Meeting registration is required to participate in CE or special events.

Confirmation
Online registrants will receive an electronic confirmation following registration. All registrants will be mailed a registration confirmation, name badge, and Continuing Education and/or event ticket(s) before the meeting if your Registration Form is received by January 27, 2012. If your registration is received after January 27, you can pick up your badge and tickets at the “BADGE PICK UP ONLY” registration counters on-site.

Cancellation Refund Policy
All requests for cancellations and/or refunds must be received in writing at SOT Headquarters by February 17, 2012. These refunds will be processed, less a $50 cancellation fee, following the Annual Meeting. Refund requests received after February 17, 2012, will not be processed.

Exhibitors
To register exhibitor booth staff, please visit www.ToxExpo.com and log into the Exhibitor Service Center using your password, which was provided in your booth confirmation email. For more information, please email sot_exhibits@toxicology.org.

Americans with Disabilities Act (ADA)
The Moscone Convention Center is accessible to persons with special needs. If you have special needs, please check the special accessibility requirement box or contact Heidi Prange at SOT Headquarters: 703.438.3115 ext. 1424 or email: heidi@toxicology.org.

Global Gallery of Toxicology

Celebrate the Diversity of Toxicology Globally

Scientific societies are invited to display a poster showcasing their information, key accomplishments, and more.

Posters will be displayed prominently at the Moscone Convention Center.

Please see details on page 14.
New this year, SOT has partnered with our abstract and ToxEpo service providers to offer you multiplatform mobile solutions for the SOT Annual Meeting and ToxEpo, provided free of charge to attendees and exhibitors. These mobile tools enable you, the attendee, to engage with organizers, exhibitors, and each other, and to manage your time and maximize your experience while at the Annual Meeting.

The Next Generation Mobile Itinerary Planner: MyItinerary

With MyItinerary, you have the option of using our traditional meeting materials or browsing and searching the meeting program and creating a personalized itinerary with a mobile version of the SOT Annual Meeting Itinerary Planner.

**MyItinerary allows you to:**

- Browse sessions, events, meetings, and receptions
- View presentation details
- Add individual presentations or entire sessions to your itinerary
- View schedule conflicts and withdrawals
- Search for items based on session title, abstract title, location, or author name
- View the Moscone Convention Center map
- Access Annual Meeting information

**ChirpE Mobile Application for ToxEpo**

Access ToxEpo information and browse a real-time ToxEpo floor plan, search for 2012 exhibitors, products, and services, and virtually interact with these exhibitors.

*Among other things, ChirpE allows you to:*

- Access the real-time ToxEpo floor plan and search for products, specials, and exhibitors
- Navigate ToxEpo easily from your mobile device
- Contact Exhibitors

Access information from any mobile device, including popular smart phones, tablets, and iPads.
SOT Job Bank

YOUR RECRUITMENT AND EMPLOYMENT RESOURCE

Job Seekers—Jobs Await You in the SOT Job Bank!!!
Employers Are Looking for Candidates through This Service and You Don’t Want to Be Left Out

- All SOT members can utilize the SOT Job Bank as a job seeker free-of-charge.
- Register and enter your candidate profile; it takes only 15 minutes to complete.
- Post your resume.
- Review the positions posted by major corporations, academic institutions, government agencies, and private research organizations; positions range from junior to senior level.
- Search by geographic location, employer name, salary, and other criteria.
- Find potential matches to your skills and training at any stage of your career.
- Contact employers.
- Gain access to information that will help you plan your near-term and long-term goals and objectives.
- See which sectors are hiring.
- Stay abreast of new and emerging areas.

Employers—Recruit Highly Qualified Candidates through the SOT Job Bank!!!
The SOT Job Bank is the Ideal Place to Streamline Your Recruitment Process and Provides Your Organization with a Valuable Tool

- Search from a pool of distinguished candidates.
- Join the many employers who rely on this cost-effective and efficient database to assist with their employment needs.
- Find the right candidate from among scientists trained in toxicology and the biological sciences with the expertise and right work experience for your position.
- Schedule interviews to hold during the SOT Annual Meeting at the on-site Job Bank Center.
- Reserve interview rooms in advance or on-site.
- SOT Affiliates receive a reduced registration rate in appreciation for supporting the Society in achieving its objectives.

The Online SOT Job Bank is available any time, from any place at www.toxicology.org/jobbank
Streamline Your Job Search: Use SOT Job Bank Services

Free Job Search for SOT Members!

The SOT Annual Meeting, with over 7,500 attendees including the best toxicologists, early career scientists, and toxicology-related employers, is the best place to make your connection, whether you are looking for a position or searching for the right candidate. To facilitate job searches, the SOT online Job Bank is available at all times, and provides you the opportunity to prepare to take full advantages of the on-site Job Bank Center in San Francisco.

Job Bank

Access Available Any Time, Any Place!

The online Job Bank includes positions available at corporations, academic institutions, government agencies, and private research organizations. Last year over 200 positions were posted at the time of the Annual Meeting. Employers rely on this service to provide them with a robust database of candidates available for career opportunities ranging from junior to senior level positions. As a member benefit, SOT members can search Job Bank listings at no cost. SOT Affiliates may use this system at a reduced rate in appreciation of their commitment to helping further the objectives of the Society. Candidates and employers alike can access this year-round service any time, any place at www.toxicology.org/jobbank.

The SOT online Job Bank allows you to:

- Register as a candidate or employer
- Post employment positions or resumes
- Search the Job Bank database
- Contact employers or candidates

Once registered, candidates may search the listing of available jobs and employers may browse candidate profiles. Both employers and candidates have the option of making a confidential posting, in which no identifying information is displayed. Communication with a desired employer or candidate can even be made via email messages created within the system to protect confidentiality. Candidates will want to update their CV and contact information due to the increased traffic to the Job Bank at the time of the Annual Meeting.

Annual Meeting Job Bank Center

Located in the Moscone Convention Center in rooms 272, 274, and 276, the on-site Job Bank Center provides access to the SOT Job Bank as well as assistance in facilitating interviews at the SOT Annual Meeting. We offer personalized assistance if you are new to the Job Bank or have questions. For your convenience, printers will be available for producing hard copies of candidate profiles and position descriptions. All candidates and positions must be sought online.

The Center is available during the following hours of operation:

- Sunday .................. 1:00 PM–5:00 PM
- Monday .................. 9:00 AM–5:00 PM
- Tuesday .................. 8:30 AM–5:00 PM
- Wednesday .............. 8:30 AM–5:00 PM

Employers recognize and appreciate that the Annual Meeting Job Bank Center provides a cost-effective and efficient way to interview a distinguished pool of candidates. For your convenience, we provide eight interview rooms on-site during the hours listed above. In advance of the meeting, employers will be able to make reservations for these interview rooms, allowing better scheduling for employers and candidates.

As with the online Job Bank, SOT Members have free access to the Center. All users with current Job Bank registration at the time of the Annual Meeting will be permitted to use this service. Although you are encouraged to preregister before entering the Job Bank Center, you can register on-site.

Job Bank access will be available—as always—through your personal computer or mobile device and at the Annual Meeting Email Center. Access to the online Job Bank in the Job Bank Center is limited to short searches for updates or new information. For additional information, contact Kelly Martin at SOT Headquarters: 703.438.3115 ext. 1660 or email: kelly@toxicology.org.

Mentor Match

Online Mentoring Program

The Society of Toxicology recognizes the importance of mentoring in the scientific and professional development of its members. The objective of the online mentoring program, Mentor Match, is to provide a service that matches mentees with potential mentors from the SOT membership to provide advice on career path selection, professional development, and life/work balance issues. SOT members are encouraged to share their professional knowledge and experience by serving as mentors for colleagues and for the next generation of toxicologists. The SOT Annual Meeting provides a great opportunity for the mentor and mentee to meet in person. We strongly encourage members of the Society to visit the Mentor Match site and register online as mentors and/or mentees. The Mentor Match program will develop as individuals register, allowing the quantity of profiles to increase to a robust combination of both mentors and mentees. The Mentor Match program is accessible to all active SOT members by visiting www.toxicology.org/ai/newcrad/mentormatch.asp.
## Awards Ceremony

**Sunday, March 11, 2012**

*5:15 PM–6:30 PM, Moscone Convention Center*

### Society of Toxicology Awards

<table>
<thead>
<tr>
<th>Category</th>
<th>Recipient</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Honorary Membership</strong></td>
<td>Frank J. Gonzalez, PhD</td>
<td>National Cancer Institute, Bethesda, MD</td>
</tr>
<tr>
<td></td>
<td>Leroy Hood, MD, PhD</td>
<td>Institute for Systems Biology, Seattle, WA</td>
</tr>
<tr>
<td><strong>Achievement Award</strong></td>
<td>Donna D. Zhang, PhD</td>
<td>University of Arizona, Tucson, AZ</td>
</tr>
<tr>
<td><strong>Arnold J. Lehman Award</strong></td>
<td>Joe L. Mauderly, DVM</td>
<td>Lovelace Respiratory Research Institute, Albuquerque, NM</td>
</tr>
<tr>
<td><strong>Distinguished Toxicology Scholar Award</strong></td>
<td>Ernest Hodgson, PhD</td>
<td>North Carolina State University, Raleigh, NC</td>
</tr>
<tr>
<td><strong>Education Award</strong></td>
<td>John H. Duffus, DSc</td>
<td>Edinburgh, United Kingdom</td>
</tr>
<tr>
<td><strong>Founders Award</strong></td>
<td>John A. Moore, DVM, DABT</td>
<td>Hollyhouse Inc, Wicomico Church, VA</td>
</tr>
<tr>
<td><strong>Leading Edge in Basic Science Award</strong></td>
<td>Myung-Haing Cho, DVM, PhD</td>
<td>Seoul National University, Seoul, South Korea</td>
</tr>
<tr>
<td><strong>Merit Award</strong></td>
<td>Curtis D. Klaassen, PhD, DABT, ATS</td>
<td>University of Kansas Medical Center, Kansas City, KS</td>
</tr>
<tr>
<td><strong>Perry J. Gehring Diversity Student Travel Award</strong></td>
<td>Alba K. Gonzalez Rivera</td>
<td>University of Puerto Rico Arecibo, Arecibo, Puerto Rico</td>
</tr>
<tr>
<td><strong>Public Communications Award</strong></td>
<td>Martin A. Philbert, PhD, ATS</td>
<td>University of Michigan, Ann Arbor, MI</td>
</tr>
<tr>
<td><strong>Translational Impact Award</strong></td>
<td>John G. Benitez, MD, MPH</td>
<td>Vanderbilt University Medical Center, Nashville, TN</td>
</tr>
<tr>
<td><strong>Translational/Bridging Travel Award</strong></td>
<td>Xuemei Huang, MD, PhD</td>
<td>Penn State Hershey Medical Center, Hershey, PA</td>
</tr>
<tr>
<td><strong>Undergraduate Educator Award</strong></td>
<td>Sue M. Ford, PhD, DABT</td>
<td>St John’s University, Jamaica, NY</td>
</tr>
</tbody>
</table>

**SOT Sponsored Awards**

---

**ENDOWMENT**

Investing in the Future...
Congratulations!

Society of Toxicology
Best Publication Awards

Best Postdoctoral Publication Awards
Maryse Lemaire, PhD
Lady Davis Institute for Medical Research, Montréal, Québec, Canada

Xuefeng Ren, PhD
The State University of New York at Buffalo, Buffalo, NY

Nisha Sipes, PhD
US EPA, Research Triangle Park, NC

Board of Publications for the Best Paper in Toxicological Sciences Award

Joshua G. DeKeyser, Elizabeth M. Laurenzana, Eric C. Peterson, Tao Chen, and Curtis J. Omiecinski

Sponsored Awards

AstraZeneca Traveling Lectureship Award
Bhagavatula Moorthy, PhD
Baylor College of Medicine, Houston, TX

Colgate-Palmolive Awards for Student Research Training in Alternative Methods
Agnes Forgacs, BSc
Michigan State University, East Lansing, MI

Colgate-Palmolive Grants for Alternative Research
Mingzhu Fang, PhD
University of Medicine and Dentistry of New Jersey, Piscataway, NJ

Colgate-Palmolive Postdoctoral Fellowship Award in In Vitro Toxicology
Melanie Adler, PhD
University of Wuerzburg, Wuerzburg, Germany and Harvard Medical School, Boston, MA

Pfizer Undergraduate Student Travel Awards
Ashley Press
High Point University, High Point, NC
Brittany Winner
Sam Houston State University, Huntsville, TX

Darien Shapiro
University of Utah, Salt Lake City, UT
Frances A. Xin
St. Olaf College, Northfield, MN

Qi Wang
Rutgers, The State University of New Jersey, North Brunswick, NJ

Syngenta Fellowship Award in Human Health Applications of New Technologies
Benjamin Moeller, PhD
University of North Carolina, Chapel Hill, NC

Society of Toxicology
Global Senior Scholar Exchange Program

Jesus Olivero-Verbel, PhD
PhD Program in Environmental Toxicology, Faculty of Pharmaceutical Sciences University of Cartagena, Cartagena, Colombia

Orish Ebere Orisakwe, PhD, ERT, FATS, MRSC
Toxicology Unit, Department of Clinical Pharmacy, Faculty of Pharmacy University of Port Harcourt, Choba, Port Harcourt, Rivers State, Nigeria

up-to-date information at www.toxicology.org
SOT Developing Country Travel Fellowships
The SOT/AstraZeneca/IUTOX Travel Fellowships for seven individuals from developing countries selected in December 2011 will be honored at the Awards Ceremony.

The SOT Endowment International Fund/IUTOX Travel Fellowships for two individuals from developing countries selected in December 2011 will be honored at the Awards Ceremony.

Outstanding Graduate Student Leadership Committee (GSLC) Award
The Outstanding Graduate Student Leadership Committee (GSLC) Award recognizes a student representative who has contributed to the Society in a significant manner (i.e., above and beyond the normal expected basic service as a representative). Academic achievements are not considered for the award. Representative nominations and support letters should be submitted by February 1. The recipients will be honored at the Graduate Student/Postdoc Mixer on Sunday, March 11.

Regional Chapter, Special Interest Group, and Specialty Section Awards
Regional Chapters, Special Interest Groups, and Specialty Sections offer awards throughout the year. Check the website for full details at www.toxicology.org.

Novartis Graduate Student Fellowship Award
The Novartis Graduate Student Fellowship Award recipient selected in March 2012 will be honored at the Awards Ceremony.

SOT Award Lectures

Merit Award Lecture
Monday, March 12, 12:30 PM–1:20 PM

Lecturer: Curtis D. Klaassen, University of Kansas Medical Center, Kansas City, KS.

Leading Edge in Basic Science Award Lecture
Tuesday, March 13, 7:00 AM–7:50 AM

Lecturer: Myung-Haing Cho, Seoul National University, Seoul, South Korea.

Distinguished Toxicology Scholar Award Lecture
Environmental Chemicals: From Biochemical and Molecular Toxicology to Education and Outreach
Tuesday, March 13, 12:30 PM–1:20 PM

Lecturer: Ernest Hodgson, North Carolina State University, and the North Carolina Agromedicine Institute, Raleigh, NC.

Translational Impact Award Lecture
Medical Toxicology Evaluations of the 2008 TVA Fly Ash Spill
Wednesday, March 14, 12:30 PM–1:20 PM

Lecturer: John G. Benitez, Vanderbilt University Medical Center, Nashville, TN.

More information about award lectures can be found on pages 64–65.
Recognition and Special Events

All activities will be held at the Moscone Convention Center in San Francisco, California, unless otherwise noted.

Full details on the Special Events will be available in the Program, IT Planner, and on the website.

Committee on Diversity Initiatives Reunion

Saturday, March 10, 8:00 PM–9:00 PM
Grand Hyatt

Sponsor: Committee for Diversity Initiatives (CDI)

The Committee on Diversity Initiatives (CDI) will host the CDI Reunion from 8:00 pm–9:00 pm on Saturday, March 10. Whether as a student, peer mentor, host mentor, speaker, or organizer, anyone who has ever been involved in the SOT Undergraduate Program is invited to attend.

Visit with colleagues who have been involved in the program over the last 23 years, meet with program alums, and greet the underclassmen and seniors who are attending the program this year. The Perry J. Gehring Diversity Student Travel Award will be presented. Enjoy dessert, coffee, and tea.

Welcome Reception

Sunday, March 11, 6:30 PM–7:30 PM
Continue the celebration by attending the Welcoming Reception following the Awards Ceremony. The Welcoming Reception is a great opportunity to renew old friendships and to make new acquaintances. Please join the Society in this kick-off of the Annual Meeting.

Awards Ceremony Music

Sunday, March 11, 4:45 PM–5:15 PM

Performed by Glenn Staller

Classical guitarist, Glenn Staller will perform for SOT Annual Meeting attendees prior to and after the SOT Award Ceremony. Glenn was born in Philadelphia, Pennsylvania, and began studying the guitar at the age of 13. After moving to California, a chance meeting with renowned guitarist Jose Rey de la Torre led to classical guitar studies with Maestro Torres. Glenn later studied with pianist Julian White, jazz guitarist Bill Tapia, flamenco guitarist Chuscales, and guitarist/composer Dusan Bogdanovic at the San Francisco Conservatory of Music. The depth and breadth of his repertoire and his unique ability to integrate musical styles, from classical and contemporary to flamenco, Brazilian, Argentinean, and jazz, is a particular feature of his work. His repertoire ranges from Scarlatti and Bach to Gershwin, Debussy, Jobim, and Brubeck. He has appeared in equally diverse concert settings such as the Dean Lesher Center, Le Petit Trianon, Valley Forge Convention Center, Kennedy Center, Cowell Theater, and numerous wineries, vineyards, and resorts within the Bay Area, as well as performing on television and radio.

Awards Ceremony

Sunday, March 11, 5:15 PM–6:30 PM
SOT will recognize our prestigious award recipients at the SOT Awards Ceremony (pages 38 and 39). Please refer to the Awards and Fellowships section of the SOT website for complete details.

Welcome Reception

Sunday, March 11, 6:30 PM–7:30 PM
Continue the celebration by attending the Welcoming Reception following the Awards Ceremony. The Welcoming Reception is a great opportunity to renew old friendships and to make new acquaintances. Please join the Society in this kick-off of the Annual Meeting.

25-Year (Or More) Member Reception

Sunday, March 11, 7:00 PM–8:00 PM
If you have been a member of the Society of Toxicology for 25 years or more, please join your colleagues to celebrate and recognize the scientists who established the Society. Be sure to sport your 25-year, 35-year, 45-year, or 50-year member pin.

Global Collaboration Coffee

Monday, March 12, 9:00 AM–10:00 AM
The SOT Council and Global Strategies Task Force invite scientists representing international toxicology societies displaying posters in the Global Gallery of Toxicology, Special Interest Group Presidents, and the recipients of the SOT/AstraZeneca/IUTOX and SOT Endowment Fund Fellowships (senior scientists from developing countries) for a Global Collaboration Coffee. This event offers an opportunity for scientific leaders to meet and make plans for future collaborations. Send RSVP (required) to Renee Maisel at renee@toxicology.org.

In Vitro Toxicology Lecture and Luncheon for Students

Monday, March 12, 12:00 Noon–1:20 PM
Marriott Marquis
(Ticket Required)

Chairperson(s): Lorrene Buckley, Education Committee Chair, Eli Lilly & Company, Indianapolis, IN.

Can In Silico and/or In Vitro Testing Be Used for Toxicity Assessment Instead of In Vivo Approaches?

Lecturer: Timothy J. Shafer, US EPA, Research Triangle Park, NC.

Sponsor: Colgate-Palmolive Company

Host: Education Committee

The goal of the In Vitro Toxicology Lecture series is to feature important research using in vitro and alternative techniques to study basic mechanisms and to illustrate how these test methods benefit animal welfare by refining, reducing, and replacing animal use whenever it is feasible. Graduate students, undergraduates, postdoctoral scholars, and recipients of Colgate-Palmolive awards are among the guests at the In Vitro Toxicology Lecture and Luncheon. Students and postdoctoral scholars register via the Annual Meeting registration, and the $10 deposit will be returned upon entry to the event.
Special Events

Dr. Shafer will present an introduction to the topic, and then participants will discuss related questions and report responses. More information can be found on page 48.

Past Presidents Fun Run
Tuesday, March 13, 6:00 AM

Building on the positive response from last year, the Past Presidents Fun Run returns on the streets of San Francisco. With no registration or sign-up fee and a flexible starting point, this is truly going to be a “Fun Run.” Meet your fellow meeting attendees in the lobby of your hotel on Tuesday, March 13 at 6:00 am local time, ask the front desk for the official SOT Past Presidents Fun Run map, and begin! (All hotels in the official SOT housing block will have a copy of this map.)

Not a runner? Not a problem! This event looks to bring together runners or walkers of all levels and paces. The course accommodates everyone with a goal of having fun.

There will not be run officials, so if you plan to time yourself and would like to share, please email your name, time, and hotel to Renee Maisel at renee@toxicology.org and we will post the times to the SOT website. We also welcome photos and a small writeup to be published in the Spring Communiqué.

Postdoctoral Assembly Luncheon
Tuesday, March 13, 12:00 Noon–1:15 PM
(Ticket Required)
Chairperson(s): Michele La Merrill, Mount Sinai School of Medicine, New York, NY.

Sponsor: Postdoctoral Assembly

Amidst scrambling to attend all of the events at the meeting, this will be time for postdocs to kick back and relax! All postdoctoral scholars are invited to a casual luncheon organized by the Postdoctoral Assembly (PDA). The recipients of the Best Postdoctoral Publication Awards and the postdocs who received awards this year from Regional Chapters, Special Interest Groups, and Specialty Sections will be announced. The PDA Board members will present an overview of accomplishments and future directions for the PDA, and will introduce the new board members for 2012–2013. There will be a drawing for prizes. Postdocs can reserve a ticket for $5 when they register for the Annual Meeting.

Undergraduate Educator Network Meeting
Tuesday, March 13, 3:00 PM–4:15 PM
Chairperson(s): Sue M. Ford, St. John’s University, Jamaica, NY.

Sponsors:
Education Committee
Undergraduate Education Subcommittee

The Education Committee and the Undergraduate Education Subcommittee are hosting the Undergraduate Educator Network Meeting for all faculty involved in the teaching of toxicology to undergraduates, or for those interested in including toxicology at the undergraduate level. Hear an update on initiatives for undergraduate faculty, provide your input, and network.

SOT Annual Business Meeting
Tuesday, March 13, 4:30 PM–6:00 PM
(SOT Members Only)

Members are invited and encouraged to attend the 51st SOT Annual Business Meeting. The agenda includes discussion of the NEW 2012–2015 SOT Strategic Plan, a financial summary, and a review of the 2011–2012 activities.

Tox ShowDown
Tuesday, March 13, 7:30 PM–9:00 PM
Marriott Marquis

Chairperson(s): Sue M. Ford, St. John’s University, Jamaica, NY, and Phil Wexler, NIH-NLM, Bethesda, MD.

Sponsor: Graduate Student Leadership Committee

Join the Graduate Student Leadership Committee (GSLC) and your peers Tuesday night for the Tox ShowDown, an engaging quiz game patterned off the popular long-running show It’s Academic. Teams of three contestants will compete at answering questions concerning toxicology not only in its scientific context, but as it relates to society, the arts, and culture. Sponsored by GSLC, this event is sure to be both informative and entertaining and a perfect way to celebrate the halfway point of the SOT Annual Meeting. The game will provide attendees with a break, albeit still toxicologically oriented, from the more technical business of the meeting.
“Hoops for the Endowment Fund” Basketball Free-Throw Competition

Monday, March 12–Wednesday, March 14, Various Times
(Refer to the Annual Meeting Program and Itinerary Planner for more details.)

Sponsors:
Toxicologists of African Origin
Special Interest Group

It is with pleasure that I present this fund-raising FUN competition on behalf of the Toxicologists of African Origin Special Interest Group (TAO-SIG). While the TAO-SIG’s goal is to raise funds to ensure that its Endowment Fund reaches the status of a Permanently Restricted Net Asset Fund, all the Society and Named Funds that make up the SOT Family of Endowment Funds can benefit from your support and participation. We invite everyone attending the 2012 Annual SOT Meeting in San Francisco to join us in this endeavor and lend your energy and enthusiasm to the efforts on behalf of your favorite Endowment Fund(s)... let’s have some FUN!!!—Claude McGowan, PhD, Past President, TAO-SIG and Coordinator of TAO Fundraising, 2011–2012

The “Hoops for the Endowment Fund” fund-raising event has two essential components:

1) Preannual meeting individual and team free throw sponsorship opportunities for the purposes of raising money for SOT Endowment Funds. SOT Regional Chapters, Specialty Sections, and Special Interest Groups are especially invited to participate in this fundraising event. This will provide these component groups the opportunity to support the Funds with which they have an association. In addition to the Named Funds, groups may wish to use this opportunity to work together to support Society Funds as well.

2) Individual and team free throw play-offs to be held at the Annual Meeting for the purposes of providing an on-site fun activity and raising money for SOT Endowment Funds in an open forum. Sponsorships of individual and team participants will be available. Please consult the final Program for details on this event.

Please note that participation is open to all SOT members and all registered attendees at 2012 Annual Meeting (e.g., non-member attendees, exhibitors, etc.). Individuals will seek sponsorship for themselves and/or for their team. Teams may be formed with unlimited membership and active participation during the premeeting phase to maximize sponsorship potential.

These “virtual” teams will allow participants to be teammates regardless of where they are geographically located. For the on-site phase, each established team will designate any five (5) players to participate. Individuals may only hold membership on one team. SOT Regional Chapters, Specialty Sections, Special Interest Groups and other groups (such as the Graduate Student Leadership Council and Postdoctoral Assembly) may field as many teams as they see fit for the premeeting phase and comply with the five (5) players rule for the on-site activity.

Prizes—to be awarded at Annual Meeting Playoffs:
• Individual and Team Free-Throw Champions
• Individual and Team with the Most Attempts
• Individual and Team with the Highest Percentage of Free-Throws Made (min. 100 attempts)
• Individual and Team with the Most Donations ($ amount)

“Hoop it up” for the Endowment Fund. Be sure to participate in this FUN event!

Special thanks goes to Calvert Labs and Charles River for sponsorship of two basketball courts in the ToxExpo hall in San Francisco!
Special Events

Regional Chapter Meetings/Luncheons or Receptions

Monday, March 12, through Wednesday, March 14, Various Times (Refer to the Annual Meeting Program and Itinerary Planner for more details.)

Many of the SOT Regional Chapters meet during the SOT Annual Meeting. A list of Regional Chapter receptions will be listed in the Program Event Calendar.

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Capital Area Regional Chapter Reception</td>
<td>Monday, March 12</td>
<td>5:30 PM–7:30 PM</td>
</tr>
<tr>
<td>Northern California Regional Chapter Reception</td>
<td>Monday, March 12</td>
<td>5:00 PM–8:00 PM</td>
</tr>
<tr>
<td>Pacific Northwest Regional Chapter Reception</td>
<td>Monday, March 12</td>
<td>7:00 PM–10:00 PM</td>
</tr>
<tr>
<td>Regional Chapter Collaboration and Communications Committee Meeting</td>
<td>Wednesday, March 14</td>
<td>12:00 Noon–1:30 PM</td>
</tr>
<tr>
<td>Regional Chapter Presidents and Officers Meeting</td>
<td>Tuesday, March 13</td>
<td>7:00 AM–8:00 AM</td>
</tr>
<tr>
<td>South Central and Lone Star Regional Chapters Joint Social</td>
<td>Monday, March 12</td>
<td>7:00 PM–9:00 PM</td>
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</tbody>
</table>

Special Interest Group Meetings/Luncheons or Receptions

Monday, March 12, through Wednesday, March 14, Various Times (Refer to the Annual Meeting Program and Itinerary Planner for more details.)

Each of the six Special Interest Groups will hold a meeting/reception during the 2012 SOT Annual Meeting at various local locations. All current and prospective SOT Special Interest Group members are encouraged to attend. The Event Calendar in the Program will have an updated listing of locations and event times.

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>American Association of Chinese in Toxicology Special Interest Group Distinguished Chinese Toxicologist Lectureship Award and Seminar</td>
<td>Monday, March 12</td>
<td>5:00 PM–6:00 PM</td>
</tr>
<tr>
<td>American Association of Chinese in Toxicology Special Interest Group Reception</td>
<td>Monday, March 12</td>
<td>6:30 PM–9:00 PM</td>
</tr>
<tr>
<td>Association of Scientists of Indian Origin Special Interest Group Reception</td>
<td>Monday, March 12</td>
<td>7:00 PM–9:00 PM</td>
</tr>
<tr>
<td>Association of Scientists of Indian Origin Special Interest Group Student/Postdoc Mentoring Program</td>
<td>Tuesday, March 13</td>
<td>12:00 Noon–1:30 PM</td>
</tr>
<tr>
<td>Hispanic Organization of Toxicologists Special Interest Group Reception</td>
<td>Tuesday, March 13</td>
<td>6:00 PM–8:00 PM</td>
</tr>
<tr>
<td>Korean Toxicologists Association in America Special Interest Group Reception</td>
<td>TBD</td>
<td>TBD</td>
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<tr>
<td>Special Interest Group Collaboration Group Meeting</td>
<td>Wednesday, March 14</td>
<td>7:30 AM–8:30 AM</td>
</tr>
<tr>
<td>Special Interest Group Presidents and Officers Meeting</td>
<td>Monday, March 12</td>
<td>12:00 Noon–1:00 PM</td>
</tr>
<tr>
<td>Toxicologists of African Origin Special Interest Group Reception</td>
<td>Monday, March 12</td>
<td>5:00 PM–6:30 PM</td>
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<tr>
<td>Women in Toxicology Special Interest Group Executive Committee Meeting</td>
<td>Tuesday, March 13</td>
<td>3:00 PM–4:00 PM</td>
</tr>
<tr>
<td>Women in Toxicology Special Interest Group Mentoring Breakfast</td>
<td>Monday, March 12</td>
<td>6:15 AM–8:15 AM</td>
</tr>
<tr>
<td>Women in Toxicology Special Interest Group Reception</td>
<td>Wednesday, March 14</td>
<td>4:30 PM–6:00 PM</td>
</tr>
</tbody>
</table>
Specialty Section Meetings/Luncheons or Receptions

Monday, March 12, through Wednesday, March 14, Various Times (Refer to the Annual Meeting Program and Itinerary Planner for more details.)

Each of the 27 SOT Specialty Sections will hold either a luncheon or early evening meeting/reception during the 2012 SOT Annual Meeting. All current and prospective SOT Specialty Section members are encouraged to attend. The Event Calendar in the Program will have an updated listing of locations and event times.

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
<th>Time</th>
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<tbody>
<tr>
<td>Biological Modeling Specialty Section Reception</td>
<td>Monday, March 12</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Biotechnology Specialty Section Reception</td>
<td>Wednesday, March 14</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Carcinogenesis Specialty Section Officers Meeting</td>
<td>Monday, March 12</td>
<td>6:30 AM–8:00 AM</td>
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<tr>
<td>Carcinogenesis Specialty Section Reception</td>
<td>Tuesday, March 13</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Cardiovascular Toxicology Specialty Section Reception</td>
<td>Tuesday, March 13</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Clinical and Translational Toxicology Specialty Section Officers Meeting</td>
<td>Monday, March 12</td>
<td>6:30 AM–8:00 AM</td>
</tr>
<tr>
<td>Clinical and Translational Toxicology Specialty Section Reception</td>
<td>Wednesday, March 14</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Comparative and Veterinary Specialty Section Luncheon</td>
<td>Monday, March 12</td>
<td>12:00 Noon–1:30 PM</td>
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<tr>
<td>Dermal Toxicology Specialty Section Reception</td>
<td>Tuesday, March 13</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Drug Discovery Toxicology Specialty Section Reception</td>
<td>Monday, March 12</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Ethical, Legal, and Social Issues Specialty Section Reception</td>
<td>Monday, March 12</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Food Safety Specialty Section Reception</td>
<td>Tuesday, March 13</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Immunotoxicology Specialty Section Reception</td>
<td>Tuesday, March 13</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>In Vitro and Alternative Methods Specialty Section Luncheon</td>
<td>Wednesday, March 14</td>
<td>12:00 Noon–1:30 PM</td>
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<tr>
<td>In Vitro and Alternative Methods Specialty Section Officers Meeting</td>
<td>Monday, March 12</td>
<td>6:30 AM–8:00 AM</td>
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<tr>
<td>Inhalation and Respiratory Specialty Section Officers Meeting</td>
<td>Monday, March 12</td>
<td>6:30 AM–8:00 AM</td>
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<tr>
<td>Inhalation and Respiratory Specialty Section Reception</td>
<td>Monday, March 12</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Inhalation and Respiratory Specialty Section Technical Meeting</td>
<td>Tuesday, March 13</td>
<td>7:00 AM–8:30 AM</td>
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<tr>
<td>Mechanisms Specialty Section Officers Meeting</td>
<td>Monday, March 12</td>
<td>6:30 AM–8:00 AM</td>
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<tr>
<td>Mechanisms Specialty Section Reception</td>
<td>Monday, March 12</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Medical Device Specialty Section Reception</td>
<td>Tuesday, March 13</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Metals Specialty Section Reception</td>
<td>Tuesday, March 13</td>
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### Specialty Section Meetings/Luncheons or Receptions (continued)

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Mixtures Specialty Section Reception</td>
<td>Monday, March 12</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Molecular Biology Specialty Section Reception</td>
<td>Tuesday, March 13</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Nanotoxicology Specialty Section Reception</td>
<td>Tuesday, March 13</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Neurotoxicology Specialty Section Reception</td>
<td>Tuesday, March 13</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Occupational and Public Health Specialty Section Reception</td>
<td>Tuesday, March 13</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Ocular Toxicology Specialty Section Reception</td>
<td>Tuesday, March 13</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Regulatory and Safety Evaluation Specialty Section Officers Meeting</td>
<td>Monday, March 12</td>
<td>6:30 AM–8:00 AM</td>
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<tr>
<td>Regulatory and Safety Evaluation Specialty Section Reception</td>
<td>Monday, March 12</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Reproductive and Developmental Toxicology Specialty Section Officers Meeting</td>
<td>Monday, March 12</td>
<td>7:00 AM–8:30 AM</td>
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<tr>
<td>Reproductive and Developmental Toxicology Specialty Section Reception</td>
<td>Wednesday, March 14</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Risk Assessment Specialty Section Officers Meeting</td>
<td>Monday, March 12</td>
<td>6:30 AM–8:00 AM</td>
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<tr>
<td>Risk Assessment Specialty Section Reception</td>
<td>Tuesday, March 13</td>
<td>6:00 PM–7:30 PM</td>
</tr>
<tr>
<td>Specialty Section Collaboration and Communication Group Meeting</td>
<td>Monday, March 12</td>
<td>3:00 PM–4:00 PM</td>
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<tr>
<td>Specialty Section Presidents and Officers Meeting</td>
<td>Monday, March 12</td>
<td>4:30 PM–6:00 PM</td>
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<tr>
<td>Stem Cells Specialty Section Reception</td>
<td>Wednesday, March 14</td>
<td>6:00 PM–7:30 PM</td>
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<tr>
<td>Toxicologic and Exploratory Pathology Specialty Section Luncheon</td>
<td>Wednesday, March 14</td>
<td>12:00 Noon–1:30 PM</td>
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<tr>
<td>Toxicologic and Exploratory Pathology Specialty Section Officers Meeting</td>
<td>Monday, March 12</td>
<td>6:30 AM–7:45 AM</td>
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Congratulations on the Increased Impact Factor of 5.093!*  

Toxicological Sciences  

The Official Journal of the Society of Toxicology  

• The top original research journal in Toxicology  

• Advance Access—quick online publication, weeks ahead of print  

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OR VISIT US ONLINE AT www.toxsci.oxfordjournals.org  

* 2010 Journal Citation Reports (Thomson Reuters, 2011)
Special Events

Student and Postdoctoral Scholar Events

Chat with an Expert

Sunday, March 11–Thursday, March 15, Time Varies by Group
(Meet at the Chat with an Expert Bulletin Board in Registration Area)

Sponsor: Graduate Student Leadership Committee

The purpose of Chat with an Expert is to provide students and postdoctoral scholars the opportunity to network informally with well-established toxicologists while obtaining career advice and meeting new colleagues. Small groups are composed by matching research interests of students and postdocs with those of an expert. The expert for each group identifies a time and a place for an informal meeting (such as a coffee house or inexpensive restaurant), and the group meets at the Chat with an Expert Bulletin Board before proceeding to the meeting location. This program also includes opportunities for postdocs to host informal meetings with graduate students, and graduate students to hold informal meetings with undergraduates. Sign up via the Graduate Student section of the SOT website. Details for each group meeting will be sent to participants in advance of the meeting.

Poster Tours for Trainees

Monday, March 12–Thursday, March 15 Specific Time Varies by Group

Sponsor: Postdoctoral Assembly

New at the 2012 Annual Meeting! Students and postdoctoral scientists have the opportunity to participate in a one hour guided poster tour with an expert toxicologist. Poster Tours for Trainees will allow trainees to take part in critical evaluation of cutting-edge toxicology methods and research findings, network with an expert, and perhaps even build a long-term relationship with a senior toxicologist. Options to sign up for specific times will be provided on the Annual Meeting website.

Trainee Discussion with Plenary Speaker: Dr. Hood

Monday, March 12, 9:30 AM–10:30 AM
(Ticket Required; SOT Student and Postdoctoral members only, limited seating)

Chairperson(s): Michele La Merrill, Mount Sinai School of Medicine, New York, NY.
Lecturer: Leroy Hood, Institute of Systems Biology, Seattle, WA.

Dr. Hood will meet informally for discussion with graduate students and postdoctoral scholars after his Plenary Opening Lecture. Room size is limited, and participants register for a ticket with their Annual Meeting registration.

In Vitro Toxicology Lecture and Luncheon for Students

Monday, March 12, 12:00 Noon–1:20 PM
Marriott Marquis
(Ticket Required)

Chairperson(s): Lorrence Buckley, Education Committee Chair, Eli Lilly & Company, Indianapolis, IN.

Can In Silico and/or In Vitro Testing be Used for Toxicity Assessment Instead of In Vivo Approaches?

Lecturer: Timothy J. Shafer, US EPA, Research Triangle Park, NC.
Sponsor: Colgate-Palmolive Company
Host: Education Committee

The goal of the In Vitro Toxicology Lecture series is to feature important research using in vitro and alternative techniques to study basic mechanisms and to illustrate how these test methods benefit animal welfare by refining, reducing, and replacing animal use whenever it is feasible. Graduate students, undergraduates, postdoctoral scholars, and recipients of Colgate-Palmolive awards are among the guests at the In Vitro Toxicology Lecture and Luncheon. Students and postdoctoral scholars register via the Annual Meeting registration, and the $10 deposit will be returned upon entry to the event. Dr. Shafer will present an introduction to the topic, and then participants will discuss related questions and report responses.

Since publication of the National Academy of Science (NAS) paper on Toxicity Testing in the 21st Century, there has been an increased emphasis on the development of in silico and in vitro approaches to toxicity testing. The NAS vision is to replace the current animal-based tests, which are low throughput and often do not predict human responses well, with higher throughput toxicity pathway-based approaches that will allow testing of greater numbers of chemicals and be more predictive of toxicity to humans.
In some cases, there has been considerable progress with these approaches such that *in silico* or *in vitro* data can and are being used to make decisions regarding drug or chemical safety. Other attempts to develop *in vitro* approaches have been less successful.

Replacing *in vivo* tests with *in silico* or *in vitro* data is not a simple task, and doing so requires acceptance from regulators, the regulated community, and ultimately the public. This talk will briefly summarize the current rationale and approach to *in vitro* testing and provide some examples where *in vitro* tests have, and have not, successfully replaced *in vivo* approaches. This will be used to stimulate a discussion on whether or not *in silico* and *in vitro* approaches ever could (or should) entirely replace *in vivo* approaches.

**Postdoctoral Assembly Luncheon**

Tuesday, March 13, 12:00 Noon–1:15 PM  
(Ticket Required)

*Chairperson(s):* Michele La Merrill, Mount Sinai School of Medicine, New York, NY.  
*Sponsor:*  
Postdoctoral Assembly

Amidst scrambling to attend all of the events at the meeting, this will be time for postdocs to kick back and relax! All post-doctoral scholars are invited to a casual luncheon organized by the Postdoctoral Assembly (PDA). The recipients of the Best Postdoctoral Publication Awards and the postdocs who received awards this year from Specialty Sections and Regional Chapters will be announced. The PDA Board members will present an overview of accomplishments and future directions for the PDA and will introduce the new board members for 2012–2013. There will be a drawing for door prizes.

Postdocs can purchase a ticket for $5 when they register for the Annual Meeting. The ticket charge is not refundable, reserves your place, and defrays some of the expenses for the luncheon. Lunch is served at the beginning of the event and service concludes before the main program begins. Meal service may not be available to guests who arrive after 12:30 pm.

**Undergraduate Student Meeting**

Wednesday, March 14, 4:00 PM–5:00 PM

*Chairperson(s):* Sue M. Ford, St. John's University, Jamaica, NY.

*Sponsors:*  
Education Committee  
K-12 Subcommittee  
Toxicology Student Association at University of California Berkeley

Undergraduate students attending the meeting are encouraged to participate in an informal meeting to talk about shared interests related to career paths in toxicology, discuss undergraduate tox-related activities, clubs, and majors on their campuses, and to provide feedback to the Undergraduate Education Subcommittee.

**Education Outreach Activities and Events**

**K–12 Outreach Event**

Saturday, March 10, 10:30 AM–4:30 PM  
The Lawrence Hall of Science, University of California, Berkeley

*What Do Snow White, Romeo and Juliet, and the Madhatter Have in Common?...Toxicology!*  

*Sponsors:*  
Education Committee  
K–12 Subcommittee  
Northern California Regional Chapter

The Education Committee K–12 Subcommittee in conjunction with the Northern California Regional Chapter is hosting special activities at the Lawrence Hall of Science on the University of California Berkeley campus to engage visitors in activities related to toxicology and to investigate toxicology careers. Through interactive drama and experiments, families will explore how the dose makes the poison. Toxicologists will share why they think toxicology is a great career. Undergraduate students will assist with the activities.

The Lawrence Hall of Science is a premier science museum for preschoolers on up with fascinating exhibits, ingenuity lab, live science demonstrations, and a planetarium.

For more information, please visit the Special Events section of the Annual Meeting website.
Special Events

High School Research Poster Presentations

Tuesday, March 13 and Wednesday, March 14
Chairperson(s): Daniel E. Arrieta, Chevron Phillips Chemical Company LP, The Woodlands, TX.
Sponsors: Education Committee and K-12 Subcommittee
High school students are invited to submit research posters for consideration for presentation in a special area in the SOT Pavilion. Deadline to submit is January 15. This display recognizes student effort and provides the high school students who have engaged in research with scientific meeting experience. Meeting attendees are invited to drop by to visit with these outstanding potential future toxicologists. More information is available on the SOT Annual Meeting website.

Undergraduate Education Program

Saturday, March 10–Monday, March 12
Chairperson(s): Jennifer L. Rayner, SRI, Inc, Arlington, VA.
Sponsor: Committee for Diversity Initiatives (CDI)
Saturday, March 10
Grand Hyatt
• 5:15 PM–5:45 PM—Orientation for SOT Hosts, Peer Mentors, and Advisors
  Organizers: Sudheer Reddy Beedanagari, Bristol-Myers Squibb Company, East Brunswick, NJ; Natalie M. Johnson, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD; and Ofelia A. Olvero, National Cancer Institute, NIH, Bethesda, MD.
  • 5:15 PM–5:45 PM—Registration for Undergraduate Students
  • 5:45 PM–6:15 PM—Opening Event
    Convenor: Jennifer L. Rayner, CDI Chair, SRI, Inc, Arlington, VA.
  • 6:15 PM–7:00 PM—Dinner
Sunday, March 11
Marriott Marquis
Introductions and Special Toxicology Lectures—Open to undergraduates in the travel award program and those who register through the Annual Meeting registration
Chairperson(s): Jennifer L. Rayner, SRI, Inc, Arlington, VA, and Nathan J. Cherrington, University of Arizona, Tucson, AZ.
• 8:00 AM–8:15 AM—Welcome
  Jon C. Cook, SOT President, Pfizer, Groton, CT.
• 8:15 AM–8:55 AM—Toxicology of the Blood-Blood-Cerebrospinal Fluid Barrier—A Comparative Approach
  Alice R. Villalobos, Texas A&M University, College Park, TX.
• 9:00 AM–9:45 AM—Exposure to Cigarette Smoke In Utero: Fetal Injury and Life Long Consequences
  Judith Zelikoff, New York University School of Medicine, Tuxedo Park, NY.
• 10:00 AM–10:40 AM—Optical Nanotechnologies for Imaging of Cellular Processes and Neurosurgery
  Martin A. Philbert, University of Michigan, Ann Arbor, MI.
• 10:45 AM–11:30 AM—Interactive Presentation: Identifying the Poison: Case Study in Toxicology
  Lauren M. Aleksunes, Rutgers University, Piscataway, NJ.
Breakout Sessions for Undergraduate Students
• 12:45 PM–1:45 PM—What Is Graduate School and What Can I Expect?
  How to Get into Graduate School: An Academic Advisor’s Perspective

Breakout Session for Undergraduate Advisors
• 12:45 PM–1:45 PM—Tips for Advising Prospective Graduate Students or How to Get Your Students Accepted to Graduate School!!

All Participants
• 2:00 PM–2:50 PM—Career Opportunities in Toxicology—Panel Discussion
• 3:00 PM–3:30 PM—Host Mentors and Peer Mentors Feedback Session
Chairperson(s): Sudheer Beedanagari, Bristol-Myers Squibb Company, East Brunswick, NJ, and Natalie M. Johnson, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD.
• 3:00 PM–5:00 PM—Open time with Academic Toxicology Program Directors and Internship Sponsors

Monday, March 12
Convention Center
• 7:30 AM–8:00 AM—Meeting for Students, Advisors, Peer Mentors, and SOT Hosts
  Chairperson(s): Jennifer L. Rayner, SRI, Inc, Arlington, VA.
• 8:00 AM–9:00 AM—Plenary Lecture: Systems Medicine, Systems Toxicology, Transformational Technologies, and the Revolution from Reactive to Proactive (P4) Medicine
  Lecturer: Leroy Hood, Institute of Systems Medicine, Systems Toxicology, Transformational Technologies, and the Revolution from Reactive to Proactive (P4) Medicine, Tuxedo Park, NY.
• 9:00 AM–10:50 AM—Poster Session for Visiting Students—ToxExpo

Marriott Marquis
• 11:00 AM–12:00 Noon—Program Wrap Up
  Chairperson(s): Jennifer L. Rayner, SRI, Inc, Arlington, VA.
• 12:00 Noon–1:20 PM—In Vitro Lecture and Luncheon for Students
  Can In Silico and/or In Vitro Testing Be Used for Toxicity Assessment Instead of In Vivo Approaches?
  Speaker: Timothy J. Shaffer, US EPA, Research Triangle Park, NC.
Thank You

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William Slikker Jr. ........................................ Vice President
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Vishal S. Vaidya ............................... Member
Tao Wang ........................................ Member
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Continuing Education

Continuing Education Courses

The Continuing Education Program offers a wide range of courses that cover established knowledge in toxicology, as well as new developments in toxicology and related disciplines. Courses can be applied toward certifying and licensing board requirements and may also be used for recertification with the American Board of Toxicology (ABT). Both basic and advanced course topics are offered. The basic course is intended to provide a broad overview of an area or to assist individuals in learning new techniques or approaches. The advanced course is intended to be of interest to individuals with previous knowledge of the subject or already working in the field.

All courses will be held on Sunday, March 11, 2012, at the Moscone Convention Center. Please check the signage in the registration area and at the CE Booth for room assignments. Note: Your course materials will be available in the room immediately prior to the course (they will not be available at the registration area). If you have your course ticket, go directly to the assigned room. If you have not received your course ticket or have not registered, please go to the registration area on Saturday afternoon/evening or on Sunday morning. If you have misplaced your ticket, please go to a Continuing Education Booth at the Convention Center on Sunday. The booths will be open from 6:30 am–5:30 pm.

Please Note: Each Continuing Education Course is offered in one of three time blocks:

<table>
<thead>
<tr>
<th>Time Block</th>
<th>Description</th>
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<tbody>
<tr>
<td>SR—Sunrise</td>
<td>7:00 AM–7:45 AM</td>
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<tr>
<td>AM—Morning</td>
<td>8:15 AM–12:00 Noon</td>
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<tr>
<td>PM—Afternoon</td>
<td>1:15 PM–5:00 PM</td>
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Registration for the Annual Meeting and a separate CE course ticket are required.

Target Areas

The Continuing Education Program offers a wide range of courses that cover established knowledge in toxicology, as well as new developments in toxicology and related disciplines. Continuing Education courses related to these Target Areas appear under each target description. The Target Areas will be identified throughout the Preliminary Program with a 🔴. Continuing Education Courses will also be tracked by Scientific Program Theme and identified throughout the Preliminary Program with a 🔵. An Overview of the Scientific Thematic Track is located on pages 8–9.

Drug Metabolism

Xenobiotic metabolism and/or handling by gene products such as Cytochrome P450s, Glucuronosyl S-Transf erases, and drug transporters is central to chemical disposition in all organisms. In-depth understanding of how chemicals are modified, how major metabolic products behave, become selectively sequestered, or eliminated from different tissues, and how all of these processes relate to determine both the fate of the agent and the responses that transpire as a result of exposure is of paramount significance to basic research scientists involved in safety assessment and drug development and to clinicians. The multidisciplinary field of drug metabolism has made considerable advances in recent years, including new methods to more accurately study and predict compound fate and/or action using advanced in vitro and in silico technologies, the incorporation of systems biology and ‘omics approaches to gain a more comprehensive appreciation of the impact of chemicals in an organism, and the identification of new gene product families that contribute to drug disposition. The CE committee welcomes proposals that will highlight novel approaches to evaluate drug metabolism and its impact on toxicological/safety assessment research, the drug development process, and application to clinical care, including pharmacogenomic considerations. Proposals may focus on teaching specific methodologies such as functional assays for different systems, high-throughput technologies, and/or in silico technologies to predict metabolism.

Stay Competitive with CEd-Tox: SOT Online Courses

Access Selected 2009–2011 Continuing Education Courses Online

Toxicology is an ever-changing field. SOT Continuing Education courses are an excellent way to enhance your professional development and learn new techniques. SOT is dedicated to providing such opportunities and resources to the scientific community, and the Continuing Education Committee is excited to offer online CE courses through the SOT website. Currently there are 21 online courses from the past three Annual Meetings, several with English transcripts. Special discounts for members from eligible developing countries. Whether you want a refresher course, or want to expand your knowledge, CEd-Tox offers you a convenient way to stay competitive!

Visit the SOT website for more information.
Courses may also instruct attendees on regulatory requirements for safety assessment of drugs and metabolites or novel approaches for assessing pharmacodynamic effects. Course proposals under the "Drug Metabolism" target area are expected to be in-depth and focused on a central theme. Therefore, multiple proposals addressing different aspects of this general theme are encouraged to ensure adequate coverage of this rapidly advancing and important field.

**Noncoding RNAs and Their Role in Biology and Toxicology**

Small, medium, and long noncoding RNAs have been identified in many species, including humans. Their functions are still not fully understood, but they are becoming increasingly recognized as important factors in physiology, xenobiotic sensitivity, and disease. For example, microRNAs (miRs) are small noncoding RNAs that regulate gene expression primarily through base-pair interactions with 3'-untranslated regions of target genes and this results in altered gene expression. It is estimated that miRs regulate up to 30% of all genes in humans: In contrast, larger intergenic noncoding RNAs (lincRs) such as HOTAIR regulate chromatin structure through epigenetic pathways. The number and function of noncoding RNAs being discovered is continually increasing. It is certain that they will play an important role in toxicology and pharmacology. The CE committee is interested in receiving proposals that will provide in-depth instruction on noncoding RNAs, including what they are and how they function, their effects on xenobiotic sensitivity and disposition, their importance in disease risks and phenotypes, and their relevance to toxicological research, including human environment responses, heritable environmentally-induced changes, and the integration of their novel characteristics into studies of xenobiotic mechanisms and the drug development/safety assessment processes. Proposals highlighting vital roles of noncoding RNAs in human diseases, particularly environmentally influenced diseases, and the significance of physiological changes due to noncoding RNAs in the treatment of conditions are also of interest.

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**2012 Continuing Education Courses**

**Alternative In Vitro Toxicology Testing for the 21st Century**

**SR01**

**Chairperson(s):** Stephen H. Safe, Texas A&M University, College Station, TX.

**Endorsed by:**

Risk Assessment Specialty Section

Over the last two decades, alternatives to animal testing were strongly driven by animal welfare considerations. A culture of organotypic cell models, quality assurance, and validation developed, which resulted in a number of novel approaches for regulatory testing. Progress to replace especially the systemic and chronic types of tests has been limited. Novel programs to assess large numbers of substances such as existing chemicals (REACH and the emerging TSCA reauthorization), nanoparticles, or mixtures, as well as new products such as biologicals and cell therapies now add to the need to move to another approach for toxicity testing. Additionally, interest in health effects like endocrine disruption, developmental neurotoxicity, immunotoxicity, obesity, atherosclerosis, or childhood asthma require extensive and new types of testing. This is often referred to as Toxicity Testing for the 21st Century (Tox-21c), after the respective NAS vision document from 2007, which was made US EPA’s toxicity testing strategy in 2009. The central change is moving from apical “black box” animal models to mechanism or pathway of toxicity (PoT). The biotechnology and bioinformatics revolution of recent years has made it possible to develop systems biology, here systems toxicology, approaches. The experiences from the field of alternative methods now prove to be the most important to implement a new regulatory approach. Standardization and validation of cell cultures is crucial for PoT identification as well as the implementation of high-throughput types of tests based on PoT. The first projects to systematically map the entirety of human PoT, the Human Toxome, have started. The validation of these novel tests represents an enormous challenge. It is proposed to follow the role model of evidence-based medicine. For this purpose, the evidence-based toxicology collaboration was started at SOT 2011 and is currently shaping its procedures and governance.

- **Alternative In Vitro Toxicology Testing for the 21st Century.**
  Thomas A. Hartung, John Hopkins University Center for Alternatives to Animal Testing (CAAT), Baltimore, MD.
### Applications of Biomarkers in the Assessment of Health and Disease

**Chairperson(s):** Vishal S. Vaidya, Harvard Medical School, Boston, MA, and Donna L. Mendrick, US FDA, Jefferson, AR.

**Sponsor:**
- Drug Discovery Toxicology Specialty Section

**Endorsed by:**
- Association of Scientists of Indian Origin Special Interest Group
- Disease Prevention Task Force
- Risk Assessment Specialty Section

Biomarkers serve as quantitative measures of chemical exposures and biologically effective doses, early warning signals of biologic effect, predict outcome in a patient with disease, and identify who will respond to an intervention and whether the intervention is working. The current era of scientific discovery has brought seemingly limitless opportunities for improvements in medical care. Translational biomarkers that can be measured in blood or urine in both experimental animals and man are of particular interest. Given the importance to the clinical, pharmaceutical, and regulatory communities motivated by more specific and timely diagnoses, early intervention, and safer therapies, clinically useful biomarkers have evolved over time, reflecting the scientific and technologic progress made over the centuries. An increasing number of clinically relevant tests and procedures are available to estimate organ injury and guide treatment. The use of molecular signals in the assessment of health and disease is not new; however, the concept of what constitutes a useful biomarker has evolved considerably in the past two to three decades given the advanced enabling technologies, the deeper molecular understanding of disease, and the advent of a regulatory framework for biomarker qualification. Our panel experts will highlight the potential of these molecular signals over a wide variety of applications spanning preclinical–clinical safety and disease monitoring in therapeutic and environmental exposures pertaining to cancer, and lung, heart, and kidney disease. Coordinated efforts at biomarker discovery and validation as well as technologies for biomarker measurement will help ensure that the ultimate goal of safer drugs, a cleaner environment, and improved patient outcomes is realized.

- **Introduction.** Donna L. Mendrick, US FDA, Jefferson, AR.
- **Discovering Cancer Biomarkers: From Diagnosis and Prognosis through Therapy.** Marsha A. Moses, Children’s Hospital-Boston, Harvard Medical School, Boston, MA.
- **Advanced Molecular Biomarkers in Understanding Lung Exposure Biology.** David E. Christiani, Harvard School of Public Health, Boston, MA.
- **Kidney Safety Signal: From Identification to Point of Care Testing.** Vishal S. Vaidya, Harvard Medical School, Boston, MA.

### Basic Embryology and Developmental Toxicity Testing

**Chairperson(s):** Christopher J. Bowman, Pfizer Worldwide Research and Development, Groton, CT, and Lori A. Dostal, Exponent, Inc., Farmington Hills, MI.

**Sponsor:**
- Reproductive and Developmental Toxicology Specialty Section

**Endorsed by:**
- Regulatory and Safety Evaluation Specialty Section

Embryonic and fetal development in mammalian species is a complex process that is sensitive to the effects of maternal and environmental factors. The timing of development of the major organ systems varies between humans and other animal species, but the basic biology of development is similar in all species, thus allowing extrapolation of animal testing results for xenobiotics to humans. The course will begin by providing an overview that highlights developmental biology from fertilization of the gametes to normal maturation of a full-term placenta and fetus, including examples of developmental toxicants and teratogens with known modes of action. Subsequently, applied toxicology concepts for evaluation of the potential for bio/ pharmaceuticals and chemicals to affect pregnancy and embryo-fetal development will be discussed. Global regulatory strategies and requirements to minimize health effects on women and unborn children will also be addressed. Finally, key information will be presented to provide for a better understanding of the biological and toxicological basis of prenatal developmental toxicity testing and the impact of various outcomes on drug development, chemical use, environmental impact, and human health risk.

- **Introduction.** Lori A. Dostal, Exponent, Inc., Farmington Hills, MI.
- **Implantation, Placentation, and Early Embryonic Development.** John M. DeSesso, Exponent, Inc., Alexandria, VA.
- **Demystifying Mammalian Embryogenesis.** Kathleen K. Sulik, University of North Carolina, Chapel Hill, NC.
- **The Importance of Developmental Toxicity Testing to Pharmaceutical Development.** Kimberley A. Treinen, Merck, Summit, NJ.
**Characterizing Toxic Modes of Action and Pathways to Toxicity**

**Cutaneous Toxicity: In Vitro Methods for Toxicity and Safety Evaluation**

**AM04 CE ADVANCED**

**Chairperson(s):** William G. Reifenrath, Stratacor Inc., Richmond, CA, and Cynthia A. Ryan, Procter & Gamble Company, Cincinnati, OH.

**Sponsor:** Dermal Toxicology Specialty Section

**Endorsed by:** In Vitro and Alternative Methods Specialty Section

Skin is the largest external organ and serves as a living, dynamic protective envelope surrounding the body. As such, it is constantly exposed to environmental hazards, including hazardous compounds; these exposures account for a major portion of all reported industrial illnesses. Skin exposures may also occur from pharmaceuticals or consumer products that are intentionally applied. In vitro methods are important as a first step to estimate skin permeation, and the potential of skin irritation and sensitization for compounds or mixtures of compounds that are directly toxic to the skin or systemically toxic. In exploration of these issues we will provide an overview of the current status of in vitro models for cutaneous toxicity safety evaluations and the regulatory requirements for establishing the nonclinical safety of dermal drug products. This important topic has relevance to toxicologists involved in safety evaluations and risk assessments for chemicals that contact the skin.

- **Use of the Excised Human Skin Model for Percutaneous Risk Assessment.** Thomas J. Franz, Cetero Research, Fargo, ND.
- **Direct Comparison of In Vitro and In Vivo Dermal Absorption of Several Chemicals.** Jeffrey J. Yourick, US FDA, Laurel, MD.
- **Specialized Procedures for Lipophilic and Semivolatile Compounds and Their Influence on Comparative In Vitro—In Vivo Skin Absorption.** William G. Reifenrath, Stratacor, Inc., Richmond, CA.
- **Skin Sensitization: Underlying Mechanisms, Hazard Identification, and a Quantitative Risk Assessment Approach.** Cynthia A. Ryan, Procter & Gamble Company, Cincinnati, OH.
- **Skin Irritation: In Vitro Models.** John W. Harbell, Mary Kay Inc., Dallas, TX.

**Continuing Education**

**Regulatory Science: Bridging the Gap between Discovery and Product Availability**

**Frontiers and Applications in Predictive Toxicology: In Silico Methods for Risk Assessment, Toxicology, and Metabolism**

**AM05 CE BASIC**

**Chairperson(s):** Christopher A. Reilly, University of Utah, Salt Lake City, UT, and Sneha Bhatia, Research Institute for Fragrance Materials, Inc., Woodcliff Lake, NJ.

**Sponsor:** In Vitro and Alternative Methods Specialty Section

**Endorsed by:** Food Safety Specialty Section Molecular Biology Specialty Section Regulatory and Safety Evaluation Specialty Section Risk Assessment Specialty Section

With the integration of open source programs, in silico tools, and bioinformatics, the role of the computer continues to transform daily activities and work for the modern scientist. Furthermore, the call for reduced animal testing in toxicity evaluation has led to an expansion of in silico resources, quantitative structure-activity relationship (QSAR) programs, chemoinformatics systems, and predictive metabolism tools. Regulatory authorities, and the pharmaceutical, chemical, and food industries are actively using such tools in the safety evaluations of novel drug candidates, food additives, environmental contaminants, and consumer products. We will begin by providing a basic introduction to various in silico tools, specifically predictive toxicology and metabolism platforms, and how their algorithms compute results and influence the decision process. A composed set of didactic lectures will be used to introduce the basic concepts and activities surrounding the use of in silico tools in ADME/Tox and safety studies. In follow-up, participants will be provided with a brief summary of various platforms with practical tutorials of the computational toxicology platforms discussed.

- **Introduction to Computational Toxicology.** Sneha Bhatia, Research Institute for Fragrance Materials, Inc., Woodcliff Lake, NJ.
- **Computational Models for Predicting Human Toxicities.** Sean Ekins, Collaborations in Chemistry, Inc., Fuquay-Varina, NC.
- **Computational Approaches to the Prediction of Metabolism and the Simulation of Metabolic Pathways.** Anthony Long, Lhasa Limited, Leeds, United Kingdom.
Continuing Education

- **Computational Safety Analysis for Regulatory Decision-Making and Research at FDA.** Luis G. Valerio, Jr., US FDA, Silver Spring, MD.
- **Computational Approaches: Linking Chemical Exposures and Human Disease.** Dale E. Johnson, Emiliem, Inc., Emeryville, CA and University of California Berkeley, Berkeley, CA.
- **Predictive Toxicology Platforms: Tools for the Trade?** Eugene Ahlborn, Givaudan Flavors, Cincinnati, OH.

**Regulatory Science: Bridging the Gap between Discovery and Product Availability**

**Overview and Application of the WHO/IPCS Harmonized Guidance for Immunotoxicity Risk Assessment for Chemicals**

AM06  CE BASIC

*Chairperson(s):* Andrew A. Rooney, NIEHS, Research Triangle Park, NC, and Henk Van Loveren, National Institute of Public Health and the Environment (RIVM), Bilthoven, Netherlands.

*Sponsor:* Immunotoxicology Specialty Section

*Endorsed by:* Regulatory and Safety Evaluation Specialty Section Risk Assessment Specialty Section

The WHO/IPCS harmonized guidance document is the first comprehensive guidance document for risk assessment in toxicology. Immunotoxicity risk assessment of chemicals is an evaluation of the potential for unintended effects of chemical exposure on the immune system. These effects manifest as four principal types of immunotoxicity, which are categorized as immuno-suppression and -stimulation, autoimmunity, and sensitization. We will provide an overview of the methods used to detect and characterize immunotoxicity and the potential consequences of unintended immunomodulation. It is well established that xenobiotic-related immunosuppression can lead to reduced resistance to infections and certain neoplastic diseases. Exposure to xenobiotics has been shown to be associated with development or worsening of autoimmune disease. It has been established that xenobiotics can elicit hypersensitivity responses directly as an allergen, or they can enhance the induction or severity of allergic sensitization to pollen or dust mites. The determination of risk associated with immunostimulation may be more difficult, but unexpected stimulation should not be disregarded as it may result in nonspecific inflammation or the skewing of normally protective immune responses to favor induction or exacerbation of autoimmunity and hypersensitization. The fundamental concepts of risk assessment as they apply to the evaluation of immunotoxicity as well as the application of the guidance will be highlighted. We will begin by reviewing case studies that include data that focuses on different areas of immunotoxicity—suppression, sensitization, and autoimmunity. The studies will demonstrate application of the guidance, particularly the development of weight of evidence conclusions from the available data. Finally, we will illustrate that risk assessment for a given chemical should consider the full range of immune effects for that chemical, and data should be evaluated separately for evidence of suppression, stimulation, autoimmunity, and sensitization.

- **Immunotoxicity Risk Assessment.** Andrew A. Rooney, NIEHS, Research Triangle Park, NC.
- **Assessment of Immunosuppression, Immunostimulation, and Autoimmunity.** Robert W. Luebke, US EPA, Research Triangle Park, NC.
- **Assessment of Sensitization and Allergic Response.** Peter Griem, Symrise AG, Holzminden, Germany.
- **Case Study 1: Lead.** Michael I. Luster, West Virginia University, Morgantown, WV.
- **Case Study 2: Halogenated Platinum Salts.** Peter Griem, Symrise AG, Holzminden, Germany.
- **Case Study 3: Mercury.** Andrew A. Rooney, NIEHS, Research Triangle Park, NC.

**Stem Cells in Toxicology**

AM07  CE BASIC

*Chairperson(s):* Michael P. Waalkes, NIEHS, Research Triangle Park, NC, and Erik J. Tokar, NIEHS, Research Triangle Park, NC.

*Sponsor:* Stem Cells Specialty Section

*Endorsed by:* Biotechnology Specialty Section Carcinogenesis Specialty Section Reproductive and Developmental Toxicology Specialty Section

Stem cells are revolutionizing toxicological research and remain an area with tremendous potential. Recently, research on stem cells has generated tremendous public and professional interest. However, some areas of toxicological research have lagged behind in the integration of stem cells as a concept in toxicant-induced disease etiology. We will describe the utility and suitability of the assorted types of stem cell models (e.g., embryonic, fetal, progenitor, induced pluripotent, and immortalized stem cell lines) for various research purposes, including disease modeling, drug discovery and toxicity testing in order to describe the potential applications of stem cells in toxicological research.
This important overview of stem cells will highlight their nomenclature, properties, and roles in the genesis of various diseases.

- **Stem Cells in Toxicology.** Erik J. Tokar, NIEHS, Research Triangle Park, NC.
- **The Concepts and Methods for Stem Cells.** Ying Xia, University of Cincinnati, Cincinnati, OH.
- **Stem Cells in Carcinogenesis.** Michael P. Waalkes, NIEHS, Research Triangle Park, NC, and Erik J. Tokar, NIEHS, Research Triangle Park, NC.
- **Stem Cells and Regenerative Medicine.** R. Clark Lantz, University of Arizona, Tucson, AZ.
- **Stem Cells in Safety Testing.** Kyle L. Kolaja, Hoffmann-La Roche, Inc., Nutley, NJ.

**Regulatory Science: Bridging the Gap between Discovery and Product Availability**

**Concepts of Green Chemistry and Its Role in the Identification and Design of Safer Chemicals and Products**

PM08 CE BASIC

*Chairperson(s):* Pamela J. Spencer, Dow Chemical Company, Midland, MI, and John Warner, Warner Babcock Institute for Green Chemistry, Wilmington, MA.

*Endorsed by:* Molecular Biology Specialty Section

Hazard identification, dose-response characterization, and exposure potential are the underpinning of product safety assessments. These basic principles help regulatory agencies, manufacturers, and formulators determine the conditions for safe use of chemicals, raw materials, and products for a given application to reduce adverse impacts to human health and the environment. Today, as a part of the growing interest in green chemistry, the pendulum is shifting. The large number of companies engaging in sustainability initiatives, coupled with increased consumer demand for greener products, is driving a new process where impacts of chemical products and processes are included as design criteria. Reducing intrinsic chemical hazards up front is a strategy used in developing safer alternatives to existing chemicals. Thus green chemistry is raising the bar for chemical safety assessments. Our panel of experts will begin with a background of green chemistry, its basic principles, and why it is useful, and highlight key certification programs/tools used to identify safer alternatives, including their methods and criteria with specific emphasis on the Green Screen for Safer Chemicals alternatives assessment tool. There are unique opportunities for toxicologists to assist molecular designers in reducing the intrinsic hazards of their molecules by providing insight into toxicological mechanisms and data that support the application of green chemistry principles in the design of new chemicals and products. To underscore the importance of this issue, we will illustrate how principles of green chemistry are applied in a consumer products and a chemical company. The caveats and challenges will be addressed by using case studies. The exploration of this topical area will provide an understanding of green chemistry, awareness of the tools and programs immediately available and how to access and use them, and an appreciation for some of the practical challenges associated with implementing principles of green chemistry into product development and assessments of safer alternatives.

- **Introduction.** Pamela J. Spencer, Dow Chemical Company, Midland, MI.
- **Introduction to the Concepts of Green Chemistry and Its Role in the Design of Safer Chemicals and Products.** John Warner, Warner Babcock Institute for Green Chemistry, Wilmington, MA.
- **Using Comparative Hazard Assessments: Green Screen for Safer Chemicals.** Lauren Heine, Lauren Heine Group LLC, Juneau, AK.
- **Strategies and Methods for Incorporating Green Chemistry into the Design of Chemicals and Products.** Thomas G. Osimitz, Science Strategies, LLC, Charlottesville, VA.
- **Application of the Principles of Green Chemistry in a Chemical Company: Overview and Case Studies.** J. Craig Rowlands, Dow Chemical Company, Midland, MI.
- **Application of the Principles of Green Chemistry in a Consumers Products Company: Overview and Case Studies.** Donald Versteeg, Procter & Gamble Company, Cincinnati, OH.

**Innate Immunity and Its Relevance to Toxicology**

PM09 CE BASIC

*Chairperson(s):* Wendy J. Freebern, Bristol-Myers Squibb, North Brunswick, NJ, and Jacintha M. Shenton, MedImmune, Inc., Cambridge, United Kingdom.

*Sponsor:* Immunotoxicology Specialty Section

The innate immune system is the host’s first line of defense against infection. Thus, knowing the what, why, how, and when of innate immune function assessment in toxicology evaluations is important. This course will introduce the components of the innate immune system and its role in host defense, discuss clinical observations resulting from inhibition or stimulation of innate immune function in nonclinical species, provide case examples where understanding intentional or inadvertent effects on innate immune function has had utility in toxicity testing, and explain the what and how of innate immune measurements and the gaps in capabilities thereof. Innate immunity assessments to be discussed include bacterial killing assays and an array of macrophage, neutrophil, and natural killer cell...
activity assessments, which will be described within the context of various target organs, animal models, and toxicology programs. In addition, investigating innate immune function on a molecular level through evaluating cell signaling molecules and regulated expression of antimicrobial peptides, chemokines, and cytokines will be discussed. In closing, the application of innate immunity testing in the clinic and translatability of nonclinical findings to the clinic will be examined. This course should be of broad interest to toxicologists with the desire to learn about the innate immune system and how innate immune evaluations can be applied to toxicology testing. In addition, the course will appeal to scientists who are interested in learning methodologies of innate immune function testing and applicability thereof.

- **Innate Immunity and Its Relevance to Toxicology: An Introduction.** Jacintha M. Shenton, MedImmune, Inc., Cambridge, United Kingdom.

- **Not Just a Physical Barrier: Cellular and Molecular Innate Immune Defense Mechanisms of the Epidermis.** Jamie J. Bernard, Rutgers University, Piscataway, NJ.


- **Accessing Natural Killer Cell Activity in Nonclinical Toxicity Studies.** Christina Satterwhite, Charles River Laboratories, Reno, NV.

- **Innate Immunity in Drug-Induced Liver Injury.** Cynthia Ju, University of Colorado, Aurora, CO.

- **Translating Nonclinical Innate Immune Testing into the Clinic.** Wendy J. Komocsar, Eli Lilly and Company, Indianapolis, IN.

## Aberrant Gene Expression in Toxicity and Disease—Epigenetics and microRNAs

### Noncoding RNAs and Their Role in Biology and Toxicology

**MicroRNAs in Biology and Toxicology**

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**Chairperson(s):** Neelakanteswar Aluru, Woods Hole Oceanographic Institution, Woods Hole, MA, and Carmen J. Marsit, Dartmouth Medical School, Hanover, NH.

**Sponsor:** Molecular Biology Specialty Section

MicroRNAs (miRNAs) constitute a critically important class of noncoding, small RNAs, which post-transcriptionally regulate gene expression. miRNAs are approximately 18–24 nucleotides (nt) in length, that regulate gene expression by binding to 3’untranslated regions (UTR), coding sequences or 5’UTR of target messenger RNAs (mRNAs), and leading to inhibition of translation or mRNA degradation. It is estimated that miRNAs regulate approximately 30% of the human protein-coding genome. miRNAs control the expression of genes involved in several biological processes, including apoptosis, proliferation, differentiation, and metastasis. Given the prominent role miRNAs play in organismal function, it is not surprising that the aberrant expression of miRNAs can lead to a wide range of human diseases and disorders, including cancer, neurodegenerative diseases, diabetes, and a variety of cardiovascular and hepatic disorders. In addition to contributing to the underlying cause of a particular disease, miRNAs can also represent potential therapeutic targets and diagnostic biomarkers. The recent discovery of circulating miRNAs are promising biomarker candidates since they can be detected from readily attainable blood samples. On account of the critical role that miRNAs play in biological function and the diverse range of applications in which miRNA analysis is of value, significant effort has been invested over the past decade to develop new detection methods. We will provide an overview of existing and emerging tools for miRNA analysis, with particular emphasis placed on the current state of the art and important developments in this emerging field.

- **Overview of microRNA Quantification Methods.** Neelakanteswar Aluru, Woods Hole Oceanographic Institution, Woods Hole, MA, and Carmen J. Marsit, Dartmouth Medical School, Hanover, NH.

- **MicroRNA Functions in Stress Responses.** Anthony Leung, John Hopkins University, Bloomberg School of Public Health, Baltimore, MD.

- **Evaluating the Toxicological Role of microRNAs during Development.** Robert L. Tanguay, Oregon State University, Corvallis, OR.

- **MicroRNAs in Cancer.** Stephen H. Safe, Texas A&M University, College Station, TX.

- **MicroRNA Profiling in Population-Based Studies of Exposure-Related Health Outcomes.** Carmen J. Marsit, Dartmouth Medical School, Hanover, NH.
Drug development is a highly regulated but science-driven process from early discovery to marketing. Once the drug candidate has been discovered, preclinical safety evaluations are required to ensure the safety of the drug during clinical trials, ultimately bridging the gap between drug discovery and marketing. The preclinical development of four types of drugs, small molecular-weight drugs, biologics, oligonucleotide-based therapeutic drugs, and antibody drug conjugates (ADCs), will be illustrated to emphasize the cross-functional nature of regulatory sciences. In exploration of this important topic, we will begin with a focus on small molecular-weight drug candidates, which require a sliding scale for the degree of development from relatively minimal regulatory requirements for oncology drug development to the much more stringent requirements for the development of drugs for nonlife, threatening conditions and chronic treatment. Next the focus will shift to large molecule biologics and will provide illustrations of the unique challenges the regulatory safety assessment and clinical development that biologic drug candidates present. Our panel of experts will then focus on oligonucleotide-based therapeutics since many of the overarching oligonucleotide class-based properties have been well established, but there unique considerations remain for each subclass of oligonucleotide. This talk will discuss the preclinical development of oligonucleotide-based therapeutic drugs, including antisense, siRNA, and immunostimulatory and aptamer applications. This course will also cover ADCs, which are composed of monoclonal antibodies (biologics) conjugated with drugs or cytotoxins (small molecules). Standard approaches for preclinical safety evaluation of each of the individual components of these conjugates may not always be necessary. The regulatory expectations for this class of therapeutics are continuing to be defined. We will illustrate the safety assessment challenges and development strategies associated with certain ADCs.

diverse universe of mixtures, including those found in air, water, soil, and food, and apply to environmental, industrial, pharmaceutical, intentional, and accidental mixtures. The course will be useful to toxicologists as understanding how their data are used to assess risk will enable the design and conduct of more meaningful and useful multipollutant experiments. Additionally, understanding underlying assumptions will foster design and conduct of experiments to replace assumptions with evidence-based understanding.

- **Risk Assessment Methods for Whole Mixtures.** Jane Ellen Simmons, US EPA, Research Triangle Park, NC.
- **Beyond Relative Potencies: Uncertainties in the Application of TEFs in Risk Assessment.** Michael J. DeVito, NIEHS, Research Triangle Park, NC.
- **Using Dose Addition: Hazard Index, Target Organ Toxicity Hazard Index, and the Interaction-Weighted Hazard Index.** Richard C. Hertzberg, Biomathematics Consulting, Atlanta, GA.
- **The Use of Binary Weight of Evidence to Characterize Chemical Interactions for Risk Assessment.** Moiz Mumtaz, ATSDR, Atlanta, GA.

**Drug Metabolism**

**The Use of Physiologically-Based Pharmacokinetic Modeling to Inform Early Life Sensitivity to Chemical Toxicity**

**Chairperson(s):** Harvey J. Clewell, The Hamner Institutes for Health Sciences, Research Triangle Park, NC, and Miyoung Yoon, The Hamner Institutes for Health Sciences, Research Triangle Park, NC.

**Endorsed by:**
- Regulatory and Safety Evaluation Specialty Section

A major challenge in assessing potential susceptibility to environmental chemicals during in utero and postnatal development is uncertainty regarding the actual exposure in the target subpopulation. We will demonstrate the value of PBPK modeling in quantitative health risk assessments for infants and children by providing a scientifically sound tool to predict the target tissue dose in the young. A thorough understanding of dynamic changes in physiological and biochemical factors is essential to predict the target tissue exposure during development. Factors that influence the kinetic behavior of chemicals in early life include ontogeny in metabolizing enzymes, changes in transporter expression, maturation of biological barriers such as the blood brain barrier, differential growth of tissues, and distinct exposure patterns compared to adults. PBPK modeling provides a means to integrate these factors in the proper context and thus reduce uncertainty in conducting risk/safety assessment for early life.

The presentations will provide an overview of pharmacokinetic factors affecting early life sensitivity and two case studies of PBPK approaches for gestation/lactation and childhood exposures, plus a demonstration of how PBPK modeling of development can be used to evaluate neonatal epidemiological results. The course participants will get in-depth understanding of the value of PBPK modeling in addressing issues of potential sensitivity in infants and children and the possible application scenarios of this valuable tool.

- **Physiological and Pharmacokinetic Factors Affecting Early Life Sensitivity to Chemical Exposures.** Rebecca A. Clewell, The Hamner Institutes for Health Sciences, Research Triangle Park, NC.
- **PBPK Modeling of Manganese Exposures during Gestation and Lactation.** Miyoung Yoon, The Hamner Institutes for Health Sciences, Research Triangle Park, NC.
- **Modeling of Pyrethroid Exposures in Early Life.** Rogelio Torner-Velez, US EPA, Research Triangle Park, NC.
- **Use of PBPK Models of Perfluorinated Compounds to Evaluate Whether Epidemiologic Associations Are Due to Reverse Causality.** Matthew P. Longnecker, NIEHS, Research Triangle Park, NC.
Building for the Future

Contributors to the SOT Endowment Fund are helping to build for the future of toxicology through long-term financial support, which also generates critical resources that enable the Society to fulfill its mission, now and in the years to come.

Since its inception in 2006, Contributors to the Endowment have:

• Underwritten more than 100 Student Travel Awards to the SOT Annual Meeting.
• Recognized colleagues who have made enormous contributions to improving human health and the environment.
• Created funds that acknowledge the contributions of educators in toxicology to undergraduate students in toxicology and toxicology-related areas.
• Strengthened global participation by providing financial support to scientists from developing countries to attend the SOT Annual Meeting.

Make a Difference by Becoming a Contributor to the SOT Endowment Fund.

For a complete Fund listing and contributions over the past five years, go to www.toxicology.gift-planning.org.

Please help SOT continue to make a difference by becoming a contributor to the SOT Endowment Fund. For more information, go to www.legacy.vg/toxicology.
Featured Sessions

**Plenary Lecture**

**Plenary Opening Lecture**

**Systems Medicine, Systems Toxicology, Transformational Technologies and the Revolution from Reactive to Proactive (P4) Medicine**

**Monday, March 12, 8:00 AM–9:00 AM**

![Leroy Hood](image)

*Lecturer: Leroy Hood, Institute of Systems Biology, Seattle, WA.*

The challenge for biology in the 21st century is the need to deal with its incredible complexity. One powerful way to think of biology is to view it as an informational science. This view leads to the conclusion that biological information is captured, mined, integrated by biological networks and finally passed off to molecular machines for execution. Hence the challenge in understanding biological complexity is that of deciphering the operation of dynamic biological networks across the three time scales of life—evolution, development, and physiological responses. Systems approaches to biology are focused on delineating and deciphering dynamic biological networks and their interactions with simple and complex molecular machines.

Dr. Hood’s focus will be on our strategies for taking a systems approach to disease—looking at prion disease and liver toxicity in mice. We have published a study on prion disease that has taken more than 6 years—that lays out the principles of a systems approach to disease including new insights into pathophysiology, new approaches to diagnosis and therapy, as well as dealing with the striking signal to noise problems of high-throughput biological measurements and biology itself. Also has studied two types of liver toxicity and these studies have also yielded insights similar to those discussed above. We have made blood a window for assessing health and disease through the use of blood organ-specific markers (for both brain and liver).

Dr. Hood will also discuss the emerging technologies (measurement and visualization) that will transform medicine and the analyses of toxicity over the next 10 years—including next generation DNA sequencing, targeted mass spectrometry, microfluidic protein chips, and single-cell analyses.

It appears that systems approaches to disease, together with pioneering changes in technology and the development of powerful new computational and mathematical tools will transform medicine over the next 5–20 years from its currently reactive state to a mode that is predictive, personalized, preventive, and participatory (P4).

In conclusion, Dr. Hood will describe what P4 medicine will do for the individual patient. He will also consider the societal impact of P4 medicine and how ISB has created global strategic partnerships to bring P4 medicine to patients.

**Keynote Medical Research Council (MRC) Lecture**

**Role of microRNAs in Control of Gene Expression in Human Physiology and Pathology**

**Tuesday, March 13, 8:00 AM–9:00 AM**

![Witold Filipowicz](image)

*Lecturer: Witold Filipowicz, Friedrich Miescher Institute for Biomedical Research, Basel, Switzerland.*

MicroRNAs (miRNAs) are a novel class ~20-nt-long regulatory RNAs expressed in eukaryotes. MiRNAs regulate gene expression posttranscriptionally, by imperfectly base-pairing to 3’UTR of mRNAs, which results in translational repression or mRNA deadenylation and degradation. The number of different miRNAs in humans reaches ~1,000, and ~50% of all human genes are predicted to be subject to miRNA regulation. Although specific functions and target mRNAs have been assigned to only a fraction of identified miRNAs, much evidence exists that miRNAs participate in the regulation of nearly all cellular and developmental processes. Expression of many miRNAs is tissue or development-specific and major changes in miRNA expression are observed in human pathologies, including cancer. Clearly, discovery of miRNAs added a new dimension to the complexity and regulation of eukaryotic genomes.

This lecture will provide current knowledge about the mechanism of miRNA-mediated repression of gene expression, procedures to identify miRNA targets, as well as a role of miRNAs in selected human pathologies and the use of miRNA profiling as a diagnostic tool in human diseases and in tissue and cell injuries. MiRNAs have been found to be secreted from cells via exosomes and their profiling in human serum and other body fluids appears to be a promising diagnostic tool in different pathologies. MiRNAs may also play important roles in cellular responses to xenobiotic stresses and in control of drug-metabolizing enzymes. In addition, miRNAs or compounds blocking their function represent promising therapeutic agents.
Featured Sessions

**Special Symposium**

**Meet the Directors**

Wednesday, March 14, 9:00 AM–11:45 AM


Each year this unique session provides an opportunity for the leaders of agencies to provide an overview of their organizations’ scientific directions, funding opportunities, and scientific concepts/achievements. This year, our panel of experts from the Agency for Toxic Substances and Disease Registry (ATSDR), National Institute of Environmental Health Science (NIEHS), Environmental Protection Agency (EPA), and the European Chemical Agency (ECHA) will provide information of interest to the SOT membership during their individual talks.

We hope you’ll join them as they deliver the most recent updates related to important issues that have an impact on toxicology.

**Award Lectures**

**Merit Award Lecture**

**Title to Be Announced**

Monday, March 12, 12:30 PM–1:20 PM

Lecturer: Curtis D. Klaassen, University of Kansas Medical Center, Kansas City, KS.

**Leading Edge in Basic Science Award Lecture**

**Title to Be Announced**

Tuesday, March 13, 7:00 AM–7:50 AM

Lecturer: Myung-Haing Cho, Seoul National University, Seoul, South Korea.

**Distinguished Toxicology Scholar Award Lecture**

**Environmental Chemicals: From Biochemical and Molecular Toxicology to Education and Outreach**

Tuesday, March 13, 12:30 PM–1:20 PM

Lecturer: Ernest Hodgson, North Carolina State University, and the North Carolina Agromedicine Institute, Raleigh, NC.

Knowledge of modes of toxic action and risk analysis are approaching the point where systems biology will be essential for understanding. Human environments are also complex, from pristine ecosystems to those contaminated by human activities such as the agroecosystem, industrial workplaces, military deployments and home environments. Each environment has numerous variants that overlap within and between categories and the exposome concept may also become essential. The speaker has been fortunate to be involved in a number of these aspects and as Distinguished...
Toxicology Scholar has an opportunity to discuss their past, present, and future. Successes, failures and disappointments include such items as the mechanism of action of benzodioxole synergists, aryl hydrocarbon receptor (AhR)-independent induction of cyp1a2, human metabolism of agrochemicals, metabolic interactions, and agromedicine. Our studies have identified environmental chemicals that interact in humans based on induction, on enzyme inhibition by organophosphorus toxicants of both exogenous substrate and steroid hormone metabolism and on activation of naphthalene metabolism. Microarray studies of the effect of chlorpyrifos on gene expression in human hepatocytes identified regulated genes and characterized the affected biological pathways.

**Translational Impact Award Lecture**

**Medical Toxicology Evaluations of the 2008 TVA Fly Ash Spill**

Wednesday, March 14, 12:30 PM–1:20 PM

**Lecturer:** John G. Benitez, Vanderbilt University Medical Center, Nashville, TN.

At approximately 1:00 am on 22 of December 2008, the retaining dike broke at the TVA Kingston Fossil Plant, releasing more than 5.4 million cubic yards of coal ash onto TVA property, private property and the Emory River. The ash flow filled several sloughs with ash debris and embankment material. The communities surrounding the spill site had an additional concern regarding health risks because of living next to the site, ash on their property, the emergency response, and planned remediation efforts. Through partnership with the Oak Ridge Associated Universities and the Tennessee Poison Center, residents living in the vicinity of the Kingston TVA plant had medical evaluations by a medical toxicologist including a history and physical exam, routine laboratory evaluations, pulmonary function testing, chest radiographs, and blood and urine metal evaluations. Three hundred twenty participants signed up initially; 200 were seen by the medical toxicologist. One hundred ninety-eight of these had blood and urine testing, 208 had chest radiographs, and 194 had pulmonary function tests. Many participants had ear, nose, throat, and pulmonary complaints. No pattern of heavy metal exposure, abnormal blood testing, pulmonary function testing, and chest radiographs were found.

**SOT/EUROTOX Debate**

**Comparative Hazards: Chemicals in the Environment Are the Largest Risk to Human Health**

Monday, March 12, 4:30 PM–5:50 PM

**Chairperson(s):** Lois D. Lehman-McKeeman, Bristol-Myers Squibb Company, Princeton, NJ, and Ruth A. Roberts, AstraZeneca UK, Macclesfield, United Kingdom.

**SOT Debater:** Stephen Safe, Texas A&M University, College Station, TX.

**EUROTOX Debater:** David R. Bell, European Chemicals Agency, Helsinki, Finland.

**Endorsed by:**

Society of Toxicology (SOT)
European Societies of Toxicology (EUROTOX)

Each year the SOT Annual Meeting includes a debate that continues a tradition that originated in the early 1990s in which leading toxicologists advocate opposing sides of an issue of great toxicological importance. This year, our debaters will address the proposition: Comparative Hazards: Chemicals in the Environment Are the Largest Risk to Human Health

Chemicals have been introduced into the environment through a variety of industrial and agricultural processes. They are measured in the air we breathe, the water we drink and the food we eat. Although there are many chemicals that serve to improve the quality of life, there are also unintended hazards that are associated with their use. This debate is intended to focus on chemicals in the environment as the largest risk to human health, particularly when compared to other potential health hazards.

Regardless of framework differences and personal convictions, each scientific delegate will present relevant evidence and compelling scientific arguments to persuade and appeal to the response of the audience in order to obtain the approval or refusal of the motion. In addition to being a featured session at the SOT Annual Meeting, this debate will again take place in Stockholm, Sweden during the 2012 Eurotox Annual Congress, June 17–20.
Featured Sessions

Issues Session

**Building for the Future: Strategic Initiatives for the SOT Endowment Fund**

**Thursday, March 15, 7:30 AM–8:50 AM**

**Chairperson(s):** Norbert E. Kaminsky, Michigan State University, East Lansing, MI, and Lois D. Lehman-McKeeman, Bristol-Myers Squibb Company, Princeton, NJ.

An important goal emerging from the Society’s strategic initiatives is to continue support of programs and activities that cultivate the long-term interests and professional development of its members. Achieving this goal requires sufficient resources to address specific needs, including adequate research funding and providing the next generation of scientists with the tools and opportunities to advance their science and facilitate harmonization in a global marketplace.

As part of the strategic plan, SOT Council has directed the SOT Endowment Fund Board to develop aspirational goals that would generate the enthusiasm necessary to grow the Endowment Fund and to initiate new activities that broadly support membership development and engagement.

We invite you to join us for this very informative and important Issues Session. We will discuss the strategic initiatives and plans to create a margin of excellence for supporting the priority needs and advancing the science of toxicology. We also encourage and value membership input and perspective on these efforts, particularly in this critical early stage when plans are being developed.

Research Funding Sessions

**Research Funding Resource Room**

**Tuesday, March 13 and Wednesday, March 14, 9:30 AM–4:30 PM**

**Chairperson(s):** Nancy Kerkvliet, Oregon State University, Corvallis, OR.

**Sponsor:** Research Funding Committee

Representatives from federal agencies funding research, including NIH program and review staff of the Center for Scientific Review and NIEHS, will be available in the Research Funding Room for individual conversations. Make an appointment with your program officer in advance or at their exhibit booth, or check the posted schedule, to meet with the staff member who can discuss with you aspects of scientific review or specific grant opportunities. New investigators are especially encouraged to meet with program staff. Handouts will be available.

**Brown Bag Luncheon**

**Tuesday, March 13, 12:00 Noon–1:30 PM**

**Chairperson(s):** Nancy Kerkvliet, Oregon State University, Corvallis, OR.

**Sponsor:** Research Funding Committee

Bring your lunches and learn what three young investigators have to say about preparing successful grant packages. Panelists will explain the ins and outs of what makes a successful grant submission, what you should do before putting pen to paper, how to write the grant, and what tips they used to help make their grant submission stand out.
Consider Organizing a Contemporary Concepts in Toxicology (CCT) Meeting

CCT Meetings expand the opportunities and forums for members to engage in the exchange of ideas and information relevant to toxicology. CCT meetings are one- to two-day focused, open registration, scientific meetings in contemporary and rapidly progressing areas of toxicological sciences.

If you think that your research area could be enhanced by thought leader collaboration or that public health and safety could be improved by disseminating your research findings more broadly, please consider organizing a SOT CCT. The CCT Conference Committee and the SOT Headquarters staff are prepared to help move your meeting forward.

CCT Meetings focus on a wide range of topics and future CCTs address the following:

- **Building for Better Decisions: Multiscale Integration of Human Health and Environmental Data**—May 8–11, 2012, Research Triangle Park, North Carolina, United States


- **Future Tox: Building the Road for the 21st Century Toxicology and Risk Assessment Practice**—October 18–19, 2012, Arlington, Virginia, United States

In order to sustain the quality standards of the Society, only meetings in which SOT maintains scientific and administrative control will be considered. Meetings developed and administered by other organizations may be eligible for endorsement by the Society of Toxicology.

For additional information, visit the SOT website: [www.toxicology.org](http://www.toxicology.org)
MONDAY

Clinical Toxicology from Bedside to the Bench and Back

Dietary Supplement Adulteration and Impact on Human Health

Monday, March 12, 9:15 AM to 12:00 Noon


Sponsor: Food Safety Specialty Section

Endorsed by: Clinical and Translational Toxicology Specialty Section

The purposeful adulteration of dietary supplements, and ingredients destined for such products, can cause serious health problems in consumers and presents many challenges to the industry. These problems and challenges extend to the consumer, who would not expect such natural products to contain adulterants such as prescription drugs and who may be at risk of adverse effects; industry members who must be vigilant of their supply chains and product quality; and regulatory authorities, who are required to monitor the market in order to detect signals of potential product adulteration, and to take action if such products are found in their countries. The main product types which are reportedly susceptible to adulteration are those indicated for erectile dysfunction, weight loss, and body building. Instances of adulteration can cause adverse effects in the consumer and will always reflect badly on, and reduce public confidence in, the specific product lines and dietary supplements as a whole. Quality standards that specify criteria suitable to verify the authenticity of dietary supplements and their ingredients are an advantageous and readily usable tool to provide some measure of purity and authenticity to all industry partners throughout the whole supply chain as well as regulators, and ultimately benefit the consumers through increased protection of the risk such adulteration may present.


Symposia

Characterizing Toxic Modes of Action and Pathways to Toxicity

DNA Damage Responses and Repair

Monday, March 12, 9:15 AM to 12:00 Noon

Chairperson(s): Richard S. Paules, NIEHS, Research Triangle Park, NC, and Leona D. Samson, Massachusetts Institute of Technology, Cambridge, MA.

Sponsor: Carcinogenesis Specialty Section

Endorsed by: Molecular Biology Specialty Section

Exposure to agents that have the potential to damage DNA occurs every day and is in fact a normal part of life. As a consequence, extremely efficient processes have developed that protect the genome from deleterious alterations by recognizing DNA damage in what is referred to as the DNA Damage Response (DDR) and initiating a series of cellular signal transduction pathway responses that lead to a coordination of regulation of cell cycle proliferation and repair of DNA lesions, if possible, or to the initiation of a cell death process, if appropriate repair is not possible. DNA damage can arise from both endogenous and exogenous sources, and, if not repaired properly, may lead to mutations, development of diseases such as cancer, cellular, or tissue toxicity, or ultimately to the death of the organism. Activation of the DDR results in the activation of the DNA damage sensor kinases ATM and ATR, which can then initiate an inhibition of cell cycle progression through the activation of a DNA damage checkpoint, in order to allow time for the repair of DNA lesions and to prevent the transmission of damaged or incompletely replicated genetic material. By repair of the DNA damage and restoration of the integrity of the DNA duplex, genomic stability can be maintained. DNA repair mechanisms that function to maintain genomic stability and to avoid toxicity include base excision repair, nucleotide excision repair, double-strand break repair, as well as translesion DNA synthesis. We will present important updates on the progress made in elucidating the consequences of genetic and pharmacological modulations of the levels and functions of certain DNA damage repair and response gene products on both toxicities of exposures, as well as exciting possible new therapeutic approaches. We will focus on recent advances in understanding the molecular mechanisms of the DDR and DNA repair, both to provide molecular insight into toxicity and disease processes, and also potentially to provide novel targets for therapeutic strategies for treating individuals with certain diseases such as cancers.

- Complex Responses of Mice to Alkylation and Inflammation Induced Toxicity. Leona D. Samson, Massachusetts Institute of Technology, Cambridge, MA.
Symposia

- **Cell Signaling in Response to PARP Inhibition and Alkylating Agent Exposure.** Samuel Wilson, NIEHS, Research Triangle Park, NC.
- **Identifying Translational Components of the DNA Damage Response.** Thomas Begley, State University of New York at Albany, Albany, NY.
- **Damage-Specific Pathways for the Regulation of Postreplication Repair.** Karlene Cimprich, Stanford University, Stanford, CA.
- **Redundancy and Cross-Talk in Pathways and Functions in DNA Damage Responses to the Highly Toxic DNA Double-Strand Break.** Richard S. Paules, NIEHS, Research Triangle Park, NC.

**Characterizing Toxic Modes of Action and Pathways to Toxicity**

**The Thick and Thin of Nuclear Receptors and Nrf2 in Diabetes and Obesity**

**Monday, March 12, 9:15 AM to 12:00 Noon**

*Chairperson(s):* Angela Slitt, University of Rhode Island, Kingston, RI, and Lauren Aleksunes, Rutgers University, Piscataway, NJ.

*Sponsor:* Molecular Biology Specialty Section

*Endorsed by:* Cardiovascular Toxicology Specialty Section  
Mechanisms Specialty Section  
Molecular Biology Specialty Section

Xenobiotic nuclear receptors, such as CAR, PXR, AHR, FXR, and Nrf2 are best known for transcription regulation and induction of Phase I and Phase II biotransformation enzymes, as well as transporters. These receptor pathways are of interest because they are activated by diverse chemicals—drugs, chemicals of environmental exposure, as well as endogenous chemicals such as hormones and bile acids. It is well established that there are chemical-receptor interactions—especially in the liver, which lead to transcriptional upregulation of gene batteries and result in coordinate regulation of metabolism and transport. However, recent evidence points to nuclear receptors and the role for these receptors in diseases related to metabolic syndrome, dyslipidemia, and glucose homeostasis. As the incidence of obesity and obesity-related diseases, which culminate in metabolic syndrome, increase worldwide, understanding the mechanisms of obesity is of high interest for human health. As these receptors are targeted by drugs and environmental chemicals, it is of importance to understand how activators of these xenobiotic receptors affect aspects of adipocyte differentiation, adiposity, and pancreatic function in adults, as well as sensitive populations, specifically pregnant women and children. Our findings will be presented for various receptor-mediated pathways with regard to various obesity and diabetes models. Presentations will cover nuclear receptor-mediated gene induction and research findings related to nuclear receptors with regard to obesity and diabetes. Finally, findings will be presented regarding what is currently known regarding nuclear receptor function in caloric restriction, the practice most recommended to combat obesity and obesity-related disorders. The information presented will be useful to those interested in nuclear receptors, aspects of metabolic syndrome, mouse models of obesity and diabetes, aspects of metabolic syndrome and drug interactions, therapeutic drug targets, and environment-obesogen effects.

- **A Novel Function of the Xenobiotic Receptor CAR in Obesity and Type-2 Diabetes.** Wen Xie, University of Pittsburgh School of Pharmacy, Pittsburgh, PA.
- **Paradoxical Roles of Nrf2 Activation in Arsenic-Induced Pancreatic β-Cell Dysfunction and Insulin Resistance.** Jingbo Pi, The Hamner Institute, Research Triangle Park, NC.
- **Bile Acid and Nuclear Receptor Signaling in Diabetes and Obesity.** John Chiang, Northeastern Ohio Universities, Rootstown, OH.
- **Hepatobiliary Transporter Regulation in Diabetic Pregnancy: Influence of Nrf2 and FXR-Shp Signaling.** Lauren Aleksunes, Rutgers University, Ernest Mario School of Pharmacy, Piscataway, NJ.
- **Reversing Obesity and Metabolic Syndrome: Do Nuclear Receptors Have a Role in Weight Loss?** Angela Slitt, University of Rhode Island, Kingston, RI.

**Aberrant Gene Expression in Toxicity and Disease—Epigenetics and microRNAs**

**Toxicological Considerations of Epigenetic Targets in Product Development**

**Monday, March 12, 9:15 AM to 12:00 Noon**

*Chairperson(s):* Melissa Rhodes, GlaxoSmithKline, Research Triangle Park, NC, and Brandon Jeffy, Celgene, San Diego, CA.

*Sponsor:* Drug Discovery Toxicology Specialty Section

*Endorsed by:* Carcinogenesis Specialty Section  
Mechanisms Specialty Section  
Molecular Biology Specialty Section  
Regulatory and Safety Evaluation Specialty Section  
Reproductive and Developmental Toxicology Specialty Section

In recent years, epigenetic factors have been implicated in the etiology of various diseases including cancers, psychiatric disorders, and diabetes/obesity. As epigenetic mechanisms have become more extensively characterized, new opportunities for therapeutic intervention
Many epigenetic targets for pharmacological inhibition have recently been identified. While pharmaceutical inhibitors of epigenetic targets such as histone deacetylases and DNA methyltransferases have recently gained regulatory approval, the field of pharmacoepigenetics is still relatively young. As greater understanding of the epigenome is evolving, previously approved drugs are now serendipitously being found to have epigenetic modulatory properties and are currently under evaluation for new indications. With the rapid emergence of multiple novel epigenetic targets for pharmacological inhibition, new considerations for the field of toxicoepigenetics are becoming apparent as well. In order to address the potential toxicological consequences associated with pharmacological inhibition of potential therapeutic epigenetic targets, toxicologists are addressing the need for new models and endpoints to be considered in the safety assessment of epigenetic targets. These important toxicological issues, which may be unique to epigenetic targets, will be addressed.

- **Epigenetics Meets Toxicology: An Integrated View of Mechanisms Controlling Transcription That Are Superimposed on DNA Base Sequence.** Jay Goodman, Michigan State University, East Lansing, MI.

- **Evaluation of Potential Safety Risks of Pharmacological Inhibitors of Epigenetic Targets in Discovery Toxicology.** Brandon Jeffy, Celgene, San Diego, CA.

- **Epigenomics—Impact for Drug Safety Sciences.** Jonathan Moggs, Novartis, Basel, Switzerland.

- **Investigation of Transgenerational Epigenetic Inheritance in Product Safety Assessment.** Reza Rasoulpour, The Dow Chemical Company, Midland, MI.

- **Current and Future Epigenetic Therapies.** Nessa Carey, Pfizer, Cambridge, United Kingdom.

**Regulatory Science: Bridging the Gap between Discovery and Product Availability**

**21st Century Validation Strategies—One Size No Longer Fits All**

Monday, March 12, 2:00 PM to 4:45 PM

Chairperson(s): Suzanne C. Fitzpatrick, US FDA, Silver Spring, MD, and Richard A. Becker, American Chemical Council, Washington, DC.

Sponsor:  
*In Vitro* and Alternative Methods Specialty Section

Endorsed by:  
Regulatory Safety Evaluation Specialty Section  
Risk Assessment Specialty Section

Recent advances in systems biology and related scientific fields offer the potential to fundamentally change the way that chemicals and drugs are tested for their risk to humans. This new vision of toxicology testing will be based upon human rather than animal biology and will involve a strong commitment to the 3Rs—replacement, reduction, and refinement of animal use in research and testing. There are many challenges to fully implementing this vision. Current formal approaches to validation involve lengthy and expensive processes that require validating *in vitro* data against *in vivo* data. This approach may not be relevant or even feasible for the new pathways and endpoints being measured. Consequently, applying a one size fits all approach to validation is not conducive to the rapid incorporation of emerging science or technology into the regulatory decision-making framework. As new safety testing evolves, new approaches to demonstrating that a test is reliable and relevant for a particular purpose must also evolve. Such approaches may differ for different tests and be based on their intended use (e.g., as part of screening or other algorithmic approaches versus intended replacement of existing tests). To meet this challenge will require an active dialogue and early collaboration among all stakeholders, including federal regulatory agencies, other regulators, NGOs, academia, and industry scientists. This session offers an opportunity for such a dialogue about what could constitute a more flexible approach to demonstrating that these new toxicology testing methods are scientifically valid and address the fundamental questions of human safety and efficacy.

- **Challenges to Incorporating New Technologies into the Toxicology Regulatory Testing Paradigm.** Wallace Hayes, Harvard University, Andover, MA.

- **Biomarker Qualification—A Pathway for Acceptance of Alternative Toxicology Test Methods by Regulatory Agencies.** Marc Walton, US FDA, Silver Spring, MD.

- **Developing Scientific Confidence in Computational Approaches for Hazard Evaluation.** Richard A. Becker, American Chemical Council, Washington, DC.

- **Toxicity Test Validation in the 21st Century.** Vicki Dellarco, US EPA, Washington, DC.

- **In Vitro/In Silico/Exploratory Assessment of Pharmaceuticals.** Abigail Jacobs, US FDA, Silver Spring, MD.

- **An Evolving Example of Integrating In Vitro Risk Signals.** Robert Chapin, Pfizer, Inc., Groton, CT.
**Symposia**

**Breast Cancer As a Multifactorial Disease: Interaction of Genetics, Life Stage, and the Environment**

Monday, March 12, 2:00 PM to 4:45 PM

*Chairperson(s):* David L. Eaton, University of Washington, Seattle, WA, and Joyce S. Tsuji, Exponent, Inc., Bellevue, WA.

*Sponsor:*
Carcinogenesis Specialty Section

**Endorsed by:**
- Disease Prevention Task Force
- Mechanisms Specialty Section
- Occupational and Public Health Specialty Section
- Reproductive and Developmental Toxicology Specialty Section
- Women in Toxicology Special Interest Group

Despite decades of research into its causes and treatments, breast cancer remains the most common invasive cancer and the second leading cause of cancer mortality for women in the United States. Known risk factors include genetic mutations; birth weight and stature; timing of breast development, child bearing, lactation, and senescence; body fat; and physical inactivity. Some common external, environmental risk factors include radiation, hormone therapy, diet, alcohol, and perhaps smoking and shift work/circadian rhythm disruption. Several environmental chemicals have also been implicated in the etiology of breast cancer. Although toxicological studies indicate potential hazards through endocrine disruption and even some hormone independent mechanisms, strong epidemiological evidence is largely lacking. Animal bioassays for breast and other types of cancer typically assess each chemical independently, and exposure periods usually do not include potentially sensitive windows of susceptibility, such as *in utero*, the neonatal period, puberty, or menopause. Nevertheless, emerging epigenetic data support the concept that exposure during sensitive early life stages when the mammary gland is developing can result in developmental reprogramming of breast cells, thereby increasing breast cancer risk later in life. Similarly, stimulation of breast cell division later in life by endocrine-active agents may increase mutation rates or promote tumors at a life stage in which DNA repair is waning. This important topic explores the complex interaction among the potential contributors to breast cancer risk in follow up to the 2011 report of the Institute of Medicine Committee on Breast Cancer and the Environment (funded by Komen for the Cure).

- **Gene-Environment Interactions in Breast Cancer Risk.** Mary-Claire King, University of Washington, Seattle, WA.
- **The Complex Etiology of Breast Cancer: A Life-Course Approach.** Robert Hiatt, University of California, San Francisco, CA.
- **Early-Life Exposures to Endocrine-Active Chemicals Promotes Breast Cancer Risk Later in Life.** Linda Birnbaum, NIEHS, Research Triangle Park, NC.
- **Dietary and Occupational Disruption of Endocrine Signaling: Implications for Breast Cancer Risk.** Helmut Zarbl, Robert Wood Johnson Medical School, Environmental and Occupational Health Sciences Institute, Princeton, NJ.
- **Environmental Epigenomics: Developmental Reprogramming of Cancer Susceptibility.** Cheryl Walker, University of Texas MD Anderson Cancer Center, Smithville, TX.
- **New Directions for Future Research on Environmental Influences on Breast Cancer.** Joyce Tsuji, Exponent, Inc., Bellevue, WA.

**Evaluation of Ocular Safety in the Development of New Drugs**

Monday, March 12, 2:00 PM to 4:45 PM

*Chairperson(s):* Brian J. Christian, Covance Inc., Verona, WI, and James N. Ver Hoeve, University of Wisconsin, Madison, WI.

*Sponsor:*
Ocular Toxicology Specialty Section

**Endorsed by:**
- Biotechnology Specialty Section
- Regulatory and Safety Evaluation Specialty Section

Interest in the research and development of therapies for age-related ocular disease has increased as the size of the aging population grows. In recent years significant advances in treating ocular disease have been developed such as the application of antineovascular drugs, previously used in oncology, for use in treating vascular disease of the eye. The development of sustained release formulations has similarly expanded the application of therapies for anterior segment ocular disease to diseases of the posterior segment. The eye poses a unique challenge to drug development as a consequence of the anatomic and physiologic barriers to drug access to intraocular targets. The complexity of the structure and function of the eye, the need to use nonroutine, specialized safety evaluation techniques, and the important role of vision in normal function, all add to the challenges faced by both ocular toxicologists and regulatory agencies. The focus of this session will be to highlight key ocular safety assessment techniques commonly used to evaluate the anterior (i.e., multiple corneal evaluation methods) and posterior (i.e., electroretinography) segments of the eye. Data will be presented that demonstrate how the techniques may be applied in a nonclinical safety evaluation setting. In addition, case studies detailing the development of a protein biologic and a sustained release formulation for posterior segment disease will provide attendees with examples of safety assessment strategies as well as the challenges that may be encountered. Finally, pertinent issues in the assessment of ocular safety from the perspective of the regulatory agency will be presented, along with discussion of the drug development implications of selected findings.

- **Assessment of Corneal Toxicity.** Henry Edelhauser, Emory University, Atlanta, GA.
• Cardiotoxicity of Kinase Targeted Therapeutics. Thomas Force, Thomas Jefferson University, Philadelphia, PA.
• Mitochondrial Aldehyde Dehydrogenase 2, Nitroglycerin, and Myocardial Injury. Daria Mochly-Rosen, Stanford University, Stanford, CA.
• Nrf2 and GILZ As Molecular Targets for Cardiac Protection. Qin M. Chen, University of Arizona, Tucson, AZ.
• Hypoxia-Inducible Factor-1 in Cardiac Toxicity and Regeneration. Y. James Kang, University of Louisville, Louisville, KY.

Nanoparticles for Drug Delivery: Interactions with the Immune System

Monday, March 12, 2:00 PM to 4:45 PM
Chairperson(s): Sandra Casinghino, Pfizer, Inc., Groton, CT, and Marina A. Dobrovolskaya, SAIC-Frederick Inc., Frederick, MD.
Sponsor: Immunotoxicology Specialty Section
Endorsed by: Nanotoxicology Specialty Section

Nanotechnology holds great promise for targeted drug delivery. Unique chemical and physical properties of nanoparticles may lead to improvements in delivery technology in several ways. Examples include increasing the solubility of poorly soluble drugs, increasing efficacy and safety by delivering drugs directly to diseased tissues, and potentially decreasing costs by achieving therapeutic efficacy despite administration of lower doses of drugs. Many publications have discussed the toxicology of environmental and occupational nanomaterials, but more information is needed regarding nanoparticles designed for parenteral administration. These nanoparticles may present unique issues due to recognition by the innate immune system and downstream effects on adaptive immunity. Interactions with the immune system may result in premature clearance before payload delivery, disseminated intravascular coagulation-like toxicities, inflammation, anaphylaxis, and decreased resistance to infection or tumors. Nanoparticles are a very broad and diverse class of biomaterials, and there are significant gaps in our knowledge of the mechanisms by which nanoparticles interact with the immune system. Recognition by immune cells is influenced by many factors, including direct interaction of nanoparticles with red blood cell proteins as well as proteins of the complement and coagulation systems. Therefore nanomaterials may need to be screened for hemotoxicity and complement activation prior to preclinical in vivo studies. Investigation of nanomaterial effects on the function of immune cells, such as phagocytes and lymphocytes, is also important, and development of in vitro assays that are predictive of in vivo observations is critical. Further work is needed to elucidate which chemical and physical properties of nanoparticles are responsible

Symposia

Characterizing Toxic Modes of Action and Pathways to Toxicity

Molecular Basis for Prevention of Cardiotoxicity

Monday, March 12, 2:00 PM to 4:45 PM
Chairperson(s): Qin M. Chen, University of Arizona, Tucson, AZ, and Y. James Kang, University of Louisville, Louisville, KY.
Sponsor: Cardiovascular Toxicology Specialty Section

Endorsed by: Drug Discovery Toxicology Specialty Section
Mechanisms Specialty Section
Molecular Biology Specialty Section

Cardiac toxicity is an increasing concern for chemo, radiation, and gene targeting therapies. The overlapping molecular pathways of cardiac protection versus cancer cell growth, and cardiac energy metabolism versus underlying causes of diseases such as obesity or diabetes pose threats to new drug development against these diseases. Whereas anthracyclines, such as doxorubicin, are well known for inducing cardiotoxicity manifested by arrhythmia and chronic cardiomyopathy, the monoclonal antibody trastuzumab (Herceptin) targeting the epidermal growth factor receptor for cancer therapy induces apoptosis and hypertrophy of cardiomyocytes, leading to dilated cardiomyopathy. Small molecular kinase inhibitors, such as imatinib (Gleevec), cause cardiotoxicity due to induction of apoptosis of cardiomyocytes. While kinase inhibitors and gene targeting therapy have tremendous potential for pharmacological treatment of cancer and other diseases, finding the signaling pathways and genes that can protect against cardiotoxicity is an emerging issue. Thus, in exploration of this important topic, we will discuss the ways in which the heart can be protected from tissue injury by addressing signaling molecules, unique genes, and nutritional factors.

• Cardiotoxicity of Chemotherapeutic Drugs: Clinic Presentation and Treatment. Joseph Alpert, University of Arizona, Tucson, AZ.
Symposia

for specific interactions with immune system proteins or cells, and understanding these interactions may allow exploitation of nanoparticle properties to ensure both safety and efficacy of nanomedicines.

- **Immunological Properties of Engineered Nanomaterials.** Marina A. Dobrovolskaia, SAIC-Frederick, Frederick, MD.

- **Understanding the Immunological Properties of Functionalized Lipid-Polymer Nanoparticles.** Carolina Salvador-Morales, George Mason University, Fairfax, VA.

- **Recognition of Nanoparticles by Macrophages—From Principles to Consequences and Toxicity.** Anna Shvedova, NIOSH, West Virginia University, Morgantown, WV.

- **Development of CYT-6091 (Aurimmune®): A Model Cancer Nanomedicine.** Lawrence Tamarkin, CytImmune, Rockville, MD.

- **Case Study: Interaction of Dextran Nanomaterials with the Immune System—In Vivo and In Vitro Studies.** Sandra Casinghino, Pfizer, Inc., Groton, CT.

**Characterizing Toxic Modes of Action and Pathways to Toxicity**

**Toxic Cell Death: Signaling Pathways, Cross-Talk, and High-Throughput Analysis**

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**Monday, March 12, 2:00 PM to 4:45 PM**

**Chairperson(s):** Sten Orrenius, Karolinska Institutet, Institute of Environmental Medicine, Stockholm, Sweden, and William Slikker Jr., US FDA, Jefferson, AR.

**Sponsor:** Mechanisms Specialty Section

**Endorsed by:**
- Food Safety Specialty Section
- Mechanisms Specialty Section
- Neurotoxicology Specialty Section
- Ocular Toxicology Specialty Section

Cell death is the ultimate result of toxicity caused by damage to critical cell functions and/or activation of death signaling pathways. Toxicants can trigger multiple modes of cell death (apoptosis, necrosis, necroptosis, and autophagic cell death) with distinct morphological and biochemical characteristics. In fact, several cell death modalities may coexist within the same lesion with cross-talk between them. To address this important topic, we will begin by discussing the role that may coexist within the same lesion with cross-talk between them. To understand how toxicants might interfere with cell viability and function. After the description of various cell death modalities, and the possible cross-talk between them, mechanisms of apoptotic cell death caused by anesthetics in the developing brain and of lead-induced apoptosis in retinal photoreceptors will be presented as examples of cell death caused by toxic insult. These studies illustrate the critical roles of the calcium ion and of reactive oxygen species as mediators of neurotoxicity, as well as the difference in sensitivity of the mitochondrial populations in rods and cones to apoptotic stimuli. Thereafter, the mechanisms of action of certain chemotherapeutic agents and fungal toxins will be discussed to illustrate the role of sphingolipid signaling molecules in cell death and disease. Finally, a molecular epidemiology approach using novel technologies to assess cell death and environmental impact in individual cells and in human populations in a high-throughput manner will be presented. The program will cover important toxicity mechanisms in multiple target organs and will hopefully contribute to a better understanding of the role of cell death mechanisms in toxic insult and disease.

- **Modes and Pathways of Toxicant-Induced Cell Death.** Boris Zhivotovsky, Karolinska Institutet, Institute of Environmental Medicine, Stockholm, Sweden.

- **Pathways to Anesthetic-Induced Brain Cell Death and to Neuronal Protection.** William Slikker Jr., US FDA, Jefferson, AR.

- **Differential Pathways of Cell Death by Lead and Neuroprotection by Bcl-xl in Photoreceptor Synaptic and Nonsynaptic Mitochondria.** Donald A. Fox, University of Houston, Houston, TX.

- **Ceramide, Sphingoid Bases, and Sphingoid Base Metabolites As Lipid Mediators in Signaling Pathways Leading to Cell Death and Disease.** Ronald Riley, US Department of Agriculture, Athens, GA.

- **Measuring Cell Death and Genotoxicity in Single Cells and Human Populations Using Lab-on-a-Chip Technologies.** Martyn Smyth, University of California, Berkeley, CA.

**TUESDAY**

**An Intelligent Reproductive and Developmental Testing Paradigm for the 21st Century**

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**Tuesday, March 13, 9:00 AM to 11:45 AM**

**Chairperson(s):** David Dix, US EPA, Research Triangle Park, NC, and Thomas Knudsen, US EPA, Research Triangle Park, NC.

**Sponsor:** Reproductive and Developmental Toxicology Specialty Section

**Endorsed by:**
- In Vitro and Alternative Methods Specialty Section
- Regulatory and Safety Evaluation Specialty Section
- Risk Assessment Specialty Section

Addressing the chemical evaluation bottleneck that currently exists can only be achieved through progressive changes to the current testing paradigm. The primary resources for addressing these issues lie in computational toxicology, a field enriched by recent advances in computer science, bio- and chem-informatics, molecular biology, and high-throughput screening (HTS). *In vivo* testing is resource inten-
sive, particularly for multigenerational reproductive and prenatal developmental assessment. Furthermore, predicting adverse effects of chemicals for reproductive and developmental outcomes has been confounded by the lack of quantitative models that address the complex molecular and physiological factors underlying reproductive decrements and developmental malformations, and the life-stage and generational sensitivities involved. There is currently a strong focus on identifying endocrine-disrupting chemicals through a battery of in vitro and in vivo screening tests. However, the shared complexities and challenges of modeling reproductive, endocrine, and developmental toxicity, and the parallel need for higher throughput evaluation, creates the need for an integrated application of predictive models for chemical prioritization and targeted testing. Ultimately, predictive models of reproductive, endocrine, and developmental toxicity will provide a critical component in the computational toxicology toolbox that better informs regulatory testing decisions.

- **Validation, Acceptance, and Extension of a Predictive Model of Reproductive Toxicity Using Toxcast Data.** Matthew Martin, US EPA, Research Triangle Park, NC.

- **Species-Specific Predictive Models of Developmental Toxicity Using the ToxCast Chemical Library.** Nisha Sipes, US EPA, Research Triangle Park, NC.


- **Building Bridges between High-Throughput Screening Data and In Vivo Regulatory Guideline Tests: Application of Intermediate Tier In Vitro Functional Assays in the Chemical Industry.** Edward Carney, The Dow Chemical Company, Midland, MI.

- **Intelligent Approaches to DART Evaluations of Therapeutic Proteins.** Kary Thompson, Bristol-Myers Squibb Company, New Brunswick, NJ.

**Characterizing Toxic Modes of Action and Pathways to Toxicity**

**Cross-Species Analysis of Toxicogenomics Data: Approaches for Assessing Differences in Sensitivity and Conservation of Mode of Action**

*Tuesday, March 13, 9:00 AM to 11:45 AM*

**Chairperson(s):** Russell S. Thomas, The Hamner Institutes for Health Sciences, Research Triangle Park, NC, and J. Craig Rowlands, The Dow Chemical Company, Midland, MI.

**Sponsor:**
- Molecular Biology Specialty Section
- Comparative and Veterinary Specialty Section
- Mechanisms Specialty Section

Two fundamental, but interrelated, challenges in toxicology are to identify a mode of action for a particular chemical and determine whether a particular response will be conserved across species. The determination of whether a response will be conserved usually involves a mechanistic understanding of the molecular events and an assessment of whether the processes and components that comprise those events are present in both the model species and the species of interest. In light of the relationship between gene expression changes and the biological effects, cross-species toxicogenomic studies may be used to identify potential modes of action for a chemical and determine appropriate cross-species adjustment factors for use in a risk assessment. We will evaluate the application of cross-species toxicogenomics analysis of chemical toxicant-induced modes of action across species for use in risk assessment in a series of highly focused presentations. These issues will be of broad interest to investigators and regulators across environmental, industrial, consumer products, and pharmaceutical toxicology who perform and interpret cross-species studies to understand human health risks.

- **Cross-Species Comparisons of Transcriptomic Alterations in Human and Rat Primary Hepatocytes Exposed to Dioxin-Like Chemicals.** J. Craig Rowlands, The Dow Chemical Company, Midland, MI.

- **Application of Cross-Species Toxicogenomics to Understand Rodent/Canine Mode-of-Action Differences in Drug-Induced Toxicities.** Timothy Ryan, Eli Lilly and Company, Indianapolis, IN.

- **Cross-Species Transcriptomic Analysis of the Mouse and Rat Lung Exposed to Chloroprene.** Russell S. Thomas, The Hamner Institutes for Health Sciences, Research Triangle Park, NC.

- **Comparative Evaluation of Genomic Changes in the Human and Mouse Bladder following Exposures to Inorganic Arsenic and Methylated Metabolites.** Harvey Clewell, The Hamner Institutes for Health Sciences, Research Triangle Park, NC.
### Symposiums

- **Systems Biology to Inform Cross-Species Extrapolation.**
  Lyle Burgoon, US EPA, Research Triangle Park, NC.

#### Regulatory Science: Bridging the Gap between Discovery and Product Availability

#### Development of Biosimilar Products: Overview of Standards and Regulations

**Tuesday, March 13, 9:00 AM to 11:45 AM**

**Chairperson(s):** Gregory Finch, Pfizer, Inc., Groton, CT, and Barbara Mounho, Amgen, Thousand Oaks, CA.

**Sponsor:** Biotechnology Specialty Section

**Endorsed by:** Regulatory and Safety Evaluation Specialty Section

Biosimilar products are follow-on versions of approved, innovative biopharmaceuticals derived from recombinant DNA technology. As innovator biopharmaceuticals are reaching the end of their patent protection period, there is an increased interest globally in the pharmaceutical industry in the opportunity for the development and registration of biosimilar products. A number of biosimilar products are now approved in certain regions (e.g., Europe), and numerous regulatory authorities around the world have either finalized or are in the process of developing guidance documents for the approval of biosimilars. This symposium will provide an overview of the history and development of the regional guidelines for biosimilars, as well as some of the unique challenges in developing biosimilars such as CMC, nonclinical, and clinical issues. Currently approved biosimilar products will be reviewed, including a more in-depth outline of the nonclinical and clinical studies conducted to support the approval of certain biosimilar products to illustrate selected challenges in the development process. The session will also include an overview of the US Biologics Price Competition and Innovation Act and regulatory perspective on requirements for biosimilar development, as well as an update and review on the US FDA's regulatory guidance on the nonclinical and clinical approval requirements for biosimilars.

- **Overview of the History and Development of Regional Guidelines for the Approval of Biosimilar Products.** Barbara Mounho, Amgen Inc., Thousand Oaks, CA.
- **Biosimilar Drug Development—Approaches to Toxicity Evaluation.** Danuta Herzyk, Merck & Co Inc., West Point, PA.
- **Industry Perspective on Biosimilar Drug Development and Registration.** Kelly Lai, Biotechnology Industry Organization, Washington, DC.

- **Challenges and Regulatory Approach for the Approval of Subsequent Entry Biologics in Canada.** Anthony Ridgway, Health Canada, Ottawa, Ontario, Canada.
- **US FDA’s Overview of the Regulatory Guidance for the Approval of Biosimilar Products in the United States.** David Jacobson Kram, US FDA, Silver Spring, MD.

#### The Role of Danger Signals in the Development of Chemical Sensitization by Environmental and Occupational Agents

**Tuesday, March 13, 9:00 AM to 11:45 AM**

**Chairperson(s):** Marc Pallardy, Université Paris-Sud-INSERM, Chatenay-Malabry, France, and Raymond Pieters, Utrecht University of Applied Sciences—Institute for Risk Assessment Sciences, Utrecht, Netherlands.

**Sponsor:** Immunotoxicology Specialty Section

The adaptive immune response to a foreign antigen needs both the recognition of the specific antigen and the presence of a specific cellular microenvironment at the place of antigen entrance. This specific cellular microenvironment provides signals to antigen-presenting cells allowing the elicitation of the immune response instead of immune tolerance to the foreign antigen. To this extent danger signals (e.g., proinflammatory cytokines, specific molecules from pathogens, necrosis products) play a crucial role in the immune adaptive response to pathogens. Triggering the innate immune system with danger signals, for instance through specific receptors termed PRR (pattern recognition receptors) including TLR (toll-like receptors), is a prerequisite for the immune system to react to pathogens as well as environmental antigens. These danger signals can be considered as adjuvants of immunity and indeed this concept has been extensively used for vaccination by adding chemicals (aluminium hydroxide) or pathogen products in vaccines. By analogy to the immune response to pathogens, the hypothesis that chemical allergens need the presence of danger signals or provide this danger signal to induce chemical hypersensitivity reactions has been developed during the past five to ten years. In this case, the chemical will play the role of an adjuvant. Recent evidence suggests that particulate matters and nanoparticles (SiO2, TiO2) can also mimic the presence of danger signals and thus have adjuvant potential on immune responses. Recently, several in vitro models have been developed to address the adjuvant effect of chemical sensitizers as tools to predict chemical sensitizer potential.

- **Chemicals Modify the Cellular Microenvironment in the Skin Providing Endogenous Danger Signals.** Stefan Martin, University of Freiburg, Freiburg, Germany.
- **Chemical Sensitizers Can Play the Role of Danger Signals.**
  Marc Pallardy, Université Paris-Sud-INSERM, Chatenay-Malabry, France.
• Phthalates Influence the Immune and Allergic Responses. Rebecca Dearman, University of Manchester, Manchester, United Kingdom.

• Lung Dendritic Cells Are Stimulated by Ultrafine Particles and Play a Key Role in Their Immunostimulating Activity. Raymond Pieters, Utrecht University of Applied Sciences—Institute for Risk Assessment Sciences, Utrecht, Netherlands.

Aberrant Gene Expression in Toxicity and Disease—Epigenetics and microRNAs

Circulating microRNAs: A New Class of Biomarkers for Tissue-Specific Toxicity

Tuesday, March 13, 1:30 PM to 4:15 PM

Chairperson(s): Wenyue Hu, Pfizer, Inc., San Diego, CA, and Greg Falls, GlaxoSmithKline, Research Triangle Park, NC.

Sponsor:
Drug Discovery Toxicology Specialty Section

Endorsed by:
Cardiovascular Toxicology Specialty Section
In Vitro and Alternative Methods Specialty Section
Molecular Biology Specialty Section
Regulatory and Safety Evaluation Specialty Section

MicroRNAs (miRNAs) are endogenous, small noncoding RNAs that down-regulate gene expression. Some miRNAs are produced at high concentrations within cells in a tissue-specific manner, and such miRNAs have recently been reported to be remarkably stable in plasma or other accessible body fluids. More importantly, differential increases in circulating miRNA populations have been shown by numerous studies to be associated with different disease or toxicity phenotypes. For example, tumor-derived miRNAs have been shown to distinguish patients with cancer from healthy individuals. Plasma concentrations of miR-122, miR-133a, and miR-124 have recently been shown to correspond to injuries in liver, muscle, and brain, respectively. Elevation in cardiac-specific miR-208a in plasma has been implicated as a potential biomarker for early diagnosis of acute myocardial infarction in humans. Taken together, because of their size, abundance, tissue specificity, and relative stability in body fluids, miRNAs hold promise as a new class of accessible biomarkers to monitor tissue-specific injuries. Our panel will explore the importance of this topic by providing perspectives from both industry and government sectors on the application of miRNAs as potential tissue injury biomarkers, the promises and pitfalls of miRNAs, and technical issues related to miRNA profiling in tissue and biofluids. Finally, our discussion will end with the impact of miRNA biomarkers on drug development in nonclinical studies, and the potential translatability to safety assessment in clinical settings.

Symposia

In Vitro and In Vivo Alternative Models of Developmental Toxicity of Pharmaceutical Compounds

Tuesday, March 13, 1:30 PM to 4:15 PM


Sponsor:
Reproductive and Developmental Toxicology Specialty Section

Endorsed by:
In Vitro and Alternative Methods Specialty Section
Regulatory and Safety Evaluation Specialty Section

In vitro methods for testing of developmental toxicity effects of chemicals have been in use since ECVAM validated the EST (Embryonic Stem Cell Test for Embryotoxicity) assay as an alternative to in vivo developmental toxicology studies. The EST assay has been slow accept in the pharmaceutical industry, mostly due to the perceived complexity and uncertain applicability domain associated with in vitro differentiation from stem cells to cardiomyocytes, the classical EST endpoint. In recent years, considerable efforts have been undertaken to define new endpoints using genomic, proteomic, and metabolomic markers. In addition, a human stem cell-derived EST approach has been initiated as well as the validation of other alternative models such as zebrafish for embryotoxicity prediction. There are many new developments in this field such as comparing in vitro and in vivo alternative approaches and the use of models to identify primary targets of known teratogens. In addition, novel automation and culturing approaches will be reviewed that have considerably aided in the reduction of variability and work load of the EST assay. Advances in using transcriptomics for identification of predictive biomarkers will also be covered, along with the current status of development of a human EST assay. Finally, bottlenecks in the implementation of these assays in regulatory toxicology will be discussed.
Symposia

- Use of Zebrafish for Identification of Targets of Teratogenicity. Hiroshi Handa, Tokyo Institute of Technology, Yokohama, Japan.

WEDNESDAY

Aberrant Gene Expression in Toxicity and Disease—Epigenetics and microRNAs

Epigenetic and miRNA Regulations in Carcinogenesis: Toxicological Implications

Wednesday, March 14, 9:00 AM to 11:45 AM

Chairperson(s): Jessica R. Placido, Saint John’s University, Jamaica, NY, and Enrique Fuentes-Mattei, The University of Texas MD Anderson Cancer Center, Houston, TX.

Sponsor: Graduate Student Leadership Committee

Endorsed by:
- Carcinogenesis Specialty Section
- Hispanic Organization of Toxicologists Special Interest Group
- Mechanisms Specialty Section
- Molecular Biology Specialty Section
- Postdoctoral Assembly

Epigenetics is an increasingly evolving scientific field focused on mechanisms involving heritable gene expression profiles and phenotypic changes fundamental for normal development without alterations in nucleotide sequence. DNA methylation and acetylation patterns, histone modifications, germ-line reprogramming and noncoding RNAs mediate epigenetic regulations. Increasing evidence suggests that disruption and alteration of normal epigenetic regulation mechanisms are fundamental in cancer development and progression. Recent evidence shows that exposure to air toxics and environmental pollutants triggers changes in microRNA (miRNA) expression profiles. These cellular changes reveal novel mechanisms through which toxics may induce adverse health effects, including the development of leukemia and liver carcinogenesis. In addition, arsenic has been implicated in the development of human skin, lung, bladder, liver, and prostate cancers. Histone modifications have been suggested as epigenetic mechanisms related to arsenic-induced carcinogenesis. Identification and development of new therapeutic strategies with specific and selective targets in the epigenetic machinery are of utmost importance. Recent research shows that detecting alterations in miRNA expression has been associated with early stages of tumor development. These findings suggest that miRNAs may play an important role in cancer risk assessment. Alternatively, histone deacetylase inhibitors are effective in the treatment of hematological malignancies such as leukemia in children. Epigenetic alterations that result in carcinogenesis stress the importance of research efforts to characterize associated molecular mechanisms and highlight current public health issues.

- Epigenetic Effects of Formaldehyde Exposure. Julia Rager, University of North Carolina Chapel Hill, Chapel Hill, NC.
- Arsenic-Induced Alterations in Global Posttranslational Histone Modifications among Adults in Bangladesh. Yana Chernova, New York University School of Medicine, New York, NY.
- The Molecular and Epigenetic Mechanisms Involved in Mammalian LINE-1 Retroelement Silencing Are Altered by Benzo(a)Pyrene. Diego Elias Montoya-Durango, University of Louisville, Louisville, KY.
- Epigenetic and miRNA Dysregulation in Liver Nongenotoxic and Genotoxic Tumorigenesis. Kristy Kutanzi, National Center for Toxicological Research, Jefferson, AR.
- Oxidative Stress-Based Strategies for Enhancing the Efficacy of Histone Deacetylase Inhibitors (HDACi) for the Treatment of Leukemias. Nilsa Rivera-Del Valle, The University of Texas MD Anderson Cancer Center, Houston, TX.

Innovations of Applied Toxicology (IAT) Session

Nonclinical Safety Assessment of Dual-Targeting Biotherapeutics

Wednesday, March 14, 9:00 AM to 11:45 AM

Chairperson(s): Matthew S. Bogdanoff, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, and Anne Pilaro, US FDA, Silver Spring, MD.

Sponsor: Biotechnology Specialty Section

Endorsed by:
- Drug Discovery Toxicology Specialty Section
- Immunotoxicology Specialty Section
- Regulatory and Safety Evaluation Specialty Section

Engineering of protein-based biotherapeutics has advanced significantly in recent years to delivering novel molecules having
exceptional target specificity. Initial antibody-based therapies were
designed to target a single epitope. More recently, multitargeting
antibodies, including nanoparticles, are being designed to bind
and modulate multiple cellular targets having coordinated biological
pathways. These novel and highly specific constructs present new
challenges for assessing safety in the nonclinical setting, including
identification of pharmacologically relevant species, creative study
designs that support clinical development in the presence of species-
dependent pharmacokinetic behavior, and antidrug antibody assay
implementation strategies for multi-anti-idiotype immunological
responses that may interfere with pharmacological/toxicological
data interpretation. This important topic will generate interest in
this issue and bring about the discussion and challenges with regard
to assessing the safety of these cutting-edge biotherapeutic modalities.
Our panel of experts will begin by providing a brief overview of
protein engineering technologies used in the design of dual-targeting
biotherapeutics with the aim of providing a basic understanding of
the technologies and particularly the toxicology-relevant aspects
of construct design, such as the influence of amino acid sequence
homology and glycosylation patterns on species-relevant pharma-
cologic action. We will follow the introduction with a series of three
case studies that illustrate the unique issues faced when developing
clinical trial-enabling strategies, study design, and data interpreta-
tion. Finally, a brief commentary from the regulatory perspective on
the need for nonclinical safety and regulatory scientists to partner
when faced with these new challenges will close out the session. At the
conclusion of the session a summary of the challenges and proactive
commentary on the future directions of nonclinical safety assessment
of dual-targeting biotherapeutics will be presented.

- **Dual Target Construct Engineering for Target Specificity and Efficacy.** Jennifer Cochran, Stanford University, Palo Alto, CA.
- **Nonclinical Assessment of Bispecific T Cell-Engaging Antibodies.** Benno Rattel, Micromet AG, Munich, Germany.
- **Computational, Safety, and Regulatory Strategies Used in Developing a Novel Bispecific Molecule in Oncology.** Kenneth Olivier, Merrimack Pharmaceuticals, Inc., Cambridge, MA.
- **Nonclinical Characterization of a HER3 and EGFR Dual Action Antibody in Cynomolgus Monkeys.** Rodney Prell, Genentech, South San Francisco, CA.
- **Regulatory Perspective on Dual-Targeting Biotherapeutics: Approaches, Translation of Nonclinical Findings, Challenge.** Anne Pilaro, US FDA, Washington, DC.
- **Challenges and Future Directions of Multitargeting Biotherapeutic Approaches.** Warren Ku, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT.

### The Allergenicity and Immunomodulatory Effect of Food Substances

**Wednesday, March 14, 9:00 AM to 11:45 AM**

**Chairperson(s):** Greg Ladics, DuPont Agricultural Biotechnology, Wilmington, DE, and Reiko Teshima, National Institute of Health Sciences Japan, Tokyo, Japan.

**Sponsor:**
- Immunotoxicology Specialty Section

**Endorsed by:**
- Food Safety Specialty Section

A food allergy is a reaction of the immune system to an otherwise
harmless protein in food. Typically, such food allergic reactions are
mediated by IgE and occur in atopic individuals who are genetically
predisposed to allergy and who have been previously sensitized to the
allergen. The incidence of food allergy ranges from approximately
1%–2% in adults and 6%–8% in children. The normal immune
response to dietary proteins is associated with the induction of oral
tolerance, a state of active inhibition of immune responses to an
antigen by means of prior exposure to that antigen via the oral route.
The mechanism(s) responsible for the development of oral tolerance
are still the subject of research and debate. This symposium will
present several hypotheses regarding the role that dietary triglycerides
and synbiotics may play in the development of oral tolerance as well
as the role immunomodulating factors (e.g., environmental factors)
may play in breaking oral tolerance to protein allergens. Additionally,
the structural and functional biology of allergenic food proteins will
be discussed along with *in vitro* models to predict the potential cross-
reactivity of food proteins.

- **Structural and Functional Biology of Allergenic Food Proteins.** Heimo Breiteneder, Medical University of Vienna, Vienna, Austria.
- **Food Allergy and the Role of Dietary Triglycerides in Sensitization and Anaphylaxis against Dietary Antigens.** Erik Eckhardt, University of Kentucky, Lexington, KY.
- **Antiallergic Effects of a Specific Mixture of Oligosaccharides or Combined with a Probiotic Strain (Synbiotics).** Leon Knippe, Danone Research, Wageningen, Netherlands.
- **Food Sensitization and Its Induction by Immunomodulating Factors.** Tomoko Shindo, Hatano Research Institute, Hadano Kanagawa, Japan.
- **In Vitro Provocation Study.** Ryosuke Nakamura, National Institute of Health Sciences, Tokyo, Japan.
Symposia

The Toxicological Impact of Metals, Crude Oil, and Chemical Dispersants from the Gulf of Mexico Oil Crisis on Human and Wildlife Health

Wednesday, March 14, 9:00 AM to 11:45 AM

Chairperson(s): John Pierce Wise Sr., University of Southern Maine, Ocean Alliance, Portland, ME, and Joe Griffitt, University of Southern Mississippi, Hattiesburg, MS.

Sponsor:
Metals Specialty Section

Endorsed by:
Comparative and Veterinary Specialty Section
Mixtures Specialty Section
Toxicologic and Exploratory Pathology Specialty Section

The 2010 Gulf of Mexico oil crisis was the worst environmental pollution disaster in US history. By the time the well was capped, more than 200 million gallons of crude oil poured into the Gulf over an 87-day period. To combat the crisis, a marine toxicology strategy was deployed to decrease the toxic potential of the crisis to inshore species by increasing the toxic potential to offshore species. Thus, over two million gallons of chemical dispersants were applied to the oil, which prevented oil accumulation at the ocean surface and, instead, moved it into the water column and onto the ocean floor. This approach decreased the amount of surface oil reaching inshore waters and beaches. However, it is unclear if it ultimately decreased toxicity to inshore species because the acute and chronic toxicity of dispersants, dispersed oil, and oil-related metals in the water column are unknown. Also unknown are the toxic outcomes of this approach for offshore species. During this session our panel of experts will present and discuss some of the first studies to evaluate the impact of this toxicological strategy considering the toxicity of crude oil, dispersants, dispersed oil, and oil-related metals on benthic and pelagic species using a combination of field and laboratory studies. Species presented will span from microbes and invertebrates, to fish and whales with some consideration of human health effects. Outcomes discussed will range from simple survival studies to more subtle effects on reproductive and DNA integrity.

- The Deepwater Horizon Disaster. Iain Kerr, University of Southern Maine, Ocean Alliance, Lincoln, MA.
- Microbial Degradation of Oil and Gas Following the Macondo Blowout. Samantha Joyce, University of Georgia, Athens, GA.
- Assessing the Impact of Chemical Oil Spill Dispersants on Corals. Carys Mitchelmore, University of Maryland Center for Environmental Science, Solomons, MD.
- Effects of Dispersed Oil on Larval Sheephead Minnows. Joe Griffitt, University of Southern Mississippi, Hattiesburg, MS.
- Weathering and Dispersion of Crude Oil Alter Its Toxicity in the Euryhaline Teleost, Fundulus grandis. Greg Mayer, Texas Tech University, Lubbock, TX.

Innovations of Applied Toxicology (IAT) Session

Characterizing Toxic Modes of Action and Pathways to Toxicity

New Visions in Toxicology: Lysosomes—Roles in Disease, Toxicity, and Drug Development

Wednesday, March 14, 1:30 PM to 4:15 PM

Chairperson(s): Shuyan Lu, Pfizer, Inc., San Diego, CA, and James M. Willard, US FDA, Silver Spring, MD.

Sponsor:
Mechanisms Specialty Section

Endorsed by:
Drug Discovery Toxicology Specialty Section

Lysosomes, first discovered by Dr. Christian de Duve more than five decades ago, are membrane-enclosed compartments filled with acid hydrolytic enzymes that digest macromolecules from the endocytic, autophagic, and phagocytic membrane-trafficking pathways. Lysosomes are involved in various physiological processes, including cholesterol homeostasis, plasma membrane repair, bone and tissue remodeling, and pathogen defense. Lysosomal malfunction as a consequence of genetic deficiency of a lysosomal enzyme or membrane protein can trigger lysosomal storage diseases with various clinical abnormalities such as organomegaly and central nervous system dysfunction. Recently, growing lines of evidence point to a critical role of lysosomes in cell death. Leakage of lysosomal enzymes and iron has been shown to result in mitochondria-mediated apoptosis. Inducers of lysosomal membrane permeabilization include, but are not limited to, oxidative stress, lipids, caspases, microtubule toxins, and metals. A number of basic lipophilic compounds have been shown to accumulate into acidic organelles, including lysosomes, in a process known as lysosomotropism. Lysosomotropic agents include structurally diverse chemicals that are used in clinical medicine such as chloroquine, amiodarone, imipramine, tamoxifen, and imatinib. In the past, phospholipidosis associated with drug lysosomal sequestration has been investigated extensively and prevailing theory has been that the phospholipidosis is primarily an adaptive response rather than a toxic response. However, the relationship between physicochemical properties of compounds, lysosomal accumulation, cellular damage, impairment of membrane trafficking processes, including autophagy, and especially how this is associated with various toxicological manifestations has not been fully elucidated. The goal of this symposium is to highlight the potential role of the lysosome in drug-induced toxicity and recognize lysosome perturbation as a potential mechanism for organ toxicity.
• Lysosome and Lysosomal Storage Disorder. Edward Schuchman, Mount Sinai School of Medicine, New York, NY.
• TRAIL-Induced Lysosomal Pathway of Apoptosis in Hepatobiliary Cells. Gregory Gores, Mayo Clinic, Rochester, MN.
• Amine-Containing Drug Accumulation in and Egress from Lysosomes. Jeffrey Krise, University of Kansas, Lawrence, KS.
• Role of the Lysosome in the Link between Physicochemical Properties and In Vitro Toxicity. Shuyan Lu, Pfizer Inc., San Diego, CA.
• Phospholipidosis: Drug-Induced Lysosomal Storage Disorder. James Willard, US FDA, Silver Spring, MD.

Off the Beaten Path: Preclinical Approaches to Safety Evaluation of Cells/Gene Therapy, Vaccines, and Adjuvants

Wednesday, March 14, 1:30 PM to 4:15 PM
Chairperson(s): Lauren E. Black, Charles River, Reno, NV, and Sarah J. Gould, sanofi pasteur, Marcy-l’Étoile, France.
Sponsor:
• Biotechnology Specialty Section
Endorsed by:
• Immunotoxicology Specialty Section
• Stem Cells Specialty Section

Toxicologists in all fields model the human effects of test articles in animals, recognizing interspecies differences in immunology, biology, and disease status. But the toxicology of “extreme biologic” therapies raises this challenge to a new level, particularly regarding the long-lasting impact of immunomodulation. These biologics include: human cells, live microbes, or vaccines causing irreversible changes in immunity: all of these cause immunologic reactions, whether by intention or from side effects. These complexities force toxicologists out of their comfort zone to find a “relevant species”—like diseased, transgenic, or immunocompromised rodents—just to enable the test article to express its human actions. Other challenges arise from immune reactions seen in animals or humans. Do certain types of immune stimulation in animals portend hypersensitivity or autoimmune disease in humans? Are adverse events in toxicity studies arising from the model itself, primary pharmacology, or drug side-effects (immunotoxicity)? Another challenge is the possibility that drug-related immunotoxicity may cause, or activate, latent autoimmune diseases in patients. To progress, these safety programs require new immune assays/endpoints to inform human trials. Currently, we know some immunomodulatory drugs have caused autoimmune disease in humans, but there are no validated ways to predict these risks, so research goals and regulatory views will be discussed. Related issues include toxicity assessment of immunosuppressant drugs, hypersensitivity responses, and immunogenic reactions to recombinant proteins. Progress will require collaboration of industry and regulatory scientists to consider new translational methods and to apply them appropriately to immunomodulators, biologics, and vaccines.

• Vaccines, Adjuvants, and Autoimmunity. Sarah J. Gould, sanofi pasteur, Marcy-l’Étoile, France.
• Acute Phase Reactants: Translational Biomarkers for Adverse Effects of Vaccines. Martin Green, US FDA, Rockville, MD.
• The Flip Side of Immunity to Viruses—Use of Viral Vectors for Gene Therapy. Timothy MacLachlan, Novartis, Cambridge, MA.
• Safety Assessment of Therapeutic Vaccines/Adjuvants—Regulatory Considerations. Theresa Chen, US FDA, Rockville, MD.

Trivalent Arsenic Metabolites and Arsenic Toxicity

Wednesday, March 14, 1:30 PM to 4:15 PM
Chairperson(s): Luz M. Del Razo, Cinvestav-IPN, México D.F., Mexico City, Mexico, and Michael Waalkes, NIEHS, Research Triangle Park, NC.
Sponsor:
• Hispanic Organization of Toxicologists Special Interest Group
Endorsed by:
• Global Strategy Task Force
• Mechanisms Specialty Section
• Metals Specialty Section
• Molecular Biology Specialty Section
• Women in Toxicology Special Interest Group

Inorganic arsenic (iAs) is a well-known environmental toxicant that could induce a variety of adverse health effects. iAs is enzymatically methylated in human tissues to mono- and dimethylated metabolites that contain trivalent arsenic (AsIII) or pentavalent arsenic (AsV). A recently identified arsenic (+3 oxidation state) methyltransferase (AS3MT) is the key enzyme in this pathway. Notably, trivalent methylated metabolites of iAs (MAIII and DMAIII) have been shown to play an important role in iAs-associated diseases such as cancer and diabetes. There is evidence that the AS3MT metabolic pathway, which was formerly considered a detoxification pathway, may significantly increase the toxicity of iAs. Ex vivo studies using tissue cultures have consistently shown that exposures to subtoxic concentrations of MAIII and DMAIII produce effects that mirror carcinogenic effects, and noncancerous conditions such as diabetes and cardiovascular diseases. However, the relevance of these findings for in vivo responses remains an area of on-going investigation and debate. The complexity and lack of suitable methods has hindered the analysis of MAIII and DMAIII in biological samples. Lately, results of epidemiology studies suggest that MAIII and DMAIII play a role in the onset of diabetes. Critical levels of iAs exposure and other factors that are associated with an increased production of these metabolites, and
Symposia

are linked/associated with increased prevalence of diabetes, have been characterized. The significance of these recent developments will be discussed in the context of physiologically based pharmacokinetic models, and the relationship between methylation and specific organ toxicity, as well as variations in methylation ability as a function of host factors.

- **Role and Importance of Arsenic Methylation Associated with Toxic Effects.** Luz M. Del Razo, Cinvestav-IPN, Mexico D.F., Mexico City, Mexico.

- **Mode of Action of Methylated Trivalent Arsenic with a Focus on the Potential Action As a Carcinogen.** Michael Waalkes, NIEHS, Research Triangle Park, NC.

- **Analysis of Methylated Trivalent Arsenicals in Biological Samples.** Miroslav Styblo, University of North Carolina Chapel Hill, Chapel Hill, NC.

- **Role of AS3MT Polymorphism in Arsenic Metabolism: Trivalent Arsenicals.** Zuzana Drobna, University of North Carolina Chapel Hill, Chapel Hill, NC.

- **Prevalence of Diabetes and Its Association with Urinary Trivalent Methylated Arsenic Species in Endemic Regions in Mexico.** Dana Loomis, University of Nebraska Medical Center, Omaha, NE.

- **Physiologically-Based Pharmacokinetic (PBPK) Modeling Considering Methylated Trivalent Arsenicals.** Elaina Kenyon, US EPA, Durham, NC.

**Emerging Evidence for Novel Noncholinergic Mechanisms of Organophosphate-Induced Neurotoxicity**

**Thursday, March 15, 9:00 AM to 11:45 AM**

*CChairperson(s):* John H. McDonough, US Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground, MD, and Pamela J. Lein, University of California School of Veterinary Medicine, Davis, CA.

*Sponsor:*
Neurotoxicology Specialty Section

*Endorsed by:*
Mechanisms Specialty Section
Occupational and Public Health Specialty Section

Organophosphate (OP) compounds are used as pesticides and in more potent forms are chemical warfare nerve agents that have been used as terrorist weapons. Low-dose, nonlethal exposures to these compounds is known to produce changes in a number of neurobehavorial functions, to include impaired cognitive abilities that are subtle and may be reversible. In contrast, exposure to near-lethal doses of OP nerve agents can produce prolonged seizures that result in overt brain damage and long-term changes in learning, memory, and emotional behavior. With low-dose, nonlethal, exposures the relationships between the OP dose, magnitude of effects, and the impact of repeated exposures over long periods are experimental variables still under active investigation. In the case of lethal nerve agent exposure, the role of noncholinergic factors in modulating the prolonged seizures and the need for improved treatments to counteract these processes is another area of robust investigation. Also, new research into the time- and regional-dependent changes in neuropathology along with the role of neuroinflammatory processes observed in nerve agent-exposed animals offers insight into the potential for neuroprotectant treatments to prevent and/or minimize these effects. This symposium will bring together experts in each of these research areas to present their latest findings, identify areas for future work, and stimulate discussion between researchers with these common areas of interest.

**THURSDAY**

Clinical Toxicology from Bedside to the Bench and Back

**Advances in Bridging Nonclinical Cardiovascular Data to the Clinic**

**Thursday, March 15, 9:00 AM to 11:45 AM**

*Chairperson(s):* Syril Pettit, HESI, Washington, DC, and John Koerner, US FDA, Silver Spring, MD.

*Sponsor:*
Cardiovascular Toxicology Specialty Section

*Endorsed by:*
Clinical and Translational Toxicology Specialty Section

Cardiovascular adverse events remain a significant cause of attrition during drug development as well as postmarket. The availability of translatable animal data that is more predictive and sensitive for clinical outcomes is essential to overcome this public health challenge. This symposium will feature four approaches to generating and assessing the concordance between nonclinical cardiovascular endpoints and clinical outcomes.
Scientific Sessions

- Parallel Animal and Human Research Identify Neurotoxic Effects of Occupational Exposures to the Organophosphorus Pesticide Chlorpyrifos. Pamela J. Lein, University of California School of Veterinary Medicine, Davis, CA.
- Chronic Exposure to the Nerve Agent VX: Physiological, Behavioral, Histopathological, and Neurochemical Studies. Eugenia Bloch-Shilderman, Israel Institute for Biological Research, Ness Ziona, Israel.
- Soman-Induced Brain Damage and Neurological Deficits: Neuroinflammatory Disorders and Changes in Brain Metabolism—Consequences for Therapy. Pierre Carpentier, Institut de Recherche Biomédicale des Armées, La Tronche, Grenoble, France.
- Temporal, Regional, and Cellular Progression of Neuroinflammation following Organophosphate Nerve Agent-Induced Status Epilepticus in Rats. Erik Johnson, US Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground, MD.
- Neurotoxicological Effects of Exposure to Organophosphate (OP) Compounds: The Similarities and Differences between Low and High Doses. John H. McDonough, US Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground, MD.

Influence of Global Climate Change on Environmental Health Issues

Emerging Mechanistic Targets in Lung Injury Induced by Combustion-Generated Particles

Thursday, March 15, 9:00 AM to 11:45 AM

Chairperson(s): Marc Fariss, Altria Client Services, Richmond, VA, and Andrew Ghio, US EPA, Chapel Hill, NC.

Sponsor:
Inhalation and Respiratory Specialty Section

Endorsed by:
Mechanisms Specialty Section
Molecular Biology Specialty Section
Occupational and Public Health Specialty Section

Environmental combustion-generated air pollutants are a global concern, and the adverse effects of such materials on human health, particularly respiratory and cardiovascular health, are firmly established. Despite strong epidemiological evidence linking ambient air pollutants to specific human diseases and general health decline, a significant gap remains in our understanding of precisely how such materials produce nonneoplastic respiratory diseases. This symposium will highlight recent advances in our understanding of the molecular and chemical mechanisms that govern lung and lung cell toxicity by common respirable forms of complex ambient particulate materials originating from the combustion of fossil fuels, wood, or tobacco. Presentations will describe the current understanding of nonneoplastic respiratory diseases induced by combustion-derived particulate matter (PM); the participation of transient receptor potential (TRP) channels in detecting and initiating responses to unique forms of environmental combustion-derived PM to produce acute lung inflammation/injury/remodeling; the role of disrupted cell and mitochondrial iron homeostasis in wood combustion-derived PM toxicity, and the isolation and chemico-physical characterization of insoluble nanosized particles from cigarette smoke condensate including their cytotoxic potential. Attendees of this symposium session will gain up-to-date knowledge of novel cellular processes and PM components that appear to regulate the acute toxicological effects of particulate air pollutants. These effector molecules may represent important targets for future therapeutic strategies to mitigate the adverse impact of inhaled combustion-generated pollutants.

- Differential Activation of TRPA1, V1, and M8 by Combustion-Derived PM and PM Components: Relationship to Lung Inflammation and Injury. Christopher Reilly, University of Utah, Salt Lake City, UT.
- Role of TRPV4-Mediated Calcium Influx in Diesel Exhaust Particle-Induced Lung Toxicity. Wolfgang Liedtke, Duke University, Durham, NC.
- Wood Smoke Particles Sequester Mitochondrial Iron Resulting in Biological Effect. Andrew Ghio, US EPA, Chapel Hill, NC.
- Cytotoxic Insoluble Nanosized Particles in Reference Cigarette Smoke Condensate. Marc Fariss, Altria Client Services, Richmond, VA.
Symposia

Characterizing Toxic Modes of Action and Pathways to Toxicity

Realizing the Vision of 21st Century Toxicity Testing: Genetic Approaches to Pathway Analysis

Thursday, March 15, 9:00 AM to 11:45 AM


Sponsor: Molecular Biology Specialty Section

Endorsed by: In Vitro and Alternative Methods Specialty Section
Mechanisms Specialty Section

The US National Academy of Science (NAS) report, “Toxicity Testing in the 21st Century,” outlined a vision that virtually all routine toxicity testing would be conducted in human cell lines by evaluating cellular responses of toxicity pathway assays using high-throughput tests. Dose-response modeling of perturbations of pathway function would be organized around computational systems biology models of the circuitry underlying each toxicity pathway. Although there is a growing consensus that this vision will one day become reality, the difficult task of linking changes in the expression or modification of components in pathways to toxicity have yet to be fully realized. There is a clear need to better incorporate new and existing genetic tools that can be routinely used by toxicologists allowing relationships between chemical exposure, genetic networks, and phenotypic responses to be better understood. This symposium brings together experts to discuss genetic analysis of pathways that can be generally applied to toxicology and as such will help move us toward realizing the vision of the NAS report. This important topic will begin with a discussion on global approaches to discover genetic targets of disease, drugs, and environmental chemicals by coupling transcript profiling with GWAS. To expand on this information, widely applicable high-throughput approaches to identify gene, pathway, and phenotypic relationships using small inhibitor RNA arrays will be addressed. Final discussions will discuss genetic approaches in vertebrates to discover biomarkers of pathways and gene-chemical interactions applicable to predicting mode of action of cancer and developmental toxicity. The summary provided will bring together the salient findings in the previous talks to highlight bioinformatic NextGen risk assessment approaches that can assist the toxicologist to enable linkages of chemicals, genes/pathways, and diseases in chemical risk assessment. This topic will appeal to a wide audience interested in the promising approaches for the analysis and use of pathway perturbations in toxicity testing.

- Expanding the Scope of Loss of Function Genomic Screening with RNAi Cell Microarrays. Juha Rantala, Oregon Health and Science University, Corvallis, OR.
- Rapid In Vivo Assessment of Chemical-Gene Interactions in Embryonic Zebrafish. Robert Tanguay, Oregon State University, Corvallis, OR.

Submit Your Recent Scientific Research during an Extended Abstract Submission Phase

The Society is poised to have another successful Annual Meeting with currently close to 2,800 presentations scheduled to be presented in San Francisco, March 11–15, 2012.

We invite you to submit an abstract during the extended submission phase which will occur from December 12, 2011, through January 20, 2012. All abstracts will be submitted online. The cost to submit an abstract is $50.

All accepted abstracts will be programmed on Thursday, March 15 along with several dynamic symposia and workshop sessions.

Please note the established criteria that qualify an abstract to be accepted during this final submission phase.

- The research must be new and of sufficient scientific importance to merit special consideration after the standard abstract deadline. Abstracts should describe high-impact original research that could not be completed prior to the original deadline.

- Scientists who had to wait until after the original October deadline to submit due to funding issues are encouraged to submit an abstract for consideration.

- Your abstract should not be a revision of a previously-submitted one that was not accepted unless you received specific communication from the Scientific Program Committee suggesting that resubmission during the late abstract period may be appropriate.

- Not more than one abstract will be accepted by the same presenting author.

- All abstracts will be reviewed by the Scientific Program Committee and held to the same standards used to evaluate abstracts submitted for the original deadline.

- Given the Society’s current publishing deadline, the abstracts accepted will be provided as a printed addendum but searchable through the Itinerary Planner (mobile and online versions only).

We look forward to welcoming you to the Society’s Annual Meeting in San Francisco, California.
Workshops

**MONDAY**

**Alternative Approaches to the Safety Assessment of Natural Ingredients and Extracts in Cosmetics**

Monday, March 12, 9:15 AM to 12:00 Noon

*Chairperson(s):* Vinayak Srinivasan, L’Oréal, Clark, NJ, and Julie Skare, Procter & Gamble, Cincinnati, OH.

*Sponsor:*
Association of Scientists of Indian Origin Special Interest Group

*Endorsed by:*
Food Safety Specialty Section
In Vitro and Alternative Methods Specialty Section
Regulatory and Safety Evaluation Specialty Section
Risk Assessment Specialty Section

Today, there is a growing consumer demand for naturally-derived ingredients and botanical extracts such as those used as food or as flavoring agents and those in personal care products. The principles used in safety evaluation of foods can be extrapolated to cosmetic ingredients where the primary route of application is dermal versus the oral route. While quality standards exist for certification of organic and natural cosmetics, there are no globally accepted safety assessment standards for these products. Although relatively rare, adverse reactions to cosmetic and personal care products containing traditional synthetic chemicals as well as botanical ingredients have been documented in the literature. The safety assessment of plant materials for which no or only a limited record of human exposure can be established is complex, given that traditional, standard safety testing methods for synthetic chemicals cannot be applied to natural plant ingredients for various reasons. Therefore, chemical grouping, comparative, and read-across approaches as well as the concept of the Threshold of Toxicological Concern (TTC) and other in silico based animal alternative methodologies are pragmatic, logical, and reliable tools for the safety assessment of plant-derived cosmetic ingredients.

- Application of the Threshold of Toxicological Concern (TTC) to the Safety Evaluation of Cosmetic Ingredients. Corrado Galli, University of Milan, Milan, Italy.
- Assessment of Naturally Occurring Mixtures. Tim Adams, Flavor and Extract Manufacturers Association, Washington, DC.
- Use of Threshold of Toxicological Concern at the FDA. Diego Rua, Office of Cosmetics and Colors, US FDA, Washington, DC.
- Regulatory Use of Computational Toxicology Tools and Databases at the FDA. Kirk Arvidson, Office of Food Additive Safety, US FDA, Washington, DC.
- Application of In Silico Approaches in Cosmetics—Juniper Berry Oil. Tom Re, L’Oréal, Clark, NJ.

**Regulatory Science: Bridging the Gap between Discovery and Product Availability**

**High-Throughput In Vitro Toxicity Testing: A Midcourse Assessment of Predictive Accuracy for In Vivo Endpoints and Use in Decision-Making**

Monday, March 12, 9:15 AM to 12:00 Noon

*Chairperson(s):* Russell S. Thomas, The Hamner Institutes for Health Sciences, Research Triangle Park, NC, and William D. Pennie, Pfizer, Inc., Groton, CT.

*Sponsor:*
In Vitro and Alternative Methods Specialty Section

*Endorsed by:*
Drug Discovery Toxicology Specialty Section
Molecular Biology Specialty Section
Regulatory Safety Evaluation Specialty Section

Over the past five years there has been a broad-based discussion on the future direction of toxicology and how safety testing is performed. This discussion has spawned multiple research efforts looking to use high- and medium-throughput in vitro screening data in identifying chemical hazards. For industrial and agricultural chemicals, research efforts in United States and Europe have characterized the in vitro biological activity of chemicals using multiple in vitro assays and technologies in order to predict in vivo toxicity and prioritize compounds for conventional toxicity testing. For pharmaceuticals, high-throughput in vitro screening assays have been integrated early into preclinical drug development to identify toxic compounds and guide medicinal chemistry efforts. In both cases, the application of in vitro toxicity screening for prioritization and hazard identification relies on its ability to accurately predict the results of in vivo laboratory animal studies and humans. The efforts in the United States and Europe are now several years old and a significant amount of data has been collected to provide an evaluation of the strengths and limitations of the using high- and medium-throughput screening for predicting in vivo apical responses. This session will be of broad interest to investigators and regulators looking to use in vitro assays for toxicological testing and safety assessment of environmental, industrial, and pharmaceutical chemicals.

- Feasibility of Predicting In Vivo Mode of Action Using Pathway Based In Vitro Screens. Richard Judson, US EPA, Research Triangle Park, NC.
The Epididymis—The Forgotten Target of Toxicants

Monday, March 12, 9:15 AM to 12:00 Noon

Chairperson(s): Daniel G. Cyr, INRS-Institut Armand-Frappier, Laval, Québec, Canada, and Robert E. Chapin, Pfizer, Inc., Groton, CT.

Sponsor: Reproductive and Developmental Toxicology Specialty Section

Endorsed by: Toxicologic and Exploratory Pathology Specialty Section

The epididymis is the major component of the testicular excurrent duct system. Testicular input to the tissue is conveyed via the efferent ducts, which anastomose to form a single, highly convoluted epididymal duct. The epididymis can be divided into two main compartments: the epithelium and the lumen. In adults, the lumen contains sperm that are bathed in luminal fluid whose composition varies markedly along the tissue. The blood-epididymis barrier, formed by epithelial principal cells, regulates this luminal environment and distinguishes it from blood. Functional sperm maturation in the epididymis is the result of their exposure to the luminal environment. Thus, the ability of the epididymis to provide the appropriate milieu for sperm maturation is critical. This is created by several processes, most notably the highly absorptive and secretory activities of the epithelial cells that line the duct. Many epididymal functions are either androgen or estrogen-dependent. The critical functions of the epididymis for sperm maturation and its reliance on hormonal regulation make it a prime target for toxic action. Several studies have shown that endocrine-disrupting chemicals, such as phthalates, can alter the development of the epididymis, and, in extreme cases, lead to its absence. Other chemicals, such as dioxins, affect sperm maturation via alterations to epididymal functions. However, epididymal function is frequently ignored in toxicity studies. Yet, posttesticular and idiopathic male infertility represents a significant problem, suggesting that alterations in epididymal sperm maturation may have greater significance than previously thought. This session will provide an overview of epididymal functions and regulation and show examples of how environmental toxicants may alter male fertility by targeting the epididymis.

Therapeutic Immunomodulation and Cancer Risk: Science, Risk Assessment, and Risk Communication

Monday, March 12, 9:15 AM to 12:00 Noon

Chairperson(s): Marc Pallardy, Université Paris-Sud—INSERM, Chatenay-Malabry, France, and Shawn Heidel, Eli Lilly and Company, Indianapolis, IN.

Sponsor: Immunotoxicology Specialty Section

Endorsed by: Biotechnology Specialty Section

Therapeutic immunomodulators have evolved from broad-spectrum immune system antagonists used in the treatment of organ transplantation to newly emerging targeted therapeutics treating specific immune-mediated diseases. Whereas broad-acting agents have been implicated with increased cancer risk in chronically-treated patients, the risks associated with targeted immunotherapies can be anticipated to be driven by their mechanism of action. This session will discuss current paradigms around immunomodulation and cancer, available tools for the assessment of cancer risk applied to therapeutic immunomodulators, risk assessment, and views from industry and regulators. The discussions in this presentation coincide with recent international regulatory and industry efforts to update ICH S6(R1), which guides the nonclinical development of large molecule therapeutics.

- Immunomodulation and Cancer: An Overview. Rafael Ponce, Amgen, Inc., Seattle, WA.
Workshops

- Effects of Immunosuppressive Drugs in Preclinical Models of Neoplasia. Mindi Walker, Centocor, Radnor, PA.
- Immunomodulation and Cancer: Risk Assessment and Weight of Evidence Evaluations. Helen Haggerty, Bristol-Myers Squibb, New Brunswick, NJ.
- Adverse Outcome Pathways As a Unifying Concept in Environmental Toxicology. Kevin Crofton, US EPA, Research Triangle Park, NC.
- Mixtures Risk Management: Moving beyond TEQs and Hazard Indices. Paul Price, Dow Chemical Company, Midland, MI.

Regulatory Science: Bridging the Gap between Discovery and Product Availability

Concepts Critical to the Next Generation of Human Health and Ecological Risk Assessment

Monday, March 12, 2:00 PM to 4:45 PM

Chairperson(s): P. Robinan Gentry, ENVIRON International Corporation, Monroe, LA, and Betty Locey, ARCADIS, Ann Arbor, MI.

Sponsor: Risk Assessment Specialty Section

Through the collaborative effort between the SOT Risk Assessment Specialty Section and the SETAC Human Health Risk Assessment Advisory Group, this session was developed to highlight the challenges currently facing the next generation of risk assessors. With the release of the recent National Academy of Sciences reports on toxicity testing that present a vision for movement from in vivo testing to in vitro and in silico testing, as well as the most recent changes in risk assessment guidelines by regulatory agencies, risk assessors are faced with the challenge of integrating innovative data (e.g., genomics) into the current risk assessment paradigms or with the development of new paradigms or methods to address changing issues in risk assessment. In considering all the biological changes and scientific information, many of these new methods attempt to integrate all of the available scientific information of a compound to better inform both human health and ecological risk assessment/risk management decisions. Our panel of experts will provide information on new programs and approaches within regulatory agencies, as well as in the private sector, that will be important in the next generation of risk assessment.

- Using Transcriptional Data in the Risk Assessment Paradigm. Russell S. Thomas, The Hamner Institutes for Health Sciences, Research Triangle Park, NC.

TUESDAY

Assessing the Bioavailability and Risk from Metal-Contaminated Soils and Dusts

Tuesday, March 13, 9:00 AM to 11:45 AM


Sponsor: Metals Specialty Section

Endorsed by: Occupational and Public Health Specialty Section

Exposure to contaminated soil and dust is an important pathway in human and ecological risk assessment and often is the risk-driver for metal-contaminated soil. Site-specific soil physical and chemical characteristics, as well as biological factors, determine the bioavailability of soil contaminants. Within a single sample, contamination may be from multiple sources of toxic elements that may exist as different forms and species. The bioavailability of soil and dust contaminants has a direct impact on human health risk assessment and risk management practices. Novel research efforts focusing on development and application of in vitro and in vivo methods to measure the bioavailability of metal-contaminated soils have advanced in the past few years. Our panel of experts will provide information on the recent developments in assessing the bioavailability and risk from metal-contaminated soils and dusts. The presentations include the relative bioavailability of arsenic-contaminated soils, metal contamination in urban residences in Canada, and potential children’s exposures to toxic elements in house dust. The information can be found in a community-based study known as the “West Oakland Residential Lead Assessment Study,” which provides details of the bioavailability of soil cadmium, chromium, nickel, and mercury, and human exposures to contaminated Brownfield soils. These presentations cover issues related to human health and bioavailability along with the most recent studies on community participation in assessing metal contamination, studies of children’s exposures to residential contamination, and recent in vitro and in vivo methods development for assessing the bioavailability of metals in soils and dusts. This session seeks to provide a forum for discussing the implications of these latest developments on incorporating bioavailability into the risk assessment and management process.
The Thematic Track information can be found on pages 8–9.

Workshops

- Metal Contamination in Urban Residents in Canada and Potential Children’s Exposures to Toxic Elements in House Dust. Pat Rasmussen, Health Canada, Ottawa, Ontario, Canada.
- Beyond Lead and Arsenic: How Are Other Metals Being Addressed? Rosalind Schoof, ENVIRON International Corporation, Seattle, WA.
- Contaminant Mixtures and Mixed Exposure Pathways: Using In Vitro Digestors to Tease Out Human Exposure to Brownfield Soils and Identify Engineering Solutions That Reduce Risk. Steven Siciliano, University of Saskatchewan, Saskatoon, Saskatchewan, Canada.

Characterizing Toxic Modes of Action and Pathways to Toxicity

State of the Science and the Future for the Predictive Power of In Vitro and In Vivo Models for Nanomaterials Toxicity Testing

Tuesday, March 13, 9:00 AM to 11:45 AM

Chairperson(s): Alison Elder, University of Rochester, Rochester, NY, and Srikanth Nadadur, NIEHS, Research Triangle Park, NC.

Sponsor:
- Nanotoxicology Specialty Section

Endorsed by:
- Inhalation and Respiratory Specialty Section
- Risk Assessment Specialty Section

The proliferation of engineered nanomaterials (ENMs) in commerce has led to a growing concern about the consequences of exposure for those who produce and use them. The National Institute of Environmental Health Sciences recognized the importance of gaining a more fundamental understanding of the potential influence of ENMs on human health and, so, initiated a high priority research program (Nanotechnology Environmental Health and Safety, Nano EHS) with the availability of funds through the American Recovery and Reinvestment Act. This Nano Grand Opportunity (NanoGO) program was developed to address major issues of inconsistency in results reported for similar engineered nanomaterials investigated at different laboratories, a problem that significantly impedes both hazard and risk assessment for this class of materials. The disparities in results likely arise from poor communication about material characteristics, lack of assay validation, and/or inconsistencies in methodology. The goal of the NanoGO initiative was to support the development of reliable and reproducible methods and models to assess biological response through coordinated research efforts. As a result of this program, the NanoGO Consortium was established with 13 investigators/institutions in November 2009. The Consortium selected a library of ENMs and identified a set of in vitro and in vivo assays to be used in interlaboratory comparisons using standardized protocols. This session will focus on the study design, specific objectives, and consensus findings from interlaboratory in vitro and in vivo toxicology and particle characterization studies that were done with the library of engineered metal oxide and carbonaceous nanoparticles within the NanoGO Consortium, with an emphasis on how the findings can be used in the context of hazard assessment.

- Overview of the NIEHS-Sponsored NanoGO Program. Srikanth Nadadur, NIEHS, Research Triangle Park, NC.
- Physicochemical Property-Dependent In Vitro Effects of Engineered Nanomaterials in Lung Target Cells: Lessons from Interlaboratory Comparison Studies. Andrij Holian, University of California Davis, Davis, CA.
- Physicochemical Property-Dependent In Vivo Effects of Engineered Nanomaterials in the Respiratory Tract: Lessons from Interlaboratory Comparison Studies. Kent Pinkerton, University of Montana, Missoula, MT.
- Nanoparticle Dosimetric Considerations for In Vitro and In Vivo Model Systems: Consideration of Dispersion Status, Dose, and Dose-Rate for Study Design and In Vivo-In Vitro Response Comparisons. Günter Oberdörster, University of Rochester, Rochester, NY.

Sufficient Similarity of Whole Representative Mixtures or a Relative Potency Factor Approach: Polycyclic Aromatic Hydrocarbons As a Case Study

Tuesday, March 13, 9:00 AM to 11:45 AM

Chairperson(s): Cynthia V. Rider, NTP/NIEHS, Research Triangle Park, NC, and Julia M. Gohlke, University of Alabama at Birmingham, Birmingham, AL.

Sponsor:
- Mixtures Specialty Section

Endorsed by:
- Risk Assessment Specialty Section

Predicting the toxicity of complex and dynamic mixtures represents a difficult challenge for risk assessment, as demonstrated recently by seafood safety concerns following the Deepwater Horizon oil spill. Two established approaches for addressing this challenge are the relative potency factor (RPF) approach and the sufficient similarity (SS) of whole mixtures approach. The RPF approach requires knowledge of dose-response relationships of the individual mixture components.
These data are then input into a dose additivity model to predict the toxicity of the mixture. Alternatively, with the SS approach, representative whole mixtures are used as a basis for predicting the toxicity of related environmental mixtures. Polycyclic aromatic hydrocarbons (PAHs) offer a useful case study for comparing the advantages and disadvantages of RPF and SS approaches. These ubiquitous contaminants are found in many mixtures to which humans are regularly exposed. PAHs are a large and diverse group of chemicals with complex mechanisms of action. Much work has been dedicated to developing an RPF approach for estimating cancer risk associated with exposure to unsubstituted PAHs. However, there is no clear path forward for expanding risk assessments to include substituted PAHs or noncancer endpoints, such as immune and reproductive toxicity. Currently, individual PAH dose-response data is incomplete and insufficient for accurately evaluating risk to human health. In order to better characterize toxicity associated with PAH mixtures, more work is needed. Determining which approach is more appropriate is a necessary step in deciding how to focus research resources. In effect, an RPF approach would dictate additional individual chemical toxicity testing; whereas, an SS approach would necessitate deciding on appropriate representative mixtures and testing those mixtures. This session will provide the framework and cover topics including advantages and disadvantages of each approach, consideration of the complex mechanisms of action of PAHs, critical data needs, and novel techniques available for filling data gaps and refining testing.

- Lessons from the Deepwater Horizon Blowout: Developing Approaches to Estimate Risk from Complex Exposures. Julia M. Gohlke, University of Alabama at Birmingham, Birmingham, AL.
- Multiple Mechanisms of PAH Toxicity Revealed through Screening with Zebrafish Embryos. John Incardona, NOAA, Seattle, WA.
- Utilizing Quantitative Structure-Activity Relationship (QSARs) to Predict Toxic Endpoints for Polycyclic Aromatic Hydrocarbon (PAH) Risk Assessment. Erica D. Bruce, Baylor University, Waco, TX.
- The Relationship between Aromatic Ring Class Content and the Toxicity of High-Boiling Petroleum Substances. Russell White, American Petroleum Institute, Washington, DC.

**Beyond Traditional Monoclonals: New Biologics Formats and Preclinical Challenges**

*Tuesday, March 13, 1:30 PM to 4:15 PM*

**Chairperson(s):** Vladimir Vexler, Hoffmann-La Roche, Nutley, NJ, and Kenneth J. Olivier Jr., Merrimack Pharmaceuticals, Cambridge, MA.

**Sponsor:** Biotechnology Specialty Section

**Endorsed by:** Immunotoxicology Specialty Section

Antibody-based biotherapeutics currently enjoy unprecedented success, growth, and recognition of their potential. Almost all FDA-approved therapeutic antibodies and the vast majority of those in clinical trials are full-size bivalent monoclonal antibodies (mAbs) mostly in IgG1 format of about 150 kDa size. This success and enthusiasm in the drug development community can be largely explained by the properties of antibodies: their exquisite binding specificity and low intrinsic toxicity. A fundamental problem for such large molecules is their poor penetration into tissues and poor or absent binding to regions on the surface of some molecules that are only accessible by molecules of smaller size. In addition, for certain applications it is desirable to increase the potency of mAbs or deliver them locally. Advances in protein engineering have led to the generation of a number of antibody derivatives and various scaffold proteins, which due to their smaller size can be beneficial in various aspects such as immunogenicity, biodistribution, renal clearance, and tissue penetration. Several approaches are being evaluated to improve the potency by the linkage of mAbs to highly cytotoxic drugs (antibody-drug conjugates, ADC), by targeted delivery of cytotoxic drugs (ADC, immunoliposomes), by engineering antibodies with dual specificity, or by enhancing antibody effector function by engaging T cells and effector cells using bispecific T cell engagers (BiTE®) or glycoengineered antibodies. Due to their smaller size (e.g., nanobodies), format (e.g., ADC, immunoliposome), or pharmacology (e.g., bispecific), the development of these novel biotherapeutics presents an unusual toxicological challenges such as off-target toxicity (e.g., ADC, immunoliposome), immunotoxicity (e.g., BiTE®), and preclinical immunogenicity. This workshop will discuss general considerations for how to conduct nonclinical pharmacology and toxicology studies for these novel unconventional biotherapeutics with special focus on immunosafety assessment and the impact of nonclinical findings on clinical development.

- **Safety Evaluation of Antibody-Drug Conjugates.** Willy Solis, Roche Genentech, San Francisco, CA.
Hispanics comprise not only the largest minority group in the United States, but also the largest number of new farmer and migrant workers in the nation. US Pesticide usage exceeds 1.2 billion pounds per year and exposures among Hispanic farm workers and their families have become a serious public health threat. An estimated 3 million Hispanic farmworkers are at high risk of exposure (34% being women) to the most prominent classes of pesticides; organochlorines (OC), organophosphates (OP), carbamates, and pyrethroids. Exposure to these ubiquitous compounds is primarily through inhalation of the particulate components, skin absorption, and ingestion of pesticides in the food supply. Recent epidemiological studies indicate a link between exposures to complex pesticide mixtures and various chronic adverse health effects that impact the central nervous, reproductive, immune, cardiovascular, renal, and hepatic systems. However, the exact mechanism(s) by which pesticide exposure is linked to such diseases and the role that genetic susceptibility plays in these outcomes remain unclear. Previous studies have suggested that OC exposure increases breast cancer risk in migrant workers by up-regulation of the BRCA genes and carcinogen-metabolizing genes. Furthermore, target genes such as paraoxonase and glutathione-S-transferase gene polymorphisms may be an important susceptibility factor for these deleterious effects.

• Environmental Exposures and Disease Prevalence in Hispanics along the Texas-Mexico Border. Kenneth Ramos, University of Louisville, Louisville, KY.

• Genomic Instability in Mexican-American Children Exposed to Environmental Toxins. María Hernández-Valero, University of Texas MD Anderson Cancer Center, Smithville, TX.

• Prenatal Exposure to Organophosphate Pesticides and IQ in Seven-Year Old Latino Children. Brenda Eskenazi, University of California Berkeley, Berkeley, CA.

• Inhalation Exposure of Pesticides among Hispanic Mothers at the US-Mexico Border. Claudia Miller, University of Texas Health Science Center, San Antonio, TX.

• Pesticide Exposure and Health Effects of Children Living in an Agricultural Community. Diane Rohlman, Oregon Health and Science University, Portland, OR.

Biomarkers and Associated Health Consequences of Pesticide Exposures in Hispanic Populations

Tuesday, March 13, 1:30 PM to 4:15 PM
Chairperson(s): Azita K. Cuevas, New York University School of Medicine, Tuxedo, NY, and Kenneth Ramos, University of Louisville, Louisville, KY.
Sponsor: Hispanic Organization of Toxicologists Special Interest Group
Endorsed by:
Global Strategy Task Force
Molecular Biology Specialty Section
Occupational and Public Health Specialty Section
Reproductive and Developmental Toxicology Specialty Section

Environmnetal Toxins

The liver is a common target for chemicals and drugs and is frequently the most sensitive tissue target in two-year bioassays. Given the number of chemicals that need to be assessed for hepatotoxicity by the pharmaceutical and chemical industries, investigators currently use many types of in vitro rodent and human models, from simple primary hepatocytes and hepatocyte-derived cell lines to more complex three-dimensional cocultures containing many liver cell types. These in vitro models have been used to predict different types of liver toxicities including cancer in rodents and cytotoxicity in humans. Additionally, transcript profile information is routinely used to identify altered pathways and to predict mode of action. As advances are rapidly being made in this area, we must assess the current strengths and limitations of these in vitro models and methods to predict chemical toxicity in the intact liver. To begin, we will explore the European perspectives partly, driven by REACH, which will include a discussion of the value of stem cell-derived human hepatocyte
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models. We will then turn our attention to the US EPA and industry perspectives, focusing on pathway prediction and next generation coculture models. The final overview will provide a platform to discuss the bioinformatic tools to mine databases used to predict drug hepatotoxicity from the perspective of the US FDA. At the conclusion of this session, our panel of experts will engage participants in an interactive discussion about the topic. The diversity of speakers will allow perspectives from a number of groups whose work is driven by various regulatory pressures. This session is sure to be of interest to those interested in high-throughput screening, hepatotoxicity, toxicogenomics, and mode of action research.

- Interindividual Variability in Genomic Responses in Human Primary Hepatocytes and Comparison with Human Cell Lines. Joost van Delft, Maastricht University, Maastricht, Netherlands.
- Translational Biomarkers for Drug-Induced Liver Injury. Weida Tong, US FDA, Jefferson, AR.

Clinical Toxicology from Bedside to the Bench and Back

Nonclinical and Clinical Applications of Translational Organ-Based Imaging

Tuesday, March 13, 1:30 PM to 4:15 PM

Chairperson(s): Syril Pettit, HESI, Washington, DC, and Norman Barlow, sanofi-aventis, Bridgewater, NJ.

Sponsor: Toxicologic and Exploratory Pathology Specialty Section

Endorsed by: Cardiovascular Toxicology Specialty Section Comparative and Veterinary Specialty Section Drug Discovery Toxicology Specialty Section Neurotoxicology Specialty Section Reproductive and Developmental Toxicology Specialty Section

Multimodal imaging is a widely applied and accepted standard of care in many medical settings. Innovations in imaging capabilities have developed rapidly, allowing noninvasive collection of an ever increasing quantity and quality of morphologic, functional, and even molecular data from humans and animals. Accordingly, imaging is becoming an important component of the clinical biomarker toolbox. However, advances in imaging strategies that have allowed for use in animals, including rodents, have not driven a large-scale integration of these capabilities into modern toxicology assessment or environmental hazard identification. Although a number of imaging and biomarker “opportunities” are outlined in the FDA’s “Critical Path Opportunities List,” an organized effort to explore integration of imaging into nonclinical safety assessment and hazard evaluation paradigms is just beginning. We will provide an overview of an organ-based approach to novel imaging methodologies in nonclinical safety assessment and translational toxicology. The presentations will describe how preclinical imaging can be an innovative tool for toxicity assessment, and how translational imaging can be used to bridge the gap between nonclinical safety assessment and clinical testing.

- Cardiovascular Imaging in Nonclinical Safety Studies: Increasing Acceptance and Application. Robert Coatney, GlaxoSmithKline, King of Prussia, PA.
- Multimodal Imaging in Developmental and Reproductive Toxicology. Xiaoyou Ying, sanofi-aventis US, Bridgewater, NJ.
- Preclinical Assessment of Neurotoxicity with Imaging. William Slikker Jr., US FDA, Jefferson, AR.
- Lessons Learned from Lung Imaging in Multicenter Studies. Eric Hoffman, University of Iowa Carver College of Medicine, Iowa City, IA.

Characterizing Toxic Modes of Action and Pathways to Toxicity

Novel Topics in Environmental Polycyclic Aromatic Hydrocarbon Metabolism Leading to Carcinogenesis

Tuesday, March 13, 1:30 PM to 4:15 PM

Chairperson(s): Danielle Carlin, NIEHS, Durham, NC, and Bhagavatula Moorley, Baylor College of Medicine, Houston, TX.

Sponsor: Carcinogenesis Specialty Section

Endorsed by: Mechanisms Specialty Section Mixtures Specialty Section Risk Assessment Specialty Section

Epidemiological evidence indicates that exposure to complex environmental polycyclic aromatic hydrocarbon (PAH) mixtures increases the risk of lung cancer. However, most animal studies have focused on single PAH components. Moreover, little is known regarding the interactions between different PAH metabolites that lead to carcinogenesis. Thus, our panel of experts will provide
The Thematic Track information can be found on pages 8–9.

WEDNESDAY

Characterizing Toxic Modes of Action and Pathways to Toxicity

Caught in the Act: Free Radical Detection and Implications in Pathways to Toxicity

Wednesday, March 14, 9:00 AM to 11:45 AM

Chairperson(s): Arno Siraki, University of Alberta, Edmonton, Alberta, Canada, and Maria Kadiiska, NIEHS/NIH, Research Triangle Park, NC, United States.

Sponsor:
Molecular Biology Specialty Section

Endorsed by:

Free radicals are known to cause a multitude of effects in living systems, which span the spectrum of blunt injury to signal transduction pathways. Although it is important to understand the result of oxidative stress in toxicological pathways, the astute identification of the specific free radical initiators and mediators can provide insight into the source(s) of these species and their modulation, and their unique downstream targets that lead to activation of toxicity pathways. There are many diverse methods that are used to detect free radicals such as ROS (qualifed as oxidative stress) but the diversity in the quality of data obtained can vary considerably. This session will focus on characterizing the free radical intermediates themselves and describe the consequences of their generation in terms of toxicological effects. These methods will be used to demonstrate the importance in making an association with a particular oxidant with specific toxic outcomes. We will discuss the various approaches to determine free radical species and highlight their advantages, disadvantages, and where improvements can be made. There are many issues to consider including electron paramagnetic resonance (EPR) spectroscopy which is considered the gold standard for free radical detection and identification but entails technical challenges and specialized expertise. Analytical methods such as HPLC and MS represent a more general approach but likely require previous findings with EPR to rationalize their use. Spectrophotometric and fluorimetric assays are quite popular, but either lack specificity or exaggerate findings due to the detection of artifacts. More recently, the detection of free radicals on macromolecules (protein, DNA) by immunooassays has presented an unprecedented opportunity to sensitively observe free radicals in vitro and in vivo. The discussions will focus on when and where each approach succeeds and fails and how each technique can be used to identify specific free radicals in pathways to toxicity.

- The Quinone/Semiquinone/Hydroquinone Triad: Free Radical Formation versus Thiol Conjugation in Toxicity. Garry Buettner, The University of Iowa, Iowa City, IA.
Enzymatic Functions Defined by Tracking Redox Reactions: The Example of Manganese Superoxide Dismutase. Marcelo Bonini, University of Illinois at Chicago, Chicago, IL.

Intra- and Intercellular Signaling Pathways As Modulators of Free Radical Toxicity. Lars-Oliver Klotz, University of Alberta, Edmonton, Alberta, Canada.

Free Radicals and Oxidized Macromolecules: Roles in Biomarker Toxicology. Maria Kadiiska, NIEHS/NIH, Research Triangle Park, NC.

Distinguishing Free Radical Metabolites of Aromatic Amine Drugs Based on Reactivity and Their Potential In Vivo Toxicity. Arno Siraki, University of Alberta, Edmonton, Alberta, Canada.

Cooperative Epidemiology and Toxicology Research: HEI’s National Particle Component Toxicity (NPACT) Initiative

Wednesday, March 14, 9:00 AM to 11:45 AM

Chairperson(s): Matthew J. Campen, University of New Mexico, Albuquerque, NM, and Geoffrey Sunshine, Health Effects Institute, Boston, MA.

Sponsor: Cardiovascular Toxicology Specialty Section

Endorsed by:
- Disease Prevention Task Force
- Inhalation and Respiratory Specialty Section
- Occupational and Public Health Specialty Section

In 2006, the Health Effects Institute (HEI) funded two major studies to address the comparative toxicity of components of particulate matter (PM) at multiple places across the United States where PM components and the sources of PM would differ. The goal of the program was to integrate toxicological and epidemiological approaches to address this issue. Both teams, one led by Sverre Vedal at the University of Washington, the other by Mort Lippmann at New York University (NYU), investigated the effects of PM components on cardiovascular endpoints in the same strain of mouse, ApoE knockout, but took contrasting approaches. In research conducted at Lovelace Respiratory Research Institute, Dr. Vedal’s team exposed the mice to well-characterized, lab-generated pollutant atmospheres that included vehicular—diesel + gasoline engine emissions—resuspended road dust, and secondary nitrates and sulfate particles. Dr. Lippmann’s team exposed the mice to particles concentrated from ambient air at four sites across the US. The NYU team also collected PM samples of different size ranges—ultrafine, fine, and coarse—at these sites to evaluate cardiovascular effects in another strain of mice.

The epidemiological analyses in both studies used well-established cohorts with participants throughout the US and with some overlap between the locations studied by both groups. Dr. Vedal’s team focused on evaluating associations between long-term exposure to PM components with cardiovascular endpoints in participants in the Multi-Ethnic Study of Atherosclerosis (MESA) and Women’s Health Initiative (WHI) studies. Dr. Lippmann’s team evaluated associations in multiple cities between PM components and daily mortality and hospital admissions endpoints, as well as between exposures to components and annual mortality in the American Cancer Society.
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Scientific

(ACS) cohort. These integrated studies provide important lessons on how to design and execute population and laboratory-based research in a cooperative manner.

• The University of Washington (UW)—Lovelace Respiratory Research Institute (LRRI) NP ACT Initiative on the Cardiovascular Health Effects of PM2.5 Components. Sverre Vedal, University of Washington, Seattle, WA.

• Cardiovascular Toxicology of Simulated Complex Air Pollution Atmospheres. Jacob D. McDonald, Lovelace Respiratory Research Institute, Albuquerque, NM.

• Overview of the NYU NP ACT Initiative on the Health Effects of PM Components. Morton Lippmann, New York University, Tuxedo Park, NY.

• Alterations of Cardiac Function and Plaque Progression in ApoE−/− Mice by Subchronic Inhalation Exposure of Concentrated Ambient PM2.5: The Roles of PM Components and Source Categories. Lung Chi Chen, New York University, Tuxedo Park, NY.

• In Vitro and In Vivo Effects of PM: Influence of Size, City, and Season. Terry Gordon, New York University, Tuxedo Park, NY.

Clinical Toxicology from Bedside to the Bench and Back

Progress in Developing New Biomarkers of Drug-Induced Liver Injury (DILI): What You Don’t Know Can Hurt You

Wednesday, March 14, 9:00 AM to 11:45 AM


Sponsor: Drug Discovery Toxicology Specialty Section

Endorsed by: Clinical and Translational Toxicology Specialty Section
Regulatory and Safety Evaluation Specialty Section
Toxicologic and Exploratory Pathology Specialty Section

Current biomarkers of drug-induced liver injury (DILI) are able to identify damage once it has occurred and when it becomes severe. Serum ALT and bilirubin are the accepted standards for hepatocellular injury and impaired liver function, respectively. The use of combined ALT and bilirubin levels (Hy’s Law) is considered a useful hallmark of whether an individual drug may cause severe DILI, which results in a 10–50% chance of transplantation or mortality. However, many patients who exhibit combined drug-induced ALT and bilirubin elevations do not develop severe DILI but rather adapt; therefore these biomarkers do not reliably predict risk of severe liver injury in man. Also, during the preclinical drug development phase, ALT can increase in the absence of injury and this can result in a program delay or termination. More specific markers that distinguish true injury from these false signals would improve liver injury signal detection and provide novel therapies to patients faster. The C-Path Preclinical Safety Testing Consortium and the IMI SAFE-T program are in the process of identifying and qualifying novel biomarkers of liver injury and function. Other liver biomarker discovery and qualification efforts are under way in academic, industrial, and government laboratories, such as the National Center for Toxicological Research. The greatest need is to find biomarkers for adaptation to liver injury, and to identify patients who will progress to DILI before the injury is severe and resolve false ALT signals. Our panel of experts will provide information and foster discussion on the major needs for DILI biomarkers, and highlight major areas of research under way on DILI biomarker discovery and qualification efforts.

• Qualification of Preclinical Biomarkers of DILI: Current Gaps, Research Efforts and Future Directions. Wendy Bailey, Merck & Co. Inc., West Point, PA.

• Qualification of Clinical Biomarkers of DILI: Current Gaps, Research Efforts, and Future Directions. Michael Merz, Novartis, Basel, Switzerland.


• Biomarkers of BSEP Inhibition Relating to DILI. Gerry Kenna, AstraZeneca, Macclesfield, United Kingdom.


Regulatory Science: Bridging the Gap between Discovery and Product Availability

Advancing Food Safety in a Global Marketplace

Wednesday, March 14, 1:30 PM to 4:15 PM

Chairperson(s): Nicola Stagg, Dow AgroSciences LLC, Indianapolis, IN, and Michael Bolger, US FDA, College Park, MD.

Sponsor: Food Safety Specialty Section

Endorsed by: Global Strategy Task Force
Mixtures Specialty Section
Regulatory and Safety Evaluation Specialty Section
Risk Assessment Specialty Section

Advancements in packaging technology, such as those that extend food shelf-life, agricultural products including pesticides and genetically modified crops, and a more integrated and global marketplace
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have led to increased food quantity and quality, but as a consequence have also led to concerns about food safety and potential risks to public health. These global food safety concerns range from incidental or deliberate food contamination from micro-organisms or toxic substances, chemicals migrating into food from food containers, pesticide residues on food, and genetically modified foods. Our panel of experts will highlight the science-based approaches being used to regulate food safety in the food, chemical, and agricultural industries across the world. To underscore the important of these issues, we will identify opportunities for advancing technologies and science across many sectors including academia, industry, government, and public health organizations, to build confidence in the safety of our food to protect human health.

- Evaluating the Safety of Materials Used in Food Contact Materials. Daniel Wilson, The Dow Chemical Company, Midland, MI.
- Regulating the Safety of Foods and Feeds Derived from Genetically Modified Crops. Bruce Chassy, University of Illinois, Urbana, IL.
- Risk Assessment and Management Options for Chemical Contaminants in a Global Food Supply. Clark Carrington, US FDA, College Park, MD.

Characterizing Toxic Modes of Action and Pathways to Toxicity

Discovering Novel Hypotheses for Mechanisms of Toxicity from High-Content Data Sets

Wednesday, March 14, 1:30 PM to 4:15 PM

Chairperson(s): Nigel Greene, Pfizer, Inc., Groton, CT, and Ahmed Enayetallah, Pfizer, Inc., Groton, CT.

Sponsor:
- Biological Modeling Specialty Section

Endorsed by:
- Molecular Biology Specialty Section

For over a decade researchers have sought to apply technologies such as genomics, proteomics, and metabolomics to either predict toxicity through the use of gene, protein, or metabolite signatures or to further understand modes of action in toxicity through chemical exposure. There have been some success stories in recent years but largely these technologies have not lived up to the promises made when they were first developed. The complex nature of biological systems and the multivariate nature of a system’s response to a xenobiotic have made it difficult to pick apart the true causes of the phenotypic changes that are observed. In addition, the explosion of data available in the public domain has made it difficult for the human brain to keep up with current knowledge and apply this effectively to a set of experimental readouts to determine cause and effect relationships. Xenobiotics often induce their biological effects via interactions with one or more biological targets, thus triggering whole cascades of events that culminate in adverse events in humans. Understanding the nature of these events, coupled with consideration of their relevance to the human mode of action and target context, will improve the scientific basis and thus increase the accuracy of risk and safety assessments. In addition, better understanding of toxicological modes of action will ultimately lead to the development of more predictive models of in vivo biological responses. Where these take the form of in vitro biochemical and cell-based assays it will lead to the reduction of the use of animals in laboratory experiments. This session will outline some of the cutting-edge research and methodologies for distilling down the vast array of public information into more manageable sets of knowledge and relationships. We will discuss novel in silico approaches to mine these relationships and formulate hypotheses for modes of action of the compound or biological target under study and present some applications of these methods in understanding toxicological mechanisms.

- Predicting Mechanisms of Chemical Toxicity Using the Comparative Toxicogenomics Database (CTD). Carolyn Mattingly, The Mount Desert Island Biological Laboratory, Salisbury Cove, ME.
- A Novel Computational Approach for Early Prediction of Target-Based Toxicity through Downstream Molecular Causal Reasoning. Daphna Laifenfeld, Selventa, Inc., Cambridge, MA.
- Toxicity Biological Networks Using Causal Reasoning to Leverage High-Throughput Quantitative SILAC Proteomics. Ahmed Enayetallah, Pfizer, Inc., Groton, CT.
- Identifying Mechanisms of Drug-Induced Toxicity Using Metabolomics. David F. Grant, University of Connecticut, Storrs, CT.
Clinical Toxicology from Bedside to the Bench and Back

Muscle Toxicity—Current Challenges in Translatable Biomarkers

Wednesday, March 14, 1:30 PM to 4:15 PM

Chairperson(s): Warren Glaab, Merck, West Point, PA, and Denise Robinson-Gravatt, Pfizer, Inc., Groton, CT.

Sponsor: Regulatory and Safety Evaluation Specialty Section

Endorsed by:
- Clinical and Translational Toxicology Specialty Section
- Drug Discovery Toxicology Specialty Section
- Molecular Biology Specialty Section
- Toxicologic and Exploratory Pathology Specialty Section

Compound-related injury to cardiac and skeletal muscle are common preclinical and clinical toxicities observed in drug development, and have resulted in the withdrawal of several pharmaceutical agents from the market. Current biomarkers for detecting muscle injuries can be both insensitive and nonspecific as well as poorly predictive. Improving the ability to detect drug-induced muscle injuries will facilitate preclinical and clinical drug development and help ensure patient safety. This session will focus on a consortium approach to qualify novel muscle biomarker candidates and seek regulatory endorsement for specific use claims, and will include presentations on the biomarker qualification approach being used by the Critical Path Institute’s Predictive Safety Testing Consortium (PSTC) in partnership with the US FDA and EMA; a pathological assessment of cardiac and skeletal muscle drug-induced toxicities; a Biomarker Qualification Submission (BQS) for skeletal muscle biomarkers consisting of ~40 rat studies from consortium member companies; a clinical qualification strategy for the proposed skeletal muscle biomarker candidates; cardiac hypertrophy biomarker candidates based on clinical data and a reverse translational strategy for their qualification into preclinical use; and, the US FDA perspective on novel safety biomarker qualifications for preclinical and clinical applications.

Data will be presented highlighting the qualification and implementation of these novel cardiac and skeletal muscle biomarkers in drug development, as well as discussion about the importance of agency endorsement to further promote translation to clinical applications and better enable drug development.

- Biomarkers of Cardiac and Skeletal Muscle Toxicity—Preclinical Qualification and Translation to Clinical Use. Denise Robinson-Gravatt, Pfizer Inc., Groton, CT.
- Drug-Induced Toxicities of Cardiac and Skeletal Muscle. Greg Hall, Eli Lilly and Company, Indianapolis, IN.

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- Qualification of Novel Skeletal Muscle Toxicity Biomarkers by the PSTC Working Group. David Watson, Eli Lilly and Company, Indianapolis, IN.
- Clinical Translation of Skeletal Muscle Biomarkers. Warren Glaab, Merck Research Laboratories, West Point, PA.
- Reverse Translating Clinical Biomarkers—A Nontraditional Approach to Qualify NT-proANP. Michael Dunn, Roche, Nutley, NJ.

Progenitor and Stem Cells As Targets of Environmental Pollutants

Wednesday, March 14, 1:30 PM to 4:15 PM

Chairperson(s): Daniel J. Conklin, University of Louisville, Louisville, KY, and Petra Haberzettl, University of Louisville, Louisville, KY.

Sponsor: Cardiovascular Toxicology Specialty Section

Stem and progenitor cells, including hematopoietic stem cells (HSC), endothelial progenitor cells (EPC), and mesenchymal stem cells (MSC), are potential important targets of environmental pollutants due to their capacity to differentiate and divide. These progenitor/stem cells are mobilized from their niches (e.g., bone marrow and spleen) by a variety of stimuli to the circulation where they effectively regulate organ and tissue homeostasis and repair after injury. Epidemiological studies suggest these cells play an important role in the development of human disease and indicate environmental exposures affect both the number and function of circulating stem/progenitor cells. For example, exposures to 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) are associated with an increased risk of specific hematological diseases, whereas inhalation of particulate and volatile air pollutants is associated with decreased circulating endothelial progenitor cells, which is a risk factor of cardiovascular disease. Thus, the level of circulating stem/progenitor cells could be a sensitive biomarker of pollutant exposure, as well as being a mechanism by which pollutant exposure affects disease risk. The mechanisms and signaling pathways by which different pollutants affect stem/progenitor cell number and function are not well understood. This session will provide an overview of how different types of adult stem/progenitor cells are measured in number and function, and also address the underlying mechanisms by which diverse environmental pollutant exposures affect these important cells.

- Exposure to Airborne Fine Particulate Matter PM2.5 and Defects in Circulating Stem Cells in Humans and Mice. Timothy E. O’Toole, University of Louisville, Louisville, KY.
- The Effects of Nickel Nanoparticles on Bone Marrow and Circulating Progenitor Cells in Mice. Eric Liberda, New York University, Tuxedo, NY.
Workshops

- Volatile and Particulate Environmental Air Pollutants Impede VEGF-Mediated EPC Mobilization from Bone Marrow: A Common Mechanism? Petra Haberzettl, University of Louisville, Louisville, KY.


- Adverse Effects of Polycyclic Aromatic Hydrocarbons on Bone Marrow Progenitor Cells and Its Relationship to Reduced Cellularity in the Spleen and Thymus. Charles Czuprynski, University of Wisconsin, Madison, WI.

T-Dependent Antibody Responses in Nonhuman Primates: Challenges and Opportunities

Wednesday, March 14, 1:30 PM to 4:15 PM

Chairperson(s): Jacintha Shenton, MedImmune Ltd., Granta Park, Cambridge, United Kingdom, and Hervé Lebrec, Amgen Inc., Seattle, WA.

Sponsor: Immunotoxicology Specialty Section

Endorsed by: Biotechnology Specialty Section
Regulatory and Safety Evaluation Specialty Section

Increasingly, the T-cell dependent antibody response (TDAR) assay is used as a means to evaluate immunomodulation—immunopharmacology or immunotoxicology—in nonhuman primates (NHPs). This is primarily due to the plethora of immunomodulatory biopharmaceuticals in development. Our focus will be on several key topics relevant to the TDAR and other measures of immune responses to T-dependent (TD) antigens. Traditionally, the TDAR has been used as a means to evaluate immunosuppression. It is less clear whether it is possible or appropriate to use the TDAR to evaluate immunostimulation. In addition, although the read-out of the TDAR is by definition the generation of antigen-specific antibodies, T-helper cells, as well as antigen presenting cells, are also involved in the response, while poorly characterized in the context of this assay in NHPs. There is, for instance, little information on T-cell differentiation towards T-helper [Th]1 versus Th2 responses in this context. Cellular immune responses to TD antigens may also be evaluated using the delayed-type hypersensitivity (DTH) response; however, DTH is notoriously difficult to produce in NHPs and correlative data between the systemic and local responses to the TD antigen are lacking. Although immune responses to TD antigens are routinely evaluated nonclinically there is little understanding of translational data across species and to humans. Furthermore, the increased use of the TDAR in NHPs is associated with a disparity of protocols as well as methods for data interpretation; any discussions on standardization/best practices generally result in significant debate. The goal of this session is to share data and progress in our understanding of the measurable endpoints of the immune response to TD antigens and to provide a forum for discussion on the utility of these endpoints within drug development.

- Use of the T Cell-Dependent Antibody Response to Evaluate Immunostimulation. Jacques Descotes, Poison Center and Pharmacovigilance Department, Lyon, France.

- Beyond Antibodies: Characterization of the Cellular Immune Response to Keyhole Limpet Hemocyanin. Lynne LeSauteur, Charles River, Montréal, Québec, Canada.

- Correlations between Systemic and Local Responses to T-Dependent Antigens. Margreet Jonker, Biomedical Primate Research Centre, Rijswijk, Netherlands.

- Translation of the Immune Responses to T-Dependent Antigens between Nonhuman Primates and Humans. Jacintha Shenton, MedImmune, Cambridge, United Kingdom.


THURSDAY

Regulatory Science: Bridging the Gap between Discovery and Product Availability

Challenges and Opportunities in Evaluating Protein Allergenicity across Biotechnology Industries

Thursday, March 15, 9:00 AM to 11:45 AM

Chairperson(s): Nicola Stagg, Dow AgroSciences LLC, Indianapolis, IN, and Hanan Ghantous, US FDA, Silver Spring, MD.

Sponsor: Biotechnology Specialty Section

Endorsed by: Food Safety Specialty Section
Immunotoxicology Specialty Section

Biotechnology is a field at the cutting-edge of science, using living cells and materials produced by cells to prevent and fight disease, improve food production, and benefit other industries as well, but there are increasing concerns over the allergenicity of biotechnology products that continue to receive increasing attention in public and regulatory domains. These concerns range from the transfer of an existing allergen or cross-reactive protein into another crop or increasing endogenous (existing) allergens in crops to accidental
up-to-date information at www.toxicology.org

51st Annual Meeting and ToxExpo

The Thematic Track information can be found on pages 8–9.

Workshops

Scientific

Chemical Standardization of Botanical Medicines for Safe and Effective Use As Therapeutic Agents

Thursday, March 15, 9:00 AM–11:45 AM

Chairperson(s): Madhu Soni, Soni & Associates Inc., Vero Beach, FL, and Brinda Mahadevan, Abbott Laboratories, Abbott Park, IL.

Sponsor:
Association of Scientists of Indian Origin Special Interest Group

Endorsed by:
American Association of Chinese in Toxicology Special Interest Group
Food Safety Specialty Section
Mixtures Specialty Section
Regulatory and Safety Evaluation Specialty Section
Risk Assessment Specialty Section

Botanical medicines have been used for millennia to cure ailments in traditional societies around the world. According to the World Health Organization (WHO), in Asian and African countries, over three fourths of the population rely on botanical medicines for their primary health care needs. The use of botanical medicines in the developed world is increasingly on the rise with individuals seeking alternate and/or complementary medicine options. The popular belief is that because botanical medicines are derived from natural sources, they are safe and pose no harm when used. However, within the scientific community, botanical medicines are under increased scrutiny due in part to concerns regarding their safety and clinical efficacy. Safety issues often arise from lack of controlled manufacturing conditions, unproven formulations, improper storage, and poor or ineffective quality control measures. In addition, a number of plant materials have been found to be contaminated with toxicological substances, including heavy metals and interfere with the actions of commonly prescribed medications, which has resulted in a number of adverse patient effects. Thus, use of botanical medicines is further confounded with considerable variations in chemical composition, inclusion of known toxic components during the processing, uncertain therapeutic potency, and potential safety issues when used alone or in combination with pharmaceutical agents. In an effort to broaden the understanding of the aforementioned issues pertaining to botanical medicines, the following key aspects will be addressed: the toxicity of botanical medicines; if it's natural, is it necessarily safe; successful scientific strategies that are needed to ensure safe and effective use of botanical medicines; quality and safety issues of botanical medicines; chemical standardization of botanical medicines; and current state and federal regulations affecting this line of therapeutic agents.

• Characterization and Use of Herbal Preparations As Test Articles in Safety Assessments—Analytical Challenges and Reasonable Solutions. Cynthia Smith, NIEHS, Research Triangle Park, NC.


• Integrity of a Product: Use of Validated Methods in Assessing the Quality and Safety of Botanicals. Ikhlus Khan, University of Mississippi School of Pharmacy, Oxford, MS.

• Standardizing Snowflakes: Using Technology to Normalize Nature. Craig Hopp, NIH, Bethesda, MD.

• Chemical Standardization of an Herbal Formulation As a Safe and Effective Therapeutic Agent for Parkinson's Disease—A Case Study. Bala Manyam, Penn State University, Hershey, PA.

Existing and Emerging Methods and Techniques for Assessing Allergenicity of Genetically Modified Crops. Greg Ladics, DuPont, Wilmington, DE.

Evaluating the Potential Allergenicity of Vaccines. Robert House, DynPort Vaccine Company, LLC, Frederick, MD.

Food Regulatory Perspective on Evaluation of Allergenicity. Steven Gendel, US FDA, College Park, MD.


modification of therapeutic proteins resulting in autoimmune reactions to endogenous molecules. This session will provide important information on allergenicity testing requirements and research in the agricultural chemical/biotech sector, pharmaceutical/biopharma sector, and vaccine sector and includes speakers from industry and regulatory. An anticipated outcome is discussion over why allergenicity is a concern, what tools are available to evaluate allergenicity in the different areas of biotechnology, and any challenges we face with this testing.

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Scientific Roundtables

TUESDAY

Regulatory Science: Bridging the Gap between Discovery and Product Availability

Evolving the EPA Endocrine Disruptor Screening Program: From Using High-Throughput Screening Assays for Prioritization to Reducing Reliance on Whole Animal Tests

Tuesday, March 13, 12:00 Noon to 1:20 PM


Sponsor: Reproductive and Developmental Toxicology Specialty Section

Endorsed by: In Vitro and Alternative Methods Specialty Section

Testing has begun as part of the EPA Endocrine Disruptor Screening Program (EDSP) Tier 1 battery of 11 in vitro and in vivo tests. A recognized issue with the EDSP is that the current Tier 1 screening battery is highly resource intensive in terms of cost, time, and animal usage for the large numbers of chemicals with unknown endocrine potential that need to be evaluated. The significant advances in both computational and molecular technologies have enabled a more rapid identification of markers for adverse outcome pathways since EPA began work on developing and implementing the EDSP. The EPA is proposing to evolve the EDSP by incorporating in vitro high-throughput screening (HTS) assays that can rapidly detect potential interactions of chemicals with the estrogen, androgen, thyroid hormone, and steroidogenesis (EATS) pathways. In the near term, incorporating HTS assays will focus on developing a prioritized list of chemicals for evaluation in the current Tier 1 battery. Prioritization would continue to take other factors into account, including exposure and use. A longer term goal is to evolve the Tier 1 battery by fully incorporating HTS assays in order to increase reliance on non-animal screens for which there is confidence in their ability to predict in vivo adverse effects. Although the overall approach is reasonable, it is highly provocative and debatable for a number of reasons. On the one hand, this proposal has the potential to greatly improve the speed, cost effectiveness, and mechanistic specificity of the EDSP using fewer animals, but on the other hand, there are concerns about reliability and relevance of the HTS assays and lack of full validation (e.g., transferability between laboratory evaluation) metabolic capacity, etc. Our panel of experts will present the case for and against using this approach and will allow time for open discussion with the audience.


- One View from Industry on the Promises and Challenges of Using HTS Assays in EDSP. Sue Marty, Dow Chemical Company, Midland, MI.

- A View from the EPA Regulatory Offices on the Promises and Challenges of Using HTS Assays in the EDSP. Vicki L. Dellarco, US EPA, Washington, DC.

- HTS Assays Covering Key Pathways Covered by EDSP Tier 1 Do Not Yet Exist. Thomas Zoeller, University of Massachusetts, Amherst, MA.

Regulatory Science: Bridging the Gap between Discovery and Product Availability

Improving Chemical Safety Assessment through Harmonization: Why, How, and When?

Tuesday, March 13, 12:00 Noon to 1:20 PM

Chairperson(s): Haitian Lu, Dow AgroSciences LLC, Indianapolis, IN, and Michael Holsapple, Battelle, Columbus, OH.

Sponsor: Regulatory and Safety Evaluation Specialty Section

Endorsed by: American Association of Chinese in Toxicology Special Interest Group Global Strategy Task Force Risk Assessment Specialty Section

Chemical safety assessment for the protection of human health is not harmonized globally. Toxicology data requirements and test guidelines that differ across geographies could result in repetition of studies and therefore waste of animals and resources. The other prominent difference is that although exposure and risk assessment are critical components of well-established regulatory frameworks, the chemical safety regulations differ in several emerging geographies and heavily rely on hazard-based approaches. What also remains to be discussed is how more harmonized approaches for risk assessment can be achieved globally, considering potential geographic differences in exposure scenarios, and the utility of hazard-based approaches under certain circumstances. A roundtable session on opportunities for more harmonized paradigms and practices of chemical safety assessment is both important and timely as emerging geographies are becoming increasingly influential in the global economy, and several of them are actively developing their regulatory frameworks. This session intends to provide a unique opportunity for stakeholders from all over the world, including regulators from emerging geographies, to review the current status, exchange views on the challenges and opportunities, dialogue on potential solutions on the basis of sound science in toxicology and risk assessment, and brainstorm on a path forward. Overall, this session seeks to facilitate the participants to reach mutual understanding of current challenges and opportunities,
Testing of Nanomaterials for Genotoxicity: Necessity or Waste of Time?

Tuesday, March 13, 12:00 Noon to 1:20 PM

Chairperson(s): Stefan Pfuhler, Procter & Gamble, Cincinnati, OH, and Andre Nel, University of California, Los Angeles, CA.

Sponsor: Nanotoxicology Specialty Section

Endorsed by:
Carcinogenesis Specialty Section
Risk Assessment Specialty Section

The selection or use of genotoxicity assays for testing nanomaterials remains a controversial issue. There are published studies indicating that some nanomaterials are genotoxic in vitro as well as in vivo, yet there are many unknowns and confounding factors that impact our ability to come up with the right approach. Genotoxicity tests were designed for testing chemicals and may not be suitable for the screening of particulate material. Furthermore, the classical direct interaction of a chemical or its metabolite with DNA, which our assays are optimized for, will not play a role in the majority of nanomaterials. Because we are still learning about the mechanisms by which nanomaterials can exert genotoxic effects, we can see a clear pattern evolving from acute and chronic toxicity studies. The bulk of nanomaterials that caused toxic effects seem to induce inflammatory processes that will generate oxidative stress. DNA damage triggered by inflammatory processes is viewed quite differently in risk assessment, and the question of whether a material triggers genotoxic activity directly or through a threshold mechanism has a huge impact on public health decisions. How should this impact the selection of our assays? Does the performance of standard genotoxicity assays make sense at all? As the scientific community is facing the challenge of conducting hazard/risk assessments on nanomaterials today, guidance is desperately needed. Our panel of experts will share recent data in order to fuel discussion and seek consensus as to whether standard in vitro and in vivo genetox assays should have a place in the assessment of these materials, whether additional assays should be added on, or whether we are in need of a paradigm shift for this class of materials.

- Protection of Public Health from Chemicals in Europe: How Important in Exposure? Alan Boobis, Imperial College, London, United Kingdom.
- Criteria for Toxicological Evaluation for Human Health in Brazil. Ana Maria Vekic, Agência Nacional de Vigilância Sanitária, Brasilia, Brazil.
- In Vitro Genotoxicity Testing Strategies for Nanomaterials. Shareen H. Doak, Swansea University, Swansea, Wales, United Kingdom.
- DNA Damaged Caused by Nanoparticles May Be Secondary to Inflammation and May Be Predicted by a Systems Biology Approach. Meredith Crosby, Procter & Gamble, Cincinnati, OH.
- High-Throughput Screening (HTS) for Nongenotoxic Responses to Engineered Nanomaterials. Andre Nel, University of California, Los Angeles, CA.

WEDNESDAY

Placing Bisphenol A Risks in a Human Exposure Context: Is Internal Exposure to Bioactive Bisphenol A in Humans Similar to Levels in Affected Rodent Test Species?

Wednesday, March 14, 7:30 AM to 8:50 AM

Chairperson(s): Justin G. Teeguarden, Pacific Northwest National Laboratory, Richland, WA, and Jeffrey Fisher, National Center for Toxicological Research, Jefferson, AR.

Sponsor: Medical Device Specialty Section

Endorsed by:
Food Safety Specialty Section
Regulatory and Safety Evaluation Specialty Section
Reproductive and Developmental Toxicology Specialty Section
Risk Assessment Specialty Section

Human external and internal exposure to Bisphenol A (BPA) is widespread. Hydrolysis or leaching of unreacted monomer from polymeric products can release low levels of BPA leading to human exposure through the diet, handling of some paper products, and use of some medical devices utilized in neonatal/pediatric intensive care units. However, BPA undergoes substantial presystemic Phase II metabolism in the gut and liver following oral administration, producing inactive metabolites and limiting internal exposure to the active monomer, aglycone, or unconjugated BPA. Inconsistent reports
of high (ng/ml) concentrations of aglycone BPA in human blood/tissue samples collected and/or analyzed in an uncontrolled manner and controversy regarding the pharmacokinetics of BPA in rodents and primates have fueled concerns that internal exposure to BPA may be high enough to cause endocrine disruption in humans. Recently published and emerging research funded by NIEHS/NTP, FDA, and EPA (STAR program) offer an exceptional scientific basis for assessing the significance of BPA exposure to human health. This session will introduce the BPA cause célèbre, present new data on internal exposures to unconjugated BPA in humans, the pharmacokinetics of aglycone and conjugated BPA in adult, neonatal, and fetal rodents and nonhuman primates, and present new rodent toxicity studies that concomitantly characterized internal BPA exposure and potentially adverse biological effects. These data will be synthesized and used to critically examine the hypothesis that human internal exposure to aglycone BPA is sufficiently high to produce a demonstrably adverse health outcome and identify key uncertainties and data needs. The conclusions will be discussed in a final session.

- Pharmacokinetics and Biomonitoring of BPA in Humans: Promises and Pitfalls. Jeffrey Fisher, National Center for Toxicological Research, Jefferson, AR.
- Internal Concentrations of Bioactive BPA in the Adult and Perinatal Period in Humans. Justin G. Teeguarden, Pacific Northwest National Laboratory, Richland, WA.
- Bioactive BPA Exposure and Pharmacokinetics in the Adult and Perinatal Period in Experimental Animals. Daniel R. Doerge, National Center for Toxicological Research, Jefferson, AR.
- Relating Internal BPA Doses to Adverse Effects in Rodent Toxicity Studies. K. Barry Delcos, National Center for Toxicological Research, Jefferson, AR.
- Does Internal Dosimetry Inform Us About the Likelihood of Adverse Effects in Humans at Current Exposure Levels? Richard M. Sharpe, University of Edinburgh, Edinburgh, United Kingdom.

Regulatory Science: Bridging the Gap between Discovery and Product Availability

Scientific, Regulatory, and Public Perspectives on the Credibility and Use of Alternative Toxicological Test Methods in a Legislative Framework

Wednesday, March 14, 12:00 Noon to 1:20 PM

Chairperson(s): Daland Juberg, Dow AgroScience, Indianapolis, IN, and Robert Skoglund, 3M Company, Saint Paul, MN.

Sponsor:
- In Vitro and Alternative Methods Specialty Section
- Endorsed by:
  - Ethical, Legal, and Social Issues Specialty Section
  - Regulatory and Safety Evaluation Specialty Section

The role of toxicology and toxicity testing in legislation and regulatory decision-making continues to change and an understanding of the opportunities, as well as challenges, that accompany the consideration of alternative test methods in a legislative framework is critical for forward progress in public health protection. It is well-established that toxicology in the twenty-first century has taken on many faces, but none perhaps so well-recognized as that of the introduction of new tools, technologies, and alternative test approaches to testing and how these may play a role in legislation. These tools and approaches have moved beyond the laboratory and are being considered by regulatory authorities in decision-making and by lawmakers as they consider how to modernize chemical legislation. The timetable and suitability of these alternative approaches to supplement or replace existing test methods continues to deserve attention and discussion. This session will review how various existing test approaches are used, and then will bring in three important perspectives—a scientific, regulatory, and a public view, on the credibility and applicability of alternative approaches for use in legislation and regulation. This transformation in toxicity testing will continue to occur and it is critical that new approaches be met with acceptance and be suitable from all three perspectives if the transformation is to meet with success, be integrated into a legislative framework, and advance public health for decades to come.

- The Role of Toxicology Testing in Regulation. Linda Birnbaum, NIEHS, Research Triangle Park, NC.
- Scientific Suitability of Alternative Test Methods. Melvin E. Andersen, The Hamner Institutes of Health Sciences, Research Triangle Park, NC.
The Thematic Track information can be found on pages 8–9.

San Francisco, California

Roundtables

- **Public Perspective on the Credibility of Alternative Test Methods.** Martin L. Stephens, Humane Society of the United States, Gaithersburg, MD.
- **A Scientific Roadmap to the Regulatory Use of Alternative Approaches.** Thomas A. Hartung, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD.

The Future of Toxicology Education: Outcomes of the Toxicology Educational Summit

Wednesday, March 14, 12:00 Noon to 1:20 PM

*Chairperson(s):* Aaron Barchowsky, University of Pittsburgh, Pittsburgh, PA, and Mary Beth Genter, University of Cincinnati, Cincinnati, OH.

*Sponsor:* Education Committee

*Endorsed by:* Professional Needs Assessment Task Force

The Society of Toxicology convened the Toxicology Educational Summit on October 20 and 21, 2011, to address updating and modernizing toxicology education at multiple levels to meet the needs of an ever advancing profession. As with many other scientific disciplines and professions, toxicology and careers in toxicology are undergoing rapid and dramatic changes as new discoveries, technologies, and hazards advance at a blinding rate. There are new demands on toxicologists to keep pace with expanding global economies, global threats to public health, and ever-evolving complex hazards that pose health risks. These demands must be met with new paradigms for multidisciplinary, technologically complex, and collaborative approaches that require advanced and continued education in toxicology and associated disciplines. This requires paradigm shifts in educational programs that both support development and training of the modern toxicologist and allow retraining of the midcareer professional to keep pace and sustain careers in industry, government, and academia. This session will present the outcome of discussions and strategic planning developed at the summit and solicit participation from the audience to discuss conclusions and recommendations from the summit, as well as SOT strategic objectives to address these recommendations to advance toxicology education. This session will consist of a series of short presentations from summit topics and conclusions, and will conclude with comments on each topic from the audience.

- **Overview of the Toxicology Education Summit.** Aaron Barchowsky, University of Pittsburgh, Pittsburgh, PA.
- **Building for the Future of Toxicology.** Stephen H. Safe, Texas A&M University, College Station, TX.
Informational Sessions

MONDAY

Global Health and Environmental Impacts of E-Waste Recycling

Monday, March 12, 12:10 PM to 1:30 PM

Chairperson(s): Erica L. Dahl, Exponent, Alexandria, VA, and Bruce Fowler, ICF International, Fairfax, VA.

Sponsor: Disease Prevention Task Force

Endorsed by: Ethical, Legal, and Social Issues Specialty Section

Global Strategy Task Force

Communicating electronically is considered inherently green because it reduces paper waste and its associated transit. Rapid innovation has produced a constantly growing inventory of outdated electronic equipment that is eventually disposed of as electronic waste, or e-waste. Concerns about contamination from e-waste have led to bans from local landfills and the development of a new e-waste recycling industry to reclaim valuable metals and ideally manage the release of hazardous materials. The current production of e-waste overwhelms local recycling sites and e-waste is sometimes exported along with donations of usable electronics to developing countries, where workers often lack the technology and training to dispose safely of e-waste. Informal recycling releases heavy metals and persistent organic pollutants into the soil, water, and air. Global efforts to reduce damage caused by e-waste include the Basel Treaty, which aims to reduce exports of e-waste to developing countries. Efforts to quantify the hazardous components of e-waste are underway in California, where high levels of brominated flame retardants have been found in residents and wildlife. Although the toxicology of many e-waste components is well characterized, some newer materials, such as gallium and indium arsenides found in newer semiconductors, are less well understood. Their incorporation into nanomaterials may increase bioavailability in unanticipated ways. Developing children and fetuses may be particularly vulnerable to toxins found in e-waste, and early epidemiological studies near informal e-waste recycling sites indicate potential developmental neurotoxicity. Understanding the hazards of e-waste, the impacts of its disposal, and the dangers of informal or careless recycling will help reduce or prevent disease outcomes associated with exposure to e-waste components.

• The Scope of the Problem—International Regulation and the Basel Treaty. Oluwasanmi O. Areola, Nashville Metro Public Health Department, Nashville, TN.

• Regulated and Unregulated Contaminants in California Waste Streams. Myrto Petreas, California Department of Toxic Substances Control, Berkeley, CA.


• E-Waste Recycling in Developing Countries: Concerns of Developmental Toxicity. Aimin Chen, University of Cincinnati College of Medicine, Cincinnati, OH.

NIEHS Centers for Nanotechnology Health Implications Research: Building the Scientific Foundation for Evaluating Public Health Impacts of Engineered Nanomaterials

Monday, March 12, 12:10 PM to 1:30 PM

Chairperson(s): Srikanth Nadadur, NIEHS, Research Triangle Park, NC, and Gwen Callman, NIEHS, Durham, NC.

Sponsor: Nanotoxicology Specialty Section

Endorsed by: Cardiovascular Toxicology Specialty Section

Inhalation and Respiratory Specialty Section

The NIEHS established the NIEHS Centers for Nanotechnology Health Implications Research (NCNHIR) consortium to gain a comprehensive understanding of how physical and chemical characteristics of engineered nanomaterials (ENMs) influence their molecular interactions with biological matrices and elicit biological responses. This consortium includes eight centers funded in 2010 through a multi-project cooperative agreement (U19) and research grant (U01) mechanisms, along with additional investigators supported by Nano-EHS research program at NIEHS. Together, the consortium and individual investigators are exploring a library of engineered nanomaterials selected by NCNHIR with an overarching research focus that integrates physical and chemical characteristics of ENMs with biological effects. The research projects at these centers are investigating how the physical and chemical characteristics of ENMs dictate biological interactions at the molecular and cellular level. This knowledge can be translated to predict biological responses in vivo such as absorption, distribution, metabolism, and elimination (ADME) as well as physiological and pathobiological events in target and secondary organs, using appropriate routes of exposure and dose metrics. This information can be used to develop and apply predictive models in hazard characterization and assessment due to accidental or incidental exposure to ENMs. This session will highlight some of the recent findings and efforts of the consortium and provide scientific leads for a better understanding of the potential adverse health effects associated with ENM exposure.

• NIEHS Centers for Nanotechnology Health Implications Research. Srikanth Nadadur, NIEHS, Research Triangle Park, NC.

• High Content and High-Throughput Approaches for ENM Hazard Ranking and Building Predictive Models for Inhalation Toxicology. Andre Nel, University of California Los Angeles, Los Angeles, CA.
Informational Sessions

- **Using Systems Genetics to Elucidate Quantum Dot Nanoparticle Toxicity.** Terrance J. Kavanagh, University of Washington, Seattle, WA.
- **Influence of Life Stage and Associated Physiology on Carbon ENM Kinetics and Effects.** Timothy Fennell, RTI International, Research Triangle Park, NC.
- **Modulation of ENM Interactions: Contributions of Gut Microflora.** Martin A. Philbert, University of Michigan, Ann Arbor, MI.
- **Predictive Modeling Efforts for ENMs Toxicity Assessment.** Justin G. Teeguarden, Pacific Northwest National Laboratory, Richland, WA.

**WEDNESDAY**

**Getting Certified As a Toxicologist: Why, When, Where, and How**

*Wednesday, March 14, 7:30 AM to 8:50 AM*

**Chairperson(s):** MaryJane Selgrade, ICF International, Durham, NC, and John A. Wisler, Amgen, Inc., Thousand Oaks, CA.

**Sponsor:** Career Resource and Development Committee

The purpose of this session is to provide information on the different certification options available to toxicologists and to highlight the benefits of certification. This session is intended for those who are considering certification and want to learn more about it. Practicing toxicologists come from different training backgrounds, are engaged in a diverse array of activities including research, risk assessment, product development, consulting, etc., and work in several different sectors. The SOT membership embodies this diversity and includes scientists from academia, government, nonprofits, and industry who practice toxicology in the United States and abroad. The diverse nature of the field makes certification particularly challenging and in truth many toxicologists are self-branded. However, several certification organizations exist worldwide, each with different foundations and requirements. Our panel of experts will explore what makes a toxicologist, understand the different certification options and their benefits, and identify opportunities for harmonization. Providing an overview of the requirements for each review body will be representatives from the American Board of Toxicology (ABT), the Academy of Toxicological Sciences (ATS), European Registered Toxicologists (ERT), and the Japanese Society of Toxicology (JSOT).

- **Introductory Talk: What Makes a Toxicologist?** MaryJane Selgrade, ICF International, Durham, NC.
- **Certification through the American Board of Toxicology (ABT).** John A. Wisler, Amgen, Inc., Thousand Oaks, CA.
- **Certification through the Academy of Toxicological Sciences (ATS).** William J. Brock, Brock Scientific Consulting, Montgomery Village, MD.
- **Certification As a European Registered Toxicologist (ERT).** Nancy D. Claude, Servier Group, Courbevoie, France.
- **Certification through the Japanese Society of Toxicology (JSOT).** Shuji Tsuda, Iwate Institute of Environmental Health Sciences, Iwate, Japan.
- **Opportunities for Harmonization.** Lewis L. Smith, Syngenta Crop Protection, Inc., Macclesfield, United Kingdom.

**Good Laboratory Practice (GLP) in China**

*Wednesday, March 14, 7:30 AM to 8:50 AM*

**Chairperson(s):** Jiaqin (Jack) Yao, US FDA/CDER, Silver Spring, MD, and Cai Cao, Chinese State Food and Drug Administration, Beijing, China.

**Sponsor:** American Association of Chinese in Toxicology Special Interest Group

China has experienced an increase in nonclinical studies conducted for submission to the US, Chinese, and other regulatory authorities. Both industry and regulators should be familiar with requirements and challenges in the emerging Chinese landscape. This session will review requirements and challenges of GLP regulations seen by both Chinese and US regulatory authorities, as well as provide industry perspectives on meeting and clarifying those challenges. Our panel of experts will highlight the current status of GLP laboratories certified by the Chinese State Food and Drug Administration (SFDA) and nonclinical GLP studies conducted in China for multinational regulatory submissions. Industry and regulatory leaders will participate in this session to share important perspectives to help achieve understanding and compliance with requirements. This particular topic will be useful to those interested in conducting nonclinical studies in China and those reviewing nonclinical studies conducted by Chinese contract research organizations (CROs).

- **Chinese Preclinical Safety GLP Laboratories.** Gene Ching-Hung Hsu, Shanghai InnoStar Bio-Tech Co., Ltd., Shanghai, China.
- **Experience on Conducting Nonclinical GLP Studies in China.** John Gong, JOINN Laboratories, Suzhou, China.
- **Pharmaceutical Industry Perspective.** James Yan, Hutchison MediPharm Ltd, Shanghai, China.
- **Perspective of GLP Regulations on Nonclinical Studies Conducted in China for US FDA Submission.** Zhou Chen, US FDA, Silver Spring, MD.


**Pregnancy in the Workplace: Managing Occupational Safety for a Unique Subpopulation**

**Wednesday, March 14, 12:00 Noon to 1:20 PM**

**Chairperson(s):** Linda G. Roberts, Chevron Energy Technology Company, San Ramon, CA, and John M. DeSesso, Exponent, Inc., Alexandria, VA.

**Sponsor:** Occupational and Public Health Specialty Section

**Endorsed by:**
- Ethical, Legal, and Social Issues Specialty Section
- Reproductive and Developmental Toxicology Specialty Section
- Women in Toxicology Special Interest Group

Work site supervisors need to appreciate the physiological changes specific to pregnancy and breastfeeding, and develop processes to communicate reproductive hazards and prevent harmful exposures. Changing workforce demographics, as well as equal employment opportunities, have increased the proportion of reproductive-age women in nontraditional jobs with potential reproductive hazards. There are unique physiological factors important to maintaining a safe worksite during pregnancy. This session will begin with an overview of the physiological changes that occur during pregnancy. A pregnant woman’s body differs dramatically from her nonpregnant state; for instance, the size of her uterus, breasts, volume of distribution, and blood protein-binding change as her body, baby, and placenta mature throughout pregnancy. These changes in physiology may result in situations wherein safe occupational settings that were set for nonpregnant adults are hazardous to pregnant/lactating women and their unborn babies. Physical stressors such as lifting, heat, shift work, and radiation may be unsafe for pregnant women. Occupational exposure limits, typically developed for healthy adults rather than pregnant women, may not be protective and do not provide sufficient guidance for a safe environment to the pregnant worker. Standard job safety analyses should be re-examined; pregnant employees need behavioral and exposure assessments that identify hazardous processes relative to their unique physiological state. Appropriate exposure controls can transform an unsafe situation to one that is acceptable. The session will cover physiological changes during pregnancy and lactation, chemical and nonchemical hazards, exposure control options, occupational exposure limit factors, and risk management options.

- **Pregnancy in the Workplace: Managing Occupational Safety for a Unique Subpopulation.** Linda G. Roberts, Chevron Energy Technology Company, San Ramon, CA.
- **Chemical and Nonchemical Occupational Risks to Reproductive Health.** Anthony R. Scialli, Tetra Tech Sciences, Arlington, VA.
- **Protecting against Workplace Pregnancy Hazards: The Status of Occupational Exposure Limits.** Julia Quint, California Department of Public Health, Richmond, CA.
- **Industrial Hygiene Considerations: Evaluating a Work Site for Reproductive Hazards.** Gayle Hunting, Chevron Energy Technology Company, San Ramon, CA.

**Evolution and Implementation of Combined Chemical Exposure Methods: International Perspectives**

**Wednesday, March 14, 4:30 PM to 5:50 PM**

**Chairperson(s):** Moiz Mumtaz, ATSDR, Atlanta, GA, and Bette Meek, University of Ottawa, Ottawa, Ontario, Canada.

**Sponsor:** Mixture Specialty Section

**Endorsed by:**
- Regulatory and Safety Evaluation Specialty Section
- Risk Assessment Specialty Section

The global risk assessment community, in response to recognition of the importance of the impact of combined exposure to multiple chemicals and other stressors, has been collaborating to coordinate efficient methods development. Important in these efforts is sharing of international expertise and experience gained in individual countries through global planning, strategic research, and coordinated assessment methodology. These efforts are being led by the World Health Organization/International Programme on Chemical Safety (IPCS), the Organization for Economic Cooperation and Development (OECD), and the International Life Sciences Institute (ILSI). The laws passed by United States and other governments have resulted in federal guidance for combined exposures assessment and joint toxicity assessment of multiple environmental contaminants/stressors. WHO and OECD have developed a framework for assessment of combined exposures with an emphasis on the critical content of problem formulation, the role of predictive tools in grouping of chemicals for consideration, and the importance of explicit delineation of uncertainty and sensitivity for tiered exposure assessment. The European Commission has supported the development of a state of art report for the predictive assessment of the toxicity of combined exposures in a regulatory context. ILSI’s Health Environmental Science Institute (HESI) has pursued efforts to study the likelihood of synergism at low dose levels and the application of the threshold of toxicological concern (TTC) in Tier-0 screening approaches. Our expert panel will discuss the evolution of methods, harmonization of efforts of the recent past, and the role of coordinated research in future developments.
Informational Sessions

- **Mixtures Toxicity Assessment: A Public Health Perspective.** Moiz Mumtaz, ATSDR, Atlanta, GA.
- **Evolution of the WHO IPCS Framework on Combined Exposures to Multiple Chemicals.** Bette Meek, University of Ottawa, Ottawa, Ontario, Canada.
- **Global Collaborations to Advance Combined Exposure Assessment: Highlights of ILSI-HESI Projects.** Alan R. Boobis, Imperial College, London, United Kingdom.

**Proposition 65: Twenty-Five Years of Implementing California’s Unique and Far-Reaching Law Regulating Organic and Metallic Carcinogens and Developmental/Reproductive Toxins**

**Wednesday, March 14, 4:30 PM to 5:50 PM**

**Chairperson(s):** Linda G. Roberts, Chevron Energy Technology Company, San Ramon, CA, and George V. Alexeeff, Cal/EPA, Oakland, CA.

**Sponsor:** Ethical, Legal, and Social Issues Specialty Section

**Endorsed by:**
- Metals Specialty Section
- Northern California Regional Chapter
- Reproductive and Developmental Toxicology Specialty Section
- Risk Assessment Specialty Section
- Women in Toxicology Special Interest Group

Proposition 65 requires the Governor to publish, at least annually, a list of chemicals known to the state to cause cancer or reproductive toxicity. Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, was enacted as a ballot initiative in November 1986. The Proposition was intended by its authors to protect California citizens and the State's drinking water sources from chemicals known to cause cancer and birth defects or other reproductive harm, and to inform citizens about exposures to such chemicals. The first list of chemicals was developed in 1987. Since then over 530 chemicals have been listed for cancer, including Cr(VI), nickel, and arsenic compounds and many organic and metallic/metalloid carcinogens, and 300 chemicals have been listed for reproductive toxicity. The statute states that “no person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving a clear and reasonable warning...” The Proposition has resulted in product warnings, reformulations, and the identification of toxic substances in products from candy to jewelry. The law has also resulted in extensive discussions of the nexus between science and the law. The session will discuss this nexus with regard to the law’s implementation and enforcement, its strengths and weaknesses, and its influence on science and toxicology. The session will include business and environmental perspectives on what works and what doesn’t.

- **The Proposition 65 Science Advisory Board.** Joseph R. Landolph Jr., University of Southern California, Los Angeles, CA.
- **Enforcement of Proposition 65.** Susan Fiering, California Attorney General’s Office, Oakland, CA.
- **Examples of the Industry’s Experience with Proposition 65.** Jeffrey B. Margulies, Fulbright & Jaworski L.L.P., Los Angeles, CA.
- **What Works and What Doesn’t—NGO Perspective.** Michael Green, Center for Environmental Health, Oakland, CA.
Education-Career Development Sessions

TUESDAY

Career Alternatives and Transitions: New Challenges and Opportunities in Today’s Job Market for Toxicologists

Tuesday, March 13, 1:30 PM to 4:15 PM

Chairperson(s): Richard D. Storer, Merck Research Laboratories, West Point, PA, and James A. Popp, Stratoxon LLC, Lancaster, PA.

Sponsor:
Career Resource and Development Committee

Endorsed by:
Education Committee
Postdoctoral Assembly

New toxicology graduates have traditionally pursued a diverse spectrum of career opportunities in teaching and research, in industrial or contract toxicology laboratories, or in regulatory agencies and affiliated institutes. Downturns in the global economy, together with a wave of consolidation and downsizing in industry, particularly in the pharmaceutical sector, has created a challenging environment for job seekers. This has compelled new graduates, as well as toxicologists at all phases of their careers, to confront new challenges in securing initial or continuing employment in their area of specialization, consistent with their career goals. This session will explore alternatives available to new graduates as well as to established toxicologists facing career transitions. To begin this important dialogue targeted to new graduates, postdocs, and nontenured faculty, we will examine the challenges facing toxicologists pursuing career paths in research and teaching and will touch on alternative career paths for which the skills developed in completing a doctorate and postdoctoral research in toxicology are transferable. Our panel will review the options and challenges facing the mid- to late-career industry toxicologist confronted with the prospect or actuality of layoffs or early retirement due to corporate downsizing. The focus of the talk will be on the current landscape for toxicology consultants either as independent consultants, employees of established consulting companies, or individuals pooling resources to form new consulting groups. If you are considering transitioning your career in a regulatory agency, a review of the opportunities and challenges for toxicologists will be provided. The final talk will provide insight on the impact of cutbacks in the pharmaceutical industry and trends favoring outsourcing of toxicology testing on career development opportunities in contract research. At the conclusion of the talks, a significant amount of time has been set aside by the panelists to allow time for questions from participants.

- Current Challenges in Pursuit of Careers in Academia. Barbara Kaplan, Michigan State University, East Lansing, MI.
- Career Transition to Toxicology Consulting. James A. Popp, Stratoxon LLC, Lancaster, PA.
- Career Transitions from Industry to Government. Hanan Ghanous, US FDA, Silver Spring, MD.

The Art of Negotiation: A Fundamental Skill for Scientists

Tuesday, March 13, 4:30 PM to 5:50 PM

Chairperson(s): Larissa M. Williams, Woods Hole Oceanographic Institution, Woods Hole, MA, and Ebany J. Martinez-Finley, Vanderbilt School of Medicine, Nashville, TN.

Sponsor:
Postdoctoral Assembly

Endorsed by:
Career Resource and Development Committee
Graduate Student Leadership Committee
Hispanic Organization of Toxicologists Special Interest Group
Women in Toxicology Special Interest Group

Negotiation is an essential skill for scientists of every rank and job sector to navigate their career successfully, yet it is often not part of a scientist’s formal training. Fundamentally, negotiation culminates in the attainment of a mutually acceptable agreement between two or more parties—however there is an art to reaching such an agreement. Because negotiations typically occur behind closed doors, few will ever experience a negotiation until they represent one of the parties involved. In an ever-changing world it has become imperative to understand the nuances of negotiation, and this session offers attendees a unique opportunity to bring negotiations out in the open. This session will introduce scientists to the intricacies of negotiations in the workplace and to discuss idiosyncrasies in negotiation tactics across toxicology sectors. The session will be delivered in two segments: a formal lecture and a panel discussion delivered by speakers from academia, industry, and government. Our panel will deliver important information on the art of negotiation, addressing conflict styles and the basics of interest-based negotiation. The panel will then discuss their personal experiences in negotiation throughout their careers and address best practices in negotiation as it relates to their sector of toxicology. Topics covered will include preparation for negotiating, how to initiate negotiation, importance of body language, gender differences in negotiation, negotiating for salary and start-up in academia, negotiating for labor and represented management at the bargaining table in government, and negotiation practices in the pharmaceutical industry. At the end of the session, participants will come away with a better understanding of how negotiations work and how to use them to their advantage.

- Negotiation: Getting What You Want without Giving In. Ellen Kandell, Alternative Resolutions, LLC, Silver Spring, MD.
Education-Career Development Sessions

• Negotiating within Academia. Robert C. Smart, North Carolina State University, Raleigh, NC.
• Negotiating within Industry: A Perspective from Pharma. Ronald J. Gerson, Gerson Pharma Solutions, LLC, Lincoln University, PA.

WEDNESDAY

Refining Your Science Communication Skills

Wednesday, March 14, 4:30 PM to 5:50 PM

Chairperson(s): Minerva Mercado-Feliciano, NIEHS, Research Triangle Park, NC, and Nancy B. Beck, Office of Management and Budget, Washington, DC.

Sponsor: Communications Committee

Endorsed by: Hispanic Organization of Toxicologists Special Interest Group
Regulatory and Safety Evaluation Specialty Section

Attendee questions during a Science Policy Opportunities Education-Career Development Session at the 2010 SOT Annual Meeting highlighted the importance of effective communication as a key skill needed to succeed in the field of science policy. As scientists progress in their careers and/or transition into the science policy arena or into positions that require interactions with the public sector, effective written and oral communication becomes a vital skill. This session is designed to share information on key aspects and topic areas that are of critical importance when communicating science to fellow scientists and non-scientists alike. We will begin this session by covering the importance of effective communication skills and show students and postdoctoral fellows how to begin building a skill set, thus preparing themselves for careers in science, policy, or public health. From there, tips and advice will be provided on communicating science to the general public, as well as how to communicate science to other scientists—a skill that is often overlooked within academic environments. Rounding out this important information will be delivery of the art of the one-page memo, explaining how to summarize large scientific documents for the benefit of nonscientist decision makers.

All the presentations will underscore the necessity of educating a target audience that needs to understand complex scientific concepts and critical issues regarding impacts on stakeholders—taxpayers, shareholders, etc.—in order to facilitate decision-making, but has limited prior background of the science at hand. Time will be allotted for a robust discussion period, including questions and answers directed at all the speakers.

• The Importance of Science Communication. Timothy P. Pastoor, Syngenta, Research Triangle Park, NC.
• Effective Communication: Tips on Communicating Science to the Public. George M. Gray, George Washington University, Washington, DC.
• Selling Your Science up the Food Chain: Tips on Communicating Your Science to Upper Management. Nigel J. Walker, NIEHS, Research Triangle Park, NC.
• The Art of the One-Pager. Nancy B. Beck, Office of Management and Budget, Washington, DC.
Regional Interest Sessions

MONDAY

Regulatory Science: Bridging the Gap between Discovery and Product Availability

Bridging the Green Chemistry Gap between Product Discovery and Availability

Monday, March 12, 2:00 PM to 4:45 PM

Chairperson(s): Abby Li, Exponent Health Sciences, San Francisco, CA, and Lauren Zeise, Cal/EPA, Berkeley, CA.

Sponsor: Ethical, Legal, and Social Issues Specialty Section

Endorsed by: Northern California Regional Chapter
Occupational and Public Health Specialty Section
Regulatory and Safety Evaluation Specialty Section
Risk Assessment Specialty Section

Recent government and industry initiatives seek to identify chemicals of toxicological concern in products to reduce their use or replace them with safer chemicals. At the same time, sustainable approaches to product manufacture and use that account for energy consumption, product life cycle, and societal benefit are being emphasized. This creates the challenge of developing sound scientific approaches for identifying important chemical hazards and evaluating alternative, safer chemicals or products, all done within the context of risk and benefit trade-offs. Two laws recently passed in California (Chapters 559 and 560, Statutes of 2008) direct the state’s implementation of such green chemistry strategies. The US government, several states and cities, and industry are similarly exploring approaches for alternative analyses that can include hazard, risk, environmental, life cycle, and carbon impact assessments. A primary goal is a rapid and streamlined review and assessment to ensure the availability of safer and more effective products for the consumer and general public, at reduced costs and with minimal environmental impacts. Our panel of regulators and scientists from different sectors will explore approaches that can be used to implement green chemistry goals. It begins with a government perspective on challenges of development and implementation of legislation that will be effective, enforceable, and practical. This session features toxicity methods and case studies for hazard and risk-informed screening strategies utilizing high-throughput data, structure activity, and other toxicity information. It also considers how toxicity assessments can be utilized together with evaluations that account for carbon footprint and other impacts of product manufacture, use, and disposal for green chemistry decision-making. At the conclusion of this session, two experts will lead a panel discussion and provide their expertise in exposure and risk assessment, regulatory policy decision-making, and occupational clinical medicine.

- Weighing Multiple Variables in Improving the Green Profile of Consumer Products. George Daston, Procter & Gamble, Cincinnati, OH.

What’s the Buzz: Bee Health and California’s Agricultural Industry

Tuesday, March 13, 9:00 AM to 11:45 AM

Chairperson(s): Moire Creek, Valent USA Corporation, Walnut Creek, CA, and Karen Steimetz, SRI International, Menlo Park, CA.

Sponsor: Northern California Regional Chapter

There is a significant honey bee health crisis in California and globally that may threaten the future of California’s agricultural industry. Over half of California crops are dependent upon pollinators, including honey bees, with a potentially staggering economic impact approaching tens of billions of dollars. Some colonies collapse from the rapid loss of adult bees with the queen, a handful of bees, and some brood still present in the hive. In the US, this set of symptoms has been called Colony Collapse Disorder, or CCD. This condition is one component of a more general problem of colony losses, which has reached record highs in the past decade. Colony numbers in the US have been declining since the late 1940s because of the declining US have been declining since the late 1940s because of the declining number of beekeepers. This trend continues but is now accelerated because of the challenge of keeping bees healthy and productive. Beekeeper surveys indicate annual colony losses of 30% and more. Multiple stressors, including Varroa and tracheal mites, Nosema, foulbroods diseases, numerous viruses, and small hive beetles, may be present in hives and can explain most of the colony losses. Other potential contributing factors are being investigated as well. Our panel brings together scientists, stakeholders, and regulators to discuss different viewpoints on the complex world of bees and what might be causing the honey bee health crisis. Pesticide testing methodologies and results will also be addressed. We will provide an overview on the current status of bee and colony health and an introduction into
Regional Interest Sessions

The multifactorial issues that affect bee health. This discussion will be followed by a presentation on the potential health threats posed by infectious agents. Next, a State of California representative will outline the steps being taken to protect bee health while balancing the need for agricultural crop protection tools. Finally, the complex approaches to understanding the relationship between pesticide residues and bee health and the logistical challenges of addressing these in a regulatory context will be discussed.

- **The Current State of Honey Bees and Colony Health.** Eric Mussen, University of California Davis, Davis, CA.

- **Temporal Analysis of the Honey Bee Microbiome Reveals Four Novel Viruses and Seasonal Prevalence of Known Viruses, Nosema, and Crithidia.** Joseph DeRisi, Howard Hughes Medical Institute, University of California San Francisco, San Francisco, CA.

- **Pesticide Risk Assessment for Honey Bees—A California Perspective.** Richard Bireley, California Department of Pesticide Regulation, Sacramento, CA.

- **Honey Bee Field Study Design Considerations and Implications for Studies in California.** Dick Rogers, Bayer CropScience, Research Triangle Park, NC.
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**ToxExpo Hours:**

**Monday, March 12**
9:00 AM–4:30 PM

**Tuesday, March 13**
8:30 AM–4:30 PM

**Wednesday, March 14**
8:30 AM–4:30 PM

**ToxExpo Time!**

In addition to the standard Exhibit Hall hours and poster presentation times, one hour of dedicated ToxExpo Time has been allotted in the scientific program for attendees to visit with exhibitors.

ToxExpo Time will take place on Wednesday, March 14, from 1:00 pm–2:00 pm.
# 2012 Exhibitor Listing

### Current 2012 ToxExpo Exhibitors (as of 11/30/11):

- **2012 Annual Meeting Sponsors are indicated by the star.**
- *See complete listing of sponsors on page 128 and Inside Back Cover.*
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**SOT’s 51st Annual Meeting**

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Check the product category listing on www.toxexpo.com

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Exhibitor Hosted Sessions

**MONDAY**

**Development of a Fully Human Monoclonal Antibody for the Treatment of Inflammatory Disease**

*Monday, March 12, 9:15 AM–10:15 AM*

**Presented by:**

*Huntingdon Life Sciences*

Monoclonal antibodies are in development to treat a wide range of diseases. One such therapeutic area is that of inflammatory disease. Performing nonclinical studies to assess the safety of these therapies is a very important aspect of the development program. Studies highlight the need for strong focus upon disease biology.

**Developmental Toxicity Testing of Preventive Vaccines**

*Monday, March 12, 9:15 AM–10:15 AM*

**Presented by:**

*MPI Research*

Vaccination is the primary means of preventing pandemic disease outbreak. The concern for vaccine safety has received increasing attention from the medical community and the public. Toxicity assessments for preventive vaccines can be conducted either in dedicated stand-alone toxicity studies or combination safety/immunogenicity studies with toxicity.

**Safeguarding Rodent Toxicology Study Results—Auditing Animal Biosecurity Programs**

*Monday, March 12, 10:30 AM–11:30 AM*

**Presented by:**

*Harlan Laboratories, Inc.*

Periodic review of an animal biosecurity program will help minimize the chance of a microbial pathogen outbreak and subsequent alteration of study results. After auditing our United States rodent production sites, lessons were learned about the biosecurity auditing process that can help other institutions review their own programs.

**Regulated Laboratory Sciences for Toxicologists**

*Monday, March 12, 10:30 AM–11:30 AM*

**Presented by:**

*Charles River*

Successful GLP-compliant toxicology programs are reliant upon appropriate and well-timed communication. Toxicologists and Study Directors often work with scientists from multiple laboratory-based disciplines. This session is designed to provide a brief overview of Laboratory Sciences and focus on the unique regulatory and logistical requirements of each discipline.

**Juvenile Preclinical Safety Evaluations of Biopharmaceuticals: Combining Data from Repeat Dose General and Pre/Postnatal Toxicology Studies**

*Monday, March 12, 10:30 AM–11:30 AM*

**Presented by:**

*SNBL USA, Ltd.*

To maximize data use and minimize additional animal experiments, preclinical/clinical data may be re-evaluated for pediatric testing proposals. The challenge is identifying relevant data from different studies. This presentation discusses how to determine which data are relevant to the experimental goals with focus on nonhuman primate (NHP) study data.

**Application of Ultrasensitive Immunoassay Technology for Preclinical Toxicity Testing**

*Monday, March 12, 2:15 PM–3:15 PM*

**Presented by:**

*Singulex*

Drug safety and toxicity testing often requires precise monitoring of biomarker response, but analytical methods capable of providing the requisite sensitivity and dynamic range are lacking. The talk presents an ultrasensitive immunoassay technology and how it improves biomarker utility in preclinical/clinical testing.
Preclinical research customized for you.

See you in San Francisco at SOT 2012!

MPI Research is your responsive CRO partner, delivering customized solutions and adaptability to changing needs. We look forward to greeting you at SOT in booth 1105 and discussing how we can help move your drug development projects forward.

Our comprehensive scope of preclinical research includes drug safety evaluation, discovery services and bioanalytical/analytical support. You can count on MPI Research for quick quotes, frequent updates, rapid turnaround, and scientific rigor. At every stage and at every level, we adapt to your most exacting needs.

Explore the breadth of capabilities that make us your responsive CRO at www.MPIResearch.com.

Exhibitor Hosted Sessions

TUESDAY

Development Challenges for Antibody Drug Conjugates (ADCs)

Tuesday, March 13, 8:30 AM–9:30 AM
Presented by:
MPI Research
ADCs combine the targeting potential of mAbs with the pharmacology of small molecules. These are significant challenges in the development of ADCs such as lot variation as well as the need to simultaneously determine safety margins for intact ADC, drug-free mAb, and small molecules that are released in vivo.

Human Induced Pluripotent Stem Cell Technology in Predictive and Mechanism-Based Drug Discovery and Toxicity Testing Using Photometric-Based Assays

Tuesday, March 13, 8:30 AM–9:30 AM
Presented by:
Promega Corporation
Human iPSC-technology and photometric assays provide rapid and predictive assessments of viability/toxicity and ADME properties during drug development. This tutorial will highlight recent developments in human iPSC-derived cell types from CDI and reporter assays from Promega while demonstrating the advantages of these technologies in accurate assessment of drug-induced cellular responses.


Tuesday, March 13, 8:30 AM–9:30 AM
Presented by:
Vet Path Services
This presentation will cover pathology peer review in the industrial, GLP setting, with discussions of who does a peer review, what the peer review achieves, when it is performed, why should a peer review be done, and how a pathologist goes about a peer review. It will highlight current common practices in the current regulatory environment.

Current Strategies for Juvenile Toxicity Testing

Tuesday, March 13, 9:45 AM–10:45 AM
Presented by:
Charles River
Since issuance of the pediatric rule 14 years ago, we have conducted over 300 juvenile toxicity studies in rodent and nonrodent animals for numerous therapeutics (large and small molecule) and chemicals. This seminar will cover what we have learned, current global regulatory expectations, and program designs including species, dose routes, and evaluation.

Experience Results: Lessons Learned Developing New Anticancer Drugs and Biotherapeutics

Tuesday, March 13, 9:45 AM–10:45 AM
Presented by:
Accelera Srl
Case stories from the direct experience of safety assessment for different drug development programs, including some marketed products, are presented with special emphasis on anticancer drugs and biotherapeutics. Challenges, key issues, and lessons learned are described in the context of scientific and regulatory requirements.

Developing a Novel Gene Therapy Product for the Treatment of Rare X-Linked Disease

Tuesday, March 13, 9:45 AM–10:45 AM
Presented by:
Huntingdon Life Sciences
Safety assessment of gene therapy products is a complex business with multiple safety risks. Standard paradigms do not exist and approaches must be designed on a case-by-case basis. A case study will be discussed that highlights considerations for a gene therapy to treat an x-linked disease.

Innovative Models and Techniques for the Investigation of Nanotoxicity

Tuesday, March 13, 11:00 AM–12:00 Noon
Presented by:
Fraunhofer ITEM
The session will focus on the state of the art and future of in vivo inhalation tests, innovative in vitro and ex vivo models as significant tools in inhalation toxicology, and sensitive methods to detect lung damage potentially induced by nanoparticles including carbonanotubes.
Searching for Drug Safety, Efficacy, and Performance: Scientific and Regulatory Perspectives

Tuesday, March 13, 11:00 AM–12:00 Noon
Presented by: PointCross Life Sciences

Nonclinical scientists and regulatory reviewers are increasingly confronted with the need to assess safety, efficacy, and performance of drug candidates across study data, reports, chemical structures, and other artifacts. This session focuses on practical ways to search and navigate disparate information from the perspective of R&D and US FDA reviewers.

ADME Studies in Knockout Rats Lacking Key Drug Transporters

Tuesday, March 13, 12:15 PM–1:15 PM
Presented by: SAGE Labs

Advances in genetic engineering have enabled the generation of targeted knockout rats. We will discuss the technology used to develop Mdr1a, Bcrp, and Mrp2 drug transporter knockouts. Data from these models demonstrate they may serve as more relevant and specific tools for the elucidation of compound efflux and DMPK studies.

Dermal Drug Development

Tuesday, March 13, 12:15 PM–1:15 PM
Presented by: CiToxLAB

The session will present the toxicology studies to support the development of a dermal drug, covering early screening assays, IND-enabling package, and full development. In addition, the session will cover the skin histology in laboratory animals and issues relating to broken skin and wound healing.

New Capabilities of Noninvasive Telemetry Used for Cardiovascular Respiration and CNS Assessments

Tuesday, March 13, 1:30 PM–2:30 PM
Presented by: emka TECHNOLOGIES INC.

The presentation will explain how the new features of emka TECHNOLOGIES’ latest generation of noninvasive telemetry and associated software allow for a significant increase in power and efficiency of preclinical investigations. The focus will be on blood pressure and respiration analysis, subject-specific QT correction and arrhythmia detection, and EEG signal collection and use in sleep or epilepsy studies.

The Key Role of Experience in Toxicological Study Design and Data Interpretation

Tuesday, March 13, 1:30 PM–2:30 PM
Presented by: RTC, Research Toxicology Centre S.p.A.

RTC senior science experts in different areas of toxicology will share some special cases for which practical experience played an important role during preclinical development. In fact, for an effective translational approach, it is important to define appropriate study designs and apply a critical interpretation of equivocal results.

Utility of Primary Stem Cell Colony Assays in Drug Development

Tuesday, March 13, 1:30 PM–2:30 PM
Presented by: STEMCELL Technologies, Inc.

A potential side effect of anticancer and some novel inhibitor drugs is damage to stem cells, including those of the hematopoietic (blood) system. Impairment of proliferation and differentiation can result in neutropenia, anemia, or thrombocytopenia. This talk outlines the value of hematopoietic in vitro clonogenic assays for prediction of hematotoxicity.
Exhibitor Hosted Sessions

**WEDNESDAY**

**Toxicokinetic Evaluation in the Virtual Animal**

Wednesday, March 14, 8:30 AM–9:30 AM

Presented by:
MPI Research

Routinely generated *in vitro* ADME data can be used as prior knowledge to develop PBPK models in virtual animals (rat, dog, mouse) using the Simcyp Simulator. Optimisation of toxicokinetic/safety pharmacology studies can be undertaken focusing upon systemic xenobiotic concentrations rather than dose alone and reducing the need for iterative *in vivo*.

**Beyond Antibodies: Characterization of the Cellular Immune Response to Keyhole Limpet**

Wednesday, March 14, 9:45 AM–10:45 AM

Presented by:
Charles River

Production of antigen-specific antibodies is the principal readout in the T-cell dependent antibody response (TDAR) assay. However, generation of specific antibodies requires participation of antigen-presenting cells, T and B lymphocytes. Given that this has not been well characterized, we will provide an overview of what is known about the cell mediated immune response in the TDAR.

**Predicting Safety, Prophylactic and Therapeutic Efficacy in an African Green Monkey RSV Model Dosed via Continuous Infusion**

Wednesday, March 14, 9:45 AM–10:45 AM

Presented by:
Huntingdon Life Sciences

RSV is an important unmet medical need in newborns. The development of an intravenous anti-RSV drug from target selection through proof of concept in the African Green Monkey RSV model is discussed. The development program start was impacted by surgical issues, which were successfully mitigated by an HLS surgical team.

**Nanotechnology: US-EU Cooperative Research Opportunities**

Wednesday, March 14, 2:45 PM–3:45 PM

Presented by:
US EPA

In March, US National Nanotechnology Initiative Agencies and the European Commission held a joint Workshop to promote cooperation in environmental, health, and safety research ([http://us-eu.org](http://us-eu.org)). This session will summarize US and EU Nanotechnology research programs, and seek to establish US-EU Communities of Research in defined areas.
Deadline for Proposals for SOT 2013 Annual Meeting Sessions: April 30, 2012

Why Submit a Proposal?

1. To present new developments in toxicology.
2. To provide attendees an opportunity to learn about state-of-the-art technology and how it applies to toxicological research.
3. To provide attendees an opportunity to learn about the emerging fields and how they apply to toxicology.

2013 Thematic Approach

The Scientific Program Committee will continue the thematic approach for the 2013 Annual Meeting. Additional details regarding the themes will be available on the SOT website.

Please note that while we are actively soliciting proposals for the themes, all proposal submissions will be reviewed for their timeliness and relevance to the field of toxicology.

Session Types

**Continuing Education**—Emphasis on quality presentations of generally accepted, established knowledge in toxicology

*Note: CE Courses will be held on Sunday.*

**Symposia**—Cutting-edge science; new areas, concepts, or data

**Workshops**—State-of-the-art knowledge in toxicology

**Roundtables**—Controversial subjects

**Historical Highlights**—Review of a historical body of science that has impacted toxicology

**Informational Sessions**—Scientific planning or membership development

**Education-Career Development Sessions**—Sessions that provide the tools and resources to toxicologists that will enhance their professional and scientific development

**Regional Interest**—Central topics of relevance that describe public health and/or ecological problems of a particular region

Submit your proposal online at [www.toxicology.org](http://www.toxicology.org)
Sponsorship Opportunities

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