The FSC is an independent nonprofit organization established to promote the responsible management of the world's forests. All papers used in this publication are FSC-certified and contain recycled postconsumer waste. The use of this recycled paper is consistent with SOT's mission.
Dear Colleagues:

I cordially invite you to attend SOT’s 52nd Annual Meeting, March 10–14, 2013, at the Henry B. Gonzalez Convention Center in San Antonio, Texas. 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 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 52nd Annual Meeting an event to remember.

Sincerely,

William Slikker Jr., PhD, ATS
2012–2013 SOT President
Scan these QR (Quick Response) codes with your smartphone or mobile device to access the information or service directly. The codes can be decoded by most camera-equipped smartphones or devices with a free downloadable application or reader, thereby offering a direct link to the latest and greatest SOT Annual Meeting information and services on the Internet. Access the latest meeting information at www.toxicology.org/2013.

This year we are happy to announce we are leveraging the services of QuickMobile to provide you, our guests, with a mobile event app. This app offers you multiplatform mobile solutions for the SOT Annual Meeting and ToxExpo, provided free of charge to attendees and exhibitors. The mobile event app will be available late January via the SOT website and app market places. Attendees also can access the website version of the app to access meeting resources and plan their schedule.
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 52nd Annual Meeting to be held from March 10–14, 2013, at the Henry B. Gonzalez Convention Center in San Antonio, Texas.

As always, it is our goal to construct a program that reflects the best science as well as the breadth of interests across the SOT membership. We believe that the 2013 Symposia, Roundtables, Workshops, and other special sessions are timely and highly informative and span a broad spectrum of topics to meet the diversity of our membership.

We are very pleased to confirm the participation of Dr. Bruce Beutler as the Plenary Opening Lecturer. Dr. Beutler, currently Director of the Center for the Genetics of Host Defense at the University of Texas Southwestern Medical Center in Dallas, was one of the recipients of the 2011 Nobel Prize in Physiology or Medicine. He has been recognized for his pioneering work in identifying tumor necrosis factor as a key factor in the inflammatory response, the identification of toll-like receptor 4 (TLR) as the cellular receptor for bacterial lipopolysaccharide and deciphering the signaling pathways activated by TLRs. Collectively, this research has been seminal to understanding the molecular regulation of inflammation and innate immunity, and is highly relevant to toxicology. We look forward to a stimulating scientific Plenary Lecture to open the meeting.

In addition to the diverse scientific sessions, the meeting will feature lectures from the recipients of distinguished Society Awards. These include the Merit and Distinguished Toxicology Scholar Awards reflecting sustained contributions in toxicology, along with the Leading Edge in Basic Science Award which will highlight significant contributions that impact toxicology and contribute to enhancing human health. Although a busy scientific program, this year’s program has been organized to dedicate some time for networking with colleagues, an important adjunct to the outstanding scientific content of the meeting.

We are very excited about our first meeting held in San Antonio, a city filled with culturally-significant art, history, museums, and food. The convention center is conveniently located near the River Walk, a vibrant public park that features a network of walkways along the banks of the San Antonio River. It is lined by shops, restaurants and bars providing a great opportunity for postsession networking or just relaxing after a long day. And of course, while in San Antonio, don’t miss the Alamo, the most frequently visited attraction in Texas.

In addition to the 2,500+ abstracts to be presented during the Annual Meeting, interested participants are welcome to submit late-breaking abstracts from December 12, 2012, through January 20, 2013. Abstracts accepted during this final submission phase will be programmed into poster sessions that will be presented on Thursday, March 14, and will not be included in the printed copy of The Toxicologist. Late-breaking abstracts should be submitted online at www.toxicology.org.

We look forward to welcoming you to San Antonio, Texas.

Warmest regards,

Lois D. Lehman-McKeeman, PhD, ATS
SOT Vice President and
Scientific Program Committee Chairperson, 2012–2013

1821 Michael Faraday Drive, Suite 300, Reston, Virginia 20190
Tel: 703.438.3115 Fax: 703.438.3113 Email: sothq@toxicology.org Website: www.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 Henry B. Gonzalez Convention Center.

Please see details on page 16.
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

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Program Overview</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>
</tr>
<tr>
<td>Thematic Session Index</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 52nd Annual Meeting the Society will highlight 54 Thematic Sessions and CE courses.</td>
</tr>
<tr>
<td>Special Events</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 52nd 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>
</tr>
<tr>
<td>Continuing Education Courses</td>
<td>These pages list the 2013 CE course descriptions and presenter information. These courses have separate registration fees. Each participant in a CE course will receive a copy of the course booklet. These are available for sale to noncourse registrants on-site at the meeting, while supplies last.</td>
</tr>
<tr>
<td>Featured Sessions</td>
<td>This section lists the Keynote and other special lectures and sessions for the 2013 Annual Meeting. Detailed information for these sessions will be available in the final Program.</td>
</tr>
<tr>
<td>Scientific Sessions</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, Historical Highlight, Informational, Education-Career Development, and finally the Regional Interest sessions.</td>
</tr>
<tr>
<td>Exhibits</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/Sponsor-Hosted sessions.</td>
</tr>
</tbody>
</table>

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 101).

Exhibitor/Sponsor-Hosted Sessions (60 minutes) — Informative sessions developed by an exhibiting company (page 110).

Featured Sessions (50–165 minutes) — Keynote and other special lectures (page 63).

Historical Highlight Sessions (80 minutes) — Sessions that provide a review of a historical body of science that has impacted toxicology (page 97).

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 98).

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 104).

Roundtable Sessions (80 minutes) — These provide an overview of controversial subjects, followed by questions and discussion (page 94).

Symposium Sessions (165 minutes) — Cutting-edge science, emphasizing new areas, concepts, and data (page 68).

Thematic Sessions (45–225 minutes) — Timely topics of relevance to toxicology (check the specific session type).

Workshop Sessions (165 minutes) — Generally accepted, state-of-the-art knowledge in toxicology in informal interactive presentations with ample time for discussion (page 80).

*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 event app or the online event website to plan your schedule to make the most of your time at the Annual Meeting (available in January). See pages 26 and 35 for more details.
Recent technological advances allow the study of multiple interacting networks in cellular application of genomics, proteomics, metabolomics, computational modeling, and bioinformatics to cell-specific and organ-specific toxicity, as well as to broader questions in toxicology continues to develop. Application of these technologies will provide for systems to improve predictive toxicity tools, enable more complete understanding of the mechanisms underlying the toxicity of pharmaceutical agents and environmental chemicals, and facilitate the interrogation of disease etiology and prevention.

The development of biomarkers that can be applied to assessing exposure, predicting toxicity, defining mechanisms of toxicity and improving translation of preclinical and clinical toxicity has impacted how toxicology research is carried out. Developing the basic biology and analytical tools to support biomarker identification, development, and validation is critical to the successful incorporation of biomarkers in all areas of toxicology research.

Research in the toxicology of nanomaterials has expanded along with the application of this technology in material science research and development. Factors that influence the potential for toxic responses and identification of relevant target organs for exposure and toxicity are critical to the development of cogent and reliable risk assessment for these materials. Basic, applied, and regulatory science must converge in order to address the needs for this class of materials that will advance understanding of potential impacts on human and environmental health.

Many toxicants alter gene expression and many types of toxicities can be affected by variation in gene expression or genetic polymorphisms. Similarly, age-dependent gene expression can influence toxic responses and epigenetic perturbations influences heritable gene expression. Both genetic and epigenetic differences can influence the individual’s response to pharmaceuticals and environmental chemicals. It is recognized that single nucleotide polymorphisms that directly affect genetic differences on rates of metabolism, but for other responses, such as behavior, the connections are more complex. Linking genetic and environmental variables with exposure data is essential to accurately define potential beneficial or adverse effects of chemicals and to assess disease susceptibility and prevention.

Regulatory science encompasses the science(s) used to evaluate the safety, efficacy, quality, and performance of any product. Advancements in regulatory science will facilitate the development and evaluation of innovative new products. As we modernize the tools used to assess the potential risks from drugs, environmental chemicals, food and other products, we must also consider the global applications of such methods and strategies to drive better risk assessment decisions. This theme is intended to foster session content that will provide for perspective on ongoing efforts to improve hazard identification and risk assessment with emphasis on how best to coordinate these efforts for more consistent regulatory practices around the world.
Monday, March 11

8:00 AM to 9:00 AM

PLENARY OPENING LECTURE

Genetic Analysis of Innate Immune Sensing
Lecturer: Bruce Beutler, University of Texas Southwestern Medical Center

9:15 AM to 12:00 Noon

SYMPOSIUM SESSIONS

- Genetic and Epigenetic Determinants of Susceptibility to Environmental and Occupational Toxicants
- Predictive Toxicology Paradigms for Understanding Carbon Nanotube Toxicity in the Lung
- Translatable Indicators of Testicular Toxicity: Inhibin B, microRNAs, and Sperm Signatures

WORKSHOP SESSIONS

- Biology of Low-Dose Response for DNA-Reactive Chemicals
- Incorporation of Exposure Data and Chemical Properties into Early In Vitro Screening Studies: Putting Early Hazard Identification into Appropriate Context
- Inhaled Mixtures: A Mode-of-Action Framework Applied to the Criteria Air Pollutants

REGIONAL INTEREST SESSION

- Toxicological Challenges in Food Production in Texas and the Gulf Coast

PLATFORM SESSIONS

- Advances in Neurobehavioral and Neuropathology Assessment of Chemicals
- Inhalants and Metabolic Disorders

9:30 AM to 12:30 PM

POSTER SESSIONS

- Bioinformatics and Computational Toxicology: Systems and Strategies
- Biotransformation/Cytochrome P450
- Carcinogenesis
- Cardiovascular Toxicity: Telemetry and In Vitro Systems
- Chemical and Biological Weapons
- Developmental Toxicity—Nonmammalian
- Ecotoxicology
- Endocrine Disruptor Screening
- Inflammation and Disease
- Inhalants and Cardiopulmonary
- Medical Devices
- Pharmacogenomics/Genetic Polymorphisms

12:10 PM to 1:30 PM

ROUNDTABLE SESSIONS

- A Decade of Nanotoxicology: Where Do We Stand Now?
- Predicting Human Thorough QT (TQT) Study Outcomes with Nonclinical Data—How Good Are We and How Good Do We Need to Be?

HISTORICAL HIGHLIGHT SESSION

- Diesel and Gasoline Exhaust and Cancer

EDUCATION-CAREER DEVELOPMENT SESSION

- From New Submissions to Competitive Renewals: Different Phases of Grant Writing

12:30 PM to 1:20 PM

MERIT AWARD LECTURE

Lecturer: Frederick Peter Guengerich, Vanderbilt University Medical Center

1:00 PM to 3:30 PM

SPECIAL SYMPOSIUM

Meet the Directors

1:00 PM to 4:30 PM

POSTER SESSIONS

- Animal Models of Disease
- Animal Models—Measurements and Validation
- Biological Modeling: Target Tissues and Toxicants
- Chemical Mixtures
- Epidemiology: Exposures and Associations
- Epigenetics
- Gene Expression and Signal Transduction
- Immunotoxicity
- Liver
- Nanotoxicology—Carbonaceous Materials
- Pesticide Toxicology
- Pharmacokinetics and Disposition
- Risk Assessment I: Advances in Approaches and Technologies
- Systems Biology and Toxicology

2:00 PM to 4:45 PM

SYMPOSIUM SESSIONS

- Human Health and Environmental Concerns around Natural Gas Production Using Hydraulic Fracturing
- Role of Metabolic Syndrome and Perivascular Adipose in Exposure-Induced Vascular Dysfunction
- Environmental Factors in Neurodegenerative Diseases
- Life-Course Models for Ensuring Children’s Health Protection
- NanoInformatics: Computational Challenges for Nanomaterial Hazard Assessment
- Scientific and Regulatory Advances in Genetic Toxicology Safety Assessment

WORKSHOP SESSIONS

- Biomonitoring: Emerging Markers and Methods
- Mode of Action and Human Relevance of Rodent Tumors
- Toxicity of Nanoparticles—Cerium Oxide

4:45 PM to 6:00 PM

SOT/EUROTOX DEBATE

In the Near Foreseeable Future, Much of Toxicity Testing Can Be Replaced by Computational Approaches

(continued on next page)

View featured speaker bios, connect with other attendees, and create your own schedule using the new event mobile app or the event website—available from the SOT website in January.
Tuesday, March 12

8:00 AM to 8:50 AM
LEADING EDGE IN BASIC SCIENCE AWARD LECTURE

Lecturer: Donald Ingber, Harvard University

9:00 AM to 11:45 AM
SPECIAL SYMPOSIUM

Frontiers for Toxicology Session: Systems and Computational Biology As Foundations for Toxicology Research

SYMPOSIUM SESSIONS

• From Inhaled Particles to Cardiovascular Disease and Toxicity: Evidence from Studies in Volunteers, Experimental Animals, and Cell-Based Systems
• The Dynamics of Neuroinflammation and Inflammatory Cell Responses in Neurologic Disease

WORKSHOP SESSIONS

• Advances in Carcinogenic Risk Assessment of Low-Level Genotoxic Impurities in Pharmaceuticals
• Health Risks of Sodium (Salt) Intake: Too Much or Too Little!
• Unique Challenges in Biologic Drug Development: Separating Mechanism of Action from Mechanism of Toxicity

POSTER SESSIONS

• Alternative Models—Eye and Skin
• Biomarkers I: Preclinical and Translational Approaches
• Carcinogenesis: Models and Mechanisms
• Cardiovascular Toxicity and Hemodynamics
• Computational Toxicology: Liver and Life Stage Characterizations
• Data Integration and Decision Support: Databases, Tools, and Ontologies
• Developmental Basis of Adult Disease
• Developmental Toxicity
• Liver and Model Systems
• Metals I
• Neurotoxicology: General
• Skin

9:30 AM to 4:30 PM
RESEARCH FUNDING SESSION

Research Funding Information Room

12:00 Noon to 1:30 PM
RESEARCH FUNDING SESSION

Brown Bag Luncheon

12:30 PM to 1:30 PM
TOXEXPO TIME

1:00 PM to 4:30 PM
POSTER SESSIONS

• Alternative High-Throughput Models I
• Autoimmunity and Hypersensitivity
• Developmental Neurotoxicity
• Exposure Assessment: New Characterizations, Methods, and Models
• Genotoxicity Testing
• Metals II
• Nanotoxicology—Silver and Gold
• Natural Products—In Vivo Safety Assessment
• Neurotoxicology: Pesticides
• Pharmaceutical Safety Assessment: Drug Development II
• Receptor-Mediated Toxicity
• Regulatory Policy: Programs and Approaches
• Safety Assessment: Nonpharmaceuticals
• Stems Cells: Emerging Applications in Toxicology

1:30 PM to 4:15 PM
SYMPOSIUM SESSIONS

• Application of Systems Biology to Identify Molecular Mechanisms and Biomarkers of Lead (Pb) Neurotoxicity: Implications in a Developmental Origin of Alzheimer’s Disease
• Bone As a Target Tissue for Environmental Toxicants
• Nonmonotonic Dose-Response Curves and Endocrine-Disrupting Chemicals: Fact or Falderal?
• Understanding Toxicities of Abnormal Lipid Metabolism: Alcoholic, Nonalcoholic, and Toxicant-Induced Fatty Liver Disease

WORKSHOP SESSIONS

• “Air”-ing on the Side of Caution: Anticipating Impacts of Emerging Issues in the Health Effects of Air Pollution
• Breaking the Routine: Is There Room for Modern Techniques of Neuropathology Assessment in Routine Preclinical Safety Studies?
• Drug Safety Assessment and Regulatory Landscape in Emerging Markets

PLATFORM SESSION

• Bioinformatics: Pathways, Profiles, and Predictions

4:30 PM to 5:50 PM
EDUCATION-CAREER DEVELOPMENT SESSION

• The Symbiosis of Mentoring: Getting the Most out of the Mentor-Mentee Relationship

4:30 PM to 6:00 PM
SOT ANNUAL BUSINESS MEETING

Wednesday, March 13

8:00 AM to 9:00 AM
KEYNOTE MEDICAL RESEARCH COUNCIL (MRC) LECTURE

Phenotyping the Patient Journey: Making Systems Medicine Work in the Real World

Lecturer: Jeremy K. Nicholson, Imperial College London

9:00 AM to 11:45 AM
SYMPOSIUM SESSION

• Role of Systems Biology in Characterizing Risk of Developmental Origins of Disease
• Toxicopigenomics, Disease Susceptibility, and Implications for Risk Assessment

WORKSHOP SESSIONS

• Dietary Arsenic—Forms, Hazards, and Risks
• Pulmonomics, the Exposome, and Microbiomes in Immunotoxicology
• The Placenta in Toxicology: Target or Travel Agent?

INFORMATIONAL SESSIONS

• K-12 Toxicology Outreach Activities: Regional Chapter Successes and Resources
• The Regulatory Framework for Cosmetics: Current Status, Recent Science, and Future Prospects

PLATFORM SESSION

• Validation and Application of Neurotoxicology In Vitro Methods
9:00 AM to 12:30 PM
POSTER SESSIONS

- Biomarkers II: Preclinical and Translational Approaches
- Cell Death/Apoptosis
- Children’s Health and Juvenile Toxicity
- Endocrine Toxicology
- Genetic Toxicology and DNA Repair
- Manganese, Parkinson’s, and Other Neurodegenerative Diseases
- Nanotoxicology—In Vitro
- Natural Products—In Vitro
- Oxidative Injury and Redox Biology
- Persistent Organic Pollutants
- Pharmaceutical Safety Assessment: Drug Development I
- Risk Assessment II: Critical Considerations and Characterizations

9:30 AM to 4:30 PM
RESEARCH FUNDING SESSION

Research Funding Information Room

12:00 Noon to 1:20 PM
ROUNDTABLE SESSION

- Skeptically Examining the Limits of Toxicology Evidence in the Courtroom

9:00 AM to 11:45 AM
SYMPOSIUM SESSIONS

- Biomarkers of Disease and Toxicity: Exploiting the Interconnections
- Mechanistic Role(s) of Cytochrome(s) P450 in Oxidative Stress and Inflammation: New Opportunities for Drug Discovery
- Molecular Basis of Age-Related Susceptibility to Chemicals and Environmental Hazards: From Model Systems to Humans

1:30 PM to 4:15 PM
SYMPOSIUM SESSIONS

- Challenging the Limits of Nonclinical Safety Assessment of Pediatric Medicines
- Nanotoxicology: Computational Strategies, Advances, and Challenges
- Toxicogenomics in Risk and Safety Assessment: Recent Advances and Continuing Challenges

1:00 PM to 4:30 PM
POSTER SESSIONS

- Alternative High-Throughput Models II
- Arsenic
- Clinical and Translational Toxicology
- Food Safety and Nutrition
- Immunotoxicity Methods
- Immunotoxicity—Biochemical/Molecular
- Inflammation: Methods and Mechanisms
- Kidney
- Male Reproductive Toxicology
- Metal Neurotoxicity: Methylmercury, Lead, Aluminum, and Iron
- Nanotoxicology—In Vivo
- Pharmaceutical Safety Assessment: Drug Discovery
- Reproductive Toxicity
- Risk Assessment III: New Derivations and Updated Estimates
- Toxicology Education

4:30 PM to 5:50 PM
ROUNDTABLE SESSION

- Nonhuman Primate Sexual Maturity: What Is the Capacity to Endure Uncertainty?

9:00 AM to 11:45 AM
SYMPOSIUM SESSIONS

- From Immunotoxicity to Nanotherapy: The Effects of Nanomaterials on the Immune System
- Modeling Human Genetic Variability and Susceptibility in the Laboratory
- Role of Air Pollution As a Risk Factor for Central Nervous System Diseases and Disorders
- Translational Methods to Assess the Safety of Natural Health Products, Including Traditional Medicines and Dietary Supplements

12:30 PM to 1:20 PM
DISTINGUISHED TOXICOLOGY SCHOLAR AWARD LECTURE

Lecturer: John J. LeMasters, Medical University of South Carolina

1:30 PM to 4:15 PM
SYMPOSIUM SESSIONS

- Assessment of Environmental, Dietary, and Biological Risk Factors Impacting Liver Cancer Incidence in Texas

12:30 PM to 1:20 PM
DISTINGUISHED TOXICOLOGY SCHOLAR AWARD LECTURE

Lecturer: John J. LeMasters, Medical University of South Carolina

1:30 PM to 4:15 PM
SYMPOSIUM SESSIONS

- New and Integrated Approaches for Genetic Toxicity Evaluation
- New Insights into Organophosphate-Induced Neurotoxicity: Pathology, Mode of Action, Modulation, and Protection
- Risk Analysis: Refining Predictions and Systematic Approaches

LATE-BREAKING INFORMATIONAL SESSION

- Exposure Science in the 21st Century: Perspectives from the NAS and What It Means for Toxicology

EDUCATION-CAREER DEVELOPMENT SESSION

- Toxicological Writing for Industrial and Regulatory Audiences

Thursday, March 14

8:30 AM to 12:00 Noon
POSTER SESSIONS

- Late-Breaking Poster Session
  See page 67 for submission information.

9:00 AM to 11:45 AM
SYMPOSIUM SESSIONS

- Are We Like Rodents, Rabbits, or Something Else? Mechanisms of Developmental and Reproductive Toxicity across Species
- Cumulative Risk: Toxicity and Interactions of Physical and Chemical Stressors
- Mechanistic, Occupational, and Clinical Aspects of Lead Exposure
- Ocular Medical Devices and Ocular Drug Delivery Systems: Challenges and Opportunities

up-to-date information at www.toxicology.org
Application of Systems Biology to Toxicology
Recent technological advances allow the study of multiple interacting networks in cellular application of genomics, proteomics, metabolomics, computational modeling, and bioinformatics to cell-specific and organ-specific toxicity, as well as to broader questions in toxicology continues to develop. Application of these technologies will provide for systems to improve predictive toxicity tools, enable more complete understanding of the mechanisms underlying the toxicity of pharmaceutical agents and environmental chemicals, and facilitate the interrogation of disease etiology and prevention.

- Application of Systems Biology to Identify Molecular Mechanisms and Biomarkers of Lead (Pb) Neurotoxicity: Implications in a Developmental Origin of Alzheimer’s Disease—Symposium Session
- Role of Systems Biology in Characterizing Risk of Developmental Origins of Disease—Symposium Session
- Systems and Computational Biology As Foundations for Toxicology Research—Symposium Session
- T4: Tools and Technologies in Translational Toxicology—Continuing Education Course (PM11)
- Toxicogenomics in Risk and Safety Assessment: Recent Advances and Continuing Challenges—Workshop Session

Biomarkers for Exposure Assessment, Safety Evaluation, and Translational Medicine
The development of biomarkers that can be applied to assessing exposure, predicting toxicity, defining mechanisms of toxicity and improving translation of preclinical and clinical toxicity has impacted how toxicology research is carried out. Developing the basic biology and analytical tools to support biomarker identification, development, and validation is critical to the successful incorporation of biomarkers in all areas of toxicology research.

- A Refresher of Immunoglobulin and Fc-Receptor Biology and Advances Related to Therapeutic Antibody Development—Continuing Education Course (SR01)
- Biomarkers II: Preclinical and Translational Approaches—Poster Session
- Biomarkers of Disease and Toxicity: Exploiting the Interconnections—Symposium Session
- Chemical and Biological Weapons—Poster Session
- Children’s Health and Juvenile Toxicity—Poster Session
- Clinical and Translational Toxicology—Poster Session
- From Inhaled Particles to Cardiovascular Disease and Toxicity: Evidence from Studies in Volunteers, Experimental Animals, and Cell-Based Systems—Symposium Session
- Mechanistic, Occupational, and Clinical Aspects of Lead Exposure—Workshop Session
- Predicting Human Thorough QT (TQT) Study Outcomes with Nonclinical Data—How Good Are We and How Good Do We Need to Be?—Roundtable Session
- Pulmonomics, the Exosome, and Microbiomes in Immunotoxicology—Workshop Session
- Translatable Indicators of Testicular Toxicity: Inhibin B, microRNAs, and Sperm Signatures—Symposium Session
- Understanding Toxic Neuropathy in Drug Development: Both Clinical and Nonclinical Perspectives—Continuing Education Course (PM12)

Effects of Nanomaterials on Biological Systems
Research in the toxicology of nanomaterials has expanded along with the application of this technology in material science research and development. Factors that influence the potential for toxic responses and identification of relevant target organs for exposure and toxicity are critical to the development of cogent and reliable risk assessment for these materials. Basic, applied, and regulatory science must converge in order to address the needs for this class of materials that will advance understanding of potential impacts on human and environmental health.

- A Decade of Nanotoxicology: Where Do We Stand Now?—Roundtable Session
- Advances in Nanotoxicology—Challenges—Continuing Education Course (PM06)
- From Immunotoxicity to Nanotherapy: The Effects of Nanomaterials on the Immune System—Symposium Session
- Nanoinformatics: Computational Challenges for Nanomaterial Hazard Assessment—Workshop Session
- Nanotoxicology: Computational Strategies, Advances, and Challenges—Workshop Session
- Predictive Toxicology Paradigms for Understanding Carbon Nanotube Toxicity in the Lung—Symposium Session
- Regulatory-Based Nanotoxicology: Evolving National Strategies, and Research to Address Engineered Nanomaterial Health Risk Assessments—Informational Session

The 2013 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.
Molecular Basis for Genetic Variability and Susceptibility to Toxicants

Many toxicants alter gene expression and many types of toxicities can be affected by variation in gene expression or genetic polymorphisms. Similarly, age-dependent gene expression can influence toxic responses and epigenetic perturbations influences heritable gene expression. Both genetic and epigenetic differences can influence the individual’s response to pharmaceuticals and environmental chemicals. It is recognized that single nucleotide polymorphisms that directly affect genetic differences on rates of metabolism, but for other responses, such as behavior, the connections are more complex. Linking genetic and environmental variables with exposure data is essential to accurately define potential beneficial or adverse effects of chemicals and to assess disease susceptibility and prevention.

- Genetic and Epigenetic Determinants of Susceptibility to Environmental and Occupational Toxicants—Symposium Session
- Modeling Human Genetic Variability and Susceptibility in the Laboratory—Symposium Session
- Molecular Basis of Age-Related Susceptibility to Chemicals and Environmental Hazards: From Model Systems to Humans—Symposium Session
- Role of Air Pollution As a Risk Factor for Central Nervous System Diseases and Disorders—Symposium Session
- Role of Metabolic Syndrome and Perivascular Adipose in Exposure-Induced Vascular Dysfunction—Symposium Session
- The Dynamics of Neuroinflammation and Inflammatory Cell Responses in Neurologic Disease—Symposium Session
- Toxicopigenomics, Disease Susceptibility, and Implications for Risk Assessment—Symposium Session
- Understanding Toxicities of Abnormal Lipid Metabolism: Alcoholic, Nonalcoholic, and Toxicant-Induced Fatty Liver Disease—Symposium Session
- Weighing in on Nutrition—Essential Concepts for Toxicologists—Continuing Education Course (PM13)

Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment

Regulatory science encompasses the science(s) used to evaluate the safety, efficacy, quality, and performance of any product. Advancements in regulatory science will facilitate the development and evaluation of innovative new products. As we modernize the tools used to assess the potential risks from drugs, environmental chemicals, food and other products, we must also consider the global applications of such methods and strategies to drive better risk assessment decisions. This theme is intended to foster session content that will provide for perspective on ongoing efforts to improve hazard identification and risk assessment with emphasis on how best to coordinate these efforts for more consistent regulatory practices around the world.

- "Air"-ing on the Side of Caution: Anticipating Impacts of Emerging Issues in the Health Effects of Air Pollution—Workshop Session
- Advances in Carcinogenic Risk Assessment of Low-Level Genotoxic Impurities in Pharmaceuticals—Workshop Session
- Approval of Biosimilar Monoclonal Antibodies: Scientific, Regulatory, and Legal Challenges—Continuing Education Course (AM04)
- Are We Like Rodents, Rabbits, or Something Else? Mechanisms of Developmental and Reproductive Toxicity across Species—Workshop Session
- Basic Principles of Human Risk Assessment—Continuing Education Course (AM02)
- Breaking the Routine: Is There Room for Modern Techniques of Neuropathology Assessment in Routine Preclinical Safety Studies?—Workshop Session
- Challenging the Limits of Nonclinical Safety Assessment of Pediatric Medicines—Workshop Session
- Cumulative Risk: Toxicity and Interactions of Physical and Chemical Stressors—Workshop Session
- Drug Safety Assessment and Regulatory Landscape in Emerging Markets—Workshop Session
- Harnessing Electronic Standards and Informatics to Transform the Use of Regulatory Toxicological Data—Informational Session
- Incorporation of Exposure Data and Chemical Properties into Early In Vitro Screening Studies: Putting Early Hazard Identification into Appropriate Context—Workshop Session
- Nonmonotonic Dose-Response Curves and Endocrine-Disrupting Chemicals: Fact or Falderal?—Symposium Session
- Regulatory Science and Risk Assessment: Lessons for Early-Career Scientists on What to Expect and How to Pursue this Career Path—Education-Career Development Session
- Scientific and Regulatory Advances in Genetic Toxicology Safety Assessment—Workshop Session
- Stem Cells: Emerging Applications in Toxicology—Poster Session
- The REACH Regulation and Safety Assessment Approaches for Chemicals That Come in Contact with the Skin—Continuing Education Course (PM10)
- The Regulatory Framework for Cosmetics: Current Status, Recent Science, and Future Prospects—Informational Session
- The What, When, and How of Nonclinical Support for an IND Submission—Continuing Education Course (AM05)
- Toxic Effects of Metals—Continuing Education Course (AM07)

Use the new event mobile app or the event website to plan your schedule using the thematic track option. Navigating sessions for each theme is easy and convenient within this new planning tool.

up-to-date information at www.toxicology.org
<table>
<thead>
<tr>
<th>Company</th>
<th>Location</th>
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<tr>
<td>Abbott Laboratories</td>
<td>Abbott Park, Illinois</td>
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<td>Alcon Research Ltd.</td>
<td>Fort Worth, Texas</td>
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<td>American Chemistry Council</td>
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<td>Pomezia, Italy</td>
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<td>Sanofi</td>
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<td>Sequani, Ltd.</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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<tr>
<td>WIL Research</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

You are cordially invited to attend the Society of Toxicology’s (SOT) 52nd Annual Meeting and ToxExpo, March 10–14, 2013, at the Henry B. Gonzalez Convention Center in San Antonio, Texas. The SOT Annual Meeting is the largest meeting of its kind. This annual event features a broad range of scientific sessions and a thematic program that provides participants with a unique opportunity to deepen their knowledge in topical areas and interact with leaders in their respective disciplines. The scientific program includes a plenary session, the MRC Lecture, symposia, workshops, roundtable discussions, informational sessions, regional sessions, as well as platform and poster sessions. The Society anticipates that more than 7,300 toxicologists from more than 50 countries will attend. The SOT Annual Meeting also features the ToxExpo, which is the largest exhibition of its kind. The exhibition features 350 exhibitors, exhibitor/sponsor-hosted sessions, and the opportunity to debut cutting-edge products, services, and technologies.

You will want to attend because…

Innovative Perspectives: The SOT Annual Meeting provides the most complete and in-depth coverage of toxicology. The Scientific Program Committee’s (SPC) mission is to devise a scientific program that covers the diverse areas of science that toxicology encompasses. The meeting is the venue for toxicologists to learn about the scientific advances that have taken place over the past 12 months. The Scientific Program Committee reviews more than 2,500 abstracts to deliver the most comprehensive and up-to-date program imaginable.

A Global Audience

Nearly 20 percent of SOT’s Annual Meeting and ToxExpo attendees represent scientists from countries outside the United States.

ToxExpo Attendees Are Engaged in One or More of the Following Areas of Research

- Biological Modeling
- Biotechnology
- Carcinogenesis
- Cardiovascular Toxicology
- Clinical and Translational Toxicology
- Comparative and Veterinary Toxicology
- Dermal Toxicology
- Drug Discovery Toxicology
- Epigenetics
- Ethical, Legal, and Social Issues
- Food Safety
- Immunotoxicology
- In Vitro and Alternative Methods
- Inhalation and Respiratory Mechanisms
- Medical Device
- Metals
- Mixtures
- Molecular Biology
- Nanotoxicology
- Neurodegenerative Disease
- Neurotoxicology
- Occupational and Public Health
- Ocular Toxicology
- Pathology
- Pharmacokinetics
- Pharmacology
- Regulatory and Safety Evaluation
- Reproductive and Developmental Toxicology
- Risk Assessment
- Stem Cells

Countless Networking Opportunities: With more than 7,300 toxicologists from more than 50 countries in attendance, this five-day event allows everyone the opportunity to network with colleagues and leading scientists from around the world.

In-Depth Analysis: The Scientific Program Committee has devised a thematic approach that encompasses five themes of topical interest. This year, these themes are (full descriptions on pages 10–11):

- Application of Systems Biology to Toxicology
- Biomarkers for Exposure Assessment, Safety Evaluation, and Translational Medicine
- Effects of Nanomaterials on Biological Systems
- Molecular Basis for Genetic Variability and Susceptibility to Toxics
- Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment

Online Marketplace at ToxExpo.com

ToxExpo exhibitors are listed online year-round 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 networking time has been allotted in the scientific program for attendees to visit with exhibitors. ToxExpo Time will take place on Tuesday, March 12, from 12:30 pm–1:30 pm.

Highly Influential Audience

Eighty percent of ToxExpo attendees are involved in purchasing decisions.

We’ve Got the Numbers You Want

We are expecting to attract more than 7,300 scientists and industry professionals to attend SOT’s 52nd Annual Meeting and ToxExpo. What better opportunity to…

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

ToxExpo: A Great Opportunity for Exhibitors

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

up-to-date information at www.toxicology.org
A Global Audience: More than 20 percent of the attendees come from outside North America, including countries as far away as Australia, Egypt, China, Latin America, and Africa. Toxicologists can explore lessons learned, and share scientific findings, and novel approaches with other toxicologists at this annual event, which is designed to showcase the year’s latest in research.

Value: The SOT Annual Meeting is one of the most cost-effective meetings you can attend. For example, compared to three comparable Societies, you pay $300 for early bird registration compared to an average cost of $461 for the other meetings. If you register on-site, the SOT member pays $420 compared to $615, the average cost of attending one of the three meetings. SOT has contracted with various air carriers to ensure that we can offer our attendees economical fares to San Antonio. Also, SOT has reserved and arranged for SOT Annual Meeting attendee discounted room rates at various hotels in the San Antonio area through the SOT hotel room block. If you work for the Federal Government, you may need to provide your employer with additional justification for attending the SOT meeting given the cutbacks and additional scrutiny that those organizations are experiencing. Go to the SOT Annual Meeting website to find more information about the importance of this annual five-day event and why it should be the one meeting you do attend.

The ToxExpo

The ToxExpo is the profession’s largest trade show. Attendees and exhibitors from around the world gather to exchange information on the latest products and services that science has to offer. Exhibitors debut cutting-edge products and attendees have an opportunity to gain first-hand knowledge about the latest advances from more than 350 exhibitors. The benefits of this exhibition extend beyond the three-day event.

Use the new event mobile app or the event website to create your own personal list of exhibitors that you want to connect with at ToxExpo. You can search the exhibitor listing to view detailed exhibitor information and pinpoint their location on the interactive ToxExpo map.

The following are the exhibit hours for the 2013 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 regular exhibit hours, attendees will have the opportunity to visit the exhibit floor during an hour devoted to networking. ToxExpo time will take place on Tuesday, March 12, from 12:30 pm–1:30 pm.

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

An Invitation to International Attendees

Scientists from around the world are invited to register for the 52nd Annual Meeting and ToxExpo in San Antonio, March 10–14, 2013. Please note that individual invitations are not required for attendance. Because the meetings are open scientific events, SOT extends an invitation to all interested individuals 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. 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 to by sending your name, address, and fax number to the SOT Registration Department. While you will receive an invitation you will still need to pay for registration. 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.
- www.nationalacademies.org/visas
  - For additional visa information, contact the International Visitors Office (IVO) of the National Academies of the Sciences at the above website. This should serve as a visa resource for all visiting scientists and scholars traveling to the United States. Additionally, a survey is available that can be used to assist future travelers with the visa process.
- Make an Appointment
  - To visit the United States Embassy or Consulate. Make sure you ask if there are any fees required. Most fees must be paid before your appointment. Wait times for appointments may be longer than in the past. Schedule the appointment as soon as possible. Information on Visa wait times can be found at the US Department of State website at http://travel.state.gov/temp/wait/wait_4638.html.
- Get Your Documents Ready
  - Organize passport, applications, and documents to support the application with employment details (reason for travel along with financial status), and proof of payment of fees.
- Submit Your Application
  - Send your application and passport along with supporting documents to the United States Embassy or Consulate.
- Start Early
  - Additional reviews may be required. This could add an additional four to six weeks to the processing time.
Accessibility for Persons with Disabilities

The Henry B. Gonzalez 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 (LSA) is a nationwide full-service firm providing translators and interpreters in 180 languages.

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 25, 2013, will receive badges and registration materials in the mail. Attendees who already have their 2013 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 Antonio, 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 Antonio has a mild climate. The typical temperature range for March is an average low of 48°F and an average high of 70°F. For an up-to-date, detailed weather forecast, visit the National Weather Service Forecast Office at www.srh.noaa.gov/ewx.

Coat/Luggage Check

For your convenience, a coat/luggage check will be available in the Henry B. Gonzalez Convention Center. The coat/luggage check will be open Sunday, March 10 through Thursday, March 14. There will be a fee of $2 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

Coat/luggage check hours are subject to change.
General Information

First Aid and Security
If an emergency should occur while at the Henry B. Gonzalez Convention Center, proceed directly to the nearest house phone, located throughout the facility, and dial 7773 for security. You will be connected directly to the 24-hour manned security department at the Convention Center. From your cell phone, dial 210.207.7773, which will connect directly to security.

A First Aid room will be located in Room H62 just inside Exhibit Hall C. A First Aid Administrator will be on duty:

- Sunday .................. 7:00 AM–8:00 PM
- Monday ................. 7:00 AM–5:00 PM
- Tuesday ............... 7:00 AM–5:00 PM
- Wednesday .......... 7:00 AM–5:00 PM
- Thursday ............ 7:00 AM–12:00 Noon

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

Global Gallery of Toxicology
Toxicology Societies from anywhere around the world are invited to participate in the Global Gallery of Toxicology. Now in its third 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. In addition, the 2013 Global Gallery poster session will be listed in the scientific program with an “author attended” poster time from 11:00 am–12:30 pm on Monday, March 11. The goal of SOT and of all these societies is to increase the reliance of international decision makers on the science of toxicology to advance human health and disease prevention. For more information about participating in the Global Gallery, please contact Katie Moore at 703.438.3115 ext. 1423 by January 7, 2013.

In addition, the city of San Antonio offers a bike-sharing program, a food donation program provided to Daily Bread Ministries and the San Antonio Food Bank, with an average of 1,000 meals a month and more. For more information pertaining to the City’s Mission Verde Initiative, please go to www.sanantonio.gov/oep/center.asp#sustainability.

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 Grand Hyatt.

Green in San Antonio
The City of San Antonio has made a substantial commitment to the greening of the community via the Mission Verde Initiative. This initiative is taking a holistic approach to sustainability by creating the following programs:

- Creation of a 21st century urban energy infrastructure in San Antonio
- Creation of a multitech venture capital fund in San Antonio
- Creation of a Green Jobs Program
- Adoption of a green, high-performance building code for new residential and commercial construction

The Henry B. Gonzalez Convention Center is also committed to the sustainable practice at the Center with the goal of reducing the carbon impact on the environment while being the best stewards they can be with their resources. The current green initiatives include: Waste reduction, energy conservation, water conservation, and green purchasing.

Use our QR (Quick Response) codes and go green!
QR codes are the fast, easy way to save paper while getting the most out of your SOT Annual Meeting experience. Simply scan the desired code with any tablet or smart phone QR code reader and find a wealth of information regarding the 52nd SOT Annual Meeting, ToxExpo, and the surrounding city of San Antonio. See more details on page 2.
Housing Information

The Society of Toxicology has reserved and arranged for discounted room rates at various San Antonio hotels—known as the SOT hotel room block. Booking a room in the room block is an important way to support the association and keep overall meeting costs as low as possible. Your patronage of these official meeting hotels makes it possible for SOT to secure the space necessary for this event at a greatly reduced cost. The hotels not only offer discounted rates and the best networking opportunities, but staying in the group blocks helps the association meet its obligation to the hotel, avoid penalties, and keeps meeting registration prices down. Please assist the Society by making your hotel reservation through the online housing reservation system.

Room Share Program

The Society is pleased to provide a Room Share 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

All reservations for housing must be made through the SOT Housing Bureau and not with the hotels directly. The deadline date for new housing reservations is February 8, 2013. Please choose only one option to make your reservation:
- www.toxicology.org/ai/meet/am2013/housing.asp
- Mail: Housing Form to:
  SOT Housing Bureau
  203 S. St. Mary’s Street, Suite 200
  San Antonio, TX 78205
- Fax: 210.207.6702
  (International and Domestic)
- Tel: 210.207.6734 (USA and International)

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

Confirmations

Hotel confirmations will be emailed, faxed, or mailed to you 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 the SOT Housing Bureau at 210.207.6734.

Changes and Cancellations

The deadline date for new reservations is Friday, February 8, 2013. Between February 9 and February 15, hotels will be downloading their lists and no changes can be made. After February 15, 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. For information regarding your hotel room reservation on-site, please visit the SOT Housing Desk located in the SOT registration area of the Henry B. Gonzalez Convention Center.

SOT is launching a special project for the SOT 52nd Annual Meeting by asking attendees to make a small donation to St. Jude’s Ranch. We would like St. Jude’s Ranch for Children in Texas to remember the compassion of toxicologists and the SOT mission, which is to create a safer and healthier world.

See page 16 for more details.
### General Information

#### Hotel Accommodations

1. **Courtyard by Marriott San Antonio Riverwalk**
   - $155 single/double
   - 207 N. St. Mary’s Street
   - San Antonio, TX 78205
   - Tel: 210.223.8888
   - Fax: 210.223.8893
   - Website: [www.marriott.com/satcr](http://www.marriott.com/satcr)
   - Club: Marriott Rewards
   - Check in: 3:00 PM
   - Check out: 12:00 Noon
   - 6 blocks from Convention Center
   - $29.19/day valet parking
   - Complimentary wireless Internet in lobby, complimentary wireless Internet in guest rooms

2. **Grand Hyatt San Antonio**
   - *SOT Headquarters Hotel*
   - $249 single/double
   - 600 E. Market Street
   - San Antonio, TX 78205
   - Tel: 210.224.1234
   - Fax: 210.451.6162
   - Website: [www.grandsanantonio.hyatt.com](http://www.grandsanantonio.hyatt.com)
   - Club: Hyatt Gold Passport
   - Check in: 4:00 PM
   - Check out: 11:00 AM
   - Adjacent to Convention Center
   - $33/day valet parking, $25/day self parking
   - Complimentary wireless Internet in lobby, complimentary wireless Internet in guest rooms is $12.95/day

3. **Hilton Palacio del Rio**
   - $239 single/double
   - 200 S. Alamo, Street
   - San Antonio, TX 78205
   - Tel: 210.222.1400
   - Fax: 210.270.0761
   - Website: [www.palaciodelrio.hilton.com](http://www.palaciodelrio.hilton.com)
   - Club: Hilton HHonors
   - Check in: 3:00 PM
   - Check out: 12:00 Noon
   - Across the street from Convention Center
   - $35.50/day valet parking, $22/day self parking
   - Complimentary wireless Internet in lobby, wireless Internet in guest rooms is $9.95/day

4. **Historic Menger Hotel**
   - $150 single/double
   - 204 Alamo Plaza
   - San Antonio, TX 78205
   - Tel: 210.223.4361
   - Fax: 210.228.0022
   - Website: [www.mengerhotel.com](http://www.mengerhotel.com)
   - Club: Stash Rewards
   - Check in: 3:00 PM
   - Check out: 12:00 Noon
   - 2 blocks from Convention Center
   - $28/day valet parking
   - Complimentary wireless Internet in lobby, complimentary wireless Internet in guest rooms

5. **Holiday Inn San Antonio Riverwalk**
   - $155 single/double
   - 217 N. St. Mary’s Street
   - San Antonio, TX 78205
   - Tel: 210.224.2500
   - Fax: 210.527.9589
   - Website: [www.holidayinn.com/sat-riverwalk](http://www.holidayinn.com/sat-riverwalk)
   - Club: Priority Club
   - Check in: 4:00 PM
   - Check out: 12:00 Noon
   - 5 blocks from Convention Center
   - $26/day valet parking, $18/day self parking
   - Complimentary wireless Internet in lobby, complimentary wireless Internet in guest rooms

6. **Hotel Contessa—Suites on the Riverwalk**
   - $179 single/double
   - 306 W. Market Street
   - San Antonio, TX 78205
   - Tel: 210.229.9222
   - Fax: 210.229.9228
   - Website: [www.thehotelcontessa.com](http://www.thehotelcontessa.com)
   - Club: Real Prefer
   - Check in: 4:00 PM
   - Check out: 11:00 AM
   - 2 blocks from Convention Center
   - $30/day valet parking
   - Complimentary wireless Internet in lobby, complimentary wireless Internet in guest rooms

7. **Hotel Valencia Riverwalk**
   - $159 single/double
   - 150 E. Houston Street
   - San Antonio, TX 78205
   - Tel: 210.227.9700
   - Fax: 210.227.9701
   - Website: [www.hotelvalencia-riverwalk.com](http://www.hotelvalencia-riverwalk.com)
   - Club: VVIP
   - Check in: 4:00 PM
   - Check out: 11:00 AM
   - 6 blocks from Convention Center
   - $29/day valet parking
   - Complimentary wireless Internet in lobby, complimentary wireless Internet in guest rooms

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*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 SOT Housing Bureau.*
### General Information

**8) Hyatt Regency San Antonio Riverwalk**
- $229 single/double
- 123 Losoya Street
- San Antonio, TX 78205
- Tel: 210.222.1234
- Fax: 210.227.4925
- Website: www.sanantonioregency.hyatt.com

  - Club: Hyatt Gold Passport
  - Check in: 3:00 PM
  - Check out: 12:00 Noon
  - 3 blocks from Convention Center
  - $33/day valet parking, $25/day self parking
  - Complimentary wireless Internet in lobby, wireless Internet in guest rooms is $12.95/day

**9) La Quinta Inn and Suites Convention Center**
- $162 single/double
- 303 Blum Street
- San Antonio, TX 78205
- Tel: 210.222.9181
- Fax: 210.228.9816
- Website: http://501.lq.com

  - Club: LQ Rewards
  - Check in: 3:00 PM
  - Check out: 12:00 Noon
  - 2 blocks from Convention Center
  - $22.75/day valet parking, $18.45/day self parking
  - Complimentary wireless Internet in lobby, complimentary wireless Internet in guest rooms

**10) Residence Inn by Marriott—Downtown/Alamo Plaza**
- $155 single/double
- 425 Bonham Street
- San Antonio, TX 78205
- Tel: 210.212.5555
- Fax: 210.212.5554
- Website: www.residenceinn.com/satrw

  - Club: Marriott Rewards
  - Check in: 3:00 PM
  - Check out: 12:00 Noon
  - 3 blocks from Convention Center
  - $24/day valet parking, $24/day self parking
  - Complimentary wireless Internet in lobby, complimentary wireless Internet in guest rooms

**11) San Antonio Marriott Rivercenter**
- $239 single/double
- 101 Bowie Street
- San Antonio, TX 78205
- Tel: 210.223.1000
- Fax: 210.223.6239
- Website: www.marriott.com/satrc

  - Club: Marriott Rewards
  - Check in: 4:00 PM
  - Check out: 12:00 Noon
  - 1 block from Convention Center
  - $33/day valet parking, $25/day self parking
  - Complimentary wireless Internet in lobby, wireless Internet in guest rooms is $12.95/day

**12) San Antonio Marriott Riverwalk**
- $239 single/double
- 889 E. Market Street
- San Antonio, TX 78205
- Tel: 210.224.4555
- Fax: 210.224.2754
- Website: www.marriott.com/satdt

  - Club: Marriott Rewards
  - Check in: 4:00 PM
  - Check out: 12:00 Noon
  - Across the street from Convention Center
  - $33/day valet parking, $25/day self parking
  - Complimentary wireless Internet in lobby, wireless Internet in guest rooms is $12.95/day

**13) Westin Riverwalk**
- $239 Cityside/$259 Riverside
- 420 W. Market Street
- San Antonio, TX 78205
- Tel: 210.224.6500
- Fax: 210.444.6000
- Website: www.westinriverwalksanantonio.com

  - Club: SPG Starwood
  - Check in: 3:00 PM
  - Check out: 12:00 Noon
  - 3 blocks from Convention Center
  - $30/day valet parking, $15/day self parking
  - Complimentary wireless Internet in lobby, wireless Internet in guest rooms is $13.95/day

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

- All hotels have Internet access.
- Hotel sales tax is currently 16.75%

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

- All hotels have Internet access.
- Hotel sales tax is currently 16.75%
Use the new event mobile app or the event website to access a complete San Antonio city guide including, hotels, restaurants, attractions, nightlife, and shopping. The event website and app will be available in January via the SOT website and app market places.
### Hotel Services

<table>
<thead>
<tr>
<th>Hotel Services</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>In-Room Safe</th>
<th>Fitness Center</th>
<th>Swimming Pool</th>
<th>Business Center</th>
<th>Room Service</th>
<th>Gift Shop</th>
<th>Overnight Self-Parking</th>
<th>Early Departure Fee</th>
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<tr>
<td>1) Courtyard by Marriott San Antonio Riverwalk</td>
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</tr>
<tr>
<td>2) Grand Hyatt San Antonio* * SOT Headquarters Hotel</td>
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<td>Adjacent</td>
<td></td>
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<td>1 Night Room and Tax</td>
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</tr>
<tr>
<td>3) Hilton Palacio del Rio</td>
<td>Hilton HHonors</td>
<td>Across Street</td>
<td></td>
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<td>4) Historic Menger Hotel</td>
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<tr>
<td>5) Holiday Inn San Antonio Riverwalk</td>
<td>Priority Club</td>
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<td>6) Hotel Contessa—Suites on the Riverwalk</td>
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<td>8) Hyatt Regency San Antonio Riverwalk</td>
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<td>1 Night Room and Tax</td>
<td>4-Diamond</td>
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</tr>
<tr>
<td>9) La Quinta Inn and Suites Convention Center</td>
<td>LQ Rewards</td>
<td>2 Blocks</td>
<td></td>
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<tr>
<td>10) Residence Inn by Marriott—Downtown/Alamo Plaza</td>
<td>Marriott Rewards</td>
<td>5 Blocks</td>
<td></td>
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<td>✓</td>
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<td>None</td>
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</tr>
<tr>
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</tr>
<tr>
<td>12) San Antonio Marriott Riverwalk</td>
<td>Marriott Rewards</td>
<td>Across Street</td>
<td></td>
<td>✓</td>
<td>✓</td>
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<td>4-Diamond</td>
<td></td>
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</tr>
<tr>
<td>13) Westin Riverwalk</td>
<td>SPG Starwood</td>
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<td>1 Night Room and Tax</td>
<td>4-Diamond</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.
General Information

Internet Access at the Convention Center

SOT understands the importance of being connected to your daily activities while attending the Annual Meeting and provides several ways for you to access the Internet while at the Henry B. Gonzalez Convention Center.

@SOT Center—Internet Access and Technology Training Center

SOT will provide computers you can use to access the Internet. These computers are available to attendees in the @SOT Center, located outside the ToxExpo entrance.

Free Wireless Internet Access

Free wireless Internet access is available in designated “Wi-Fi Zones” located in ToxExpo Exhibit Halls C-D. The wireless network name is SOT2013.

Free wireless Internet is also available in the common areas including the Entrance Lobby, East and West Registrations, foyer outside of Meeting Rooms 208 through 218. The network name is free Internet.

Internet is available for purchase by the attendee at $12.95 per day, per device, everywhere in the building, except in the exhibit halls. To connect, go to view available wireless networks on your laptop, connect to Instant Internet network, and open your browser and the splash page for Instant Internet to load. Follow the directions and you will be connected. A receipt for the purchase will be emailed to you.

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, go to www.toxicology.org/ai/meet/ancillarymtg. Ancillary functions may only be hosted by SOT Affiliates, Exhibitors, Sponsors, or organizations otherwise associated with SOT. All ancillary functions are held outside of the Convention Center in nearby hotels. Hospitality suites and ancillary meeting spaces book quickly—submit your request now! Only meeting requests made by December 14, 2012, will be listed in the Annual Meeting Calendar and the Program.

San Antonio Area Activities

Any time you go to San Antonio you will be impressed by the diversity of the architecture and culture that have helped make this one of the most unique destinations in the United States. San Antonio is a city of contrasts between the old world and the new, the quaint and the contemporary. Native Americans originally lived near the San Antonio River and between the old world and the new, the quaint and the contemporary. Native Americans originally lived near the San Antonio River and then in 1691, a group of Spanish explorers and missionaries came upon the river and the Native American settlement on June 13, the feast day of St. Anthony of Padua and named the place and River, San Antonio.

All of San Antonio’s history is alive in buildings such as the Alamo, the La Villita Historic Arts Village, The King William Historic District, the Espada, and the San Jose, San Juan Capistrano and Concepcion missions. The heart of the city is made up of the Alamo, Military Plaza, the San Antonio River and the Main Plaza, which dates back to the early 1700s. Given all of the available activities to do in San Antonio, be sure to book your tours early with your hotel concierge. The following is a suggested list of sites to visit during your stay in this most intriguing city:

- **The River Walk**—The celebrated Paseo del Rio is a winding, and welcoming oasis that meanders through the downtown area. The River Walk is lined with numerous shops, restaurants, and other attractions such as the Aztec on the River, which is the only surviving exotic-themed movie palace in Texas.

- **Rio San Antonio Cruises** hosts daily tours of the River Walk Downtown Reach. Ticket booths are located at River Center Mall, river level of the Aztec Theatre, and at the new lock and dam on Brooklyn Avenue.

- **The Alamo**—This mission is San Antonio’s most famous landmark. Originally named Misión San Antonio de Valero, the Alamo served as home to missionaries and their Indian converts for nearly seventy years. Construction began on the present site in 1724. In 1793, Spanish officials secularized San Antonio’s five missions and distributed their lands to the remaining Indian residents. These men and women continued to farm the fields and participated in the growing community of San Antonio. In the early 1800s, the Spanish military stationed a cavalry unit at the former mission. The soldiers referred to the old mission as the Alamo (the Spanish word for “cottonwood”) in honor of their hometown Alamo de Parras, Coahuila. When Antonio Lopez de Santa Anna rescinded the Mexican Constitution of 1824, violence engulfed many states. In a series of battles, the Texian Army succeeded in forcing Mexican soldiers out of the settlement.
In December 1835, Texian forces captured San Antonio from forces commanded by General Martin Perfecto de Cos, Santa Anna's brother-in-law. In the spring of 1836, Santa Anna marched on San Antonio. The Battle of the Alamo took place from February 23–March 6, 1836. This final battle constitutes the most celebrated military engagement in Texas history. For many Americans and most Texans, the battle has become a symbol of patriotic sacrifice.

- **The Spanish Governor’s Palace**—The Palace is a National Historic Landmark in the city of San Antonio. Completed in 1749, it was originally intended to protect the nearby San Antonio de Valero Mission (the Alamo) and the growing colony and is considered the sole remaining example of an aristocratic early Spanish house in Texas. The National Geographic Society has called the landmark “the most beautiful building in San Antonio.”

- **La Villita Historic Arts Village**—The Village was a settlement of primitive huts for the Spanish soldiers stationed at the Mission San Antonio Valero (The Alamo). The La Villita was the site of General Santa Ana’s cannon line in the Battle of the Alamo. Today, La Villita is a thriving art community that features shopping, restaurants, and several art galleries.

- **Institute of Texan Cultures**—The museum, which is affiliated with the Smithsonian Institute, is part of the University of Texas at San Antonio. It plays a role in the university’s community engagement initiatives by developing quality, accessible resources for educators, and lifelong learners on topics of cultural heritage. It strives to develop a rich and vibrant culture in the arts and humanities that will expand the community’s awareness and appreciation of Texas through an engaging series of exhibits, programs, and special events. Among other things, the exhibits include the more than 20 ethnic groups that settled in Texas.

- **King William Historic District**—The District is a replica for San Antonio’s 19th century, which was booming because of the German bankers and millers who created the term “Sauerkraut Bend.” In the late 1800s, the District was the most elegant residential area of the city. Prominent German merchants originally settled the area. Today, it is a 25-block area near downtown on the south bank of the San Antonio River, which is still considered a fashionable neighborhood.

- **Texas Star Trail**—If you enjoy walking then you’ll love this tour! Pick up a map at the San Antonio Visitor Center and explore 2.6 miles of historical San Antonio and learn about 79 historic buildings, objects, places, events, and customs of San Antonio and Texas through history. The San Antonio Conservation Society first produced the tour in 1986.

- **Casa Navarro State Historic Site**—This historic site is nestled in downtown San Antonio. The half-acre site is the restored home of Texas patriot José Antonio Narvarro.

- **Spanish Missions**—The Southern part of San Antonio includes four missions including the Mission San José, Mission Concepción, Mission San Francisco de la Espada, and San Juan Capistrano. Mission San José is called the “Queen of the Missions.” It was established in 1720 and only relocated once. Today, it provides the most complete picture of a working mission. Mission Concepción is the closest replica of the halcyon period, which was marked by colonial expansion. Missions San Francisco de la Espada and San Juan are smaller missions, which were important in keeping farms thriving. Here, you can visit the Espada Dam and aqueduct, which is considered a marvel of 18th century engineering.

- **HemisFair Park**—The Park was built to host the 1968 World’s Fair, and includes lushly landscaped areas, and dramatic cascading waterfalls, and several historic buildings.
General Information

- **Majestic Theatre**—The ornate theatre is one of the few remaining vintage vaudeville movie palaces. Its Moorish interior, twinkling lights and moving clouds adorn the ceiling, all of which make the theatre a site worth visiting.

- **Natural Bridge Caverns in the Heart of San Antonio**—Experience a thrilling and physically demanding three- to four-hour excursion into one of the world’s premier caverns. Climb, crawl, rappel, explore—with only the light of your helmet to guide you. Once outfitted with caving gear, you’ll be lowered by rope through a 160-foot well shaft. Travel approximately one mile, going down to 230 feet below surface level to the Fault Room which features one of the longest soda straw formations in North America—14 feet in length.

- **Southwest Research Institute (SwRI)**—Headquartered in San Antonio, Texas, and is one of the oldest and largest independent, nonprofit, applied research and development (R&D) organizations in the United States. Founded in 1947 by Thomas Baker Slick Jr., an oilman and philanthropist, SwRI provides contract research and development services to industrial and government clients in the United States and abroad. His goal was to establish an internationally known scientific research center in San Antonio and he challenged a group of pioneer scientists and engineers from around the nation to move to the new center to seek revolutionary advancements in many areas by developing and applying technology.

- **Bracken Bat Cave**—Bracken Bat Cave is the summer home of the world’s largest bat colony. With millions of Mexican free-tailed bats living in the cave from March thru October, Bracken holds one of the largest concentration of mammals on earth. The cave and 697 acres of the surrounding Texas Hill Country is owned and protected by Bat Conservation International.

Science the San Antonio Way

- **Bound Outdoors**—San Antonio offers some extraordinary opportunities to explore science outside of the SOT Annual Meeting. With Bound Outdoors, you can explore the newest area of the San Antonio River Walk through a team building program that is part adventure and part discovery. Your program begins aboard the San Antonio River Taxi, where the Bound Outdoors Guides will greet everyone as the boat glides upstream towards our starting point.

  From there, a handheld GPS takes each team to build bridges, solve a water shortage, unlock riddles inside the San Antonio Museum of Art, and much more. Along the way, guides from Bound Outdoors will work with each team as they explore nature, history, and technology together.

- **EmisFair Park**—The Alamo, one of five Missions in San Antonio, was moved twice, even though it is probably the oldest Mission.

  1. The Alamo, one of five Missions in San Antonio, was moved twice, even though it is probably the oldest Mission.

  2. The Chili Queens were once enterprising women who were laundresses by day and by night brewed chili at the doorstep of the Spanish Governor’s palace.

  3. St. Paula Square was named for the oldest African-American church in town.

  4. Ellis Alley, located near downtown San Antonio, was settled by African-Americans, but changed in nature once the railroad arrived. It then became a venue for jazz. Performers include Ella Fitzgerald and Duke Ellington.

  5. The San Antonio Zoo is the third largest in the nation.

  6. VIA streetcars, one of San Antonio’s metropolitan transit systems, are reproductions of authentic San Antonio railcars dating back more than 50 years.

  7. The San Antonio Sports Hall of Fame is located on the first floor of the Alamodome.

  8. The San Antonio National Cemetery was established in 1867 as the resting place for Union soldiers.

  9. HemisFair Park is the site of the 1968 World’s Fair.

  10. According to the 2000 Census, the city proper had a population of 1,144,646, making it the ninth most populated city in the country. The 2011 census estimate for San Antonio—New Braunfels areas now makes it the 24th most populous metro areas in the US.

  11. The River Walk extends some 2½ miles and attracts several million visitors every year.

  12. The Fairmount Hotel, built in 1906, is San Antonio’s second oldest hotel and in the Guinness World Records is listed as one of the heaviest buildings ever moved intact. It was placed in its new location, three blocks south of the Alamo over four days in 1985 and cost $650,000 to move.

  13. San Antonio claims to be the birthplace of the spicy stew known as chili. San Antonio is also the home of the Frito, the Cheeto, and David Pace’s Pace picante sauce.
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 2013 Satellite Meetings will be held in and around the San Antonio area. Proposals for a Satellite Meeting should be sent by email to heidi@toxicology.org to the attention of Lois Lehman-McKennan, SOT Vice President and Scientific Program Committee Chair. Requests approved by December 14, 2012, will be published in the Program. All requests must be received by January 11, 2013.

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.

To get more information you can contact Rachel Primiano with Shepard Exposition Services at 713.398.2268 or rprimiano@shepardes.com. The order form can also be found online on the SOT Annual Meeting website at: www.toxicology.org/ai/meet/am2013/forms.asp.

General Information

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 Fund. 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 immediately inside the Exhibit Hall across from registration and is 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 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 2013, 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: The Official Record of the 2013 Annual Meeting Abstracts

The Toxicologist is an important scientific resource, as it is the official compilation of all accepted abstracts for the 52nd Annual Meeting of the Society of Toxicology. With over 2,500 abstracts for the meeting, this supplementary issue of Toxicological Sciences is a critical publication to access the latest findings in toxicology.

- A copy of the printed version of The Toxicologist may be preordered via the Registration Form or purchased on-site while supplies last for $25.
- The Toxicologist PDF is available for download via the SOT website.
- Full abstracts can be accessed via the event mobile app or event website available on the SOT website and app market places in late January.
- The Late-Breaking Abstract Supplement to The Toxicologist will not be mailed prior to the meeting and copies will be available via the SOT website and on-site in the registration area and outside Exhibit Hall A, where the posters will be presented on March 14.

The Program: The Official Guide to the SOT 2013 Annual Meeting and ToxExpo

The Program is the official guide to all the activities of the 2013 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 2013 award recipients, 2013 Honorary members, SOT Endowment Fund 2012 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 ToxExpo and a complete listing of Exhibitor/Sponsor-Hosted Sessions.

- The Program PDF is available for download via the SOT website (late January).
- Copies of the Program can be picked up on-site. In an effort to increase resources, the printed Program will be mailed ONLY by request (in the US and Canada only). If you wish to receive your printed Program before the meeting (request made by February 15), please select the "I want to receive the printed Program before the meeting by mail" checkbox on the registration form, and the Program will be mailed in late February (in the US and Canada only).

Annual Meeting Schedule and Planning Tool Enhancements

It’s an exciting time for SOT as we continue to grow, remaining always adaptable, member-focused, and relevant. This year we are happy to announce we are leveraging the services of QuickMobile to provide you with an enhanced mobile event app and event website that will allow you to:

- Connect with fellow attendees
- Build your own schedule
- View presentation details and abstracts
- View and interact with speakers
- Request meetings with attendees and exhibitors
- Navigate ToxExpo with the interactive floor plan
- And many other exciting options

In late January, you will be able to download the mobile event app from the App Store, Android Market Place, Google Play, or access it for Blackberry or your computer via the mobile event website.

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

Air Transportation

Special Airfare Discounts
SOT has established discounted rates through American and Delta Airlines originating in the United States and Canada. Be sure to use the reference numbers when making your reservations. You may purchase your ticket online, call the airline directly using the toll free numbers, or provide your travel agent with the reference/discount numbers listed below to receive the discount.

American Airlines
800.433.1790
www.aa.com
SOT Discount Code: 7833BW

American Airlines is offering a seven percent discount off the lowest applicable fare for attendees traveling to San Antonio for the SOT Annual Meeting. The discount is valid March 6–19, 2013. You may book your ticket at www.aa.com (no service fee applies); in the promotion code box, type 7833BW to receive the discount.

You may also book your reservation by calling the AA Meeting Services Desk at 800.433.1790; however, a $25 service fee will apply. International attendees should contact their fares to San Antonio from the US/Canada. Special Airfare Discounts

Delta Airlines
800.328.1111
www.delta.com
SOT Discount Code: NMEDM

Delta Airlines is offering a five percent to ten percent discount off full/nonrestricted fares to San Antonio from the US/Canada. The discount is valid March 7–17, 2013. You may book your ticket at www.delta.com (no service fee applies); select Meeting Event Code and enter the discount code NMEDM in the box provided on the Search Flight page.

You may also make reservations by calling the Delta Meeting Services Desk at 800.328.1111 from anywhere in the United States or Canada and refer to the discount code NMEDM, however, a service fee will apply.

SOT Travel Agent—Carlson Wagonlit

Carlson Wagonlit is the official travel management firm for SOT’s 52nd 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:

- Your name as it appears on your ID, and your date of birth.
- The desired dates of arrival to and departure from San Antonio
- 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)

San Antonio International Airport (SAT)

San Antonio International Airport (SAT) is located in Northern San Antonio, approximately eight and a half miles (approximately 15 minutes by car) from the downtown area. Loop 410 and US 281 are the two highways providing access to the main entry points. For up-to-the-minute departure and arrival information, airport maps, and details on shopping, dining, ground transportation, and more, visit www.sanantonio.gov/aviation.

Ground Transportation—From the Airport

Ground transportation is located curbside in front of Terminal A and B baggage claim area. Uniformed transportation agents (wearing red shirts) can describe services and provide rates to various destinations. For additional ground transportation information, please call 210.207.3411.

- Taxi Cabs—Taxi fares to San Antonio downtown areas are approximately $25 to $29 per taxi, not including tip. Up to six passengers may share a taxi for the price of one, as they do not charge per person.
- Shuttle Service—GO Airport Shuttle, is San Antonio International Airport’s authorized and single shared-ride shuttle service. Shuttles depart from 7:00 am to 1:30 am daily to downtown hotels every 15 minutes. Passengers may purchase tickets at the airport’s baggage claim area. Ticket rates are $18 per person to downtown hotels or $34 for a roundtrip ticket. There is a fuel surcharge of $1 each way. Book online and receive an additional discount. Online rates are $17 to downtown hotels and $32 for a roundtrip ticket. For more information, visit www.saairportshuttle.com or call 210.281.9900.
- City Bus (VIA)—VIA Metropolitan Transit is San Antonio’s public transportation agency. VIA’s bus stop will be halfway between Terminals A and B, clearly marked. You will catch VIA bus route 5, which operates every day and can get to beautiful downtown San Antonio in about 30 minutes for only $1.10. For information regarding VIA’s Day Pass and downtown streetcar service, see the Public Transportation section below. For more details, visit www.viainfo.net or call 866.362.2020.
General Information

Public Transportation—
Getting around Town

- **Streetcar**—Some of the VIA Metropolitan Transit Streetcars are reproductions of authentic San Antonio railcars dating back more than 50 years. Routes include the Yellow Route, which covers the Alamodome, Henry B. Gonzalez Convention Center, Market Square, Rivercenter Mall, St. Paul Square, Sunset Station, and the Tower of Americas. The Red Route covers the Alamo, Henry B. Gonzalez Convention Center, Market Square, HemisFair Park, La Villita Historic Arts Village, Rivercenter Mall, and the San Antonio Visitor Information Center. The Blue Route includes the Alamo, Blue Star Arts Complex, Central Library, Henry B. Gonzalez Convention Center, HemisFair Park, King William Historical District, La Villita Historic Arts Village, Municipal Auditorium, Rivercenter Mall, San Antonio Visitor Information Center, and Southtown.

For added convenience, VIA offers a $4 Day Pass, good for unlimited rides on all regular bus and streetcar service for the one day indicated on the pass. The Day Pass will be activated the first time boarding the bus or streetcar. Order your pass online (stores.viaonlinestore.net/storefront.bok) or stop by the Downtown Information Center at 211 West Commerce Street.

- **River Taxi**—The River Taxi stops at 39 locations on the River Walk. Purchase a one-way pass for $5, 24-hour pass for $10 or a 3-day pass for $25 (prices subject to change). Look for the river cruiser with the black and yellow checkered flag or black and red checkered flag. For more river taxi routes and other information, visit www.riosanantonio.com/rio-taxi.

- **The Sightseer Special Bus**—The Sightseer Special (Bus 7) runs daily between the city’s favorite sites. You can travel to them all for one price. Locations visited by the Sightseer Special include: River Walk Streetcar Station, Henry B. Gonzalez Convention Center, Alamo, San Antonio Museum of Art, Japanese Tea Garden, Brackenridge Park, San Antonio Zoo, Trinity University, University of Incarnate Word, Witte Museum, and San Antonio Botanical Garden.

- **Bike-Share Program**—With 14 convenient spots throughout downtown San Antonio, B-cycle is Texas’ first bike-share program and a green alternative to traditional public transit. Day visitors can purchase a 24-hour pass checked out daily between 5:00 am and 10:00 pm, and return to any B-cycle station at any time. For more information, visit www.sanantonio.bcycle.com.

Convention Center Location and Parking

San Antonio’s central and concentrated downtown makes getting around a breeze. The Henry B. Gonzalez Convention Center is an easy walk from most hotels, restaurants, and attractions, and the center itself actually crosses right over the famous River Walk.

Henry B. Gonzalez Convention Center
200 East Market Street
San Antonio, Texas 78205

See the following list for a few of the closest public parking garages to the Henry B. Gonzalez Convention Center.

- **Groos Lot**
  210.212.4011
  246 East Commerce Street (across the street from the Westin River Walk)
  $12–$15/day (prices subject to change)
  Open 24 hours/day, 7 days/week

- **Market Street Garage**
  210.212.4011
  421 West Market Street (across the street from the Westin River Walk)
  $12–$15/day (prices subject to change)
  Open 24 hours/day, 7 days/week

For a full list of parking garages in San Antonio, visit www.downtownsanantonio.org/park/parking.

Please check the SOT Hotel Accommodations and Services on pages 18–19 for valet and self parking rates for your hotel.

SOT Ride Share

SOT is offering a Ride Share Program in conjunction with the Annual Meeting. For those who live close enough to the San Antonio 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 Share 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.

Remember to Spring forward
One Hour

March 10, 2013
Day Light Saving Time Starts in the United States, Canada, and Mexico
SOT Pavilion

Your Place to Connect in the Exhibit Hall

Located in the ToxExpo Exhibit Hall, the SOT Pavilion is your place to connect and learn about SOT programs, 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.

The SOT Pavilion is located immediately inside the Exhibit Hall across from registration.

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!

*Note: Poster Tours for Trainees will begin here for scheduled participants. (Look for sign.)*

- Get one-on-one event app training
- 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

Advance Your Science

Be Connected • Be Involved • Be Informed • Be Inspired
Registration

Registration for the Annual Meeting is available now. Register by January 25 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 nonmembers are invited to register for the 2013 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 91985
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

In an effort to increase resources, the printed Program will be mailed ONLY by request (in the US and Canada only). If you wish to receive your printed Program before the meeting, please mark the checkbox on the Registration form by February 15, and it will be mailed to you in late February (in the US and Canada only). The Program will also be available for download via the SOT website in January and for pick up on-site. See pages 26 and 35 for more details about the Program and The Toxicologist.

Badges and event tickets will be mailed in advance if you register by January 25, 2013. When you arrive at the Henry B. Gonzalez Convention Center, please go to the registration area located in the Bridge Hall to pick up your registration materials that were not mailed (i.e., Program, the ToxExpo Directory, and other supplementary materials). You must present your 2013 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 25, 2013

• Standard Registration: February 15, 2013

• Final Registration after: February 15, 2013

DO NOT mail your Registration Form to SOT if it will arrive after March 6, 2013. SOT will accept Annual Meeting Registrations until March 6. After March 6, 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 6, 2013, you can easily pick up your badge at the “BADGE PICK UP ONLY” registration counter.

Registration Discount to Nonmembers

JOIN AND SAVE!

Special offer to nonmember 2013 Annual Meeting attendees: apply for membership by May 1, 2013, and if accepted, SOT will waive your 2013 dues. See page 32 for more information.

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 should register with the person they are accompanying. Reminder: Guest/Spouse registrants and children under the age of 15 are not permitted in the Exhibit Hall at any time or in scientific sessions (not held in the Exhibit Hall) unless the session chair has provided consent for the guest/spouse or child to attend.

(continued on page 34)
**Registration Form**

SOT 52nd Annual Meeting • March 10–14, 2013

(Required: Please check the appropriate box)

PLEASE PRINT CLEARLY OR TYPE

- SOT Member
- Nonmember
- 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/Telephone 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 Telephone Number: __________________ Advisor’s Email: ___________________________

Advisor’s Name: _______________________________________________________________________

Institution: ___________________________________________________________________________

Advisor’s Telephone Number: __________________ Advisor’s Email: ___________________________

**REGISTRATION FEES:**

<table>
<thead>
<tr>
<th>SOT Member</th>
<th>Standard Registration (Jan. 26 to Feb. 15)</th>
<th>Final Registration (After Feb. 15*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$300</td>
<td>$360</td>
<td>$420</td>
</tr>
</tbody>
</table>

- Nonmember**: $640 $700 $760 $ ____________

- SOT Retired/Emeritus Member: $70 $120 $170 $ ____________

- Postdoctoral SOT Member: $85 $135 $185 $ ____________

- Postdoctoral Nonmember**: $170 $220 $270 $ ____________

- Graduate Student Member: $65 $115 $165 $ ____________

- Graduate Student Nonmember**: $130 $180 $230 $ ____________

- Undergraduate Student: $0 $0 $0 $0 $ ____________

(Copy of Student ID Required)

- SOT Affiliate: $0 $0 $0 $0 $ ____________

- Press: $0 $0 $0 $0 $ ____________

- Guest/Spouse (Nonscientist): $70 $85 $100 $ ____________

**METHOD OF PAYMENT:**

All registrations submitted by hard copy or fax will be processed online 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 #: ___________________________ Expiration Date: ______________________

Signature: ________________________________________________________________________________

Cardholder’s Printed Name: __________________________________________________________________

By registering for the SOT Annual Meeting you agree to the terms and conditions outlined in the registration policies on page 34.

* After February 15, Final Registration rates apply. SOT will accept faxed Registration Forms until March 6. Online registration will be open until March 14. On-Site Registration Forms will be available at the Annual Meeting Registration Desk.

** Special offer to Nonmember 2013 Annual Meeting attendees: apply for membership by May 1, 2013, and if accepted, SOT will waive your 2013 dues.

RETURN THIS TWO-PAGE FORM WITH PAYMENT TO:

Society of Toxicology • PO Box 91895 • Washington, DC 20090-1895

Faxed forms are accepted only if using a credit card. Fax form to: 703.438.3113.

US GOVERNMENT PURCHASE ORDERS MUST BE FAXED OR MAILED WITH THE REGISTRATION FORM.

Express packages may be mailed to:

SOT Headquarters Registration Dept., 1821 Michael Faraday Drive, Suite 300, Reston, VA 20190-5332

Questions? Contact SOT • Tel: 703.438.3115 • Email: sothq@toxicology.org

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

31 (Part 2 continued on page 33)
JOIN as a new member
or upgrade to the level
of membership that’s right for you

Founded in 1961, the Society of Toxicology (SOT) includes more than 7,400 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—enrolled in a graduate degree program related to toxicology.

Postdoctoral—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—engaged in continuing professional scientific activities in toxicology.

Full—demonstrate a continuing professional interest in toxicology and have conducted and published original research and/or are generally recognized as expert in some area of toxicology.

Apply for or upgrade to the level of membership that’s right for you! Please see the “Join SOT” section of the SOT website at www.toxicology.org 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 Contemporary 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

Membership Fees:

<table>
<thead>
<tr>
<th>Membership Type</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Membership</td>
<td>$138</td>
</tr>
<tr>
<td>Associate Membership</td>
<td>$138</td>
</tr>
<tr>
<td>Postdoctoral Membership</td>
<td>$35</td>
</tr>
<tr>
<td>Student Membership</td>
<td>$20</td>
</tr>
</tbody>
</table>

Membership Fees for Members from Developing Countries*

<table>
<thead>
<tr>
<th>Membership Type</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Membership</td>
<td>$50</td>
</tr>
<tr>
<td>Associate Membership</td>
<td>$50</td>
</tr>
<tr>
<td>Postdoctoral Membership</td>
<td>$10</td>
</tr>
<tr>
<td>Student Membership</td>
<td>$10</td>
</tr>
</tbody>
</table>

*For complete information about membership in the Society of Toxicology, visit the SOT website at www.toxicology.org and select Member Information.
CONTINUING EDUCATION COURSES:

- Yes, I would like to attend the Sunrise CE Mini-Course (includes continental breakfast)
- Yes, I would like to attend the following CE courses. (Only meeting registrants may enroll in a CE course.)

<table>
<thead>
<tr>
<th>Course Details</th>
<th>AM #</th>
<th>PM #</th>
<th># of Courses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early Bird Registration (Received by Jan. 22)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SOT Member/Affiliate</td>
<td>$150 each</td>
<td></td>
<td>$150 each</td>
</tr>
<tr>
<td>SOT Retired/Emeritus Member</td>
<td>$110 each</td>
<td></td>
<td>$110 each</td>
</tr>
<tr>
<td>Nonmember</td>
<td>$300 each</td>
<td></td>
<td>$300 each</td>
</tr>
<tr>
<td>Postdoctoral (SOT Member/Nonmember)</td>
<td>$90 each</td>
<td></td>
<td>$90 each</td>
</tr>
<tr>
<td>Graduate or Undergraduate Student (SOT Member/Nonmember)</td>
<td>$45 each</td>
<td></td>
<td>$45 each</td>
</tr>
<tr>
<td>Press</td>
<td>$0 each</td>
<td></td>
<td>$0 each</td>
</tr>
</tbody>
</table>

| Standard Registration (Jan. 26 to Feb. 15) | | | |
| SOT Member/Affiliate | $185 each | | $185 each |
| SOT Retired/Emeritus Member | $145 each | | $145 each |
| Nonmember | $335 each | | $335 each |
| Postdoctoral (SOT Member/Nonmember) | $125 each | | $125 each |
| Graduate or Undergraduate Student (SOT Member/Nonmember) | $80 each | | $80 each |
| Press | $0 each | | $0 each |

| Final Registration (After Feb. 15) | | | |
| SOT Member/Affiliate | $220 each | | $220 each |
| SOT Retired/Emeritus Member | $180 each | | $180 each |
| Nonmember | $370 each | | $370 each |
| Postdoctoral (SOT Member/Nonmember) | | $160 each | $160 each |
| Graduate or Undergraduate Student (SOT Member/Nonmember) | | $115 each | $115 each |
| Press | | $0 each | $0 each |

- Yes, I would like to purchase the printed version of *The Toxicologist*.
- Yes, I want to receive the printed Program in the mail (option not available after February 15, 2013).

Student and Postdoctoral Functions:

- Yes, I am an undergraduate student and would like to attend the Sunday Undergraduate Education Program. (Limited seating and ticket required)
- Yes, I am a postdoc registrant and would like to attend the Postdoc Luncheon on Tuesday, 12:00 noon–1:15 pm. (Limited seating and ticket required)
- Yes, I am a graduate student or postdoc member registrant and would like to attend the complimentary Trainee Discussion with Medical Research Council (MRC) Lecturer: Prof. Nicholson on Wednesday, 10:00 am–11:00 am. (Limited seating and ticket required)

Print Materials:

In an effort to increase resources, the printed Program will be mailed ONLY by request (in the US and Canada only). If you wish to receive your printed Program before the meeting, please mark this checkbox and it will be mailed to you in late February (in the US and Canada only). The Program will also be available for download via the SOT website in January and for pick up on site.

- Yes, I want to receive the printed Program in the mail (option not available after February 15, 2013).

2013 registrants will receive the abstracts, a PDF of *The Toxicologist* download via the SOT website, as part of the Annual Meeting registration fee. A printed version of *The Toxicologist* will be available for purchase at $25 per copy (available while supplies last).

- Yes, I want to purchase the printed version of *The Toxicologist*.

Registart—Circle All That Apply (You Must Make One Selection/Category)

| Type of Organization | | | |
|----------------------|------|------|
| A. Type of Organization: | | | |
| 1. Academia | | | |
| 2. Consultant | | | |
| 3. Contract Research | | | |
| 4. Government | | | |
| 5. Military | | | |
| 6. Private Industry | | | |
| 7. Other | | | |

| B. Job Function: | | | |
|-----------------|------|------|
| 8. Analytical | | | |
| 10. Computer/Statistics | | | |
| 11. Health and Safety | | | |
| 12. Mgmt. Corporate | | | |
| 13. Mgmt. Facilities | | | |
| 14. Mgmt. Personnel | | | |
| 15. Marketing/Sales | | | |
| 16. Quality Assurance | | | |
| 17. Regulatory | | | |

| C. Field of Work: | | | |
|------------------|------|------|
| 18. R&D Admin. | | | |
| 19. R&D Operations | | | |
| 20. R&D Technical | | | |
| 21. Teaching | | | |
| 22. Other | | | |

| D. Product Interest: | | | |
|--------------------|------|------|
| 23. Biological Modeling | | | |
| 24. Biotechnology | | | |
| 25. Carcinogenesis | | | |
| 26. Cardiovascular | | | |
| 27. Clinical & Transl. Tox. | | | |
| 28. Comparative and Vet. | | | |
| 29. Dermal Tox. | | | |
| 30. Drug Discovery Tox. | | | |
| 31. Epidemiology | | | |
| 32. Ethical, Legal, and Social Issues | | | |
| 33. Food Safety | | | |
| 34. General Tox. | | | |
| 35. Genetic Tox. | | | |
| 36. Immunotoxicology | | | |
| 37. Inflammation Tox. | | | |
| 38. Inhalation Tox. | | | |
| 39. In Vitro and Alt. Methods | | | |
| 40. Mechanisms | | | |
| 41. Medical Devices | | | |
| 42. Metals | | | |
| 43. Methods | | | |
| 44. Mutations | | | |
| 45. Molecular Biology | | | |
| 46. Mutagenicity | | | |
| 47. Nanotoxicology | | | |
| 48. Neurotoxicology | | | |
| 49. Occup. and Public Health | | | |
| 50. Ocular Tox. | | | |
| 51. Pathology | | | |
| 52. Pharmacokinetics | | | |
| 53. Pharmacology | | | |
| 54. Risk Assessment | | | |
| 55. Reg. and Safety Eval. | | | |
| 56. Repro. and Develop. Tox. | | | |
| 57. Stem Cells | | | |
| 58. Other | | | |

| E. Purchasing Responsibilities: | | | |
|-------------------------------|------|------|
| 59. Publications | | | |
| 60. Contract Services: | | | |
| a. Analytical | | | |
| b. Aquatic Tox. | | | |
| c. Clinical Tox. | | | |
| d. Computer | | | |
| e. In Vitro Tox. | | | |
| f. Metabolic Profile | | | |
| g. Neurotoxicology | | | |
| h. Pathology | | | |
| i. Preclinical Tox. | | | |
| j. Wildlife Tox. | | | |

There will be no refunds for cancellations received at SOT Headquarters after February 15, 2013.

SOT will accept faxed Registration Forms until March 6. Online registration will be open until March 14. On-Site Registration Forms will be available at the Annual Meeting Registration Desk. There will be no refunds after February 15, 2013.
Registration

If the person they are accompanying is already registered, they must use the Guest Registration Form and mail or fax it to SOT Headquarters along with a copy of the confirmation of the person they are accompanying.

Guests are welcome to attend the Welcome Reception, but 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 Grand Hyatt.

One-Day Registration
There is no reduced fee for one-day 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 25, 2013. If your registration is received after January 25, 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 15, 2013. These refunds will be processed, less a $50 cancellation fee, following the Annual Meeting. Refund requests received after February 15, 2013, 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 Henry B. Gonzalez 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.

2013 SOT Annual Meeting Registration Policies

By registering for the 2013 SOT Annual Meeting, you are agreeing to the following terms and conditions:

For individuals who are not members of SOT, participation in SOT’s Annual Meeting and ToxExpo is available only to bona fide individuals who are engaged in or promote the field of toxicology or biotechnology research and support the growth and development of the toxicology field. For organizations, participation in the SOT’s Annual Meeting and ToxExpo is available only to bona fide organizations with public policy positions and business practices that are generally consistent with SOT’s mission, goals, reputation, and its policies and principles as determined by SOT. SOT reserves the right to review applications for participation at SOT’s Annual Meeting and ToxExpo to confirm that the applicant meets these criteria and may, at SOT’s sole discretion, reject a registration by any individual or organization or withdraw registration privileges at any time if any individual or organization is found to be inconsistent with SOT’s principles and interests.

Unless written notification by the registrant, stating otherwise, is submitted to SOT Headquarters prior to the Annual Meeting or while registering on-site, SOT Annual Meeting registrants grant SOT permission:

- To reproduce, copy, and publish image, voice, and any or all media taken at the Annual Meeting
- To share registrant contact information with organizations that we believe might have a product or service of interest to you. Limited data provided to third parties include name, affiliation, and business address. Your email, telephone, and fax numbers will not be disclosed to third parties.
- To share registrant name and affiliation with SOT exhibiting companies.
- To be included in the Attendee listing accessible to meeting registrants using the mobile event app or event website—registrant name and affiliation shared.

The policies adopted above will be enforced by the Society. Those individuals who do not comply will be asked to leave the session or ToxExpo floor.

If you have any questions regarding these policies, please contact the SOT Headquarters Office.
The SOT 2013 Annual Meeting Mobile Event App

This year we are happy to announce we are leveraging the services of QuickMobile to provide you, our guests, with a mobile event app and event website. These tools offers you multiplatform mobile solutions for the SOT Annual Meeting and ToxExpo, provided free of charge to attendees and exhibitors. The mobile event app and event website will be available late January via the SOT website and app market places. 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 mobile event app and website will allow you to:

- Connect with fellow attendees
- Build your own schedule and synchronize from the mobile event website to your iPad, tablet, and smartphone simply by logging in
- View presentation details and abstracts
- Add individual presentations or entire sessions to your schedule
- View and interact with speakers
- Search for items based on session title, abstract title, thematic track, or author name
- View the Henry B. Gonzalez Convention Center map and San Antonio city maps
- Request meetings with attendees and exhibitors
- Navigate the real-time ToxExpo floor plan and search for products, specials, and exhibitors
- Contact Exhibitors
- Integrate with Twitter and Facebook
- Scan QR codes quickly and easily within the app

Download the app late January from you favorite app market place or access the mobile event website via the SOT website.

Access information from any mobile device, including popular smartphones, tablets, and iPads—Synchronize your personal schedule by logging in.
YOUR EMPLOYMENT AND RECRUITMENT RESOURCE

Job Seekers—Jobs Await You in the SOT Job Bank!

Employers Are Looking for Candidates through This Service

- 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 fields.

Employers—Recruit Highly Qualified Candidates through the SOT Job Bank!

The SOT Job Bank is the Ideal Place to Streamline Your Recruitment Process

- 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 work experience you are looking for.
- Schedule interviews to be held 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 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 7,300 attendees including top 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 prepares you to take full advantage of the on-site Job Bank Center in San Antonio.

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 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 CVs 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 Henry B. Gonzalez Convention Center in 007D (Office) and 008 (Interview Rooms) 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.

Mentor Match

Online Mentoring Program

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 @SOT Center, formerly known as the 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 Kevin Merritt at SOT Headquarters: 703.438.3115 ext. 1601 or email: careerresources@toxicology.org.

The Society of Toxicology recognizes the importance of mentoring in the scientific and professional development of its members. The objective of the Mentor Match online mentoring program 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 is accessible to all active SOT members by visiting www.toxicology.org/ai/newcrad/mentormatch.asp.
Honorary Membership
Bruce Beutler, MD
University of Texas Southwestern Medical Center, Dallas, TX

Honorary Membership
Jeremy K. Nicholson, PhD
Imperial College London, London, United Kingdom

Achievement Award
Wei Xu, PhD
University of Wisconsin-Madison, Madison, WI

Arnold J. Lehman Award
Moiz Mumtaz, PhD
CDC-ATSDR, Atlanta, GA

Board of Publications for the Best Paper in Toxicological Sciences Award
Blood Gene Expression Profiling Detects Silica Exposure and Toxicity
Rajendran Sellamuthu, Christina Umbright, Jenny R. Roberts, Rebecca Chapman, Shih-Houng Young, Diana Richardson, Howard Leonard, Walter McKinney, Bean Chen, David Frazer, Shengqiao Li, Michael Kashon, and Pius Joseph

Distinguished Toxicology Scholar Award
John J. LeMasters, MD, PhD
Medical University of South Carolina, Charleston, SC

Education Award
Rick G. Schnellmann, PhD
Medical University of South Carolina, Charleston, SC

Enhancement of Animal Welfare Award
Martin L. Stephens, PhD
Johns Hopkins University, Baltimore, MD

Founders Award
William Alfred Suk, PhD, MPH
NIEHS-NIH, Research Triangle Park, NC

Global Senior Scholar Exchange Program
Sri Noegrohati, DrPharm
Post Graduate Program of the Faculty of Pharmacy, Gadjah Mada University and Faculty of Pharmacy, Sanata Dharma University, Jogjakarta, Daerah Istimewa Jogjakarta, Indonesia

Mohamed Mosaad Salama, MSc, MD, PhD, DTQM, DHPE
Department of Toxicology, Mansoura University, Mansoura, Dakaibleya, Egypt

Host:
Mohamed B. Abou-Donia, PhD, ATS, DABT
Duke University Medical Center, Durham, NC

Sponsored Awards

Colgate-Palmolive Grants for Alternative Research
Lei Li Kerr, PhD
Miami University, Oxford, OH
Hao Zhu, PhD
Rutgers University, Camden, NJ

Colgate-Palmolive Awards for Student Research Training in Alternative Methods
Jamie Moscovitz, BA
Rutgers, The State University of New Jersey, Piscataway, NJ
Alexandra Munoz, BA
New York University School of Medicine, Tuxedo, NY

Pfizer Undergraduate Student Travel Awards
Amy Ashworth
Northern Kentucky University, Highland Heights, KY
Naing Bajaj
New Mexico State University, Las Cruces, NM
Colgate-Palmolive Postdoctoral Fellowship Award in \textit{In Vitro} Toxicology

Melanie Adler, PhD
Brigham and Women's Hospital, Boston, MA

Adrienne R. Klinger
University of North Dakota, Grand Forks, ND

Syngenta Fellowship Award in Human Health Applications of New Technologies

Julia E. Rager, MS
University of North Carolina at Chapel Hill, Chapel Hill, NC

Anna Lang
Northern Kentucky University, Highland Heights, KY

Douglas J. Saforo
University of Louisville, Louisville, KY

Best Postdoctoral Publication Awards
(This award is presented at the Postdoctoral Assembly Luncheon on Tuesday)

Petra Haberzettl, PhD
University of Louisville, Louisville, KY


Anne Loccisano, PhD
ORISE/US EPA/NCEA/NRIS, Arlington, VA


Yuanyuan Xu, MD, PhD
National Institute of Environmental and Health Sciences, Research Triangle Park, NC


Perry J. Gehring Diversity Student Travel Award
(This award is presented at the Committee on Diversity Initiatives Reunion on Saturday)

Alexandra Colon-Rodriguez
Michigan State University, East Lansing, MI

Leading Edge in Basic Science Award
Donald Ingber, MD, PhD
Harvard University, Boston, MA

Merit Award
Frederick Peter Guengerich, PhD
Vanderbilt University Medical Center, Nashville, TN

Public Communications Award
Marti Lindsey, MLS, PhD
University of Arizona, Tucson, AZ

Translational/Bridging Travel Award
M. Shane Hutson, PhD
Vanderbilt University, Nashville, TN

Toxicology Landmarks Program
Herbert L. Needleman, MD
University of Pittsburgh Medical Center, Pittsburgh, PA

Undergraduate Educator Award
Sidhartha Ray, PhD, FACN
Manchester University College of Pharmacy, Fort Wayne, IN

up-to-date information at \url{www.toxicology.org}
SOT Award Lectures

Merit Award Lecture

Monday, March 11, 12:30 PM to 1:20 PM

Lecturer: Frederick Peter Guengerich, Vanderbilt University Medical Center, Nashville, TN

Leading Edge in Basic Science Award Lecture

Tuesday, March 12, 8:00 AM to 8:50 AM

Lecturer: Donald Ingber, Harvard University, Boston, MA

Distinguished Toxicology Scholar Award Lecture

Wednesday, March 13, 12:30 PM to 1:20 PM

Lecturer: John J. LeMasters, Medical University of South Carolina, Charleston, SC

More information about award lectures can be found on www.toxicology.org.

SOT Developing Country Travel Fellowships

The SOT/AstraZeneca/IUTOX Travel Fellowships for seven individuals from developing countries selected in December 2012 will be honored at the Awards Ceremony.

The SOT Endowment International Fund/IUTOX Travel Fellowships for two individuals from developing countries selected in December 2012 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 10.

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/awards.
Recognition and Special Events

All activities will be held at the Henry B. Gonzales Convention Center in San Antonio, Texas, unless otherwise noted.

Full details on the Special Events will be available in the Program, on the website, and via the mobile event app.

Committee on Diversity Initiatives Reunion

Saturday, March 9, 8:00 PM to 9:00 PM
Marriott Rivercenter

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 9. 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 24 years, meet with program alums, and greet the undergraduate students who are attending the program this year. The Perry J. Gehring Diversity Student Travel Award will be presented and former SOT President Ken Ramos will speak. After directing his church choir for 13 years, Galo was presented with the opportunity to study at the National Conservatory of Panama with one of the best classical guitarists in Latin America, Francisco Velásquez. Since moving to the United States, Galo now directs the famous Spanish Choir at St. Luke’s Catholic Church, teaches at the Hand on Music School, and continues to perform throughout San Antonio. To learn more about Galo Gutiérrez go to the SOT 2013 Annual Meeting website at www.toxicology.org/ai/meet/am2013/socialevents.asp.

Awards Ceremony Music

Sunday, March 10, 4:45 PM to 5:15 PM

Performed by
Galo Gutiérrez Jr.

Galo Gutiérrez will perform for SOT Annual Meeting attendees prior to and after the SOT Award Ceremony. Galo was born in Panama Republic of Panama and picked up his first guitar at the age of nine. He learned to play beautiful chords from his father and brothers who also helped him understand that music is both fun and food for the soul that he could convey to others. After directing his church choir for 13 years, Galo was presented with the opportunity to study at the National Conservatory of Panama with one of the best classical guitarists in Latin America, Francisco Velásquez. Since moving to the United States, Galo now directs the famous Spanish Choir at St. Luke’s Catholic Church, teaches at the Hand on Music School, and continues to perform throughout San Antonio. To learn more about Galo Gutiérrez go to the SOT 2013 Annual Meeting website at www.toxicology.org/ai/meet/am2013/socialevents.asp.

Awards Ceremony

Sunday, March 10, 5:15 PM to 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 10, 6:30 PM to 7:30 PM

Continue the celebration by attending the Welcome Reception following the Awards Ceremony. The Welcome 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 10, 7:00 PM to 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.

SOT Mentoring Breakfast

Monday, March 11, 6:15 AM to 7:45 AM
Grand Hyatt Hotel, Bowie Room

(Sponsor:
Career Resource and Development (CRAD) Committee
Graduate Student Leadership Committee
Postdoctoral Assembly

The Society of Toxicology recognizes the importance of mentoring in the scientific and professional development of its members. As such, the Career Resource and Development Committee, in conjunction with the Postdoctoral Assembly and Graduate Student Leadership Committee, is pleased to announce the 2nd annual Mentoring Breakfast.

The Mentoring Breakfast is for SOT members at any career stage—from graduate students to postdoctoral fellows to senior scientists—who are seeking a mentor. Brief presentations will be followed by small group discussions led by trained facilitators. Facilitators will work to match participants with compatible mentors following the Annual Meeting.

A limit of 50 participants will be accepted on a first-come, first-served basis for this event at a cost of $10/person, which includes a continental breakfast.

up-to-date information at www.toxicology.org
Special Events

Global Collaboration Coffee
Monday, March 11, 9:00 AM to 11:00 AM
The SOT Council invites all Global Gallery participants and representatives of societies from around the world to the Global Collaboration Coffee. Other invitees include SOT Special Interest Group leaders, IUTOX Executive Committee members, SOT Councilors, 2013 Global Senior Scholars and their hosts, and the 2013 recipients of the SOT/AstraZeneca/IUTOX and SOT Endowment Fund Fellowships (senior scientists from developing countries.) This event offers an opportunity for scientific leaders to meet and make plans for future collaborations. Following the coffee, attendees will adjourn together to the Global Gallery where presenters will share their posters in an "Author Attended" poster time from 11:00 am–12:30 pm on Monday, March 11. See page 16 for more information about the Global Gallery of Toxicology.

In Vitro Toxicology Lecture and Luncheon for Students
Monday, March 11, 12:00 Noon to 1:20 PM (Ticket Required)
Chairperson(s): Thomas A. Lewandowski, Education Committee Chair, Gradient, Seattle, WA, and Emily G. Notch, Dartmouth Medical School, Hanover, NH.
From Hazard Identification to Risk Assessment: Linking It Together with In Vitro Models
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. Hamadeh will present an introduction to the topic, and then participants will discuss related questions and report responses. More information can be found on page 44.

Past Presidents’ 5K Fun Run/Walk
Tuesday, March 12, 6:30 AM
Hemisfair Park
Sponsors: Millar Instruments
Seventh Wave Laboratories/PreClinical Research Services
Join us for the 3rd annual Past Presidents’ 5K Fun Run/Walk! Open to anyone interested, this event is a great opportunity to meet old friends and make new friends in a casual environment, all while showing support for SOT and its wonderful past presidents. Whether you’re in it for some friendly competition (yes, this year’s race will be a timed event) or would rather take a leisurely stroll, this event’s emphasis is on camaraderie and looks to bring together runners or walkers of all levels and paces. Come join us—we look forward to seeing you!

To register, visit the Special Events section of the SOT Annual Meeting website. Registration is only $10, and all proceeds will go towards the SOT Endowment Fund. Be sure to register by January 22 to receive a t-shirt and race goodie bag!

Postdoctoral Assembly Luncheon
Tuesday, March 12, 12:00 Noon to 1:15 PM (Ticket Required)
Chairperson(s): Enrique Fuentes Mattei, University of Texas MD Anderson Cancer Center, Houston, TX.
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 Best Postdoctoral Publication Awards will be given to three postdoctoral scholars and postdoc award recipients from SOT and Regional Chapters, Special Interest Groups and Specialty Sections will be recognized. The PDA Board members will present an overview of accomplishments and future directions for the PDA, and will introduce the new board members for 2013–2014. There will be a drawing for prizes. Postdocs can reserve a ticket for $10 when they register for the Annual Meeting.
Undergraduate Educator Network Meeting

Tuesday, March 12, 3:00 PM to 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 12, 4:30 PM to 6:00 PM
(SOT Members Only)

Members are invited and encouraged to attend the 52nd SOT Annual Business Meeting. The agenda includes discussion of plans for 2013–2014, a financial summary, and a review of the 2012–2013 activities.

Tox ShowDown

Tuesday, March 12, 7:30 PM to 9:00 PM
Marriott Riverwalk

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 four 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.

Student and Postdoctoral Scholar Events

Chat with an Expert

Sunday, March 10 to Thursday, March 14,
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 undergraduate students. 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.

Student/Postdoctoral Scholar Mixer

Sunday, March 10, 7:30 PM to 9:00 PM
(Ticket Required)

Sponsor:
- Graduate Student Leadership Committee

The Graduate Student Leadership Committee hosts this opportunity for students and postdoctoral scholars to gather, to meet new colleagues, and to reestablish relationships in an informal atmosphere at the beginning of the meeting. Tickets are obtained at no cost by registering for this event on the Annual Meeting Registration Form. Ticket and meeting badge are required. Complimentary refreshments and a cash bar will be available.

Poster Tours for Trainees

Monday, March 11 to Thursday, March 14
Specific Time Varies by Group
(Meet at the Poster Tour sign at the SOT Pavilion)

Sponsor:
- Postdoctoral Assembly

A well-received, new event at the 2012 Annual Meeting, students and postdoctoral scientists will once again 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 Lecturer: Dr. Beutler

Monday, March 11, 10:00 AM to 11:00 AM
(Ticket Required; SOT Student and Postdoctoral members only, limited seating)

Chairperson(s): David T. Szabo, US EPA, Arlington, VA.

Lecturer: Bruce Beutler, University of Texas Southwestern Medical Center, Dallas, TX.

Dr. Beutler will meet informally for discussion with graduate students and postdoctoral scholars after his Plenary Opening Lecture (see page 63). 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 11, 12:00 Noon to 1:20 PM
(Ticket Required)

Chairperson(s): Thomas A. Lewandowski, Education Committee Chair, Gradient, Seattle, WA, and Emily G. Notch, Dartmouth Medical School, Hanover, NH.

From Hazard Identification to Risk Assessment: Linking It Together with In Vitro Models


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. Undergraduate students, graduate students, 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. Hamadeh will present an introduction to the topic, challenge participants to discuss specific questions at their tables, and then participants will report responses.

Gaining insight to a molecule’s potential to cause harm to humans is a major challenge for scientists working in a variety of industries and disciplines including drug and chemical development as well as environmental protection. The range of tools that are employed range from *in silico* to *in vitro* and *in vivo* animal models in order to approximate the reaction of humans to drugs and chemicals. *In vitro* models have the obvious advantages of not requiring large quantities of given molecules for testing, they contribute to a decrease in animal testing (3Rs). One example is the use of the bile salt export pump (BSEP) functional assay for informing the potential hazard associated with molecules for causing hepatotoxicity in humans through interference with normal bile acid transport. In drug development, clinical liver injury might translate into potentially less competitive drugs. Molecules hypothesized to be associated with clinical liver injury via interference with BSEP function have often not resulted in liver injury signals in preclinical species. *In vitro* assays that can predict the potential clinical hazard in the absence of animal models are valuable not only for selecting more quality candidate drugs to advance, but also to reduce the number of animals consumed by advancing molecules with high potential for liver effects that may eventually be removed from development, depending on the indication. Several confounders that underlie the interpretation of BSEP activity data will be discussed and potential solutions that may improve the translation of the hazard signal to a risk assessment using this assay will be debated.

Postdoctoral Assembly Workshop

Monday, March 11, 1:45 PM to 3:45 PM
(Ticket Required; SOT Student and Postdoctoral members only, limited seating)

Chairperson(s): Enrique Fuentes Mattei, University of Texas MD Anderson Cancer Center, Houston, TX.

Sponsor: Postdoctoral Assembly

Tools for Bringing Creativity into Your Scientific Research


When are Legos not just for kids? When they are a valuable problem-solving tool for your scientific research. Overcoming roadblocks during a research career can be a challenge particularly when you are using the same set of tools that got you into the roadblock in the first place. Traditional research training often emphasizes linear approaches and the value of greater focus and harder work. Yet, history tells us that many of the most remarkable scientific breakthroughs occur when our attention has been diverted. Nonlinear approaches to problem solving provide additional avenues for the budding researcher. This workshop on enhancing creativity in scientific research will provide lecture material and hands-on exercises including the use of play, meditation, sleep, music, dance, art, improv, language, body adjustments, concept maps, synchronicity, and strategies for becoming the observer of your own research progress.
Postdoctoral Assembly Luncheon

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

Chairperson(s): Enrique Fuentes Mattei, University of Texas MD Anderson Cancer Center, Houston, TX.

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 Best Postdoctoral Publication Awards will be given to three postdoctoral scholars and postdoc award recipients from SOT and Regional Chapters, Special Interest Groups and Specialty Sections will be recognized. The PDA Board members will present an overview of accomplishments and future directions for the PDA, and will introduce the new board members for 2013–2014. There will be a drawing for prizes. Postdocs can reserve a ticket for $10 when they register for the Annual Meeting.

Trainee Discussion with Medical Research Council (MRC) Lecturer: Prof. Nicholson

Wednesday, March 13, 10:00 AM to 11:00 AM
(Ticket Required; SOT Student and Postdoctoral members only, limited seating)

Chairperson(s): Enrique Fuentes Mattei, University of Texas MD Anderson Cancer Center, Houston, TX.


Prof. Nicholson will meet informally for discussion with graduate students and postdoctoral scholars after his Keynote MRC Lecture (see page 63). Room size is limited, and participants register for a ticket with their Annual Meeting registration.

Undergraduate Student Meeting

Wednesday, March 13, 4:00 PM to 5:00 PM

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

Sponsors:
Education Committee
Undergraduate Education Subcommittee

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

High School Poster Exposition

Tuesday, March 12 and Wednesday, March 13

Chairperson(s): Daniel E. Arrieta, Chevron Phillips Chemical Company LP, The Woodlands, TX.

Sponsors:
Education Committee
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 28. 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.

K–12 Toxicology Outreach Activities: Regional Chapter Successes and Resources

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

Chairperson(s): Courtney E.W. Sulentic, Wright State University, Dayton, OH, and Rafael Ponce, Amgen Inc, Seattle, WA.

Sponsors:
Education Committee
K–12 Subcommittee

K–12 activities are a vital component in our mission to educate the community regarding hazards and hazard communication. Several SOT Regional Chapters have very active K–12 community outreach programs and others are interested in establishing these programs. The Education Committee and Regional Chapter Collaboration and Communication Committee, in promoting recognition of toxicology and communicating the benefit of toxicology to external audiences, support these efforts. This workshop will highlight some of the successful K–12 outreach activities supported by Regional Chapters and will include hands-on demonstrations as well as an overview of efforts to update website resources for K–12 activities. Pedagogical insights helpful to those new to educational outreach will be provided, including opportunities for skill development and pedagogical background for graduate students and postdoctoral scholars considering academic careers.

- **TOTALLY TOXIC! A K–12 Outreach Program Based on the 5E Model of Science Education.** Christine Curran, Northern Kentucky University, Highland Heights, KY.
- **Inspector Tox Outreach Activity.** Diane Hardej, St. John’s University, Jamaica, NY, and Anthony Schatz, Merck & Co Inc., Whitehouse Station, NJ.
- **Silly Science and Other Activities for K–12 Outreach.** Marie Bourgeois, University of South Florida, Tampa, FL.
Special Events

- Exploring Toxicology: Designing Learning Goals and Evaluation Strategies for Outreach Activities. Erin Shanle and Kristina Blanke, University of Wisconsin-Madison, Madison, WI.

Undergraduate Education Program

Saturday, March 9 to Monday, March 11

Chairperson(s): Erin Pias Hines, US EPA, Research Triangle Park, NC.

Sponsor: Committee for Diversity Initiatives (CDI)

For schedule details go to www.toxicology.org/ai/meet/am2013/edout.asp or contact CDI Staff liaison Susan D. Simmons at susan@toxicology.org

Saturday, March 9 Marriott Rivercenter

Open to undergraduates in the travel award program
- Orientation for SOT Hosts, Peer Mentors, and Advisors
- Registration for Undergraduate Students
- Opening program
  Icebreaker, Alice M. Villalobos, Texas A&M University, College Park, TX.
  Introduction to Toxicology, Antonio T. Baines, North Carolina Central University, Durham, NC.
- 8:00 PM–9:00 PM—CDI Reunion (Dessert and Networking)—Open to anyone previously involved with CDI programs.
  Speaker: Kenneth S. Ramos, University of Louisville, Louisville, KY.
- Recognition of the 2013 Perry J. Gehring Diversity Student Travel Award Recipient

Sunday, March 10 Marriott Rivercenter

Open to undergraduates in the travel award program and those who register through the Annual Meeting registration
- Welcome from SOT President William Slikker Jr.
- Special Toxicology Lectures
  Toxicology of the Blood-Cerebrospinal Fluid Barrier—A Comparative Approach, Alice M. Villalobos, Texas A&M University, College Park, TX.
  Exposure to Smoked and Smokeless Tobacco In Utero: Fetal Injury and Life Long Consequences, Judith A. Zelikoff, New York University School of Medicine, Tuxedo Park, NY.
  Optical Nanotechnologies for Imaging of Cellular Processes and Neurosurgery, Martin A. Philbert, University of Michigan, Ann Arbor, MI.

- Breakout Sessions
  For Students: What Is Graduate School and What Can I Expect: How to Get into Graduate School
  For Advisors: Tips for Advising Prospective Graduate Students
  Presentation
  Speaker: Linda S. Birnbaum, Director NIEHS, Research Triangle Park, NC.
  Career Opportunities in Toxicology—Panel Discussion
  Moderator: Robert P. Cassillas, MRIGlobal, Kansas City, MO.
  Academic: Darryl B. Hood, Meharry Medical College, Nashville, TN.
  Government: Ofelia Olivero, NIH-NCI, Bethesda, MD.
  Industry: Mari S Stavanja, Celanese Corporation, Dallas, TX.
  Nonprofit: Claire Redman Croutch, Midwest Research Institute, Kansas City, MO.
- Open Time with Academic Toxicology Program Directors and Internship Sponsors
  Featuring representatives from programs across the country looking for talented students interested in advanced studies in the biomedical sciences.
  Student/Postdoc Mixer

Monday, March 11 Convention Center

Open to undergraduates in the travel award program.
- Plenary Lecture
- Poster Session for Visiting Students—ToxExpo
- Program Recognitions and Wrap Up
- In Vitro Lecture and Luncheon for Students

Student/Postdoc Mixer
The Official Journal of the Society of Toxicology

Toxicological Sciences

- Premier, hypothesis-driven original research articles in all areas of toxicology
- Advance Access—quick online publication, weeks ahead of print
- Optional open access for authors

VISIT OUR BOOTH AT TOXEXPO 2013
OR VISIT US ONLINE AT
www.toxsci.oxfordjournals.org

* 2011 Journal Citation Reports (Thomson Reuters, 2012)
## Special Events

### RC, SIG, and SS Receptions

#### Regional Chapter Meetings/Luncheons or Receptions

*Monday, March 11, through Wednesday, March 13, Various Times (Refer to the Annual Meeting Program and mobile event app or event website 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>Central States Regional Chapter Meeting</td>
<td>Monday, March 11</td>
<td>7:00 AM to 8:00 AM</td>
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<tr>
<td>Lake Ontario Regional Chapter Mixer</td>
<td>Monday, March 11</td>
<td>5:00 PM to 7:00 PM</td>
</tr>
<tr>
<td>Lone Star and South Central Regional Chapters Mixer</td>
<td>Tuesday, March 12</td>
<td>4:30 PM to 6:00 PM</td>
</tr>
<tr>
<td>Michigan Regional Chapter Reception</td>
<td>Monday, March 11</td>
<td>5:00 PM to 6:00 PM</td>
</tr>
<tr>
<td>Mid-Atlantic Regional Chapter Luncheon</td>
<td>Monday, March 11</td>
<td>12:00 Noon to 2:00 PM</td>
</tr>
<tr>
<td>Midwest and Northland Regional Chapters Mixer</td>
<td>Tuesday, March 12</td>
<td>4:30 PM to 6:30 PM</td>
</tr>
<tr>
<td>National Capital Area Regional Chapter Reception</td>
<td>Monday, March 11</td>
<td>5:30 PM to 7:30 PM</td>
</tr>
<tr>
<td>Northeast Regional Chapter Student Luncheon</td>
<td>Tuesday, March 12</td>
<td>12:00 Noon to TBD</td>
</tr>
<tr>
<td>Northern California Regional Chapter Meeting/Reception</td>
<td>Tuesday, March 12</td>
<td>7:00 PM to 10:00 PM</td>
</tr>
<tr>
<td>Southeastern Regional Chapter Reception</td>
<td>Monday, March 11</td>
<td>6:00 PM to 8:00 PM</td>
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</tbody>
</table>

#### Special Interest Group Meetings/Luncheons or Receptions

*Monday, March 11, through Wednesday, March 13, Various Times (Refer to the Annual Meeting Program and mobile event app or event website for more details.)*

Each of the six Special Interest Groups will hold a meeting/reception during the 2013 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>
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<tbody>
<tr>
<td>American Association of Chinese in Toxicology Special Interest Group Distinguished Chinese Toxicologist Lectureship Award Seminar</td>
<td>Monday, March 11</td>
<td>5:00 PM to 6:00 PM</td>
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<tr>
<td>American Association of Chinese in Toxicology Special Interest Group Meeting/Reception</td>
<td>Monday, March 11</td>
<td>6:00 PM to 9:00 PM</td>
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<tr>
<td>Association of Scientists of Indian Origin Special Interest Group Lunch and Learn</td>
<td>Tuesday, March 12</td>
<td>12:00 Noon to 1:30 PM</td>
</tr>
<tr>
<td>Association of Scientists of Indian Origin Special Interest Group Reception</td>
<td>Monday, March 11</td>
<td>7:00 PM to 9:00 PM</td>
</tr>
<tr>
<td>Women in Toxicology Special Interest Group Mentoring Breakfast</td>
<td>Monday, March 11</td>
<td>6:15 AM to 7:45 AM</td>
</tr>
<tr>
<td>Women in Toxicology Special Interest Group Reception</td>
<td>Monday, March 11</td>
<td>4:30 PM to 6:30 PM</td>
</tr>
</tbody>
</table>
### Specialty Section Meetings/Luncheons or Receptions

**Monday, March 11, through Wednesday, March 13, Various Times** *(Refer to the Annual Meeting Program and mobile event app or event website for more details.)*

Each of the 27 SOT Specialty Sections will hold either a luncheon or early evening meeting/reception during the 2013 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>
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<tbody>
<tr>
<td>Biological Modeling Meeting/Reception</td>
<td>Tuesday, March 12</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Biotechnology Meeting/Reception</td>
<td>Monday, March 11</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Carcinogenesis Meeting/Reception</td>
<td>Wednesday, March 13</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Cardiovascular Toxicology Meeting/Reception</td>
<td>Monday, March 11</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Clinical and Translational Toxicology Meeting/Reception</td>
<td>Monday, March 11</td>
<td>6:00 PM to 7:30 PM</td>
</tr>
<tr>
<td>Comparative and Veterinary Luncheon</td>
<td>Tuesday, March 12</td>
<td>12:00 Noon to 1:30 PM</td>
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<tr>
<td>Dermal Toxicology Meeting/Reception</td>
<td>Monday, March 11</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Drug Discovery Toxicology Meeting/Reception</td>
<td>Tuesday, March 12</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Ethical, Legal, and Social Issues Meeting/Reception</td>
<td>Monday, March 11</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Food Safety Meeting/Reception</td>
<td>Wednesday, March 13</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Immunotoxicology Meeting/Reception</td>
<td>Tuesday, March 12</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>In Vitro and Alternative Methods Luncheon</td>
<td>Tuesday, March 12</td>
<td>12:00 Noon to 1:30 PM</td>
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<tr>
<td>Inhalation and Respiratory Meeting/Reception</td>
<td>Tuesday, March 12</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Mechanisms Meeting/Reception</td>
<td>Tuesday, March 12</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Medical Device Luncheon</td>
<td>Wednesday, March 13</td>
<td>12:00 Noon to 1:30 PM</td>
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<tr>
<td>Metals Meeting/Reception</td>
<td>Wednesday, March 13</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Mixtures Meeting/Reception</td>
<td>Tuesday, March 12</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Molecular Biology Meeting/Reception</td>
<td>Wednesday, March 13</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Nanotoxicology Meeting/Reception</td>
<td>Wednesday, March 13</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Neurotoxicology Meeting/Reception</td>
<td>Tuesday, March 12</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Occupational and Public Health Luncheon</td>
<td>Wednesday, March 13</td>
<td>12:00 Noon to 1:30 PM</td>
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<tr>
<td>Ocular Toxicology Meeting/Reception</td>
<td>Wednesday, March 13</td>
<td>6:00 PM to 7:30 PM</td>
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(continued to next page)
### Special Events

**Specialty Section Meetings/Luncheons or Receptions** *(continued)*

<table>
<thead>
<tr>
<th>Event</th>
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<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory and Safety Evaluation Meeting/Reception</td>
<td>Tuesday, March 12</td>
<td>6:00 PM to 7:30 PM</td>
</tr>
<tr>
<td>Reproductive and Developmental Toxicology Meeting/Reception</td>
<td>Monday, March 11</td>
<td>6:00 PM to 7:30 PM</td>
</tr>
<tr>
<td>Risk Assessment Meeting/Reception</td>
<td>Tuesday, March 12</td>
<td>6:00 PM to 7:30 PM</td>
</tr>
<tr>
<td>Specialty Section Collaboration and Communication Group Meeting</td>
<td>Monday, March 11</td>
<td>3:00 PM to 4:00 PM</td>
</tr>
<tr>
<td>Stem Cells Meeting/Reception</td>
<td>Monday, March 11</td>
<td>6:00 PM to 7:30 PM</td>
</tr>
<tr>
<td>Toxicologic and Exploratory Pathology Luncheon</td>
<td>Monday, March 11</td>
<td>12:00 Noon to 1:30 PM</td>
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</tbody>
</table>

### NOTES

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Thank You

Council

William Slikker Jr..............................................President
Lois D. Lehman-McKeeman ....................Vice President
Norbert E. Kaminski ..................................Vice President-Elect
John B. Morris ..............................................Treasurer
Denise Robinson Gravatt ........................Treasurer-Elect
Judith T. Zelikoff .............................................Secretary
Jon C. Cook ..................................................Past President
Lorrence A. Buckley .................................Councilor
Donald A. Fox ............................................Councilor
Dori R. Germolec .....................................Councilor
John C. Lipscomb ....................................Councilor
Ivan Rusyn .................................................Councilor
Michael P. Waalkes .................................Councilor
Shawn D. Lamb .........................................Executive Director

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J. Craig Rowlands........................................Chair
Mark E. Hurtt ............................................Co-Chair
Gayathri Chadalapaka ..............................Member
Hanan N. Ghantous ................................Member
William B. Mattes ......................................Member
James Patrick O’Callaghan ........................Member
Vishal S. Vaidya .........................................Member
Tao Wang ................................................ Member
Qiyu (Jay) Zhao ..........................................Member
Sachin Bhusari ...............................Postdoctoral Representative
Gregory Weber ..............................Graduate Student Representative
Michael P. Waalkes .................................Council Contact

Scientific Program Committee

Lois D. Lehman-McKeeman ...............Chair, Council Contact
Norbert E. Kaminski ..........................Co-Chair
Leigh Ann Burns Naas ........................Member
Michael J. Carvan III ............................Member
Paul M. D. Foster ................................Member
Mary Beth Genter ................................Member
B. Bhaskar Gollapudi ............................Member
Paul C. Howard .......................................Member
Annie M. Jarabek ....................................Member
Abby A. Li ...............................................Member
Donald R. Mattison ..............................Member
David Ross .............................................Member
James L. Stevens ....................................Member
Peter K. Working .................................Member

up-to-date information at www.toxicology.org
Continuing Education Courses Online

CEd-Tox offers a great, low-cost way to expand your professional development, or stay current in the field of toxicology, all year long. A diversity of CE courses from SOT Annual Meetings are now available, including slide presentations and audio; English language transcriptions are available for select courses. SOT Graduate Student and Postdoctoral members receive complimentary access to all courses!

Whether to update your knowledge or to explore a new area, we invite you to register for CEd-Tox. For more information or to register, visit the SOT website: www.toxicology.org/cedtox.asp.

Cardiovascular Toxicology:
• Current Nonclinical Strategies and Methods for Evaluating Drug-Induced Cardiovascular Toxicity (2011)

Dermal Toxicology:
• Cutaneous Toxicity: In Vitro Methods for Toxicity and Safety Evaluation (2012)

Drug Discovery Toxicology:

Immunotoxicology:
• Drug Hypersensitivity Reactions: Risk Assessment and Management (2011)
• Overview and Application of the WHO-IPCS Harmonized Guidance for Immunotoxicity Risk Assessment for Chemicals (2012)

In Vitro and Alternative Methods:
• Alternative In Vitro Tox Testing for the 21st Century (2012)
• Quantitative In Vitro to In Vivo Extrapolation: The Essential Element of In Vitro Assay-Based Risk Assessment (2011)

Inhalation and Respiratory:
• Comparative Biology of the Lung (2010)

Mixtures:
• Toxicology and Risk Assessment of Chemical Mixtures (2011)

Molecular Biology:
• Applications of Computational Systems Biology for Toxicology (2011)
• Epigenetics in Toxicology: Introduction, Mechanistic Understanding and Applications in Safety Assessment (2011)

Nanotoxicology:
• Evaluating Toxicity of Engineered Nanomaterials: Issues with Conventional Toxicology Approaches (2011)

Occupational and Public Health:
• Protecting Human Health: Use of Toxicological and Epidemiological Data in Determining Safe Levels for Human Exposure (2011)

Ocular Toxicology:
• Assessment of Ocular Toxicity in Toxicology Studies Conducted for Regulatory Purposes (2010)

Regulatory and Safety Evaluation:
• New Technologies and Approaches in Genetic Toxicology and Their Expanding Role in General Toxicology and Safety Assessment (2011)
• Translation of Safety Biomarkers in Drug Discovery and Development (2009)

Reproductive and Developmental Toxicology:
• Basic Embryology and Developmental Toxicity Testing (2012)
• Biology and Toxicology of the Peri- and Postnatal Development (2011)

Risk Assessment:
• Best Practices for Developing, Characterizing and Applying Physiologically-Based Pharmacokinetic Models in Risk Assessment (2011)

Stem Cells:
• Stem Cells in Toxicology (2012)
• Stem Cells Utility in Toxicology Screening (2011)

Toxicologic and Exploratory Pathology:
• Segment-Specific Renal Pathology for the Nonpathologist (2010)
• Stress As a Confounding Factor (2009)
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 10, 2013, at the Henry B. Gonzalez 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:

SR—Sunrise (7:00 AM–7:45 AM)
AM—Morning (8:15 AM–12:00 Noon)
PM—Afternoon (1:15 PM–5:00 PM)

Registration for the Annual Meeting and a separate CE course ticket are required.

2013 Continuing Education Courses

A Refresher of Immunoglobulin and Fc-Receptor Biology and Advances Related to Therapeutic Antibody Development

Biomarkers for Exposure Assessment, Safety Evaluation, and Translational Medicine

SR01
CE BASIC

Chairperson(s): Theodora W. Salcedo, Bristol-Myers Squibb Company, East Syracuse, NY.

Sponsor:
Biotechnology Specialty Section

Endorsed by:
Regulatory and Safety Evaluation Specialty Section
Toxicologic and Exploratory Pathology Specialty Section

The presentation will review the immunobiology of antibodies and Fc receptors and explore the field of therapeutic antibody development and advances in "antibody engineering" leading to the development of improved therapeutics. A basic overview will be provided on the structure and function of antibodies, as well as the various types and formats of antibody therapeutics and technological methods of production. In addition, the immunobiology of human leukocyte Fc receptors will be discussed. These receptors serve to link humoral immune responses to cellular activities within the immune system, and generally function as either antibody-binding receptors that trigger immune cell effector functions, or as transport receptors (FcRn). Highlights will include how immunoglobulin Fc sequences are now being tailored to trigger specific Fc receptors to improve therapeutic outcomes by introducing amino acid mutations, glyco-engineering, or other approaches leading to next generation formats. Known species differences in immunoglobulins and Fc receptors that may be important for pharmacologic and toxicologic evaluations will be explored, as well as other challenges in assessing the nonclinical toxicities of new antibody formats. Building upon these basic themes, the presentation will explore the current landscape of approved therapeutics and forecasts for future developments in the field. The course will provide something for those seeking basic knowledge in the field of immunology and therapeutic antibody development, as well as those seeking to refresh and enhance their knowledge of recent advances.

- A Refresher of Immunoglobulin and Fc-Receptor Biology and Advances Related to Therapeutic Antibody Development. Theodora W. Salcedo, Bristol-Myers Squibb Company, East Syracuse, NY.
Continuing Education

Basic Principles of Human Risk Assessment

**AM02** 
**CE BASIC**

**Chairperson(s):** Qiyu (Jay) Zhao, US EPA, Cincinnati, OH, and M.E. (Bette) Meek, University of Ottawa, Ottawa, ON, Canada.

**Sponsor:** Risk Assessment Specialty Section

An overview of the fundamental, evolving guiding principles, and general methods used in chemical risk assessment will be provided. These principles and methods are addressed in presentations and discussions organized by the four components identified by the National Research Council in the Risk Assessment Paradigm: Hazard Identification and Characterization; Dose-Response Assessment; Exposure Assessment; and Risk Characterization. Guiding principles and key concepts in risk assessment will be illustrated by examples from the literature and sample calculations for dose-response assessment, exposure assessment, and risk characterization will presented.

- **Introduction to Chemical Risk Assessment.** Qiyu (Jay) Zhao, US EPA, Cincinnati, OH.
- **Hazard Identification and Characterization.** Jeffrey Lewis, ExxonMobil Biomedical Sciences, Inc., Annandale, NJ.
- **Dose-Response Assessment.** John C. Lipscomb, US EPA, Cincinnati, OH.
- **Exposure Assessment.** Robinan Gentry, ENVIRON International Corporation, Monroe, LA.
- **Risk Characterization.** M.E. (Bette) Meek, University of Ottawa, Ottawa, ON, Canada.

Recent Developments in Cardiovascular Physiology-Based Toxicology

**AM03** 
**CE BASIC**

**Chairperson(s):** Travis L. Knuckles, West Virginia University, Morgantown, WV, and W. David McGuinn, US FDA-CDER, Columbia, MD.

**Sponsor:** Cardiovascular Toxicology Specialty Section

**Endorsed by:**
- Comparative and Veterinary Specialty Section
- Mechanisms Specialty Section
- Toxicologic and Exploratory Pathology Specialty Section

Contemporary drug development and toxicity assessments are focused on exploiting specific molecular targets that can improve disease outcomes with minimal untoward effects. Unfortunately, modern training in toxicology and pharmacology is directed primarily at specific ligand-receptor interactions at the expense of systems physiology. An overview of cardiovascular physiology, with a thematic focus on toxicology, will be provided. The presentations will include: overall physiological changes that manifest at the whole-animal level following toxicant exposure; *in vivo*, *in vitro*, and *ex vivo* cardiac testing protocols in the regulatory environment, and how current testing strategies may potentially miss cardiac effects that manifest chronically; vascular and microvascular effects that result from toxicity initiated in other tissues; and microvascular physiology and toxicology in the context of model development, application, and underlying pathology. The course will be of interest to a broad scope of scientists that are increasingly being requested to consider the impact of novel compounds and toxicants on the physiology of the entire cardiovascular system.

- **Introduction to Cardiovascular Physiology.** Travis L. Knuckles, West Virginia University, Morgantown, WV.
- **Role of Physiological Responses in Toxicant-Induced Cardiovascular Injury.** Medhi Hazari, US EPA, Research Triangle Park, NC.
- **The Mechanisms and Manifestations of Cardiac Toxicity Associated with Chronic Drug Administration, with Examples from Experience with Oncology Drugs.** W. David McGuinn, US FDA-CDER, Columbia, MD.
- **Principles of Microvascular Assessments in Toxicology.** Timothy Nurkiewicz, West Virginia University, Morgantown, WV.
- **Microvascular Perfusion: Where Do the Red Cells Go Following Toxicant or Oxidative Damage?** Mary (Molly) D. Frame, Stony Brook University, Stony Brook, NY.
- **Cardiovascular Responses to Particulate Matter and Nanoparticles.** Vincent Castranova, CDC-NIOSH, Morgantown, WV.

Approval of Biosimilar Monoclonal Antibodies: Scientific, Regulatory, and Legal Challenges

**AM04** 
**CE BASIC**

**Chairperson(s):** Lynne LeSauteur, Charles River Laboratories, Semneville, QC, Canada, and Jonathan D. Urban, ToxStrategies, Inc., Austin, TX.

**Sponsor:** Immunotoxicology Specialty Section

**Endorsed by:**
- Biotechnology Specialty Section

Technological advances have resulted in the development of a wide range of innovative monoclonal antibodies (mAb). As the patents for these monoclonal antibodies expire, there has been a growing interest
in the market of “generic” follow-on products, or biosimilars. These biosimilar drugs, however, are not generic in the same sense as small molecule drugs since they do not have identical active component(s) as the innovative drug product due to the differences in production. While established standard analytical methodologies enable manufacturers of generic small molecule drugs to demonstrate pharmacoequivalence, the complex and sensitive nature of even the most similar biological manufacturing systems (e.g., commercial cell lines) makes producing identical copies of the innovative monoclonal antibody products impossible. Therefore, the scientific and regulatory paradigm for demonstrating that the products are highly similar and that there are no clinically meaningful differences between a biosimilar product and an innovative therapeutic in order to obtain drug approval is necessarily much more complex. Adding to this complexity is the regulatory environment that impacts on the biosimilar approval process. Case studies will compare and contrast the scientific and regulatory approaches used for mAb biosimilar drug development. These examples will cover the GMP to clinical strategies in broad scope but focus on the preclinical breadth of studies conducted based on the extent of GMP and clinical similarity data available. Within these presentations the scientific rational for similarity with the innovator drug will be highlighted. The basic concepts of the legal challenges and recent Biologics Price Competition and Innovation Act (BPCIA), which creates an abbreviated approval framework for an innovator drug will be highlighted. The basic concepts of the legal challenges and recent Biologics Price Competition and Innovation Act (BPCIA), which creates an abbreviated approval framework for biological products that are demonstrated to be “biosimilar” to or “interchangeable” with a US FDA-licensed biological product, along with the role the patent and data exclusivity provisions will play in biosimilar drug development, will also be discussed.

- Preclinical Strategies to Support Clinical Development of Biosimilar Monoclonal Antibodies. Christine Grimaldi, Boehringer Ingelheim Pharmaceuticals, Ridgefield, CT.
- Nonclinical Development of Biosimilars: Adjusting the Strategy to Fit the Program. Michael W. Leach, Pfizer, Inc., Andover, MA.
- Regulatory Considerations for Biosimilar Monoclonal Antibodies. Marjorie Shapiro, US FDA, Washington, DC.

The What, When, and How of Nonclinical Support for an IND Submission

Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment

AM05 CE BASIC

Chairperson(s): Paul Nugent, Pfizer Worldwide Research and Development, Groton, CT, and Dorothy Colagiovanni, N30 Pharmaceuticals, LLC, Boulder, CO.

Sponsor:
- Regulatory and Safety Evaluation Specialty Section

Endorsed by:
- Cardiovascular Toxicology Specialty Section
- Drug Discovery Specialty Section
- Toxicologic and Exploratory Pathology Specialty Section

The initiation of dosing of human subjects in a Phase 1 clinical trial represents the culmination of years of drug development, and immediately preceding the start of dosing, months of work to prepare and submit the Investigational New Drug (IND) application (or Clinical Trial Application (CTA)). A critical part of the submission dossier is the sections that describe the nonclinical data and interpretation that underwrite the clinical plan; specifically, the results of studies in pharmacology, pharmacokinetics, and toxicology, and their integration into a coherent argument that justifies the clinical starting dose, escalation of dose, and stopping criteria to be used in the clinical trial. The objective of the course is to elucidate the path to a successful IND/CTA submission by outlining what needs to be done (concentrating principally on the toxicology and safety pharmacology studies), the timeline and order of activities, and the presentation of the data and its integration into a coherent risk assessment to support introduction of the investigational compound into the clinic. The focus will be the content of the Nonclinical Overview (NCO), which represents an integrated detailed summary of the nonclinical studies conducted to support the clinical plan for first-in-human (FIH) dosing. The course will address the expectations of the two main “customers” for the NCO: the US FDA pharmacology/toxicology reviewer evaluating the data to determine if it supports the safety considerations of the clinical plan, and the clinician designing the clinical protocol and conducting the FIH trial.

- Introduction. Paul Nugent, Pfizer Worldwide Research and Development, Groton, CT.
- Overview of the Nonclinical Toxicology Support for Clinical Trials. Paul Nugent, Pfizer Worldwide Research and Development, Groton, CT.
- The IND Review Process from the Perspective of the Nonclinical Reviewer. Ronald Wange, US FDA, Silver Spring, MD.
- Toxicology Studies in Drug Development and Their Contribution to the NCO. Dorothy Colagiovanni, N30 Pharmaceuticals, LLC, Boulder, CO.
• The Content of the Nonclinical Overview (NCO). J. Neil Duncan, Pfizer Worldwide Research and Development, Groton, CT.

• Clinical Perspective on the NCO. Drew Rasco, South Texas Accelerated Research Therapeutics (START), San Antonio, TX.

The Practice and Implementation of Neural Stem Cell-Based Approaches to Neurotoxicology

AM06  CE BASIC

Chairperson(s): Timothy J. Shafer, US EPA, Research Triangle Park, NC, and Aaron B. Bowman, Vanderbilt University Medical Center, Nashville, TN.

Sponsor:
Neurotoxicology Specialty Section

Endorsed by:
Mechanisms Specialty Section
Metals Specialty Section
Reproductive and Developmental Toxicology Specialty Section
Stem Cells Specialty Section

The availability and use of human pluripotent stem cells (hPSC) and human neural stem cells (hNSC) for toxicology has dramatically increased in the past decade. hNSC are powerful tools for toxicologists and can provide tissue that would otherwise be unobtainable. This includes a renewable source of neural tissue from the same genetic stock that is not transformed or derived from a tumor, a source of normal human nervous system tissue, and sources of nervous system tissue from patients with clinical disease. However, culture and differentiation of hNSC are unique from culture of primary or transformed neural tissue. The course will bring together experts in the culture of various types of neural stem cells, including embryonic human derived neural stem cells, neurospheres, and neural cells derived from hPSC. Each expert will discuss the basic approaches to culturing different types of hNSC, including propagation of the cells in a progenitor status, as well as protocols for differentiation of the cells into different types of neurons. Pitfalls that are both common to the different models as well as unique ones will be described. The goal of the course is to provide the student with knowledge regarding different types of neural stem cell cultures, the techniques to successfully culture and differentiate these models, and application of these model systems to neurotoxicology. The course will conclude with an examination of appropriate outcome measures and discuss the possibility of personalized neurotoxicological assessment.

• Introduction. Aaron B. Bowman, Vanderbilt University Medical Center, Nashville, TN.

• Cultural and Neural Differentiation of Human ESC-Derived Neural Cells. Steven L. Stice, University of Georgia and ArunA Biomedical, Inc., Athens, GA.

• Neurospheres As 3D Cultures for Developmental Neurotoxicity Testing. Ellen Fritsche, Leibniz Research Institute of Environmental Medicine, Düsseldorf, Germany.

• Culture and Differentiation of hPSC-Derived Neurons and the Promise of Personalized Toxicology. Aaron B. Bowman, Vanderbilt University Medical Center, Nashville, TN.

• Neurotoxicity Test Development and Mechanistic-Based Toxicology Using hNSC. Timothy J. Shafer, US EPA, Research Triangle Park, NC.

Toxic Effects of Metals

AM07  CE BASIC

Chairperson(s): Michael P. Waalkes, NIEHS, Research Triangle Park, NC, and Michael F. Hughes, US EPA, Research Triangle Park, NC.

Sponsor:
Metals Specialty Section

Endorsed by:
Mechanisms Specialty Section
Neurotoxicology Specialty Section
Risk Assessment Specialty Section
Stem Cells Specialty Section

Human exposures to metals are a daily occurrence because of their natural presence in the environment—their uses in production of many commercial products—are byproducts of energy production and are found in many hazardous waste sites. The objective of the course is to highlight the fundamentals of metals toxicology. Metals have unique chemical and physical properties that distinguish them from organic-based chemicals. Even though some metals are essential to life, overexposure to these and other metals may result in a toxic effect in one or more organ systems. Upon exposure, metals may be absorbed, distributed throughout the systemic circulation, metabolized, and eliminated. The response of an organism following exposure to metals may be protective (e.g., induction of the metal-binding protein metallothionein), or toxicological by several mechanisms including oxidative stress. Key organ systems such as the central nervous system, the vascular system, as well as the skeleton system are affected by metals including manganese, lead, aluminum, and others. Accumulation of metals in bone has recently gained renewed interest as an eventual source of internal exposure. Noninvasive methods such as neutron activation are now being used to quantitate bone metal levels. Metals can influence gene expression, signal transduction, and epigenetics. Various toxic and carcinogenic metals such as arsenic and chromium alter the epigenetic program in cells; these effects on DNA methylation, histone tail modifications, and microRNA may be involved in metal-induced toxicity. Metals are known to cause cancer by several proposed mechanisms, including oxidative stress and the cancer stem cell hypothesis. Recent evidence
suggestions that developmental exposure to metals may affect stem cell population dynamics, which could result in adult onset of cancer. Overall, this is intended to be a basic course on metals toxicology, and is ideal to those who desire knowledge on the health effects of metals and useful tools used in metals toxicology research.

- **Introduction.** Michael P. Waalkes, NIEHS, Research Triangle Park, NC.
- **Essentials of Metals Toxicology.** Michael F. Hughes, US EPA, Research Triangle Park, NC.
- **Metal-Induced Organ Systems Toxicities.** Wei Zheng, Purdue University, West Lafayette, IN.
- **Mode of Metals Toxicities: Example of Epigenetics.** Max Costa, New York University School of Medicine, Tuxedo Park, NY.
- **Metals in Carcinogenesis and Developmental Origins of Adult Disorders.** Erik J. Tokar, NIEHS, Research Triangle Park, NC.

**Advances in Nanotoxicology—Challenges**

**Effects of Nanomaterials on Biological Systems**

**PM08**


**Sponsor:**
- Nanotoxicology Specialty Section

Recent developments in nanotechnology have generated a degree of apprehension concerning the potential risk to human health and the environment from manufactured nanomaterials (NM). The unique chemical and physical properties of NM, coupled with their high surface area per unit mass, require an extensive array of characterization tools to effectively assess the toxicity of NM. Not only must the size and surface area of the NM be characterized prior to cellular exposure, but also a number of other specific features must be additionally evaluated, such as the size distribution, chemical composition, crystallinity, surface structure, shape, and solubility. The ionic strength of biological fluids may produce NM instability, resulting in environmental-specific aggregation tendencies that may impact toxicological results. Since aggregation of NM can modify uptake rates, transport properties, and clearance by the cell model or organ system, it is critical to interpret the data from NM toxicity experiments with a detailed knowledge of the physicochemical properties of the NM at all experimental time points. Due to the lack of standardized methods to determine the physicochemical behavior of NM in biological systems, the mechanisms and nature of acute or chronic toxicity of engineered NM cannot be fully understood at this time. An understanding of a proper manner by which NM should be introduced to a biological environment has yet to be established, and consistency between cellular assay techniques has not been verified—both situations presenting clear challenges that must be addressed. This course raises issues to consider for the toxicity assessment of NM, and addresses recent advances and technical obstructions associated with conducting or interpreting *in vitro* or *in vivo* toxicity studies. The goal is to provide a comprehensive understanding of NM characterization, as well as facilitate valuable discussions of key challenges and advancements in the newly emergent field of nanotoxicology.

- **Characterizing Techniques for Conducting Nanotoxicity: Complexity and Challenges.** Saber M. Hussain, US Air Force, Wright-Patterson AFB, Dayton, OH.
- **Robust Characterization of Nanomaterials Is Necessary before Toxicity Studies/Assessment Can Be Undertaken.** David B. Warheit, DuPont Haskell Laboratories, Newark, DE.
- **Surface Modification and Characterization of Nanomaterials for Toxicity Studies: Material Science Aspects.** Kimberly Hamad-Schifferli, Massachusetts Institute of Technology, Cambridge, MA.
- **Aggregation Behavior of Nanomaterials under Biological Exposure Conditions.** Navid Saleh, University of South Carolina, Columbia, SC.
- **In Vitro and In Vivo Toxicology Using Silicon-Based NP As an Example.** Dominique Lison, Catholic University of Louvain, Brussels, Belgium.

**Gonadal Development, Function, and Toxicology**

**PM09**

**Chairperson(s):** Barry S. McIntyre, NIEHS, Research Triangle Park, NC, and Jodi A. Flaws, University of Illinois Urbana-Champaign, Urbana, IL.

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

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

The course objectives are to provide the basic tools for toxicologists who desire a better understanding of how to assess the effects of toxicants on the male and female gonads from development through adulthood. A focus on reproductive biology, study design considerations, reproductive endpoints, data interpretation, and use of data in risk assessment will be highlighted. Reproductive toxicity studies are among the most complex and challenging studies in the field of toxicology. The studies assess multiple interrelated endpoints of male and female reproductive development and function. To properly design, conduct, and interpret these studies, a fundamental knowledge of male and female gonadal development, anatomy, physiology, and endocrinology are required. Individual lectures will discuss the anatomy and physiology of the male and female gonads, as well as endocrine regulation of these systems. Evaluation of toxicity endpoints to assess male and female reproductive function will also be discussed, including folliculogenesis, spermatogenesis, hormone analysis, cyclicity, fertility, histopathology, and proper use of statistical analysis. The regulatory expectations related to reproductive...
Continuing Education

Toxicity testing, interpretation of results, and how these results are ultimately used to assess potential risks to human reproduction, will be presented. The course will conclude with methodologies for in vitro reproductive toxicity assessments for screening and investigation of mode of action. In summary, key information required for the design of reproductive toxicology studies and interpretation of reproductive toxicity data, and provide guidance for use of the data for risk assessment of reproduction, will be presented.

- Introduction. Barry S. McIntyre, NIEHS, Research Triangle Park, NC, and Jodi A. Flaws, University of Illinois Urbana-Champaign, Champaign, IL.


- Reproductive Toxicity Testing in Product Safety Assessment. Reza Rasoulpour, The Dow Chemical Company, Midland, MI.

- Strengths and Limitations of In Vitro Test Methods for Reproductive Toxicology. Warren Foster, McMaster University, Hamilton, ON, Canada.

### The REACH Regulation and Safety Assessment Approaches for Chemicals That Come in Contact with the Skin

**Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment**

**PM10**  
CE BASIC

**Chairperson(s):** Jens Thing Mortensen, CiToxLAB Scantox, Lille Skensved, Denmark, and Jon Heylings, Dermal Technology Laboratory Ltd., Keele University Science Park, United Kingdom.

**Sponsor:** Dermal Toxicology Specialty Section

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

REACH (Registration, Evaluation, Authorization, and Restriction of Chemical substances) is the European Union regulation on chemicals and their safe use, which came into force on June 1, 2007. The aim of REACH is to improve the protection of human health and the environment through better and earlier identification of the intrinsic properties of chemical substances. REACH places greater responsibility on the industry to manage the risks from chemicals, and to provide safety information on their substances. The regulation will come gradually into force in the period up to 2018. Under REACH, 30–40,000 new and existing chemicals will have to be (re)classified and registered. The regulation requires companies to conduct risk assessment and safety classification, with a minimal use of experimental animals, and to share information via databases managed by the European Chemicals Agency (ECHA). The skin (together with the respiratory system) is important as a route of chemical exposure, and as a target organ for toxicity induced by chemicals. Since under REACH so many chemicals need to be evaluated, it is important to use and develop testing methods that reliably predict human exposure and safety, while minimizing the use of experimental animals. An overview of the REACH regulation, and its practical implications for toxicological safety evaluation of chemicals marketed in Europe, will be given. Efforts to develop new methods and validation status of alternative methods that will limit the number of experimental animals to be used will be highlighted. Specifically, state-of-the-art investigational methods in dermal toxicology will be discussed since the skin is very important, both as a barrier to exposure and as a target organ. Practical examples of the use of the collected dermal safety data in the risk assessment of chemicals under REACH will be presented.

- Introduction. Jens Thing Mortensen, CiToxLAB Scantox, Lille Skensved, Denmark.

- The REACH Process and Dermal Safety Testing. Laura Rossi, European Chemicals Agency (ECHA), Helsinki, Finland.

- Dermal Corrosivity and Irritation Testing under REACH: Application of Valid Nonanimal Test Methods. Hans Raabe, Institute for In Vitro Sciences, Gaithersburg, MD.

- Skin Sensitization Testing under REACH. David J. Esdaile, CiToxLAB Hungary, Veszprem, Hungary.

- Skin Penetration Testing under REACH: Methods and Use in Risk Assessment. Jon Heylings, Dermal Technology Laboratory Ltd., Keele University Science Park, United Kingdom.

### T4: Tools and Technologies in Translational Toxicology

**Application of Systems Biology to Toxicology**

**PM11**  
CE ADVANCED

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

**Sponsor:** Drug Discovery Toxicology Specialty Section

**Endorsed by:** Association of Scientists of Indian Origin Special Interest Group

**Biotechnology Specialty Section**

**Disease Prevention Task Force**

The last decade has seen revolutionary advances in the tools and technologies available for biomedical scientists such that researchers can now conduct transformative experiments to solve unmet medical needs moving from a single cell to whole organism, and vice versa. Novel tools and innovative technologies have facilitated the develop-
ment of sophisticated molecular diagnostics, enabled the use of new approaches in safety evaluation and risk assessment, and led to the development of targeted therapeutics. The development and utilization of novel technologies and tools requires interaction between scientists of differing backgrounds and talents (e.g., biologists, chemists, and programmers). Only with this shared effort can medicine transform itself to meet the needs of the 21st century. The panel of experts will decode and demystify the potential of these translational and transformative technologies over a wide variety of applications, including safety/efficacy screening of compounds, imaging, ‘omics, and in silico modeling. The key goals are to enable you to understand how recent advances in “T4”: 1) help in solving important problems that have been critical barriers to progress in the field and, 2) transform the field by generating foundational resources that will be widely used throughout biomedical science for safety evaluation and risk assessment.

- **Introduction.** Vishal S. Vaidya, Harvard Medical School, Boston, MA.

- **Engineered Approaches to Assess Liver Toxicity.** Salman Khetani, Colorado State University, Fort Collins, CO.

- **Nuts and Bolts of High-Throughput Compound Toxicity Testing.** Menghang Xia, NIH, Bethesda, MD.

- **Imaging Technologies in Translational Toxicology.** Serguei Liachenko, US FDA-NCTR, Benton, AR.

- **Systems Biology: In Silico Modeling to ‘Omic Biomarkers.** Donna L. Mendrick, US FDA-NCTR, Jefferson, AR.

**Understanding Toxic Neuropathy in Drug Development: Both Clinical and Nonclinical Perspectives**

- **Biomarkers for Exposure Assessment, Safety Evaluation, and Translational Medicine**

  **Chairperson(s):** Mary Jeanne Kallman, Covance Research Laboratories, Greenfield, IN, and John Benitez, Vanderbilt University, Nashville, TN.

  **Sponsor:**
  - Scientific Liaison Coalition

  **Endorsed by:**
  - Clinical and Translational Toxicology Specialty Section
  - Neurotoxicology Specialty Section
  - Regulatory and Safety Evaluation Specialty Section
  - Risk Assessment Specialty Section

  The topic of risk assessment of peripheral neuropathies is timely due to the increased clinical incidence of challenges related to multiple antecedents for the clinical presentation of neuropathies. The integration of both nonclinical and clinical dialogue on peripheral neuropathies will provide greater possibilities for successful drug development and improved patient outcomes. Peripheral nervous system toxicity is a common complication of exposure to industrial chemicals and drugs such as chemotherapeutics. Neuropathy can be caused by either limited or long-term exposure to drugs or chemicals, and toxic neuropathies can be classified by their presentation (e.g., motor vs. sensory), their electrodagnostic features or their neuroanatomical location within the peripheral nerve. Identification of toxic neuropathology prior to human exposure in the drug development process requires a multidisciplinary approach. Presentations will include information on the preclinical and clinical syndromes that have been characterized and the specific techniques for assessment. The preclinical presenters will focus on the application of preclinical data to provide risk assessment and to direct clinical assessment possibilities. The clinical presenters will emphasize the clinical situation and current treatment approaches. The course will conclude with open discussion between the presenters and the audience about opportunities for future risk assessment and the application to clinical management.

- **Overview.** Mary Jeanne Kallman, Covance Research Laboratories, Greenfield, IN.

- **Anatomy of the Peripheral Nervous System and Recognition of Common Neuropathies.** Mark Cartwright, Merck & Co. Inc., Sparta, NJ.

- **Overview Lecture on Clinical Situation and Incidence of Toxic Neuropathy Symptoms.** Amy Chappell, Eli Lilly and Company, Indianapolis, IN.

- **Assessment of Peripheral Nerve Function: Risk Assessments for Neuropathy and Potential Translation to the Clinic.** Joseph Arezzo, Albert Einstein College of Medicine, Bronx, NY.

- **Examples of Clinical Neuropathies Associated with Oncolytic Drugs.** John Benitez, Vanderbilt University, Nashville, TN.
Weighing in on Nutrition—Essential Concepts for Toxicologists

Molecular Basis of Genetic Variability and Susceptibility to Toxicants

Chairperson(s): Daniel M. Wilson, The Dow Chemical Company, Midland, MI, and Angela L. Slitt, University of Rhode Island, Kingston, RI.

Sponsor:
Food Safety Specialty Section

Endorsed by:
Cardiovascular Toxicology Specialty Section
Ethical, Legal, and Social Issues Specialty Section
Mechanisms Specialty Section
Women in Toxicology Special Interest Group

There has been an exponential increase in the attention focused on the potential role of nutrition in reducing the risk for numerous health complications, ranging from birth defects to age-associated vascular disease. Underscoring the above is the increasing number of presentations and publications related to this subject, and hallmarks such as the recently revamped Food Pyramid into a Plate Icon. Chronic nutritional diseases are accepted to be a current crisis in our society; three nutrition-related diseases alone, obesity, Metabolic Syndrome, and Type 2 Diabetes, afflict over one-third of the American population. To better understand the components and etiology of nutritional diseases, it’s essential for toxicologists to be well versed in the science of nutrition. A comprehensive understanding of nutrition has broad applications in toxicology, especially considering that many of us have roles in investigating the safety of nutrients, food additives or food ingredients, studying nutritional disease, or designing and interpreting preclinical or clinical studies wherein the need to consider and understand nutritional homeostasis is essential.

The potential for intersection of normal nutritional metabolic pathways with adverse outcome pathways is becoming even more important to delineate. This course on general nutrition, the biochemistry of nutritional pathways, the essential role of vitamins, the channeling of nutrients such as carbohydrates, proteins and fats, cellular and molecular details of nutrition, and nutritional aspects of development and reproduction, will heighten awareness of their importance in human and animal health at multiple levels. The focus will be on relevant information, starting with an introduction to nutrition, followed by a review of biochemical and metabolic reactions in nutrition, with an emphasis on their relation to toxicology. How the nutritional status of a woman can modulate the developmental toxicity of a number of diverse toxicants, including alcohol, will be presented, along with a seminar describing the tools and applications of molecular and genetic models of nutritional disease.

- Nutrition 101. Jo Ann S. Carson, University of Texas Southwestern, Dallas, TX.
- The Biochemistry of Nutrition. Daniel M. Wilson, The Dow Chemical Company, Midland, MI.
- Studying Nutritional Disease in Rodent and Cell-Based Models: Proper Selection of Molecular and Systemic Endpoints. Angela L. Slitt, University of Rhode Island, Kingston, RI.
- Nutrition and Pregnancy. Carl L. Keen, University of California Davis, Davis, CA.
Consider Organizing a Contemporary Concepts in Toxicology Meeting

Contemporary Concepts in Toxicology (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. CCT Meetings also can be held as webinars.

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 an SOT CCT Meeting. The CCT Conference Committee and the SOT Headquarters staff are prepared to help move your meeting forward.

The Society will underwrite all the liabilities of the CCT Meeting (up to the $25,000 in seed money) with the expectation that the meeting at least break even financially. Profit sharing for SOT component groups is available. For more information about CCT Meetings, please visit the SOT website at www.toxicology.org/cct.

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.

www.toxicology.org
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 six 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.toxicology.org/ai/csot/contribute.asp.
Plenary Lectures

Plenary Opening Lecture

Genetic Analysis of Innate Immune Sensing

Monday, March 11, 8:00 AM to 9:00 AM

Lecturer: Bruce Beutler, University of Texas Southwestern Medical Center, Dallas, TX.

Microbes were known to be the causative agents of infectious diseases since the mid-nineteenth century, and infections were known since antiquity for their inflammatory character. However, the molecular interactions through which microbes were recognized, and through which they triggered an inflammatory response on the part of the host, remained unknown until much more recently. A genetic approach was required to elucidate them. Applying a positional cloning approach to mice that were refractory to lipopolysaccharide (LPS), we identified the LPS receptor, and with it, a family of receptors responsible for sensing diverse molecules of microbial origin. These, the Toll-like receptors, signal by way of a system of adaptors, protein kinases, and transcription factors to induce the biosynthesis of hundreds of cytokines that orchestrate inflammation. Subsequently RIG-I-like helicases, NOD-like receptors, and C-type lectin receptors also were found to respond to infection. A number of common inflammatory diseases appear to depend upon these molecular pathways, which evolved to check the spread of micro-organisms prior to the advent of adaptive immunity.

Bruce Beutler is a Regental Professor and Director of the Center for the Genetics of Host Defense at University of Texas Southwestern Medical Center. He received his MD from the University of Chicago in 1981. As a postdoctoral associate at Rockefeller University (1983–1986), he isolated mouse tumor necrosis factor (TNF) and discovered its importance as a mediator of inflammation. Subsequently at UT Southwestern he analyzed mammalian responses to bacterial lipopolysaccharide. This work culminated in the discovery of Toll-like receptors as key sensors of the innate immune system, capable of detecting infection within minutes of the time the host is inoculated with microbes. In further studies, Beutler has used a forward genetic strategy to elucidate many aspects of mammalian immunity. He received numerous awards for his work, among them the Balzan Prize (2007), the Albany Medical Center Prize (2009), the Shaw Prize (2011), and election to the US National Academy of Sciences (2008), the Institute of Medicine (2008), and EMBO. In 2011, he shared the Nobel Prize in Physiology or Medicine for “discoveries concerning the activation of innate immunity.”

Keynote Medical Research Council (MRC) Lecture

Phenotyping the Patient Journey: Making Systems Medicine Work in the Real World

Wednesday, March 13, 8:00 AM to 9:00 AM


Systems biology tools can be applied at both individual and population levels to understand integrated biochemical function in relation to disease pathogenesis. Metabolic phenotyping offers an important window on systemic activity and both advanced spectroscopic approaches can be used to characterize disease processes and responses to therapy. There is now wide recognition that the extensive cross-talk and signalling between the host and the symbiotic gut microbiome links to both the responses to therapy and disease risk factors and indeed these also modulate drug toxicity. Such symbiotic supraorganismal interactions greatly increase the degrees of freedom of the metabolic system that poses significant challenges to fundamental notions on the nature of the human diseased state, the aetiopathogenesis of common diseases, and current systems modelling requirements for personalized medicine. We have developed scalable and translatable strategies for phenotyping the hospital patient journey using top-down systems biology tools that capitalize on the use of both metabolic modelling and pharmaco-metabonomics for diagnostic and prognostic biomarker generation to aid clinical decision making at point-of-care. Such diagnostics (including those for near real-time applications, as in surgery and critical care) can be extremely sensitive for the detection of diagnostic and prognostic biomarkers in a variety of conditions and are a powerful adjunct to conventional procedures for disease assessment that are required for future developments in precision medicine including understanding of the symbiotic influences on patient state. Many biomarkers also have deeper mechanistic significance and may also generate new therapeutic leads or metrics of efficacy for clinical trial deployment. Furthermore, the complex and subtle gene-environment interactions that generate disease risks in the general human population also express themselves in the metabolic phenotype, and, as such, the Metabolome Wide Association Study approach gives us a powerful new tool to generate disease risk biomarkers from epidemiological sample collections and for assessing the health of whole populations. Such population risk models and biomarkers can also feedback to individual patient healthcare models thus closing the personal and public healthcare modelling triangle.

Jeremy K. Nicholson has won many accolades and international prizes for his work, which spans three decades, and is the author of over 500 peer-reviewed scientific papers and many other articles/patents on the development and application of novel spectroscopic and systems biology approaches to the investigation of disturbed
Special Symposium Sessions

Frontiers for Toxicology Session

Systems and Computational Biology As Foundations for Toxicology Research

Application of Systems Biology to Toxicology

Tuesday, March 12, 9:00 AM to 11:45 AM

Chairperson(s): Annie M. Jarabek, US EPA, Research Triangle Park, NC, and James L. Stevens, Eli Lilly Corporation, Indianapolis, IN.

Sponsor:
Scientific Program Committee

Systems and computational approaches are holistic methods to elicit and understand the complex interactions among components of a biologic response network and are central to the comprehensive understanding of all biological processes. The field requires the integration of concepts from biology and physiology, computer science and applied mathematics, as well as physics and engineering. Toxicology is also a multidisciplinary science and application of systems and computational approaches can aid in unraveling the dynamic and complex nature of toxic responses. In light of the broad utility of systems biology approaches to toxicology and risk assessment, the goal of this session is to feature eminent scientists who have made seminal contributions and advances in systems and computational biology. The broad areas to be addressed include:

- General concepts of systems biology tools including network mapping and statistical challenges in assuring the validity of network analyses along with the newest tools and approaches for gaining insight into the regulation and function of complex systems;

- Applications of systems biology approaches to studying fundamental biological responses such as cell signaling and kinase networks;

- Perspectives on the application of systems networks to biomedical research and particularly for studying disease etiology and prevention;

- Computational strategies that inform the prediction of pharmacologic and toxicologic responses including the prediction of adverse drug reactions; and,

- Novel applications of machine learning and cell imaging to evaluate subcellular organization and function that inform hypothesis testing and translational details that may be useful in drug development.

- **Introduction.** Lois D. Lehman-McKeeman, Bristol-Myers Squibb Company, Princeton, NJ.

- **Turning Protein Networks into Gene Ontologies.** Trey Ideker, University of California, San Diego, La Jolla, CA.

- **Network2Canvas: Network Visualization on a Canvas with Enrichment Analysis.** Avi Ma’ayan, Mt. Sinai School of Medicine, New York, NY.

- **Computational Approaches to Predicting Adverse Drug Reactions and Mitigating Off-Target Liabilities in Early-Stage Drug Discovery.** Laszlo Urban, Novartis Institutes for Biomedical Research, Cambridge, MA.

- **Image-Derived Models of Subcellular Organization and Perturbation.** Robert Murphy, Carnegie Mellon University, Pittsburgh, PA.

Meet the Directors

Monday, March 11, 1:00 PM to 3:30 PM

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

This important session is designed to provide an opportunity for the leaders of agencies to discuss the scientific directions and strategies along with relevant concepts and achievements of their organizations. An important issue for many SOT members is the funding opportunities that various agencies can provide for toxicology research. This year, our panel of experts will focus the scientific strategies and initiatives of their respective agencies and provide relevant information on the funding opportunities that are available to support basic and applied research. Representatives and leaders from the National Institute of Environmental Health Science (NIEHS), US Environmental Protection Agency (US EPA), Department of Defense (DOD), and the National Institute for Occupational Safety and Health (NIOSH) will share their perspectives on these matters. The session is intended to be highly interactive, providing the audience with an opportunity to query the panel on issues concerning extramural funding, and other relevant topics. We hope you’ll join them as they deliver recent updates related to issues that have an impact on toxicology.
Award Lectures

Merit Award Lecture
Monday, March 11, 12:30 PM to 1:20 PM
Lecturer: Frederick Peter Guengerich, Vanderbilt University Medical Center, Nashville, TN.

Leading Edge in Basic Science Award Lecture
Tuesday, March 12, 8:00 AM to 8:50 AM
Lecturer: Donald Ingber, Harvard University, Boston, MA.

Distinguished Toxicology Scholar Award Lecture
Wednesday, March 13, 12:30 PM to 1:20 PM
Lecturer: John J. LeMasters, Medical University of South Carolina, Charleston, SC.

SOT/EUROTOX Debate

In the Near Foreseeable Future, Much of Toxicity Testing Can Be Replaced by Computational Approaches

Monday, March 11, 4:45 PM to 6:00 PM

Chairperson(s): Norbert E. Kaminski, Michigan State University, East Lansing, MI, and Aristidis Tsatsakis, University of Crete, Heraklion, Greece.

SOT Debater: Rory Conolly, US EPA, Research Triangle Park, NC.
EUROTOX Debater: George Loizou, Health and Safety Laboratory, Buxton, United Kingdom.

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: In the Near Foreseeable Future, Much of Toxicity Testing Can Be Replaced by Computational Approaches.

During the past decade significant advances have been made in the development and application of mathematical modeling and computational simulation approaches to describing as well as predicting biological events. To a large extent, the application of computational approaches to biological systems has been driven by the exponential growth in knowledge of the underlying biological processes in living organisms. Similarly, major advances have also been made in the understanding of the molecular mechanisms by which xenobiotics modify biological processes, hence the vision and desire of applying computational approaches to toxicology. In fact, many benefits could be envisioned in applying in silico approaches to toxicity testing including a reduction in animal use, decreased costs of testing, and more rapid assessments of potential toxicity, to mention a few. In contrast, skepticism and serious concerns exist that the current understanding of the underlying biology and toxicology, especially at the organismal level, make replacement of toxicity testing by computational approaches a distant dream of the future. The debate will present some of the challenges investigators and regulators will face in the integration of computational approaches to toxicity testing.

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 Interlaken, Switzerland during the 2013 Eurotox Annual Congress, September 1–4.
The Thematic Track information can be found on pages 10–11.

Featured Sessions

Research Funding Sessions

Research Funding Information Room

Tuesday, March 12 and Wednesday, March 13, 9:30 AM to 4:30 PM

Chairperson(s): David Dorman, North Carolina State University, Raleigh, NC.

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 12, 12:00 Noon to 1:30 PM

Chairperson(s): David Dorman, North Carolina State University, Raleigh, NC.

Sponsor: Research Funding Committee

Investigators from various federal agencies will be on hand for this luncheon meeting to talk about the art of preparing successful grant packages. Panelists will talk about the grant submission process and offer advice about how to submit a potentially successful grant and offer tips about how to make their submission stand out.
LATE-BREAKING ABSTRACTS
Submit Your Recent Scientific Research during an Extended Abstract Submission Phase

The Society is poised to have another successful Annual Meeting with currently more than 2,500 presentations scheduled to be presented in San Antonio, March 10–14, 2013.

We invite you to submit an abstract during the extended submission phase which will occur from December 12, 2012, through January 20, 2013. All abstracts will be submitted online. The cost to submit an abstract is $50.

All accepted abstracts will be programmed on Thursday, March 14 along with several dynamic symposia and workshop sessions.

An important criteria for abstract submission during this time is that 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.

Additional criteria that qualify an abstract to be accepted during this final submission phase include:

• 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 scheduler (mobile and online versions only).

We look forward to welcoming you to the Society’s Annual Meeting in San Antonio, Texas.
The Thematic Track information can be found on pages 10–11.

Symposia

MONEY

Genetic and Epigenetic Determinants of Susceptibility to Environmental and Occupational Toxicants

Molecular Basis of Genetic Variability and Susceptibility to Toxicants

Monday, March 11, 9:15 AM to 12:00 Noon

Chairperson(s): Berran Yucesoy, NIOSH, Morgantown, WV, and Victor J. Johnson, BRT-Burleson Research Technologies, Morrisville, NC.

Sponsor: Immunotoxicology Specialty Section

Endorsed by: Occupational and Public Health Specialty Section

The most common chronic disorders are multifactorial in nature, influenced by complex sequences of gene-gene and gene-environment interactions. While gene expression is a dynamic process that varies in response to a myriad of internal and external triggers and the surrounding microenvironment, the epigenetic mechanisms play a key role in mediating environmental influences on gene expression and epistatic interactions. In this respect, the expression of complex phenotypes should be assessed in a functional context that would look at the interplay between environmental, genetic, and epigenetic factors. Recent advances in genetic and epigenetic research offer new opportunities to integrate experimental approaches, including animal models and in vitro/in vivo translational research, with computational strategies to predict such interactions at multiple levels of complexity. The focus of this session will be on current research investigating the role of genetic factors, epigenetic factors, and gene-environment interactions in the development and outcomes of complex diseases caused by environmental and occupational toxicants.

• Genetic Susceptibility to Occupational and Environmental Exposures. David Christiani, Harvard Medical School, Boston, MA.

• Toxicogenomic and Systems Biology Approaches in the Understanding of Toxicity and Leukemogenesis Induced by Benzene. Cliona M. McHale, University of California Berkeley, Berkeley, CA.

• Integrated Genetic and Genomic Approaches to Understand Susceptibility to Toxican-Induced Lung Disease. Steven Kleeberger, NIEHS, Research Triangle Park, NC.

• Developmental Exposure to Bisphenol A and Lead: Effects on Metabolic Homeostasis and the Epigenome. Dana C. Dolinoy, University of Michigan, Ann Arbor, MI.

Predictive Toxicology Paradigms for Understanding Carbon Nanotube Toxicity in the Lung

Effects of Nanomaterials on Biological Systems

Monday, March 11, 9:15 AM to 12:00 Noon

Chairperson(s): James C. Bonner, North Carolina State University, Raleigh, NC, and André Nel, University of California Los Angeles, Los Angeles, CA.

Sponsor: Nanotoxicology Specialty Section

Endorsed by: Inhalation and Respiratory Specialty Section

Nanotechnology is rapidly developing, resulting in the production of a variety of engineered nanoparticles. Carbon nanotubes (CNTs) represent an important family of nanoparticles because they have many potential uses in engineering, electronics, and medicine due to their ease of functionalization, unusual strength, and electrical conductivity. However, these novel nanostructures also represent a potential human health risk, due to the possibility of inhalation exposure and evidence that the lung and cardiovascular systems are targets for hazardous effects. Inhalation studies in rodents show that CNTs deposit within the distal regions in the lungs and migrate to the pleura to cause inflammatory and/or fibrotic effects. Presentations in this session are aimed at elucidating the pulmonary and cardiovascular effects of CNTs, and how an increasing variety of functionalized CNTs can be evaluated via high-content screening. Because functionalized CNTs vary in toxicological activity, we will address high-content screening for the development of structure-activity relationships relevant to inhalation toxicity and safer design of nanoparticles. This will include exploration of factors that mediate toxic effects such as high aspect ratio, durability, and residual metal content and discuss how removing metal catalysts or changing surface properties alters the pattern and timing of toxicity. While the lung is a major target organ, another goal is to determine the potential for inhaled CNTs to have toxic effects that reach beyond the lung to influence the cardiovascular system. Finally, we will discuss how susceptibility factors, both genetic and environmental, determine pulmonary and cardiovascular toxicity to CNTs. The outcome of this session is to gain a better understanding of the structure-activity relationships, target organs, and susceptibility factors that will aid the development of predictive toxicology paradigms for understanding CNT toxicity.

• Time Course of Pulmonary Responses to Inhaled Multiwalled Carbon Nanotubes. Dale W. Porter, NIOSH, Morgantown, WV.

• Establishment of Carbon Nanotube Structure-Activity Relationships (SARs) That Can Be Used to Understand Pulmonary Toxicity and Safer Design. André Nel, University of California Los Angeles, Los Angeles, CA.
Translatable Indicators of Testicular Toxicity: Inhibin B, microRNAs, and Sperm Signatures

Biomarkers for Exposure Assessment, Safety Evaluation, and Translational Medicine

Monday, March 11, 9:15 AM to 12:00 Noon

Chairperson(s): Kim Boekelheide, Brown University, Providence, RI, and Robert E. Chapin, Pfizer, Inc., Groton, CT.

Sponsor: Reproductive and Developmental Toxicology Specialty Section

Endorsed by: Risk Assessment Specialty Section Toxicologic and Exploratory Pathology Specialty Section

The typical endpoints used in preclinical animal models for reproductive toxicity testing, such as histopathology, are not translatable for human clinical assessment, which typically focuses on the analyses of semen and serum hormones. Therefore, when testicular toxicity arises in preclinical toxicity testing, the methods currently available to monitor this liability in clinical trials are limited. Because of these limitations, there is a need to develop sensitive and translatable indicators that reliably reflect testicular function. In this symposium, an introductory talk will set the stage by describing testicular physiology, preclinical tests of male reproductive toxicity, and current methods for assessing testicular function in men in clinical trials. The following three talks will discuss currently active efforts to develop improved translatable indicators of testicular toxicity in men. Serum inhibin B is a product of the testicular Sertoli cell and levels fall in response to testicular injury. Testis-specific miRNAs may be released upon testicular injury, and their measurement in serum may be a measure of effect. Sperm mRNA transcripts and DNA methylation may be indicators of testicular toxicity because they are easily measured and persistently altered after testicular injury. Developing reliable and predictive translatable indicators of testicular toxicity would be valuable for drug development in the pharmaceutical industry, and for monitoring men in occupational settings where exposure to potential testicular toxicants is a concern.

Biomarkers of Testicular Injury: Where Have We Been.
Barry S. McIntyre, NIEHS, Research Triangle Park, NC.

Industry Efforts to Evaluate Inhibin B As Potential Biomarker for Testicular Toxicity. Michelle Coulson, AstraZeneca, Macclesfield, Cheshire, United Kingdom.

Circulating microRNAs As Biomarkers of Testicular Damage? Robert E. Chapin, Pfizer, Inc., Groton, CT.

Sperm mRNA Transcripts and DNA Methylation Marks As Indicators of Testicular Injury. Kim Boekelheide, Brown University, Providence, RI.

Human Health and Environmental Concerns around Natural Gas Production Using Hydraulic Fracturing

Monday, March 11, 2:00 PM to 4:45 PM

Chairperson(s): Ziad S. Naufal, Chevron Energy Technology Company, Houston, TX, and Angela J. Harris, ENVIRON International Corporation, Little Rock, AR.

Sponsor: Occupational and Public Health Specialty Section

Endorsed by: Lone Star Regional Chapter

Natural gas production from shale rock formations using hydraulic fracturing has expanded greatly over the last decade across the United States and other parts of the world. The expansion came as a result of advances in horizontal drilling technology which helped unlock large natural gas supplies in shale and other tight rock formations across the country. Calls to reduce greenhouse gas emissions, the high cost of energy, and other economic pressures also contributed to the rapid growth of shale gas drilling using hydraulic fracturing. As a result, natural gas production is the highest it has been in the United States in decades. However, with the expansion of hydraulic fracturing into rural communities and areas traditionally not familiar with oil and gas explorations, questions about public health and environmental impacts have been raised by some residents living in proximity to fracturing operations. Data gaps may exist since the growth of fracturing operations has outpaced the research efforts conducted by the broad scientific community around this issue. In general, recent research activities have focused on understanding the potential impacts of the chemical components of the fluids used to fracture rock formations. Other issues raised by the public include the increase in noise, air, and light pollution in hydraulic fracturing areas and the potential for accidental contamination of air or groundwater. This session will provide an overview of the current and projected extent of the use of hydraulic fracturing to meet energy needs, and a discussion of the questions surrounding the public health and environmental impacts of this technology.

Current Status of Tight Oil and Gas Development Using Hydraulic Fracturing. John Imse, ENVIRON International Corporation, Denver, CO.
Symposia

- **An Assessment of Exposure Pathways and Potential Impacts to Human Health Associated with Shale Gas Drilling and Production Operations.** Angela J. Harris, ENVIRON International Corporation, Little Rock, AR.

- **The Potential Toxicological Impacts of Shale Gas Drilling: An Overview.** Bernard D. Goldstein, University of Pittsburgh, Graduate School of Public Health, Pittsburgh, PA.

- **Community Exposure and Risk Near Natural Gas Production Sites: Impacts and Research Needs.** John Adgate, Colorado School of Public Health, University of Colorado, Aurora, CO.

- **Air Quality Impacts of Natural Gas Operations in Texas.** Michael E. Honeycutt, Texas Commission on Environmental Quality, Austin, TX.

**Role of Metabolic Syndrome and Perivascular Adipose in Exposure-Induced Vascular Dysfunction**

**Molecular Basis of Genetic Variability and Susceptibility to Toxicants**

**Monday, March 11, 2:00 PM to 4:45 PM**

**Chairperson(s):** Daniel J. Conklin, University of Louisville, Louisville, KY, and Matthew J. Campen, University of New Mexico, Albuquerque, NM.

**Sponsor:** Cardiovascular Toxicology Specialty Section

**Endorsed by:** Inhalation and Respiratory Specialty Section

Recent epidemiological studies indicate that ambient air pollution enhances the progression from metabolic syndrome to diabetes but not by increasing obesity. Because vascular dysfunction and vascular insulin resistance are two early events associated with metabolic syndrome and air pollution exposure, the mechanisms by which these alterations occur in the vasculature could be informative of changes in overall cardiovascular disease risk. Similarly and increasingly, there is a growing recognition that the perivascular adipose tissue (PVAT) is an important regulator of vascular tone under normal homeostatic conditions and PVAT is altered during disease states, including metabolic syndrome and diabetes. The perivascular adipose tissue structure and function are changed to a proinflammatory state both by disease, angiotensin II, and by exposure to environmental pollutants, implicating these alterations in subsequent endothelial and vascular dysfunction. This symposium will provide both an introduction to the role of perivascular adipose tissue in health and metabolic disease states and draw on evidence from environmental and experimental model studies to emphasize specific alterations in perivascular adipose tissue and how these changes contribute to subsequent vascular dysfunction and potentially increase the risk of cardiovascular disease.

**TUESDAY**

**From Inhaled Particles to Cardiovascular Disease and Toxicity: Evidence from Studies in Volunteers, Experimental Animals, and Cell-Based Systems**

**Biomarkers for Exposure Assessment, Safety Evaluation, and Translational Medicine**

**Tuesday, March 12, 9:00 AM to 11:45 AM**

**Chairperson(s):** Flemming R. Cassee, National Institute for Public Health and the Environment (RIVM), Bilthoven, Netherlands, and Howard M. Kipen, University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School, Piscataway, NJ.

**Sponsor:** Inhalation and Respiratory Specialty Section

**Endorsed by:** Cardiovascular Toxicology Specialty Section, Mixtures Specialty Section, Nanotoxicology Specialty Section

The adverse effects of air pollution on cardiovascular health have been established in a series of major observational studies. Even brief exposures to air pollution have been associated with marked increases in cardiovascular morbidity and deaths from myocardial ischemia, arrhythmia, and heart failure. The breadth, strength, and consistency of the evidence provide a compelling argument that air pollution, especially traffic-derived pollution, causes cardiovascular disease. However, these observational data are limited by imprecision in the measurement of pollution exposure, and the potential for environmental and social factors to confound these apparent associations. For a causal association to have scientific credence, a clear mechanism must be defined. What are the potential pathways through which air pollution exposure affects cardiovascular health?
pollution mediates these adverse cardiovascular effects and diseases? And are the effects caused by the nano-sized particles? This session will focus on the underlying biological mechanisms of complex particle mixtures.

- **Acute Increases in Exhaled Breath Condensate No Metabolites Suggests Oxidative Stress As a Mechanism for the Health Effects of Traffic-Related Pollutants.** Howard Kipen, University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School, Piscataway, NJ.

- **Health Effects from Traffic Particles and Noise in Road Workers.** Michael Riediker, Institute for Occupational Health Sciences, Lausanne, Switzerland.

- **Air Pollution Is Associated with Chronic Progression of Cardiovascular Disease.** Anie K. Lund, Lovelace Respiratory Research Institute, Albuquerque, NM.


- **Diesel Exhaust: The Many Ways That Nanoparticles Can Impair Cardiovascular Health.** Mark Miller, University of Edinburgh, Edinburgh, United Kingdom.

**The Dynamics of Neuroinflammation and Inflammatory Cell Responses in Neurologic Disease**

- **Molecular Basis of Genetic Variability and Susceptibility to Toxicants**

  **Tuesday, March 12, 9:00 AM to 11:45 AM**

  **Chairperson(s):** Christine P. Curran, Northern Kentucky University, Highland Heights, KY, and G. Jean Harry, NIEHS, Research Triangle Park, NC.

  **Sponsor:** Neurotoxicology Specialty Section

  **Endorsed by:**
  - Mechanisms Specialty Section
  - Metals Specialty Section

  An increasing body of evidence indicates that neuroinflammation and activation of immune cells within the nervous system are associated with neurodegenerative disease, neurodevelopmental disorders, and potentially in reaction to environmental exposures. However, it is also increasingly obvious that these responses may be beneficial or detrimental, and discriminating between these has only recently been addressed. Understanding the process by which these responses are triggered and the spatiotemporal dynamics of the response is critical to developing a strategy for translating neuroinflammatory and immune response to effective prevention or treatment of neurologic disease/injury. Three well-known neurotoxicants: trimethyltin, manganese, and mercury will be used as chemical probes to explore differences in the timing of inflammatory effects and consequences in the brain. We will conclude by discussing approaches to manipulate the lesion microenvironment and/or brain macrophage such that inflammation favors tissue repair in the spinal cord.

- **Microglia Heterogeneity in Neuroinflammation and Neurotoxicity.** Gaylia Harry, NIEHS, Research Triangle Park, NC.

- **Neuroinflammation and Developmental Vulnerability to Manganese.** Ronald B. Tjalkens, Colorado State University, Fort Collins, CO.

- **Spontaneous and Mercury-Induced Antibodies to Brain Antigens Affect Fetal Brain Development.** David A. Lawrence, Wadsworth Center, Albany, NY.

- **Manipulating Microglia and Macrophages to Promote Repair of Injured Spinal Cord.** Phillip Popovich, The Ohio State University, Columbus, OH.

**Application of Systems Biology to Toxicology**

**Tuesday, March 12, 1:30 PM to 4:15 PM**

**Chairperson(s):** Jennifer L. Freeman, Purdue University, West Lafayette, IN, and Wei Zheng, Purdue University, West Lafayette, IN.

**Sponsor:**
- Metals Specialty Section

**Endorsed by:**
- Neurotoxicology Specialty Section

The heavy metal lead (Pb) can induce a wide-range of adverse health effects depending on dose and duration of exposure. During development the nervous system is most sensitive to Pb toxicity with epidemiological studies linking neurological deficits at and below the previous CDC blood Pb level of concern. Although the toxicity of Pb is extensively studied, the underlying genetic, epigenetic, and molecular mechanisms of Pb neurotoxicity are not completely understood. Moreover, recent studies link developmental Pb exposure with latent effects that do not appear until late in life, indicating a developmental origin of adult neurodegenerative disorders. More specifically, the latent overexpression of hallmark genes and proteins in Alzheimer’s disease (AD) are reported in these studies. This session brings together a group of investigators that are actively applying systems biology (transcriptomics and epigenomics) and targeted approaches to define the mechanisms and identify biomarkers of both the developmental and late-life neurological alterations associated with a developmental Pb exposure in a variety of model systems and in human populations. Topics cover a study with the zebrafish model on...
the genetic mechanisms of developmental Pb neurotoxicity with an emphasis on transcriptomic alterations to a human comparative transcriptomic study in young adults aiming at establishing biomarkers between early-life Pb exposure and AD. The session also addresses the transcriptomic and epigenomic pathways of the developmental origin of Pb-induced neurodegenerative alterations with a specific focus on AD in rodent and primate models. Furthermore, the mechanism by which Pb increases the formation of amyloid β plaques in a transgenic mouse model is discussed. Overall, this session highlights the latest findings on the genetic, epigenetic, and molecular mechanisms of Pb neurotoxicity linking neurodevelopmental and later life impacts to further deduce the developmental origin of Pb-induced neurodegenerative disease with a specific focus on AD.

- Genetic Mechanisms of Developmental Lead Neurotoxicity and Links to Adult Neurodegenerative Disease Pathogenesis. Jennifer L. Freeman, Purdue University, West Lafayette, IN.
- Prenatal Lead Exposure and Biomarkers for Alzheimer’s Disease in Humans. Maitreyi Mazumdar, Harvard School of Public Health, Children’s Hospital Boston, Boston, MA.
- Do Epigenetic Pathways Initiate Late Onset Alzheimer’s Disease (LOAD)?: Towards a New Paradigm. Nasser H. Zawia, University of Rhode Island, Kingston, RI.
- CNS Homeostasis of β-Amyloid, Plaque Formation, and Lead Toxicity. Wei Zheng, Purdue University, West Lafayette, IN.

Bone As a Target Tissue for Environmental Toxicants

Tuesday, March 12, 1:30 PM to 4:15 PM

Chairperson(s): Jennifer J. Schlezinger, Boston University School of Public Health, Boston, MA, and Koren K. Mann, McGill University, Montreal, Quebec, Canada.

Sponsor: Metals Specialty Section

Endorsed by: Molecular Biology Specialty Section

Bone brings to mind the strong, but light, organ that provides the skeleton for vertebrates. However, bone is more than just inert, osseous tissue. The bone marrow is a multifunctional organ that supports not only ongoing bone remodeling, but also provides the microenvironmental niche for hematopoiesis and regulates whole body energy homeostasis and as such, represents a significant target for environmental toxicants. Critical cell types in the bone marrow include multipotent mesenchymal stromal cells (MSCs) and hematopoietic stem cells (HSCs). MSCs are the source of both adipocytes and osteoblasts. HSCs are the source of all blood cell lineages and the bone-resorbing osteoclasts. The interaction between osteoblasts and osteoclasts creates a balance of bone formation and resorption, which is essential for maintenance of bone quality. There also is essential crosstalk between the mesenchymal and hematopoietic compartments that supports lifelong blood cell generation. Lymphocyte development, in particular, requires stromal cell support/interaction. Understanding how environmental toxicants disturb the interplay of bone marrow compartments requires attention given the rapidly aging population who are already at risk for loss of bone quality and immune suppression. We will explore new data suggesting that bone is responsive to many environmental toxicants, which may perturb the delicate balance between bone marrow cell types. A series of presentations will define interactions within both the mesenchymal and hematopoietic compartments and how exposure to toxicants may impact bone biology. Presentations will move from a broad, multispecies analysis of the effects of persistent organic pollutants on bone to more focused analyses of effects of ethanol and metals (lead, organotins, and tungsten) on bone and the bone marrow microenvironment.

- Bone Tissue As a Target for POPs Acting As EDCs (An Overview from Wild Animals to Humans). Monica Lind, Uppsala University, Uppsala, Sweden.
- Lead Exposure and Skeletal Dysregulation: A Molecular Mechanism of Toxicity that Contributes to Osteoporosis and Other Bone Diseases. J. Edward Puzas, University of Rochester, Rochester, NY.
- Role of NADPH Oxidases and Reactive Oxygen Species in Regulation of Bone Turnover and the Skeletal Toxicity of Alcohol. Martin J. Ronis, Arkansas Children’s Nutrition Center, University of Arkansas for Medical Sciences, Little Rock, AR.
- Organotins: Unique Modulators of Bone Quality and the Bone Marrow Microenvironment. Jennifer J. Schlezinger, Boston University School of Public Health, Boston, MA.
- Tungsten: Effects on Bone Marrow and Lymphocyte Development. Koren K. Mann, McGill University, Montreal, Quebec, Canada.

Nonmonotonic Dose-Response Curves and Endocrine-Disrupting Chemicals: Fact or Falderal?

Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment

Tuesday, March 12, 1:30 PM to 4:15 PM

Chairperson(s): Leon Earl Gray Jr., US EPA, Research Triangle Park, NC, and Paul M. D. Foster, NIEHS, Research Triangle Park, NC.

Sponsor: Reproductive and Developmental Toxicology Specialty Section

Endorsed by: Molecular Biology Specialty Section

“All substances are poisons. It’s the dose that makes the poison,” (Paracelsus, 1493–1541) is a fundamental tenet in toxicology: the severity of a response to a toxicant increases proportionally to the
Low Dose and Nonmonotonic Dose-Response Curves for Endocrine-Active Compounds.

In addition to the standard endpoints, mechanisms of action are being challenged by claims that endocrine-disrupting chemicals (EDCs) often display U-shaped or inverted U-shaped nonmonotonic dose-response curves (NMDRCs) at low, environmentally-relevant exposure levels; levels below traditional NOAELs (“Current Chemical Testing Missing Low-Dosage Effects of Endocrine-Disrupting Chemicals” Endocrinology Society, 2012). In addition, the US EPAs Endocrine Disruptor Screening program (EDC program) has been severely criticized, sometimes unfairly. This symposium will review the state of the science on EDCs concerning the shape of the dose-response curve in the low-dose range and the prevalence of NMDRCs. Talks will initially discuss mechanisms of action, the biologically plausibility for NMDRCs, and then focus on chemicals that disrupt the estrogen and androgen signaling pathways and the prevalence of in vitro and in vivo NMDRCs. Presentations will also discuss the shape of the dose-response curves from “case studies” of estrogenic chemicals. These “case studies” are robust, multigenerational studies conducted in a government laboratory using a protocol that had been “enhanced” to include several estrogen-sensitive endpoints in addition to the standard endpoints. Finally, we will discuss how some governmental agencies are addressing the NMDRC-low dose issue and views on how this might impact the risk assessment of EDCs and other chemicals. Changing how EDCs are tested to accommodate NMDRCs would significantly increase the resources need for testing as it would require the addition of several “low” dose groups and if NMDRCs are prevalent, then this would significantly impact several of the default assumptions used in risk assessment, including noncancer health effects displaying a threshold, and that adverse effects do not occur below the NOAELs.

- **Molecular Pharmacology of Steroid Hormone Action:**
  - Nonmonotonic Dose-Responses. William R. Kelce, Novan Therapeutics, Durham, NC.

- **Nonmonotonic Dose-Response Curves (NMDRCs) Are Common after Estrogen or Androgen Signaling Pathway Disruption. Fact or Falderal?** Leon E. Gray Jr., US EPA, Research Triangle Park, NC.

- **Comprehensive Studies Addressing Critical Questions in the Dose-Response Assessment of Endocrine-Active Compounds.** K. Barry Delclos, US FDA, Jefferson, AR.

- **Low Dose and Nonmonotonic Dose-Response Curves for Endocrine Disruptors.** Linda S. Birnbaum, NIEHS, Research Triangle Park, NC.

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**Understanding Toxicities of Abnormal Lipid Metabolism: Alcoholic, Nonalcoholic, and Toxicant-Induced Fatty Liver Disease**

**Molecular Basis of Genetic Variability and Susceptibility to Toxicants**

**Tuesday, March 12, 1:30 PM to 4:15 PM**

**Chairperson(s):** Mayur S. Mitra, Bristol-Myers Squibb Company, Mount Vernon, IN, and Min You, University of South Florida, Tampa, FL.

**Sponsor:**
- Molecular Biology Specialty Section

**Endorsed by:**
- Association of Scientists of Indian Origin Special Interest Group
- Drug Discovery Specialty Section
- Mechanisms Specialty Section

Accumulation of excess neutral lipids in the liver, referred to as fatty liver disease (FLD), is a major metabolic disorder and risk factor for development of hepatotoxicity. It is a progressive disease that initially manifests as reversible fatty liver, which upon infliction of inflammation advances to a nonreversible steatohepatitis, and finally leading to hepatic cirrhosis. FLD is generally categorized on the basis of its etiology, the two main types being alcohol-induced steatohepatitis (ASH) and obesity-induced (nonalcoholic steatohepatitis, NASH). Another class of FLD, drug/toxicant-induced FLD (TASH), is a major cause of pharmaceutical candidate attrition. The underlying pathogenic mechanisms of hepatic lipid accumulation and their implications are not completely understood. In this symposium, recent advances in the pathogenic role of microRNAs in the development of FLD will be introduced. The molecular mechanisms by which fatty liver promotes liver injury will be discussed using examples of drug overdose, hepatic ischemia-reperfusion, and obstructive cholestasis. Further, the implications of excess hepatic lipid accumulation in regards to altered drug metabolism and cellular uptake will be presented. The symposium will end with a comparative analysis of novel clinical biomarkers of ASH, NASH, and TASH. Students, as well as toxicologists working in academia, federal, and pharmaceutical industries interested in animal models, pathogenic mechanisms, biomarkers, and drug metabolism and toxicity of ASH, NASH, and TASH will benefit from this symposium.

- **Symposium Introduction—Pathogenesis of Hepatic Fat Accumulation.** Mayur S. Mitra, Bristol-Myers Squibb Company, Mount Vernon, IN.
- **miR-217-SIRT1 Signaling and Alcoholic Fatty Liver Disease.** Min You, University of South Florida, Tampa, FL.
- **Enhanced Susceptibility of Fatty Livers to Drug Hepatotoxicity and Innate Immune Responses.** Hartmut Jaeschke, The University of Kansas Medical Center, Kansas City, KS.
Scientific Thematic Session
Symposia

- Increased Risk of Drug Toxicity Due to Altered Pharmacokinetics in Nonalcoholic Steatohepatitis. Nathan J. Cherrington, University of Arizona, Tucson, AZ.

- Biomarkers and Mechanisms for Steatohepatitis. Craig J. McClain, University of Louisville, Louisville, KY.

**WEDNESDAY**

**Role of Systems Biology in Characterizing Risk of Developmental Origins of Disease**

*Application of Systems Biology to Toxicology*

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

**Chairperson(s)**: David T. Szabo, US EPA, Arlington, VA, and Tammy L. Palenski, University of Wisconsin Madison, Madison, WI.

**Sponsor**: Postdoctoral Assembly

**Endorsed by**: Graduate Student Leadership Committee
Hispanic Organization of Toxicologists Special Interest Group
Reproductive and Developmental Toxicology Specialty Section

Systems biology is the study of complex interactions of biological components, such as nucleic acids, proteins, chemical reactions, cells, and whole organisms, at multiple levels of organization. The National Research Council recommends implementing the use of systems biology approaches in the risk assessment process. While recent advances have been made to prioritize chemicals for further screening, to better understand mode of action, strengthen weight-of-evidence, and eventually replace traditional *in vivo* screening, to better understand mode of action, strengthen weight-of-evidence, and eventually replace traditional *in vivo* animal model data with *in vitro* and *in silico* methods, these data have not been systematically considered in mainstream approaches for risk assessment which also largely focuses on adult populations. The goal of this symposium is to consider emerging knowledge and information from systems biology to inform risk assessment and decision making in the arena of developmental origins of disease. Growing evidence suggests that chemical exposures in early life can have immediate and long-term effects on the structure and function of organ systems, leading to the development of disease later in life. Systems biology approaches can aid in understanding molecular, cellular, metabolic, and morphological changes resulting from such exposures. These approaches, which include analysis of complex data sets from multiple experimental sources, interdisciplinary ‘omics’ tools, and computer simulation modeling, are increasingly being applied to better understand developmental origins of disease. We will present current systems biology approaches on how to better identify developmental origins of disease and its implications to the risk assessment process through several case studies.


**Toxicoepigenomics, Disease Susceptibility, and Implications for Risk Assessment**

*Molecular Basis of Genetic Variability and Susceptibility to Toxicants*

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

**Chairperson(s)**: Kristy R. Katunzi, US FDA, Jefferson, AR, and Mukesh Verma, National Cancer Institute, Bethesda, MD.

**Sponsor**: Molecular Biology Specialty Section

**Endorsed by**: Mechanisms Specialty Section
Reproductive and Developmental Toxicology Specialty Section
Risk Assessment Specialty Section
Women in Toxicology Special Interest Group

In the past, classical toxicology has largely focused on the genotoxic effects of environmental toxicants and chemicals. Recent studies have clearly indicated that environmental chemicals, along with their genotoxic abilities, can cause epigenetic alterations that, in concert, may lead to the development of a number of pathological states. The field of toxicoepigenomics has since emerged from the combination of epigenetics, which studies the methylation of DNA, histone modifications, and chromatin condensation, and toxicology. During the last few years, excellent progress has been made in detecting altered epigenomic profiles in response to various chemical insults. Future investigations, however, are needed to link chemical exposure to epigenetic alterations which develop over time, and, in turn, may increase the risk of disease. Although whole populations may be exposed to toxic substances, only a few people develop the disease, which may, in part, be due to the different epigenomic backgrounds of individuals. That is why the potential role of epigenetics in disease susceptibility, among the potential opportunities for epigenetic biomarkers in the assessment of toxicity and carcinogenicity of chemicals have received a lot of attention recently. Specifically, the following key aspects need to be addressed: 1) How stable are the epigenetic alterations induced by environmental toxicants?; 2) What periods of
development across the lifespan are windows of vulnerability and/or opportunity for an altered epigenome?; 3) How can exposure to toxicants in utero affect the epigenome and predispose individuals to various diseases throughout life?; 4) Are there methodological and measurement gaps to be filled to advance our understanding of toxicoepigenomics?; and 5) How can we develop risk prediction models? Evidence that epigenetic alterations can be potentially reversed may be helpful in developing treatment and preventative strategies.

- Epigenetic Alterations in Response to Exposure to Environmental Toxicants. Igor Koturbash, University of Arkansas Medical School, Little Rock, AR.
- Application of Cancer Toxicoepigenomics in Identifying High-Risk Populations. Mukesh Verma, National Cancer Institute, Bethesda, MD.
- Changes in Histone Tail Modifications and Gene Expression in PBMC from Subjects Exposed to Nickel and Arsenic. Max Costa, New York University School of Medicine, New York, NY.
- Chromatin Remodeling As a Driver and Target for Lung Cancer. Steven Belinsky, Lovelace Respiratory Research Institute, Albuquerque, NM.
- Molecular Basis for Dioxin-Induced Cardiovascular Disease. Alvaro Puga, University of Cincinnati College of Medicine, Cincinnati, OH.

**Biomarkers of Disease and Toxicity: Exploiting the Interconnections**

**Biomarkers for Exposure Assessment, Safety Evaluation, and Translational Medicine**

**Wednesday, March 13, 1:30 PM to 4:15 PM**

**Chairperson(s):** Donna L. Mendrick, US FDA, Jefferson, AR, and William B. Mattes, PharmPoint Consulting, Poolesville, MD.

**Sponsor:**
- Scientific Liaison Coalition

**Endorsed by:**
- Biotechnology Specialty Section
- Clinical and Translational Toxicology Specialty Section
- Disease Prevention Task Force
- Drug Discovery Specialty Section

With the recent focus on (a) cellular pathways involved in toxicity sequelae and (b) translational biomarkers that may link animal and in vitro model observations with clinical reality, there is a need to broaden the understanding of how experimental models may replicate human toxicity and disease processes. Multicellular organisms may have large numbers of genes and proteins, but a relatively limited repertoire in terms of pathophysiology in response to disease or toxicant exposure. This fact allows research to improve and protect human health to be founded on the use of model systems that allow for tractable experimentation. Animal models and, more recently, in vitro systems have served as a means of both exploring mechanisms and identifying hazards in terms of disease and adverse events. However, the interconnections between disease and toxicity are rarely explored leaving the information in silos. This symposium will examine organ-based toxicity and disease processes, and compare lessons learned in biomarker identification and use across toxicity, disease, and species.

- **Introduction.** Donna L. Mendrick, US FDA, Jefferson, AR.
- **Use of Biomarkers in Hepatology, Liver Disease, and Liver Toxicity.** Arie Regev, Eli Lilly & Company, Indianapolis, IN.
- **Fibrinogen: A New Kid on the Block of Translational Biomarkers for Kidney Damage.** Vishal S. Vaidya, Harvard Medical School, Boston, MA.
- **Cardiac Disease, Cardiotoxicity, and Translational Biomarkers.** James R. Turk, Amgen Inc, Thousand Oaks, CA.
- **Links between Neurological Disease and Toxicity.** Christopher P. Austin, National Center for Advancing Translational Sciences, Bethesda, MD.

**Mechanistic Role(s) of Cytochrome(s) P450 in Oxidative Stress and Inflammation: New Opportunities for Drug Discovery**

**Wednesday, March 13, 1:30 PM to 4:15 PM**

**Chairperson(s):** Bhagavatula Moorthy, Baylor College of Medicine, Houston, TX, and José E. Manautou, University of Connecticut, Storrs, CT.

**Sponsor:**
- Mechanisms Specialty Section

**Endorsed by:**
- Inhalation and Respiratory Specialty Section
- Neurotoxicology Specialty Section

The major goal of this symposium is to discuss the molecular and cellular mechanisms by which cytochromes P450 (CYP) contribute to oxidative stress, which could in turn lead to inflammatory processes, ultimately leading to many human diseases including cancer, neurodegenerative diseases, bronchopulmonary dysplasia (BPD), acute respiratory distress syndrome (ARDS), and drug-induced hepatotoxicity. Although much is known about the functional role of CYPs in drug metabolism, their role in endobiotic metabolism, in relation to oxidative stress and inflammation, is understudied. The recent findings of the novel role of CYPs in oxidative stress and inflammation in the manifestation of multiple human diseases warrant the need for a symposium to discuss the latest mechanistic research in this area and its impact on human health. Specifically, the symposium will discuss: i) the role of CYP4f in neuroinflammation, which in turn contributes to neurodegenerative diseases such as Parkinson’s and Alzheimer’s diseases; ii) the role of the Ah receptor, oxidative stress,
and inflammation in 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD)-induced hepatotoxicity; iii) the functions of CYP1A1, 1A2, and 1B1 in the metabolism of eicosanoids, which in turn play mechanistic roles in TCDD toxicity; iv) the contribution of CYP4As in eicosanoid metabolism and the mechanism of down-regulation of CYPs during infection; and v) the novel protective role of CYP1A1 and 1A2, and the pro-oxidant role of CYP1B1 in hyperoxic lung injury, in relation to BPD and ARDS. The symposium will also discuss new opportunities for drug discovery and their potential translatability in clinical settings.

- Cytochromes P450f, a Potential Therapeutic Target for Neuroinflammation. Vijayalakshmi Ravindranath, Indian Institute of Science, Bangalore, India.
- Metabolomics Identifies an Oxidative Stress-Mediated Signal Transduction Cascade Involved in Dioxin-Induced Hepatotoxicity. Frank J. Gonzalez, National Cancer Institute, Bethesda, MD.
- Lipidomic Analysis Demonstrates that 2,3,7,8-Tetrachlorodibenzo-p-dioxin Increases the Levels of Multiple Pro- and Anti-Inflammatory Cytochrome P450 Metabolites of Polysaturated Fatty Acids in Several Organs of the Mouse. Oliver Hankinson, University of California Los Angeles, Los Angeles, CA.
- Regulation and Functions of Cytochromes P450 during Infection. Edward Morgan, Emory University, Atlanta, GA.
- Mechanistic Role(s) of Cytochrome P4501A and 1B1 Enzymes in Hyperoxic Lung Injury: Implications for Bronchopulmonary Dysplasia (BPD) in Premature Infants and ARDS in Adults. Bhagavatula Moorthy, Baylor College of Medicine, Houston, TX.

**Molecular Basis of Age-Related Susceptibility to Chemicals and Environmental Hazards: From Model Systems to Humans**

- Molecular Basis of Genetic Variability and Susceptibility to Toxicants

**Wednesday, March 13, 1:30 PM to 4:15 PM**

**Chairperson(s):** Janice S. Lee, US EPA, Durham, NC, and James C. Fuscoe, US FDA, Jefferson, AR.

**Sponsor:**
- Occupational and Public Health Specialty Section

**Endorsed by:**
- Hispanic Organization of Toxicologists Special Interest Group

The susceptibility of individuals to chemicals and environmental hazards at the extremes of the population age-distribution (the very young and the very old) is often not adequately assessed. By understanding genes expressed at the various life stages, the assessment of health risk versus benefit can be more rationally determined.
THURSDAY

From Immunotoxicity to Nanotherapy: The Effects of Nanomaterials on the Immune System

Effects of Nanomaterials on Biological Systems

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

Chairperson(s): Matthew J. Smith, ImmunoTox, Inc, Richmond, VA, and Nigel J. Walker, NIEHS, Research Triangle Park, NC.

Sponsor: ImmunoToxicology Specialty Section

The potential for human exposure to the diverse and ever-changing world of nanomaterials has raised concerns about the ability of these materials to influence health and disease. The small size of nanomaterials makes them a prime target for interaction with the cells of the immune system. Exposure to nanomaterials (inhalation, dermal, oral, parenteral) can affect multiple components of the immune system. For example, a single respiratory exposure to titanium dioxide nanoparticles can significantly increase the antibody-forming cell response to sheep erythrocytes, suggesting the possibility of nanomaterial interactions with lymphocytes and/or antigen-presenting cells. Furthermore, the cells of the innate immune system, including mast cells and the cells of the mononuclear phagocytic system, are also potential targets following nanomaterial exposure. A varied spectrum of effects, including inflammation, hypersensitivity, and immunomodulation, may then occur, via mechanisms which have yet to be elucidated. While incidental exposure may be undesirable, nanomaterials and nanomedicines engineered for various clinical applications provide opportunities to develop therapies that may or may not intentionally target the immune system. The interplay between nanomaterials and the immune system and the pharmacokinetic and phenotypic responses that result from these interactions are therefore critical factors that dictate the balance between toxicity and clinical efficacy of nanomedicines.

- **Molecular Dynamics Simulations with Advanced Sampling Techniques to Study Nanoparticle-Membrane Interactions.** Martin A. Philbert, University of Michigan, Ann Arbor, MI.
- **Evaluating the Local and Systemic Immunomodulatory Effects of Nanomaterials.** Matthew J. Smith, Virginia Commonwealth University, ImmunoTox, Inc, Richmond, VA.
- **Mast Cell Directed Nanomaterial Toxicity.** Jared M. Brown, East Carolina University, Greenville, NC.
- **Phenotypically Profiling the Factors Affecting the Pharmacokinetics and Pharmacodynamics of Nanoparticle Agents in Preclinical Models and in Patients.** William Zamboni, University of North Carolina at Chapel Hill, Chapel Hill, NC.

Modeling Human Genetic Variability and Susceptibility in the Laboratory

Molecular Basis of Genetic Variability and Susceptibility to Toxicants

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

Chairperson(s): Richard P. Woychik, NIEHS, Research Triangle Park, NC, and David W. Threadgill, North Carolina State University, Raleigh, NC.

Sponsor: Risk Assessment Specialty Section

Endorsed by: Biological Modeling Specialty Section

In Vitro and Alternative Methods Specialty Section

Mechanisms Specialty Section

Regulatory and Safety Evaluation Specialty Section

Within a population of genetically heterogeneous individuals, a range of responses is observed for environmental exposures. The observed variability in response is attributable to extrinsic and intrinsic factors, including individual differences in exposure to environmental stressors and genetic/epigenetic heterogeneity, respectively. Current risk assessment practice is to account for interindividual variability with default uncertainty factors (e.g., a ten-fold decrease in allowable exposure to protect the most sensitive subpopulations), even though these defaults are seldom supported by scientific evidence. Advances in exposure science and molecular genetics are greatly increasing our ability to characterize intrinsic differences among individuals in their exposure and response to toxicants. This symposium highlights several novel and exciting approaches in safety evaluation that utilize recent advances in genetics. First, recent collaborative efforts in the complex traits community have led to the development of several new, powerful mouse resources that greatly facilitate the identification of allelic variants of genes associated with differential response to toxic exposure through genotype-phenotype associations. Second, several laboratories, including the National Toxicology Program, have begun applying these new mouse models of human population diversity to studies on the molecular mechanisms of interindividual variability in chemical metabolism and toxicity. Third, the ability to generate induced pluripotent stem (iPS) cells from population-derived human cell resources, as well as the availability of embryonic stem (ES) and iPS cells from mouse strains, makes it possible to conduct in vitro studies to investigate interindividual differences in resistance and susceptibility to xenobiotic exposures. Ultimately, these new approaches should greatly enhance our ability to characterize variability in response to toxicants and to identify those genes and pathways that contribute significantly to the observed differential responses to environmental exposures in humans.

**San Antonio Texas**

*The Thematic Track information can be found on pages 10–11.*

**Symposia**
Scientific Thematic Session
Symposia

- Modeling Genetic Heterogeneity to Understand Susceptibility to Chemical Combinations: A Mouse Population-Based Study Using Trichloroethylene (TCE) and Inorganic Arsenic (iAS). David W. Threadgill, North Carolina State University, Raleigh, NC.

- The Use of Population-Based Inbred Panels and Diversity Outbred Mouse Models to Explore Individual Variability and Toxicity to Benzene. John E. French, NIEHS, Research Triangle Park, NC.

- Modeling Genetic Variability in Response to Environmental Toxics Using Mouse ES Cells In Vitro. Ted Choi, Predictive Biology, Inc., Carlsbad, CA.

- The 1,000 Genomes In Vitro Toxicology Project: Quantitative High-Throughput Screening for Chemical Toxicity in a Population-Based In Vitro Model. Ivan Rusyn, University of North Carolina at Chapel Hill, Chapel Hill, NC.


Role of Air Pollution As a Risk Factor for Central Nervous System Diseases and Disorders

Molecular Basis of Genetic Variability and Susceptibility to Toxicsants

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

Chairperson(s): Deborah A. Cory-Slechta, University of Rochester Medical School, Rochester, NY, and Michelle L. Block, Virginia Commonwealth University, Richmond, VA.

Sponsor:
Neurotoxicology Specialty Section

Endorsed by:
Inhalation and Respiratory Specialty Section
Mixtures Specialty Section

Increasing evidence suggests that many of the adverse consequences of air pollutants extend beyond the lungs and indeed can target the brain where they produce many of the same types of inflammatory and other adverse consequences as documented in the lungs. Such findings have been variously described in experimental models for exposures such as the metal constituents of the ultrafine particulate matter of air pollution, for diesel exhaust and for ozone. Both direct effects via constituents of air contaminants translocated to the CNS and indirect effects via induction of systemic acute phase responses have to be considered. In addition, epidemiological studies have now begun to report associations of traffic- and combustion-related air pollutants with cognitive deficits in children. While our understanding of the extent of such impacts is still quite limited, these highly provocative findings could suggest that air pollution has been a greatly underappreciated risk factor for neurodevelopmental or neurodegenerative diseases. This symposium will present findings from experimental models describing the CNS toxicity of concentrated ultrafine particles in adults and in postnatally-exposed rodent models in relation to neurodevelopmental and neurodegenerative consequences, and of ozone in the context of Parkinson’s disease. In addition, recent epidemiological findings linking residential proximity to freeway with autism will be presented. The intent of the symposium is to stimulate discussion especially in the context of future research needs in this rapidly emerging area of neurotoxicology which requires a multidisciplinary approach involving expertise in the toxicology of the CNS, air pollution, mixtures, and nanoparticles in order to conduct appropriate risk assessment.

- CNS Consequences of Postnatal Exposure to UFP. Deborah A. Cory-Slechta, University of Rochester Medical School, Rochester, NY.

- Microglia and the Peripheral Immune Response in Diesel Exhaust-Induced Neuropathology. Michelle L. Block, Virginia Commonwealth University, Richmond, VA.

- Particle Translocation As an Explanation for the Adverse Effects of Inhaled Particulates in the CNS. Alison Elder, University of Rochester, Rochester, NY.

- Does Air Pollution Exposure Increase Risk for Autism? Irva Hertz-Picciotto, University of California Davis, Davis, CA.

- Ozone Pollution, Oxidative Stress, and Dysregulation of Inflammatory Responses in Rat Hippocampus. Selva Rivas-Arancibia, Facultad de Medicina. Universidad Nacional Autónoma de México, México City, Mexico.

Translational Methods to Assess the Safety of Natural Health Products, Including Traditional Medicines and Dietary Supplements

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


Sponsor:
Food Safety Specialty Section

Endorsed by:
American Association of Chinese in Toxicology Special Interest Group
Clinical and Translational Toxicology Specialty Section
Mixtures Specialty Section
Regulatory and Safety Evaluation Specialty Section

Globally, ~80% of the world’s population relies upon traditional medicines as part of standard healthcare; ~100 million Americans spend ~$28 billion annually to consume herbas, vitamins, minerals, amino acids, and other naturally occurring products in the form of dietary supplements, botanical drugs, and natural health products. The complexity of mixtures with variance in composition and quality presents a challenge for risk practitioners. To address these...
issues, new methodologies and predictive technologies are being
developed, tested and validated to mitigate risk of human toxicity
and effectively increase the quality of information useful for appli-
cation in safety assessments. Many of these methods are already
reflected in multiagency government initiatives. Such methods are
referred to as “translational” for making use of and extrapolating
data from scientifically defensible approaches towards establishing
human safety and use of viable products. In this symposium, various
in vitro, in vivo, state-of-the-art in silico (computational), and ‘omic
methodologies will be presented. Discussion will cover case studies
and regulatory science activities at US FDA/CDER and NCTR
including conventional toxicological and computational assessments
of individual chemical constituents and mixtures. Computational
tools to deconvolute complexities and predict molecular targets for
constituent phytochemicals will also be highlighted. Speakers will
also address how the United States Pharmacopeia (USP) conducts
evidence-based reviews on the safety of dietary supplements and how
to couple data from in silico structure-based methods to compliment
and strengthen evidence and support committee-based human expert
decision making regarding the suitability of dietary supplements
for monograph development on product quality. Collectively, these
presentations will provide a global picture of the state and utility of
modern methods for assessing toxicity and safety of these products.

• Session Overview: The Promise of Translational and Integrative
  Safety Assessments of Dietary Supplements, Traditional
  Medicines, and Herbal Drugs. Scott A. Jordan, Health Canada,
  Ottawa, Ontario, Canada.

• In Silico Methods As Translational Tools for Supporting the
  Safety Assessment of Natural Health Products. Luis Valerio,
  US FDA, Silver Spring, MD.

• In Vitro and In Vivo Approaches for Assessing the Safety of
  Natural Health Products. William F. Salminen, US FDA, Jefferson,
  AR.

• Computational Methods Linking Traditional Chinese Medicine
  (TCM) and Western Therapeutics. Dale E. Johnson, University of
  California Berkeley, Berkeley, CA.

• Herbogenomics As a Translational Method for the Safety
  Assessment of the Complex Mixtures in Traditional Chinese
  Medicines. Y. James Kang, University of Louisville School of
  Medicine, Louisville, KY.

• Evidence-Based Reviews As a Method for Assessing the Safety
  of Dietary Supplements. Mary Hardy, University of California Los
  Angeles, Los Angeles, CA.
**Biology of Low-Dose Response for DNA-Reactive Chemicals**

Monday, March 11, 9:15 AM to 12:00 Noon

Chairperson(s): Joanna Klapacz, The Dow Chemical Company, Midland, MI, and Bevin P. Engelward, Massachusetts Institute of Technology, Cambridge, MA.

Sponsor:  
Molecular Biology Specialty Section

Endorsed by:  
Biological Modeling Specialty Section  
Risk Assessment Specialty Section

In the risk assessment process, DNA-reactive agents are generally considered to have no thresholds for their biological effects and this assumption formed the basis for linear low-dose extrapolation of any carcinogenic effects induced by these agents. On the other hand, cells have evolved to handle DNA lesions from endogenous and many exogenous DNA-reactive agents. In fact, DNA-repair processes are strictly conserved from bacteria to humans underlying their importance in protection against the effects of these agents, such as disease and aging. In recent years, low-dose response for DNA-reactive agents has been an active domain for research in toxicology, with publication of several datasets with large numbers of doses focused on the determination of no-observed-genotoxic-effect-level (NOGEL) values. This effort has included dose-response modelling to identify the best fit between linear and nonlinear models, such as bilinear (hockey-stick) and the benchmark dose (BMD) suite of models, and most datasets have supported a bilinear or nonlinear/threshold dose response as providing best fit based on statistical criteria. However, empirical demonstration of statistically-supported nonlinear/threshold dose response alone is not sufficient to achieve a paradigm shift in risk assessment. A clear understanding of the biological processes behind the shape of the low-dose response curve is similarly a critical piece of this journey, and one where less effort has been focused to date within toxicology. This workshop will explore some of the questions that need to be addressed to understand and bridge DNA-repair processes and cellular responses with the mode-of-action driving these nonlinear/threshold dose responses for genotoxic effects. The workshop will examine existing knowledge from the field of DNA repair and link it with response to low doses of DNA-reactive agents, in order to draw specific recommendations on a path forward.

- Genotoxic Effects and Dose Response: What Do We Know So Far? Lynn H. Potterger, The Dow Chemical Company, Midland, MI.
- Role of Mismatch Repair in Mutagenesis, Cancer, and DNA-Damage Signaling. Winfried Edelmann, Albert Einstein College of Medicine, Bronx, NY.
- Computational Systems Biology Modeling of DNA-Damage Stress Pathways for Assessing Mutation Rates at Low Doses. Melvin E. Andersen, The Hamner Institutes for Health Sciences, Research Triangle Park, NC.
- Do Alkylating Agents Cause Genotoxic Thresholds through a DNA Repair Mode of Action? George Johnson, Swansea University, Swansea, United Kingdom.

**Incorporation of Exposure Data and Chemical Properties into Early In Vitro Screening Studies: Putting Early Hazard Identification into Appropriate Context**

Monday, March 11, 9:15 AM to 12:00 Noon

Chairperson(s): Robert T. Dunn II, Amgen Inc, Thousand Oaks, CA, and Yvonne Will, Pfizer, Inc, Groton, CT.

Sponsor:  
Drug Discovery Specialty Section

Endorsed by:  
In Vitro and Alternative Methods Specialty Section

Over the past several years, a multiplicity of innovative early-screening assays have been adopted to improve our ability to select drug candidates with the maximal opportunity to eventually succeed in later development. Examples of medium and high-throughput assays that can enable early hazard identification include ion channels related to cardiovascular safety (hERG, NaV1.5, and others), assays to understand CNS permeability and hepatobiliary transport (PgP, BSEP, etc.), and receptor and kinase screens, as well as screening ADME assays. These assays are typically employed early in the drug discovery process when little other data are available to help contextualize the early-screening result. Data output from these early screens is often produced, then utilized by project teams to select molecules for advancement, de-prioritization, or to accumulate the knowledge base around a compound. In this model, the early-screening data may become a static entity, such as an IC50 value, which is then stored in a database often without further consideration or re-evaluation. There is a possibility that early-screening data in such a model is underutilized or potentially misleading. An inherent problem with generating early-screening data is that it is often produced in the absence of accompanying data (e.g., in vivo exposure), which is information that can be leveraged to place these data into better context and enable more accurate predictions. In this workshop, several use case examples will be presented where in vivo exposure information and chemical compound properties have been weaved into early in vitro
toxicity screening data enabling the discovery toxicologist to conduct a more robust assessment of the hazard identification assay data.


- Lead Optimization against Toxicological End Points in Drug Discovery: Recognition of Structural Determinants of Small Molecule Target Organ Exposure and Toxicity. Dylan P. Hartley, Array Biopharma, Boulder, CO.

- The Challenges of Putting In Vitro Safety Assays into Context with In Vivo Data. Nigel Greene, Pfizer, Inc., Groton, CT.

- Relating Molecular Properties and In Vitro ADME/Tox Surrogate Assay Results to In Vivo Outcomes. Jeffrey Sutherland, Lilly Research Laboratories, Indianapolis, IN.

**Inhaled Mixtures: A Mode-of-Action Framework Applied to the Criteria Air Pollutants**

**Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment**

**Workshops**

- Monday, March 11, 9:15 AM to 12:00 Noon

**Chairperson(s):** Christal C. Bowman, Bayer CropScience, Durham, NC, and Elizabeth Owens, US EPA, Research Triangle Park, NC.

**Sponsor:** Inhalation and Respiratory Specialty Section

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

Although regulated individually, the criteria air pollutants, NOx, SOx, CO, PM, Pb, and O3, exist as a complex mixture in the atmosphere. Thus, the interactions and cumulative effects of multiple pollutants are important to consider when assessing the impact of ambient air exposures on health. The criteria air pollutants act through complex biological pathways to elicit health effects, but many share common modes of action, including oxidative stress and inflammation. Mode of action for a given toxic agent is defined as the set of key events involved in a given toxic effect. Key events are measurable endpoints along a continuum from exposure to effect, and are consistent with emerging concepts of how to use biomarkers, surrogate endpoints, and toxicity pathways to characterize health risks. Recent discussions have proposed the use of mode of action to develop a unifying framework for the evaluation of mixtures containing multiple pollutants. This session convenes experts in the modes of action of criteria air pollutants to examine how this information can be organized, beginning with a description of an emerging framework for integrating mechanism and biological plausibility information regarding the criteria air pollutants and a subset of ambient air toxics. Attendees will gain knowledge of how a mode-of-action framework can be used to consider mixtures, as well as emerging and established mechanisms of toxicity of air pollutants, focusing on potential interactions between pollutants encountered in a multipollutant context.


- The Effects of Criteria Pollutants in the Brain. Michelle L. Block, Medical College of Virginia, Richmond, VA.

- Air Pollution and Pattern Recognition Receptors: Like a Wee LCMS in Every Mouse. Matthew J. Campen, University of New Mexico, Albuquerque, NM.

- Differential Effects of PM Components: Toward a Better Understanding of Underlying Mechanisms. Annette C. Rohr, Electric Power Research Institute, Redmond, WA.

**Environmental Factors in Neurodegenerative Diseases**

**Monday, March 11, 2:00 PM to 4:45 PM**

**Chairperson(s):** Evelyn C. Tiffany-Castiglioni, Texas A&M University, College Station, TX, and Anumantha G. Kanthasamy, Iowa State University, Iowa City, IA.

**Sponsor:** Neurotoxicology Specialty Section

- Exposures to environmental pollutants are implicated in the development of neurodegenerative diseases and protein conformational diseases, including Parkinson’s Disease (PD) and Alzheimer’s Disease (AD). The purpose of this workshop is to bring together experts to discuss etiologic factors associated with PD and AD, particularly environmental pesticides, heavy metals, and other pollutants, and to discuss new directions for identifying suitable targets for therapeutic strategies. Two very promising lines of investigation into the mechanisms of dopaminergic cell death in PD will be discussed, as well as the interaction of senescence-related, genetic, and environmental factors likely contributes to the etiology of late-onset neurodegenerative diseases such as PD and AD. The interactions of heavy metals with chaperone proteins that regulate protein folding and cell death as related to protein conformational diseases will also be discussed. The workshop will address six questions: 1) Despite equivocal results, why are genetic factors still considered the primary etiologic factor in late-onset neurodegenerative disease? 2) How can existing models of neuronal cell death in neurodegenerative diseases be integrated? 3) How can cell culture models be integrated into a better understanding neurodegenerative disease processes? 4) Are there common pathways or mechanisms that are relevant to environmental exposures in protein folding diseases, including PD and AD? 5) How do chemi-

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Workshops

The Thematic Track information can be found on pages 10–11.

Workshops

in a similar class of compounds elicit very different effects on the neurodegenerative processes? 6) What is the evidence that early exposures to environmental factors predispose to neurodegenerative diseases?

- ER Chaperone-Metal Interactions: Links to Protein Folding Disorders. Evelyn C. Tiffany-Castiglioni, Texas A&M University, College Station, TX.

- Novel Oxidative Cell-Death Signaling in Neurotoxicity Models of Parkinson’s Disease. Anumantha G. Kanthasamy, Iowa State University, Ames, IA.

- Industrial Toxicants and Parkinson’s Disease. Gary W. Miller, Emory University, Atlanta, GA.

- Integrating Epidemiological and Basic Research to Assess the Role of Pesticide Exposure in Neurodegenerative Disease. Jason R. Richardson, Robert Wood Johnson Medical School, Piscataway, NJ.

Life-Course Models for Ensuring Children’s Health Protection

Monday, March 11, 2:00 PM to 4:45 PM

Chairperson(s): Sally P. Darney, US EPA, Research Triangle Park, NC, and Elaine Faustman, University of Washington, Seattle, WA.

Sponsor: Reproductive and Developmental Toxicology Specialty Section

Endorsed by:

- Neurotoxicology Specialty Section
- Occupational and Public Health Specialty Section
- Risk Assessment Specialty Section
- Scientific Liaison Coalition
- Women in Toxicology Special Interest Group

New knowledge about environmental risks to human reproduction and development directly relevant to children’s health protection derives from the fields of developmental and reproductive toxicology, exposure science, epidemiology, risk assessment, and public health. Together, this information highlights the importance of the intrauterine environment in setting the stage for lifelong health, along with the complexities of the physical, chemical, and social factors that operate during critical windows of development to impact health and wellbeing. For example, breakthroughs in genetic polymorphisms and epigenetics are extending our understanding of inherent and acquired susceptibility to effects of environmental contaminants and showing how various intrauterine stressors such as nutrition, toxicants, and social stress may alter developmental programming at the start and throughout life. These scientific advances point to the need for innovative cumulative risk assessment methods and public health intervention approaches in order to account for risks that accrue across the developmental continuum from cradle to cradle. This workshop brings together the interdisciplinary expertise needed to begin integrating new knowledge into life-course models for children’s health and wellbeing. Topics include research findings from toxicity testing and epidemiology studies specific to critical windows of exposure during pre-conception, pregnancy, and early childhood life stages to stimulate discussion on the broad challenge of optimizing testing and risk assessment models and enabling analyses across the whole life course. The workshop also features an innovative approach for evaluating and communicating complex scientific information about reproductive risks and interventions to diverse audiences including health care providers, parents (present and future), and regulators.

- Today’s Challenge for Protecting Children’s Environmental Health for a Lifetime. Elaine M. Faustman, University of Washington, Seattle, WA.

- Periconception Parental Metal Exposures, Couple Fecundity, and Child Health: Delineating the Chicken and Egg Question. Germaine Buck Louis, NICHD, Bethesda, MD.


- New Strategies for Addressing Toxicity Testing across the Lifespan. Paul M. D. Foster, NIEHS, Research Triangle Park, NC.


Nanoinformatics: Computational Challenges for Nanomaterial Hazard Assessment

Monday, March 11, 2:00 PM to 4:45 PM

Chairperson(s): Katrina M. Waters, Pacific Northwest National Lab, Richland, WA, and Stacey L. Harper, Oregon State University, Corvallis, OR.

Sponsor: Nanotoxicology Specialty Section

Endorsed by:

- Biological Modeling Specialty Section

Hazard evaluation of the growing number of nanomaterials can be expedited and enhanced through the identification of underlying quantitative relationships between their structural, chemical, and physical properties and responses in key biological systems. The Toxicity in the 21st century testing paradigm holds particular promise for nanoparticles because whole animal testing is not economically practical or feasible for every new material introduced to the market place. Important advancements have been made in this emerging but critical field, yet many challenges remain. Distillation of the large amount of phenotypic data regarding in vitro cytotoxicity and inflammation down to in vivo-relevant adverse events is a daunting
task, given the vast differences in microenvironment, temporal dynamics, and exposure. The use of systems biology approaches will enable the identification of relevant target organs/cell types, the development of mechanism-based assays for hazard assessment and computational modeling for predicting potential toxicity from human relevant exposures. This session will address computational challenges in data standards, data integration, and modeling of dose response and structure-activity relationships, including talks by experts in the areas of informatics, in vitro screening, in vivo exposures and PB/PK modeling. Included is an opening by the co-chair of the US-EU Nanoinformatics Community of Research, which seeks to facilitate intercommunication between researchers, regulators, and granting agencies on environmental health and safety issues for manufactured nanomaterials. Speakers will include current experimental and computational approaches as well as future research needs to identify relevant in vitro assays that are predictive for nanomaterial hazard assessment based on in vivo mode of action and realistic human exposures.

- **US-EU Nanotechnology Databases and Ontology Community of Research.** Nathan Baker, Pacific Northwest National Laboratory, Richland, WA.

- **High-Throughput Screening of Nanomaterial Bioactivity/Toxicity: The Computational Side Is Just As Important As the Testing Assays and Characterization.** Amy Wang, US EPA, Research Triangle Park, NC.

- **Computational Dosimetry for Nanomaterial Risk Assessment from Transciptomic and HTP Data.** Justin Teegarden, Pacific Northwest National Laboratory, Richland, WA.

- **Integrative Nanotoxicology: Linking Rapid Assays and Informatics to Predict Nanomaterial-Biological Interactions.** Stacey Harper, Oregon State University, Corvallis, OR.

- **Usefulness of In Vivo Genomics for In Vitro Screening in Nanotoxicity.** Aaron Erdely, NIOSH, Morgantown, WV.

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**Scientific and Regulatory Advances in Genetic Toxicology Safety Assessment**

**Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment**

Monday, March 11, 2:00 PM to 4:45 PM

**Chairperson(s):** Marilyn J. Aardema, BioReliance, Fairfield, OH, and Brinda Mahadevan, Abbott Laboratories, Columbus, OH.

**Sponsor:**
- Regulatory and Safety Evaluation Specialty Section

**Endorsed by:**
- Food Safety Specialty Section
- In Vitro and Alternative Methods Specialty Section
- Risk Assessment Specialty Section
- Women in Toxicology Special Interest Group

Recent reviews of genotoxicity assay performance, the use of these data in the safety evaluation process, and the development of new assays have led to important advancements in regulatory and scientific recommendations in the area of genetic toxicology. For instance, the International Conference on Harmonization (ICH) has recently finalized guidelines on genetic toxicity testing for drugs. The OECD is updating 15 year-old guidelines for genetic toxicity assays. International validation of new assays like the Comet assay have been completed. Workshops held by international expert groups on new approaches for genetic toxicology assessments highlight the importance of incorporating new approaches in drug safety evaluations. In recent years, significant progress has been made in incorporating quantitative approaches to genotoxicity dose response in order to identify a point of departure for application in risk assessment process. These important initiatives impact the science and practice of genetic toxicology safety assessments globally and across all sectors including drugs, chemicals, and consumer products. This workshop brings together international experts representing key geographies involved in leading these efforts. In an effort to discuss scientific and regulatory advances in genetic toxicology hazard assessment, the following key aspects will be addressed in this workshop: (1) US FDA implementation of ICHS2 (R1) guidelines, (2) Latest updates and new approaches in international guidelines for genetic toxicology assays, (3) Outcomes on the JACVAM Comet validation and OECD guideline development, and (4) New approaches for genotoxicity assessments and guidance on dealing with positive results. In addition, this workshop will provide a forum to discuss the scientific advances that have led to the latest regulatory guideline changes, and their implementation.

- **US FDA Implementation of the ICH S2(R1) Guideline.** Mark Powley, US FDA, Silver Spring, MD.

- **New Approaches in International Guidelines for Genetic Toxicology Assays: Latest Updates on OECD Guidelines.** Veronique Thybaud, Sanofi, Vitry-sur-Seine, France.
**Workshops**

- **JACVAM Comet Validation and OECD Guideline.**
  Makoto Hayashi, Biosafety Research Center, Iwata, Japan.

- **New Approaches for Genotoxicity Assessment and Guidance on Dealing with Positive Results.**
  B. Bhaskar Gollapudi, ILSI-HESI IVGT Project Committee, Midland, MI.

**TUESDAY**

**Advances in Carcinogenic Risk Assessment of Low-Level Genotoxic Impurities in Pharmaceuticals**

**Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment**

Tuesday, March 12, 9:00 AM to 11:45 AM

**Chairperson(s):** Warren W. Ku, Boehringer Ingelheim Inc., Ridgefield, CT, and David Jacobson-Kram, US FDA, Jefferson, AR.

**Sponsor:**
- Regulatory and Safety Evaluation Specialty Section

**Endorsed by:**
- Occupational and Public Health Specialty Section
- Risk Assessment Specialty Section

Pharmaceutical syntheses involve the use of reactive starting materials, intermediates, and reagents, some of which are known or potential genotoxicants and carcinogens. Therefore, genotoxic and potentially carcinogenic impurities may appear in the final drug product. Risk assessment approaches have focused on defining impurity limits which pose acceptable risk over a patient’s duration of drug treatment. Over the past decade, regulatory guidances (EMA, US FDA draft) have been introduced. Drug-associated genotoxic impurities became an ICH guideline topic (M7) in 2009, and an Expert Working Group is currently developing a harmonized guideline. The ICH M7 effort presents an opportunity to review existing guidelines, evaluate new information and experiences since their introduction, and improve the integration of safety and quality aspects for detection, risk management and control. This workshop will provide a historical overview and introduce newer concepts to SOT members for discussion on several approaches being considered in M7. The workshop will cover the following topics along with case studies: (1) a brief overview of regulatory risk assessment approaches developed over the past decade and introduce current M7 concepts being considered; (2) review current in silico QSAR and genotoxicity testing approaches to predict or identify hazards and qualify impurity risk; (3) introduce advances in the framework and rationale for applying less-than-lifetime acceptable risk limits during clinical development and marketing; (4) highlight differences in chemical space between pharmaceutical synthetic intermediates or impurities and that used to derive the original lifetime threshold of toxicological concern (TTC) limit, and its potential implications for risk characterization; and (5) review approaches for addressing risk of multiple genotoxic impurities in a drug product.

- **Genotoxic Impurities—Regulatory Advances in Risk Assessment Approaches.**
  Peter Kasper, Federal Institute for Drugs and Medical Devices, Bonn, Germany.

- **Advances in Mutagenic Impurity Hazard Assessment: Best Practices and Current Developments.**
  Krista Dobo, Pfizer Global Research and Development, Groton, CT.

- **Less than Lifetime (LTL) Carcinogenic Risk Limits for Mutagenic Impurities during Clinical Development and in Marketed Products.**
  Lutz Mueller, F. Hoffmann-La Roche Ltd., Basel, Switzerland.

- **Many Potential Mutagens Used in Pharmaceutical Syntheses Are in Less Potent Classes Than the Carcinogens Used to Derive the TTC, Justifying Higher Levels without Increasing Risk.**
  Sheila Galloway, Merck Research Laboratories, West Point, PA.

- **Addressing Risks of the Potential Presence of Multiple Genotoxic/Carcinogenic Impurities in Pharmaceuticals.**
  Joel Bercu, Amgen Inc., Thousand Oaks, CA.

**Health Risks of Sodium (Salt) Intake: Too Much or Too Little?**

**Tuesday, March 12, 9:00 AM to 11:45 AM**

**Chairperson(s):** Madhu G. Soni, Soni & Associates Inc, Vero Beach, FL, and P. Michael Bolger, Exponent, Annapolis, MD.

**Sponsor:**
- Food Safety Specialty Section

**Endorsed by:**
- Association of Scientists of Indian Origin Special Interest Group
- Cardiovascular Toxicology Specialty Section
- Regulatory and Safety Evaluation Specialty Section
- Women in Toxicology Special Interest Group

Public health advocates have been concerned for decades that Americans consume unhealthy amounts of dietary sodium. Recently, the Institute of Medicine (IOM) recommended a Tolerable Upper Intake Level of 2,300 mg sodium/day and an Adequate Intake of just 1,500 mg/day, based on risks of adverse health effects, particularly hypertension. However, the average sodium intake is estimated to be 3,500 mg/day. The risk for morbidity and mortality due to excessive or insufficient salt intake varies because of biochemical individuality. The available evidence from a wide variety of clinical trials shows a direct relation between salt intake and blood pressure. A recent meta-analysis suggests that salt reduction tended to increase levels of hormones (renin, aldosterone), cholesterol, and triglycerides, which are all thought to be risk factors for heart disease. It has been asserted that while the risks of consuming too much salt are real, the risks have been exaggerated for the general population, or that the studies done on the consumption of salt can be interpreted in many different ways.

**Thematic Session**

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A common safety concern of biotherapeutic agents is toxicity associated with mechanism of action (MoA). The term MoA refers to the specific biochemical interaction through which a drug substance produces its pharmacological effect. This workshop will address areas of significant impact to biotherapeutic drug development where there is a known dissociation of MoA and MoT in toxicity studies and/or in translation to the clinic. Most nonclinical toxicity studies are conducted in healthy animals which may not predict the effects of a biotherapeutic when used in the patients with specific diseases. The latest paradigms for using animal disease models, including study conduct and interpretation, will be explored. For many years, the likelihood of off-target toxicity was considered to be very low for most biotherapeutics. Data will be presented highlighting that off-target toxicity, particularly hematotoxicity, can occur and may be more prevalent than previously thought. Effort has also been put into better understanding the development and impact of antidrug antibodies (ADA) in nonclinical toxicity studies and their relevance to clinical ADA. In addition to impacting biotherapeutic drug exposure, ADA may also cause a variety of non-MoA associated toxicities including acute hypersensitivity, immune complex disease, and neutralization of the endogenous target. The incidence of ADA-associated toxicities has been increasing and the current understanding of these toxicities and their clinical relevance will be discussed.

- Introduction to the Mechanism of Action/ Mechanism of Toxicity Challenges of Biotherapeutics. Christine Grimaldi, Boehringer Ingelheim, Ridgefield, CT.
- Antidrug Antibodies: Interpreting Toxicology Studies and Translating Nonclinical Findings to the Clinic. Courtney Horvath, Genzyme Corporation, Framingham, MA.

**Unique Challenges in Biologic Drug Development: Separating Mechanism of Action from Mechanism of Toxicity**

**Tuesday, March 12, 9:00 AM to 11:45 AM**

**Chairperson(s):** Laura Andrews, Genzyme, Framingham, MA, and Marque Todd, Pfizer, Inc, Groton, CT.

**Sponsor:** Biotechnology Specialty Section

**Endorsed by:** Comparative and Veterinary Specialty Section, Toxicologic and Exploratory Pathology Specialty Section

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**“Air”-ing on the Side of Caution: Anticipating Impacts of Emerging Issues in the Health Effects of Air Pollution**

**Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment**

**Tuesday, March 12, 1:30 PM to 4:15 PM**

**Chairperson(s):** Aimen K. Farraj, US EPA, Research Triangle Park, NC, and Michelle L. Bell, Yale University, New Haven, CT.

**Sponsor:** Inhalation and Respiratory Specialty Section

**Endorsed by:** Cardiovascular Toxicology Specialty Section, Occupational and Public Health Specialty Section

Dramatic reductions in air pollution over the last three decades have largely been driven by the enactment of federal regulations (e.g., the Clean Air Act in the United States). Today, policymakers and air quality managers rely on cutting-edge science to reduce and control air pollution. Toxicology is at the forefront of this effort providing critical input on health effects of air pollution including dose-dependence, the role of constituents and size, mode of action, and relative toxicity of air pollution sources. Despite these advances, serious adverse health effects including cardiopulmonary mortality are still measurable at ambient air levels to which millions of people are currently exposed. Risk assessment of these air sheds is likely to get further complicated in light of the uncertainty posed by several

**52nd Annual Meeting and ToxExpo**

**The Thematic Track**

**information can be found on pages 10–11.**

**Scientific Workshops**
emerging issues that intersect air quality and health. Climate change is one such issue that may affect health via direct effects of weather (i.e., heat and precipitation) and indirectly through increasing concentrations in ground-level ozone and particulate matter, two key air pollutants linked to adverse health effects. The burgeoning increase in obesity and associated metabolic disorders, groups with exaggerated sensitivity to the adverse effects of air pollution, is likely to aggravate health outcomes. With the implementation of new fuel standards and increasing popularity of alternative fuels, it is unclear what impact these changes may have on health effects of traffic-related emissions. Finally, several methods of power generation, including modern coal technology, nuclear energy, and hydrofracking have recently captured public interest, yet their impacts on air quality are unknown. This workshop discusses the current state of the science including key toxicological findings and recent innovations as well as challenges in the study of these emerging issues. The workshop concludes with a prospective look at air pollution research with a discussion session that engages the audience in an effort to define data gaps and potential mitigation strategies.

- **Health Impacts from Climate Change through Atmospheric Systems: Recent Findings and Challenges.** Michelle Bell, Yale University, New Haven, CT.

- **Environmental Factors and Cardiometabolic Disease: Signals in the Air.** Sanjay Rajagopalan, The Ohio State University, Columbus, OH.


- **Fracking, Coal, and Nuclear Energy: Impacts of Contemporary Methods of Power Generation on Air Quality and Remediation Efforts.** Jacob McDonald, Lovelace Respiratory Research Institute, Albuquerque, NM.

- **Predicting the Future: Getting Ahead of Problems—A Presentation and Discussion.** Daniel Costa, US EPA, Research Triangle Park, NC.

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**Breaking the Routine: Is There Room for Modern Techniques of Neuropathology Assessment in Routine Preclinical Safety Studies?**

**Abstract:**
Neurotoxicity in routine preclinical safety studies is traditionally assessed with three H&E-stained brain sections; an approach that is not optimal, considering the brain’s complex neuroanatomy. The need to increase the sensitivity of this approach is supported by the finding that routine neuropathology assessments would fail to detect MPTP, ethanol and carbonyl sulfide induced-CNS lesions. Increasing the number of brain sections sampled and inclusion of additional histology stains have been recommended but there is no expert consensus on the feasibility of incorporating modern methods of assessment into routine preclinical safety studies. We will explore and comment on the adequacy of the traditional approach to neuropathology assessment in routine preclinical safety studies. We will also examine the current regulatory guidance on neurotoxicity assessment in routine preclinical safety studies and discuss the feasibility of changing the current approach. Examples of emerging methods, such as MRI-directed histology and detection of circulating biomarkers of CNS damage, along with strategies for incorporating these techniques into standard preclinical safety studies will also be discussed. Finally, we will attempt to build consensus on appropriate approaches for improving the sensitivity of neurotoxicity assessment in routine preclinical safety studies by fostering a discussion between the audience and panel members. This discussion will focus on the feasibility of employing the proposed new markers, endpoints, and approaches and potential issues with interpretation of results of these studies. In conclusion, we believe that by examining the adequacy of current approaches of neuropathology assessment, discussing possible improvements to regulatory guidance and presenting emerging approaches of neurotoxicity assessment that this workshop will allow for a much needed dialogue on the need and feasibility of improving the current methods of neuropathology assessment in routine preclinical safety studies.

- **Routine Neuropathology Analysis for Nonclinical General Toxicology Studies.** Brad Bolon, The Ohio State University, Columbus, OH.

Utilization of MRI Imaging to Optimize the Selection of Brain Sections for Assessment by Classical Neurohistopathology. Joseph Hanig, US FDA, Silver Spring, MD.

Translational Safety Biomarker Assessment of Neurotoxicity. Andreas Jeromin, NextGen Sciences DX, Boston, MA.

Drug Safety Assessment and Regulatory Landscape in Emerging Markets

Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment

Tuesday, March 12, 1:30 PM to 4:15 PM

Chairperson(s): Peter Mu, TeamedOn LLC, Rockville, MD, and Gopala Krishna, Supernus Pharmaceuticals, Inc., Rockville, MD.

Sponsor: Association of Scientists of Indian Origin Special Interest Group

Endorsed by:
- American Association of Chinese in Toxicology Special Interest Group
- Drug Discovery Specialty Section
- Hispanic Organization of Toxicologists Special Interest Group
- Korean Toxicologists Association in America Special Interest Group
- Regulatory and Safety Evaluation Specialty Section

With 85% of the world’s population and rapid economic growth, the emerging market countries are up and coming, and are now actively courted by large global pharmaceutical industries. Within the next decade, Asia is expected to overtake Europe in pharmaceutical sales. For example, China is predicted to be the second largest pharmaceutical market after the United States by 2015 (Nature Reviews Drug Discovery, 2010). Many large pharmaceutical companies have increased their presence in emerging markets for research and discovery, and are seeking to market their products locally. Due to the short history of innovative pharmaceutical research and development, many of the emerging countries have limited experience of first-hand review of new drugs applications, hence they rely mostly on the review decisions taken elsewhere to grant the approval in local markets. However, regulatory agencies of the emerging countries are working diligently to catch up with the international standards and in the process establishing the regulations that address their country specific needs to promote innovation and bring drugs that are appropriately tested to demonstrate safety for their own population. The establishment and expansion of regulatory agencies functions is creating local job opportunities for people with specialized skills, to help with the review of various components of the new drug applications while at the same time presenting challenges never experienced before due to the nature of innovation.

This has sometimes led to regulations that are not well defined and open to interpretation. The drug safety assessment and regulatory landscape in China, India, Korea, and Brazil will be introduced during the presentations. The similarity and difference of the regulatory environment in the emerging countries will be compared with the major ICH guidelines. The challenges and possible solutions for companies seeking regulatory approval in emerging markets will be discussed. This will also provide an open forum for regulators from emerging markets to exchange ideas on how to tackle unique situations they experience.

Framing the Workshop Theme. Saryu Goel, Supernus Pharmaceuticals, Inc., Rockville, MD.


Regulations and Developments in Safety Assessment of New Drugs in India. Yogendra Gupta, All India Institute of Medical Sciences, New Delhi, India.

Safety Assessment and Regulatory Landscape in Korea. Soon Young Han, Korea Food and Drug Administration, Osong, Korea.

Regulatory Developments in Brazil to Address Market Needs. Dirceu Barbano, Brazilian Health Surveillance Agency (ANVISA), Brasilia, Brazil.

Workshop Summarization and Question and Answer Session. Gopala Krishna, Supernus Pharmaceuticals, Inc., Rockville, MD.

WEDNESDAY

Dietary Arsenic—Forms, Hazards, and Risks

Wednesday, March 13, 9:00 AM to 11:45 AM

Chairperson(s): P. Michael Bolger, Exponent, Annapolis, MD, and Aaron Barchowsky, University of Pittsburgh, Pittsburgh, PA.

Sponsor: Food Safety Specialty Section

Endorsed by:
- Cardiovascular Toxicology Specialty Section
- Metals Specialty Section
- Regulatory and Safety Evaluation Specialty Section

Arsenic, particularly inorganic arsenic, is a well-known and ubiquitous environmental contaminant, particularly in drinking water, and it originates from both anthropogenic and natural sources. It demonstrates a myriad of toxicological effects across a broad spectrum of organ systems. It has generally been believed that arsenic in food occurs in organic forms that demonstrate minimal, if any, toxicological activity. This is particularly the case with the forms found in seafood (e.g., arsenosugars). However, there has been concern for some time that organic forms may not be the predominant forms in...
Workshops

Certain foods, like rice, where concentrations of inorganic forms in certain cultivars may be significant. In addition, other organic forms, like tri- and penta- mono- and dimethyl forms, may be found, and at levels that are not insignificant, and could potentially pose a health hazard. These organic forms may not be as innocuous as the organic forms found in seafood, as well as their potential exposures, hazards (e.g., toxicological, epidemiological) and risks to public health, and what risk management options maybe available.

- Noncancer Disease Risk Promoted by Low Level Arsenic Exposures. Aaron Barchowsky, University of Pittsburgh, Pittsburgh, PA.
- Exposure Assessment Methods for Dietary Arsenic. Leila Barraj, Exponent, Washington, DC.
- Recent Epidemiologic Studies of Arsenic and How They Apply to the Health Evaluation of Arsenic in Food. Herman Gibb, Tetra Tech Sciences, Arlington, VA.

Pulmonomics, the Exposome, and Microbiomes in Immunotoxicology

Biomarkers for Exposure Assessment, Safety Evaluation, and Translational Medicine

Wednesday, March 13, 9:00 AM to 11:45 AM


Sponsor: Immunotoxicology Specialty Section

Endorsed by:
- Biological Modeling Specialty Section
- Clinical and Translational Toxicology Specialty Section
- Inhalation and Respiratory Specialty Section

The exposome has revealed itself to be a powerful approach for assessing environmental exposures and their influences on human diseases. As we explore the origins of human disease, and the contributions made by environmental pollutants, a comprehensive understanding of systems biology is needed. This requires an integrated understanding of how environmental chemicals and other stressors of gene and protein expression are not only linked to a toxicological outcome but which may impact on chronic inflammatory diseases such as allergic asthma, COPD, and even lung cancer. Perturbations in normal cell cycle kinetics, apoptotic cell-death pathways, immune dysfunction, and a recent appreciation of the consequences of inadvertent dysregulation of the gut and lung microbiomes collectively distort normal systems biology homeostasis and the advent of adverse health effects. For the first time, this symposium presents emerging critical issues and paradigms that discuss the contributions and interplay of systems biology, the exposome, and microbiomes as they relate to immunotoxicology, dysregulation of inflammatory pathways, and chronic diseases. Invited speakers will place in context and share state-of-the-art approaches for advancing our understanding of the interplay of gene and environment and of the exposome in initiating and prolonging chronic inflammatory disease.

- Experimental Exposure of Mice to House Dust Alters Gut Microbiome and Attenuates Allergic Pulmonary Responses. Nick Lukacs, University of Michigan Medical School, Ann Arbor, MI.
- Translating the Airway Transcriptome into Biomarkers of Tobacco-Related Lung Disease. Avrum Spira, Boston University School of Medicine, Boston, MA.
- Immune-Mediated Adverse Effects of Drugs and Environmental Agents. Jack Uetrecht, University of Toronto, Toronto, Ontario, Canada.


Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment

Wednesday, March 13, 9:00 AM to 11:45 AM

Chairperson(s): Carrie G. Markgraf, Merck, Kenilworth, NJ, and Mausumee Guha, Bristol-Myers Squibb Company, Mount Vernon, IN.

Sponsor: Regulatory and Safety Evaluation Specialty Section

Endorsed by:
- Drug Discovery Special Section
- Neurotoxicology Specialty Section

Preclinical assessment of abuse liability potential for new drugs with central nervous system (CNS) activity has been a recent focus of both regulatory and industry interest. The standard animal models used for evaluation of abuse potential for these pharmaceutical candidates are self-administration and drug discrimination. These models have been well characterized in both rats and monkeys with known drugs
of abuse. However, unique challenges encountered when evaluating drugs with novel mechanisms or with difficult pharmaceutical properties raise questions: How can reinforcing properties be evaluated if there is no acceptable IV formulation? What comparator drug is appropriate for a candidate compound with a novel CNS-active mechanism? In these situations, using a nonstandard model may offer an attractive alternative. The promise of such alternative animal models is balanced by the challenge in data interpretation and in incorporation of the data into a comprehensive risk assessment. This workshop will start with a discussion of the regulatory requirements and standard data collected for a preclinical abuse potential assessment, followed by presentations on conditioned place preference (CPP) and intracranial self stimulation (ICSS)—both nonstandard animal models of drug abuse potential in a regulatory setting. The scientific rationale for their use, how each compares to standard animal models, and the use of their data in risk assessment and in an abuse potential package for submission to health authorities will be discussed.

- **Current Challenges in Abuse Liability Assessment of Drugs with Novel Mechanisms of Action.** Kristin H. Horn, Bristol-Myers Squibb Company, Mount Vernon, IN.
- **The Assessment of Abuse Liability: The Regulatory Perspective.** Silvia Calderon-Gutkind, US FDA, Silver Spring, MD.
- **Conditioned Place Preference As a Tool for Assessing Abuse Liability.** Christopher Cunningham, Oregon Health & Science University, Portland, OR.
- **Use of Intracranial Self-Stimulation for Abuse Liability Assessment.** Anton Bespalov, Abbott, Pavlov Medical University, Ludwigshafen, Germany.
- **Impact of Nonstandard Animal Models on Preclinical Study Design for Meeting Regulatory Requirements.** Mary Jeanne Kallman, Covance Inc., Greenfield, IN.

### The Placenta in Toxicology: Target or Travel Agent?

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

**Chairperson(s):** Christopher J. Bowman, Pfizer, Inc., Groton, CT, and Warren G. Foster, McMaster University, Hamilton, Ontario, Canada.

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

**Endorsed by:** Comparative and Veterinary Specialty Section

The placenta is a fascinating organ in its dynamic form and function appearing as a transient and critical tissue in the reproductive cycle. It is a collaboration of maternal and zygotic cellular layers whose major function is a conduit between mother and fetus focused on the growth and viability of the next generation whilst preserving maternal well-being. The unique physiology of biodistribution and metabolism of the placenta also render it sensitive as a target of toxicity. The human placenta is a complicated organ and understanding the comparative physiology of nonclinical species can be a critical component for drug and chemical safety assessment; both as a potential target of toxicity and as a presumed barrier to undesirable xenobiotics. As in much of toxicology, it is important to appreciate different perspectives including clinical, epidemiological, basic research, industry, and regulatory. It is only when this information is integrated and applied that we can appreciate the value and importance of basic research and the views of regulatory and industrial sciences.

- **How Predictive Are Animal Studies in Detecting Fetal Risks in Humans?** Gideon Koren, The University of Toronto, The University of Western Ontario, Toronto, Ontario, Canada.
- **Environmental Factors in Placental Toxicology and Women’s Health.** Marivana Veras, University of São Paulo, National Institute of Integrated Analysis of Environmental Risk, São Paulo, Brazil.
- **The Placenta As Therapeutic Border Patrol for Unintended Populations.** Christopher Bowman, Pfizer Inc., Groton, CT.
- **The Placenta As a Target Organ in Toxicology—A Case Study.** Bennard van Ravenzwaay, BASF SE, Ludwigshafen, Germany.
- **Regulatory Perspectives on Embry-Fetal Developmental Studies: The Placenta in Pharmacological Studies and Toxicological Assessments.** L. Steven Leshin, US FDA, Silver Spring, MD.

### Challenging the Limits of Nonclinical Safety Assessment of Pediatric Medicines

**Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment**

**Wednesday, March 13, 1:30 PM to 4:15 PM**

**Chairperson(s):** Jeffrey S. Moffit, Boehringer Ingelheim Pharmaceuticals Inc, Ridgefield, CT, and Merle Paule, US FDA, Jefferson, AR.

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

**Endorsed by:**

- Inhalation and Respiratory Specialty Section
- Neurotoxicology Specialty Section
- Regulatory and Safety Evaluation Specialty Section

Pediatric safety assessments are a fundamental and integral part of drug development programs. Introduction of regulatory guidance in the last decade has formalized the inclusion of safety evaluations in juvenile animals, leading to a better understanding of potential drug effects on developmental processes and risks specific to pediatric age groups. Toxicology studies in juvenile animals have evolved to address inherent differences in susceptibility between mature and immature systems. Pediatric safety assessments are challenged by practical and interpretive complexities of conducting toxicity studies.
in immature animals against a background of increasingly diverse disease indications. This symposium will review a number of innovative approaches that challenge the current limits of the nonclinical safety assessment of new pharmaceuticals. Our panel of experts will discuss unique approaches and case studies dealing with the challenges of supporting pediatric formulations, nontraditional routes of administration, and the complexities of developmental neurotoxicity assessments. Furthermore, our experts will discuss how information from various sources such as in vitro experiments using neonatal tissue, pharmacokinetics, and clinical pharmacology work may be brought together to build a risk assessment specific for a young infant and pediatric dosing. These innovative approaches from industry and government challenge the limits of nonclinical safety assessment and provide reassurances of safety for pediatric medicines.

- Safe and Effective Use of Established and Novel Excipients in the Development of Children's Medicines. Terry Ernest, GlaxoSmithKline R&D, Essex, United Kingdom.
- Technical Challenges and Data Interpretation Evaluating an Inhaled Long Acting β2-Agonist in Juvenile Dogs. Annerose Mauz, Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany.
- Pediatric Dosing Regimen Determination during Drug Development. Ping Ji, US FDA, Silver Spring, MD.

**Nanotoxicology: Computational Strategies, Advances, and Challenges**

**Effects of Nanomaterials on Biological Systems**

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


*Sponsor:* Nanotoxicology Specialty Section

Engineered Nanomaterials (ENM), in the range of 1–100 nm, have been found to exhibit fascinating physicochemical properties making them suitable for numerous applications, extending into numerous military, industrial, medical, and scientific specialties. However, massive quantities of ENM would need to be produced for these applications to be realized, thereby increasing the potential risk of human exposure and raising additional concern about their short and long-term toxicological effects. Nanotoxicology has recently emerged as a new branch of toxicology which deals with toxicological ramifications of these ENMs based on their physicochemical properties, such as size, shape, surface coating, and charge. Conducting toxicological studies considering massive quantities of ENM already in the market would be time consuming and resource intensive. Therefore, there is a great need to develop computational models to predict toxicity and human health effects of ENMs. A recent report (Nature Nanotechnology Vol 6, 2011 P138) has demonstrated a computational model to predict the cytotoxicity of various metal-based nanoparticles. The main objective of this workshop is to discuss modeling techniques based on the electronic and structural complexity of ENMs to predict their biological effects.

- Quantitative Nanostructure-Activity Relationships Modeling. Alexander Tropsha, University of North Carolina at Chapel Hill, Chapel Hill, NC.
- Toxicity of Nanomaterials—Major Challenges for Theoretical Predictions. Jerzy Leszczynski, Jackson State University, Jackson, MS.
- Biological Surface Adsorption Index (BSAI): A Molecular Signature for Nanomaterial Interactions. Jim E. Riviere, Kansas State University, Manhattan, KS.
- Predictive Modeling on Nanoparticle-Biomolecular Interactions. Ravindra Pandey, Michigan Technological University, Houghton, MI.

**Toxicogenomics in Risk and Safety Assessment: Recent Advances and Continuing Challenges**

### Application of Systems Biology to Toxicology

**Wednesday, March 13, 1:30 PM to 4:15 PM**

*Chairperson(s):* Chad Thompson, ToxStrategies, Inc., Katy, TX, and Michael D. Waters, Integrated Laboratory Systems, Inc., Research Triangle Park, NC.

*Sponsor:* Risk Assessment Specialty Section

Toxicogenomic studies can provide a vast amount of data with regard to the changes a chemical can have on a cell, tissue, or organism, and technological achievements continue to make it easier and cheaper to generate such data. However, the application of toxicogenomic data to environmental risk assessments and pharmaceutical safety assessments has progressed more slowly and, despite recent advances, challenges remain as to how best to harness and interpret these large and complex datasets to facilitate their practical application. This session will describe recent applications of toxicogenomics in environmental risk assessment with focus on assessing and predicting genotoxic modes of action and utilizing transcriptome changes from multidose and multi-endpoint animal bioassays in quantitative risk assessment. In addition, recent advances in the usage of toxicogenetic data...
nomics in preclinical pharmaceutical safety, clinical trial placement, and individualized medicine will be described.

- **Characterizing and Predicting Modes of Action of Carcinogenicity Based on Conventional and Toxicogenomics Methods.** Michael D. Waters, Integrated Laboratory Systems, Inc., Research Triangle Park, NC.


- **Application of Transcriptomic Data for Quantitative Chemical Risk Assessment.** Russell Thomas, The Hamner Institutes for Health Sciences, Research Triangle Park, NC.

- **Challenges and Opportunities of Toxicogenomics Analyses in Safety Assessment during Preclinical Safety Studies.** Christine M. Karowski, Amgen Inc., Thousand Oaks, CA.

- **Role of Causal Reasoning in Patient Stratification from Efficacy and Safety Perspectives.** Ahmed E. Enayetallah, Pfizer, Inc., Groton, CT.

**THURSDAY**

**Are We Like Rodents, Rabbits, or Something Else? Mechanisms of Developmental and Reproductive Toxicity across Species**

**Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment**

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

**Chairperson(s):** Reza J. Rasoulpour, The Dow Chemical Company, Midland, MI, and Kamin Johnson, Alfred I duPont Hospital for Children, Wilmington, DE.

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

Endorsed by:
- Biological Modeling Specialty Section
- Comparative and Veterinary Specialty Section
- Mechanisms Specialty Section
- Neurotoxicology Specialty Section
- Regulatory and Safety Evaluation Specialty Section

Given the inherent complexity of embryo/fetal development and reproductive biology, developmental and reproductive toxicity (DART) hazard identification and research still heavily relies on animal models. Typically, this type of research is conducted in rodents (e.g., mouse and rat) as well as nonrodent species (e.g., rabbit and nonhuman primate), which, in the face of toxicity findings, raises the question of relevance to humans. Are we more like mice, rats, or other model organisms? Not surprisingly, answering this question is a challenge, and the scientific approach may be quite different depending upon the biological system and the level of mechanistic information available. However, within this challenge is an opportunity to understand the toxicokinetic and toxicodynamic differences between the species and provide the appropriate context for developmental and reproductive findings. Providing this context can directly impact the risk assessment and regulatory decision-making process. This workshop will highlight several different approaches to relate animal reproductive and developmental toxicity findings to human health. Speakers in fields of basic research, product safety testing, epidemiology, and physiologically-based pharmacokinetic modeling will address the central theme of the workshop, which is applying different experimental strategies to analyze cross-species toxicity. Within each presentation, potential regulatory implications and feedback from agencies, when available, will be addressed. The expected outcomes of the workshop are an increased understanding of the different approaches to dissect complex toxicity mechanisms and to take the next step towards cross-species comparisons that impact human relevance and regulatory decisions.

- **Challenges in Elucidating Developmental Toxicity Mechanisms in the Context of Guideline Safety Assessment Studies.** Reza J. Rasoulpour, The Dow Chemical Company, Midland, MI.

- **Endocrine Disruption Mediated Developmental Toxicity in Mice versus Rats: Implications for Humans.** Kamin Johnson, Alfred I duPont Hospital for Children, Wilmington, DE.

- **Case Studies on Testis Toxicity in Rodent Models and Risk Management Strategies.** Sarah Campion, Pfizer Global Research and Development, Groton, CT.

- **Physiologically-Based Pharmacokinetic/Pharmacodynamic Modeling of Developmental Toxicity.** Charles Timchalk, Pacific Northwest National Laboratory, Richland, WA.

- **Using Epidemiology to Analyze Neurodevelopmental Toxicity across Species.** Julie E. Goodman, Gradient, Cambridge, MA.
Cumulative Risk: Toxicity and Interactions of Physical and Chemical Stressors

**Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment**

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

**Chairperson(s):** Jane Ellen Simmons, US EPA, Research Triangle Park, NC, and Cynthia V. Rider, National Toxicology Program, NIEHS, Research Triangle Park, NC.

**Sponsor:**
- Mixtures Specialty Section

**Endorsed by:**
- Occupational and Public Health Specialty Section
- Regulatory and Safety Evaluation Specialty Section
- Risk Assessment Specialty Section

Recent efforts to update cumulative risk assessment procedures and develop community-based risk assessment methods reflect increased interest in incorporating the totality of variables affecting human health into the risk assessment process. One key roadblock in advancement is uncertainty as to how nonchemical stressors behave in relationship to chemical stressors. An assumption that simplifies incorporation of nonchemical stressors into current risk assessment paradigms is that nonchemical stressors act in the same manner as chemicals. However, evidence is required to support this assumption. The term nonchemical stressors encompasses a diverse set of variables including physical stressors, such as noise, temperature, disease, and radiation, as well as psychosocial stressors, which involve perception of circumstances. Physical stressors offer a reasonable starting place for measuring the effects of nonchemical stressors and their modulation of chemical effects (and vice versa), as they clearly differ from chemical stressors, present many diverse and highly-relevant stressors, and “doses” of many physical stressors are easily quantifiable. There is a commonly held belief that virtually nothing is known about the impact of nonchemical stressors on chemical-mediated toxicity or the joint impact of co-exposure to chemical and nonchemical stressors. While generally true, there are several instances where a substantial body of evidence exists. The objective is to provide expert overviews, for those chemical and physical stressors that have been sufficiently studied to gain at least a limited understanding of their joint impact. In addition to providing the current state of knowledge, data gaps will be identified that should be addressed to facilitate inclusion of nonchemical stressors in risk assessment. (This abstract does not reflect US EPA or NIEHS policy.)

- **Cumulative Risk: Chemicals and Infectious Disease.** MaryJane K. Selgrade, ICF International, Durham, NC.
- **Enhancement of Noise-Induced Hearing Loss by Chemicals.** Thais Morata, NIOSH, Cincinnati, OH.
- **Exacerbation of Toxicity of Air Pollutants and Pesticides by Thermal Stress.** Christopher J. Gordon, US EPA, Research Triangle Park, NC.
- **Modulation of X-Ray Mediated Testicular Toxicity by Chemical Exposure.** Kim Boekelheide, Brown University, Providence, RI.
- **Sunlight Enhancement of the Toxicity of Air Pollutant Mixtures.** Kenneth G. Sexton, University of North Carolina at Chapel Hill, Chapel Hill, NC.

**Mechanistic, Occupational, and Clinical Aspects of Lead Exposure**

**Biomarkers for Exposure Assessment, Safety Evaluation, and Translational Medicine**

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

**Chairperson(s):** Allister Vale, University of Birmingham, Birmingham, United Kingdom, and John G. Benitez, Vanderbilt University, Nashville, TN.

**Sponsor:**
- Clinical and Translational Toxicology Specialty Section

**Endorsed by:**
- Disease Prevention Task Force
- Metal Specialty Section
- Occupational and Public Health Specialty Section

The mechanisms of lead toxicity are increasingly being explained by the ubiquitous reactivity of the bivalent lead cation and its ability to substitute for essential cations, notably calcium and zinc. By these means, lead complexes with important functional groups including thiol and carboxyl groups, and damages many fundamental cell processes and structures including enzyme pathways, phospholipid integrity, ion channel specificity and control, and intrinsic protective systems including free radical scavengers and cellular repair mechanisms. Owing to the large sample sizes involved and its nationally-representative nature, NHANES has been the subject of a number of epidemiological analyses relating blood lead concentrations to a range of adverse outcomes such as blood pressure, renal function, auditory thresholds, and a host of other cardiovascular, neurobehavioral, and other developmental or adult outcomes. Some practitioners are now proposing that, as the NHANES data suggest that lead concentrations even less than 5 μg/dL (0.24 μmol/L) can have some health consequences, chelation should be performed at even very low lead concentrations. Is this an appropriate interpretation of these data? There is concern that the occupational intervention concentrations worldwide are not only unsupported scientifically and clinically but also have been set at concentrations that permit unsafe practices to continue. A group of experts has proposed that workers should be removed from occupational exposure if a single blood lead concentration exceeds 30 μg/dL (1.45 μmol/L), or if two successive blood lead concentrations measured over a four-week interval equal or exceed 20...
µg/dL (0.97 µmol/L). Will these recommendations prevent clinically significant occupational lead exposure? Due to the paucity of clinical data, there is controversy about the lead concentration at which chelation therapy should be instituted in adults when exposure prevention has failed, the antidote to be used, and the most effective regimen to be employed.

- **Novel Mechanisms of Toxicity.** R. Clark Lantz, University of Arizona, Tucson, AZ.
- **Threshold Toxic Dose: What Can We Learn from the NHANES Studies?** Howard Hu, University of Toronto, Toronto, Ontario, Canada.
- **Occupational Exposure Limits: Do They Protect Workers?** Michael J. Kosnett, University of Colorado Denver, Denver, CO.
- **Chelation Therapy for Lead Poisoning: Unanswered Questions and Controversies.** Sally M. Bradberry, City Hospital, Birmingham, United Kingdom.

**Ocular Medical Devices and Ocular Drug Delivery Systems: Challenges and Opportunities**

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

*Chairperson(s):* James A. Render, NAMSA, Northwood, OH, and Anne G. Wiese, Allergan, Irvine, CA.

*Sponsors:*

- Medical Device Specialty Section
- Ocular Toxicology Specialty Section

*Endorsed by:*

- Biotechnology Specialty Section
- Regulatory and Safety Evaluation Specialty Section
- Toxicologic and Exploratory Pathology Specialty Section

The eye is a unique organ composed of many different structures working together to facilitate vision. The maintenance of clear vision during aging is threatened by various physiological changes (e.g., presbyopia) or diseases (e.g., age-related macular degeneration). The need for treatments is of increasing importance as the size of the aging population grows. The National Eye Institute predicts that by 2020, more than 50 million Americans will be impacted by age-related eye disease. Some of these conditions have been overcome through the use of medical devices. Ocular medical devices consist of instruments, apparatuses, appliances, and materials. Some devices are purely structural; whereas, other medical devices are a part of a delivery system that releases a drug. The five presentations in this program are designed to educate the audience on the therapeutic, safety, and regulatory challenges of developing ocular medical devices and drug delivery systems. The first presentation will cover the special requirements for developing contact lenses and contact lens solutions. The second presentation will describe the challenges associated with accommodative intraocular lenses (IOLs). The third presentation will discuss the ocular barriers (e.g., blood-eye-barrier) and how ocular medical devices and sustained release drug formulations have been designed to address these barriers with respect to developing protein therapeutics. Development of and regulatory challenges associated with a unique biodegradable small molecule ocular drug/injection applicator delivery system will be discussed in the fourth presentation. The symposium will conclude with a presentation that discusses the safety and regulatory requirements and complexities pertaining to ocular medical devices and ocular drug delivery systems.

- **Assessment of the Ocular Safety of Contact Lenses and Lens Solutions.** Mary E. Richardson, Bausch & Lomb, Rochester, NY.
- **Accommodative Intraocular Lenses: A New Class of IOLs with a New Class of Challenges.** Adrian Glasser, University of Houston, Houston, TX.
- **Safety Assessment Strategies and Challenges for Developing Intravitreally Administered Biologics.** Evan A. Thackaberry, Genentech, Inc, South San Francisco, CA.
- **Development and Regulatory Considerations for an Ocular Drug Release System for Ocular Disease.** Anne G. Wiese, Allergan, Irvine, CA.
- **Regulatory Considerations in Ocular Medical Device and Drug Delivery Systems Development.** Chandramallika Ghosh, US FDA, Silver Spring, MD.
A Decade of Nanotoxicology: Where Do We Stand Now?

Effects of Nanomaterials on Biological Systems

Monday, March 11, 12:10 PM to 1:30 PM


Sponsor: Nanotoxicology Specialty Section

Endorsed by: Association of Scientists of Indian Origin Special Interest Group

The last ten years have seen an explosion in the development and evolution of nanotoxicology. This milestone of a decade of research provides a great opportunity to look back and evaluate both the progress made, as well as identify challenges that can potentially plague future research. Early studies had few materials to work with. However, advances in material science have resulted in a large array of nanomaterials (NM) with controlled size, shape, and surface functionalities. From early on, it became apparent that the unique properties associated with NMs, (i.e., primary size, agglomeration patterns, crystal structure, shape, etc.) can dictate the observed effects. Systematic evaluation of toxicity mechanisms necessitated development of novel tools to assess NM physicochemical properties that include: enhanced microscopy techniques, dynamic and static light scattering, and quantitation of cellular uptake. However, adaptation of such characterization tools within the nanotoxicity community has been slow, due to convoluted literature reports of the same NM property measured with different techniques. Recently, the question of dosimetry has become a focus of inquiry due to such conflicting reports. Experiments are being performed to evaluate and compare the effect of dosage by mass, surface area, and number of particles. However, the evaluation of aggregation state has largely ignored the structure of aggregation, which can substantially influence NM mass exposure and uptake. In addition, another challenge in nanotoxicity is the lack of strategies to accurately extrapolate in vitro results to predict in vivo responses. This generates the need for enhanced cell model development and implementation in nanotoxicity research. The emerging field of nanotoxicology has made remarkable progress over the past decade and holds immense promise for the next. The focus of this discussion will be to highlight the current state of nanotoxicity and determine key gaps in dosimetry, interpretation of characterization to decipher mechanistic toxicity, and translating data to reliable assessment of human exposure and risk.

- A Change in Dose Metrics for Inhalation Toxicity Studies with Engineered Nanoparticles. David B. Warheit, DuPont Haskell Laboratories, Newark, DE.
- Lessons Learned from High-Content In Vivo Nano Toxicology Testing. Robert L. Tanguay, Oregon State University, Corvallis, OR.
- Accurate Aggregation Size and Structure Determination in Physiological Conditions—Ignored Fact in Nanotoxicity? Navid B. Saleh, University of South Carolina, Columbia, SC.
- Hazards and Risks in the Workplace: Have We Made Any Progress? Charles L. Geraci, NIOSH, Cincinnati, OH.

Predicting Human Thorough QT (TQT) Study Outcomes with Nonclinical Data—How Good Are We and How Good Do We Need to Be?

Biomarkers for Exposure Assessment, Safety Evaluation, and Translational Medicine

Monday, March 11, 12:10 PM to 1:30 PM

Chairperson(s): Jean-Pierre Valentin, AstraZeneca, Macclesfield, Cheshire, United Kingdom, and Oscar Della Pasqua, Leiden University, Leiden, Netherlands.

Sponsor: Cardiovascular Toxicology Specialty Section

Endorsed by: Comparative and Veterinary Specialty Section

Drug Discovery Toxicology Specialty Section

Regulatory and Safety Evaluation Specialty Section

The ability to predict and thus prevent drug-induced ventricular arrhythmia and Torsades de Pointes (TdP) is a significant public health issue and a primary focus of regulatory safety pharmacology studies. Data are generated both nonclinically (via hERG, ECG, APD studies) and clinically primarily via a thorough QT study (TQT). The speakers in this roundtable session will consider the predictive value of each of these studies individually and their utility as a panel overall. Specifically, speakers will discuss concordance between nonclinical and clinical data for safety pharmacology endpoints; discuss optimization of nonclinical study design and data collection; identify opportunities for data from additional metrics; and discuss perspectives on the collection and use of nonclinical data to inform clinical trials. The panelists will also be challenged to identify strengths and weaknesses in current testing approaches and propose recommendations to improve or modify these approaches in the future. Participants will be engaged in these discussions and provide input in the debate of the predictive value of nonclinical QT studies as well as the potential for alternative assays or extrapolations to improve our ability to anticipate clinical outcome.

- A Practical Look at Data Concordance. John Koerner, US FDA, Silver Spring, MD.
- Optimizing Nonclinical Study Design to Predict TQT. Derek J. Leishman, Eli Lilly & Company, Indianapolis, IN.
• Reconsidering Data Inputs for Predicting TdP. Lorna Ewart, AstraZeneca, Macclesfield, Cheshire, United Kingdom.

• Predicting TdP—A Clinical Perspective. Mitchell W. Krucoff, Duke University Medical Center, Durham, NC.

WEDNESDAY

Skeptically Examining the Limits of Toxicology Evidence in the Courtroom

Wednesday, March 13, 12:00 Noon to 1:20 PM

Chairperson(s): George B. Corcoran, Wayne State University, Detroit, MI, and John Norman, ExxonMobil Biomedical Sciences Inc, Annandale, NJ.

Sponsor: Ethical, Legal, and Social Issues Specialty Section

The opposing orientation of toxicology experts and select evidence can skew the accuracy and value of testimony in court. Lawyers and judges are acquiring increasing skills to evaluate technical and scientific assertions with skepticism. Scholarly scientific approaches are required to establish whether techniques and methods asserted to be scientifically sound are valid and support justice. An introduction briefly covers topics helpful to understanding what happens to experts in litigation. This includes the law's theory of expert evidence, rules of evidence and procedure relating to expert testimony, alternative admissibility rules (Frye v Daubert trilogy), the NRC report and Canadian parallels, a law-science syllogism, the adversary process in theory and practice, ethical principles, clashes of ethics, data (especially quantitative), disclosure of evidence helpful to the other side, and for whom the litigation expert works. The toxicology expert must address relevant science in a fair, representative manner and communicate effectively. The use of Bradford-Hill Criteria (1964) has been promoted to address general causation in toxic torts. While comprehensive, it poses challenges including jargon and communication. Recently, a five question approach was introduced to address specific causation. Explanations and examples of causation will be reviewed. Finally, the 2009 National Academies report recommends that forensic sciences look to academic scientific models for reliable practice and technique validation to support court testimony. Lawyers and courts have become more skeptical of unsupported opinions and increasingly aware of how to combat them. Academic toxicology can offer much to advance the legitimacy of admitted evidence, including in the area of forensics. A discussion will include foibles and solutions.

• Understanding and Attenuating the Forces in the Litigation Process That Can Distort Knowledge. Michael J. Saks, Arizona State University, Tempe, AZ.

• Addressing Skepticism by Judge and Jury with a Specific Causation—A Five Question Approach. Sol M. Bobst, Nexeo Solutions, Woodlands, TX.

• Judicial Perspective: How Can Ethical Toxicology Inform Forensic Toxicology for Use in Court? Roderick T. Kennedy, New Mexico Court of Appeals, Albuquerque, NM.

Nonhuman Primate Sexual Maturity: What Is the Capacity to Endure Uncertainty?

Wednesday, March 13, 4:30 PM to 5:50 PM

Chairperson(s): Diann L. Blanset, Boehringer Ingelheim Pharmaceuticals Inc, Ridgefield, CT, and Jeffrey S. Moffit, Boehringer Ingelheim Pharmaceuticals Inc, Ridgefield, CT.

Sponsor: Reproductive and Developmental Toxicology Specialty Section

Endorsed by: Association of Scientists of Indian Origin Special Interest Group Biotechnology Specialty Section Toxicologic and Exploratory Pathology Specialty Section

Evaluation of reproductive toxicity in regulatory studies relies on the use of sexually mature animals. This often involves the use of nonhuman primates (NHP) when lower order species are pharmacologically irrelevant. However, the decision on whether to utilize mature NHP and the criteria used to establish sexual maturity is anything but standardized. Several factors contribute to these differing opinions. Sexual maturity can occur over a wide range of ages and body weights and historical methods of predicting sexual maturity have not always correlated with the histopathological appearance of the gonads at necropsy. Evaluation of toxicity in the reproductive organs of pre/peripubertal animals is often difficult, given that the histology of the maturing reproductive organs may resemble the degenerative changes induced by reproductive toxicants in the sexually mature adult. Finally, there is a lack of consensus on the toxicological relevance and interpretation of the various possible reproductive endpoints. All of these factors result in a complicated balancing act: Ethically weighing the limited availability, high costs, and relevance of incorporating sexually mature NHP in toxicology studies against effective and meaningful evaluation of reproductive risks. This roundtable will discuss the challenges of assessing toxicity in immature vs. peripubertal vs. mature NHP, screening methods for identifying sexually mature NHP, factors that influence sexual maturity, and case studies where sexual maturity impacted the study interpretation. Overall, this session seeks to provide an opportunity for stakeholders to review the current state of the art and exchange views on appropriate paths forward to encourage ethical use of animals, while preserving appropriate risk assessments.

• Immaturity, Subordination, or Reproductive Toxicity? Challenges Facing the Pathologist Evaluating the Primate Reproductive Tract. Dianne M. Creasy, Huntingdon Life Sciences, East Millstone, NJ.
Roundtables

- In-Life Assessment of Primate Sexual Maturity—Myths and Facts. Gerhard F. Weinbauer, Covance, Muenster, Germany.
- The Cost of Uncertainty—When Maturity Influences Safety. Kimberly P. Hatfield, US FDA, Silver Spring, MD.
**MONDAY**

**Diesel and Gasoline Exhaust and Cancer**

Monday, March 11, 12:10 PM to 1:30 PM

Chairperson(s): Annemoon M. van Erp, Health Effects Institute, Boston, MA, and Jacob D. McDonald, Lovelace Respiratory Research Institute, Albuquerque, NM.

Sponsor:
- Inhalation and Respiratory Specialty Section

Endorsed by:
- Comparative and Veterinary Specialty Section
- Mixtures Specialty Section
- Occupational and Public Health Specialty Section
- Risk Assessment Specialty Section
- Toxicologic and Exploratory Pathology Specialty Section

In 1989, the International Agency for Research on Cancer (IARC) classified whole diesel exhaust as a “probable human carcinogen” and whole gasoline engine exhaust as a “possible human carcinogen.” Since then, stringent regulations on diesel engine emissions have been introduced, and there have been significant developments in engine technology and introduction of ultra-low sulfur fuel resulting in marked reductions in the hazardous components in diesel exhaust. These changes are expected to provide substantial benefits to air quality and human health. The time course for realizing the benefits will be related to the rate at which old engines are replaced with new technology. In June 2012, IARC re-evaluated the carcinogenic hazard of diesel and gasoline exhaust based on new information that has become available from studies in humans and animals, which has led to the current designation of diesel exhaust as a “known human carcinogen.” This session provides a historical overview of diesel engine technology and emissions, and the significant changes that have occurred over the past decades. We also take a look at what is known about the health effects of diesel and gasoline exhaust and its public perception over the years. We provide a detailed characterization of the June 2012 IARC Working Group re-evaluation of the carcinogenic hazard classification of diesel exhaust and gasoline emissions, both regarding the toxicologic and epidemiologic evidence, and discuss potential implications of the new hazard classification for public policy.

Although the Working Group discussed whether to distinguish between “traditional diesel exhaust” and “new technology diesel exhaust” in the cancer hazard assessment, they concluded that this was not possible due to a lack of data on health effects associated with exposure to new technology diesel exhaust.

- **A Historical Perspective on Diesel and Gasoline Engine Technology and Its Health Impacts.** Roger O. McClellan, Toxicology & Human Health Risk Analysis, Albuquerque, NM.
- **IARC Assessment of Diesel and Gasoline Exhaust: Overview of Toxicologic Evidence.** Jacob D. McDonald, Lovelace Respiratory Research Institute, Albuquerque, NM.
- **IARC Assessment of Diesel and Gasoline Exhaust: Overview of Epidemiologic Evidence.** Eric Garshick, Harvard Medical School, Boston, MA.
The Thematic Track information can be found on pages 10–11.

Informational Sessions

**WEDNESDAY**

**K–12 Toxicology Outreach Activities: Regional Chapter Successes and Resources**

Wednesday, March 13, 9:00 AM to 11:45 AM

Chairperson(s): Courtney E. W. Sulentic, Wright State University, Dayton, OH, and Rafael Ponce, Amgen Inc., Seattle, WA.

Sponsor: Education Committee

Endorsed by: Career Resource and Development Committee; Communications Committee; Ethical, Legal, and Social Issues Specialty Section; Graduate Student Leadership Committee

K–12 activities are a vital component in our mission to educate the community regarding hazards and hazard communication. Several regional SOT chapters have very active K–12 community outreach programs and others are interested in establishing these programs within their communities. Facilitating this type of outreach across all regional chapters is a tactical goal of the Regional Chapter Collaboration and Communication Committee (RCCCC) and the Education Committee. This goal ties directly into the SOT strategic plan of promoting recognition of toxicology and communicating the benefit of toxicology to external audiences. The 2011 Education Summit sponsored by SOT underscored the need for enhancing the perception of toxicology as a valuable discipline among scientists and nonscientists alike, which is vital to maintaining the discipline of toxicology and the pipeline of future toxicologists. Community outreach at the K–12 level is an important component in increasing the visibility and perceived importance of toxicology. Regional SOT chapters can be and have been a vital resource in facilitating outreach activities among the membership-at-large. This session will highlight some of the successful K–12 outreach activities supported by regional chapters and will include hands-on demonstrations, one organized and implemented by graduate students, as well as an overview of efforts to update website resources for K–12 activities. This session will also provide pedagogical insights helpful to those new to educational outreach. Promoting and facilitating K–12 activities by regional chapters has the added potential of greater graduate student and postdoc engagement and therefore increased opportunities for skill development and pedagogical background for those trainees considering academic careers.

- **TOTTALLY TOXIC! A K–12 Outreach Program Based on the 5E Model of Science Education.** Christine A. Curran, Northern Kentucky University, Highland Heights, KY.
- **Inspector Tox Outreach Activity.** Diane Hardej, St. John’s University, Jamaica, NY, and Anthony R. Schatz, Merck & Co Inc, Whitehouse Station, NJ.

- **Silly Science and Other Activities for K–12 Outreach.** Marie M. Bourgeois, University of South Florida, Tampa, FL.
- **Exploring Toxicology: Designing Learning Goals and Evaluation Strategies for Outreach Activities.** Erin K. Shanle, University of Wisconsin, Madison, WI, and Kristina L. Blanke, University of Wisconsin, Madison, WI.

**The Regulatory Framework for Cosmetics: Current Status, Recent Science, and Future Prospects**

Wednesday, March 13, 9:00 AM to 11:45 AM

Chairperson(s): Philip Wexler, National Library of Medicine, Bethesda, MD, and Shayne C. Gad, Gad Consulting Services, Cary, NC.

Sponsor: In Vitro and Alternative Methods Specialty Section; Women in Toxicology Special Interest Group

Endorsed by: Dermal Toxicology Specialty Section; Ethical, Legal, and Social Issues Specialty Section; Regulatory and Safety Evaluation Specialty Section

Cosmetic products represent an immense global industry. It has been estimated that the $60 billion cosmetics industry uses some 12,500 unique chemical ingredients in personal care products. These products and their chemical components are subject to varying degrees of regulation globally. In the US, the US FDA’s regulatory authority over cosmetics is relatively minimal and different from that of other products regulated by the Agency, such as drugs, biologics, and medical devices. Although the US FDA can inspect cosmetic manufacturing facilities, respond to complaints of adverse reactions, and conduct research on cosmetics and their ingredients to address safety concerns, the Food, Drug, and Cosmetic Act does not subject cosmetics to US FDA premarket approval. The regulation of cosmetics in the European Union is considerably more stringent. A Safe Cosmetics Act of 2011 was introduced in the US House of Representatives in June, 2011, with the aim of ensuring that all personal care products are safe. It would establish labeling requirements and a safety standard, and issue guidance prescribing good manufacturing practices for cosmetics and ingredients. People, largely though not exclusively women, are exposed to vast quantities of cosmetics over their lifetimes. Compared with the safety of most other products, cosmetics are commonly believed to present a minimal, if any, risk, and are overlooked in discussions of hazardous substances. Are the regulations currently in place adequate? What is the US government’s viewpoint?
Harnessing Electronic Standards and Informatics to Transform the Use of Regulatory Toxicological Data

**Regulatory Science: Advancing New Approaches for Hazard Identification and Risk Assessment**

**Wednesday, March 13, 12:00 Noon to 1:20 PM**

*Chairperson(s):* Laine Peyton Myers, US FDA, Silver Spring, MD, and Leigh Ann Burns Naas, Gilead Sciences, Inc., San Diego, CA.

*Sponsor:* Biotechnology Specialty Section

*Endorsed by:* Regulatory and Safety Evaluation Specialty Section

One of the major efforts in nonclinical regulatory informatics has centered on the development and testing of the electronic data submission standard, also called SEND (Standard for Exchange of Nonclinical Data). This standard was developed by the Clinical Data Interchange Standards Consortium’s (CDISC) SEND Team for nonclinical data collected from animal toxicology studies and allows for the electronic submission of tabulated toxicology data in an electronic format. The initial pilot project began in 2003 and was followed by a second pilot in 2007 focused on CDER-regulated projects. The production of the SEND 3.0 Implementation Guide in 2011 was a major step forward for the electronic submission and exchange of standardized data and enablement of data warehousing efforts that better support scientific review and regulatory science initiatives. However, it is recognized that data standards are simply enablers to support the broader goals of better exploring and exploiting diverse study data and metadata in order to answer important scientific review and regulatory science questions. The range of needs and challenges in the regulatory pharmacology and toxicology field can be daunting but many of the challenges are shared among key stakeholders (e.g., the US FDA, sponsors, and CROs). These challenges, which range from warehousing to analysis to QA/GLP ramifications, are laying the foundation for a compliant exchange of data and opportunities for collaboration through public/private partnerships. This session will discuss the current computational science initiatives at the US FDA and in industry, existing partnerships, challenges and successes, as well as the transformative effect on the CRO model.

- **US FDA/PhUSE Computational Sciences: Nonclinical Standards and SEND Implementation.** Timothy J. Kropp, US FDA, Silver Spring, MD.
- **Standardization and Integration: Exploring the Full Value of Nonclinical Safety Data.** Alain Nanzer, F. Hoffmann-La Roche Ltd., Basel, Switzerland.
- **CROs, SEND, and Data Standardization…Oh My!** Troy Smyrnios, MPI Research, Kalamazoo, MI.

**Regulatory-Based Nanotoxicology: Evolving National Strategies and Research to Address Engineered Nanomaterial Health Risk Assessments**

**Wednesday, March 13, 4:30 PM to 5:50 PM**

*Chairperson(s):* William K. Boyes, US EPA, Research Triangle Park, NC, and Srikant Nadadur, NIEHS, Research Triangle Park, NC.

*Sponsor:* Nanotoxicology Specialty Section

*Endorsed by:* Risk Assessment Specialty Section

Engineered nanomaterials are increasingly being developed and incorporated into a variety of products and applications. However, the full development of nanotechnology is hampered by an uncertainty regarding their environmental, health, and safety implications, and how these issues will be addressed by responsible regulatory agencies at the federal and state levels. Novel nanoscale materials present a number of scientific and technical challenges for assessing their potential health implications including: exposure and material characterization; adequacy of conventional toxicity testing methods/guidelines; dose metric(s) across the exposure-dose-effects paradigm; and the role of alternative testing approaches to assess their toxicity.
The Thematic Track information can be found on pages 10–11.

Informational Sessions

This session will bring together scientists from scientific advisory bodies, regulatory agencies, and the private sector to present and discuss research needs, strategies, approaches, and findings regarding the health effects testing of engineered nanomaterials and nan-enabled products as it relates to regulatory mission(s). Key topics include: assessing nanomaterial toxicity for regulatory and risk assessment applications; the status or role of alternative test methods to screen or prioritize nanomaterials for in vivo toxicity testing, and the extent to which harmonized testing can be achieved for these novel materials. Each speaker will highlight agency/institutional approaches and regulatory actions regarding the potential for health effects from engineered nanomaterials. The overall goal is to provide participants with a view of the status of the development of nanomaterial toxicological assessments that would be sufficient to evaluate health and safety for regulatory agencies.

• **Introduction: Regulatory Nanotoxicology—Where Are We?**
  Philip G. Sayre, US EPA, Bethesda, MD.

• **The Nanotechnology Research Program in NIOSH: Strategic Plan, Approaches, and Accomplishments.**
  Vincent Castranova, NIOSH, Morgantown, WV.

• **An Integrated Transdisciplinary Systems Approach to Assess and Ultimately Predict the Health Risks of Engineered Nanomaterials and Their Applications.**
  Kevin L. Dreher, US EPA, Research Triangle Park, NC.

• **The US FDA Regulatory Science Program in Nanotechnology.**
  Paul C. Howard, US FDA, Jefferson, AR.

• **Development of In Vivo and In Vitro Pulmonary Bioassays to Assess the Toxicity of Inhaled Nanomaterials.**
  David B. Warheit, DuPont Haskell Laboratories, Newark, DE.
MONDAY

From New Submissions to Competitive Renewals: Different Phases of Grant Writing

Monday, March 11, 12:10 PM to 1:30 PM

Chairperson(s): Courtney E. W. Sulentic, Wright State University, Dayton, OH, and Barbara L. F. Kaplan, Michigan State University, East Lansing, MI.

Sponsor: Career Resource and Development Committee

Endorsed by: Graduate Student Leadership Committee

Grant writing is a challenging endeavor. One must effectively communicate the significance, innovation, and approach of their research project in a clear, but concise manner with appropriate grammar. While there are some aspects of grant writing that apply regardless of the grant application phase, such as a clearly stated hypothesis and specific aims, the style, and required elements of the various phases of the grant writing process can differ significantly. Thus, the goals of this session are to discuss the various phases of the grant writing process, including preparing a new application versus a competitive renewal, composing the rebuttal and revised grant application, how best to create a “new” grant if a grant has not been funded after two review cycles, and an overview of the review process, and choosing the best scientific review group. Three speakers from NIEHS and a well-funded fourth speaker, who is also an experienced grant reviewer, will expertly cover these topics and participate in a panel discussion at the end of the session.

- Grantsmanship: The Lifeline for Academic Scientists. Jerrold J. Heindel, NIEHS, Research Triangle Park, NC.
- The Application Wasn’t Funded: Resubmissions and New Applications. Michael C. Humble, NIEHS, Research Triangle Park, NC.
- Writing Tips from a Successfully-Funded Academic Toxicologist and Grant Reviewer. Martin A. Philbert, University of Michigan School of Public Health, Ann Arbor, MI.

TUESDAY

The Symbiosis of Mentoring: Getting the Most out of the Mentor-Mentee Relationship

Tuesday, March 12, 4:30 PM to 5:50 PM


Sponsor: Postdoctoral Assembly

Endorsed by: Career Resource and Development Committee Committee on Diversity Initiatives Education Committee

Mentoring is a critical element in the career development of all toxicologists, both in terms of making the most of potential mentors and developing effective mentoring skills. Whether through involvement in academia, or helping to develop the expertise of an early-career scientist, most toxicologists will provide mentoring at some point in their career. The mentor role serves to transfer knowledge, give advice and provide support to a trainee or developing scientist, while the mentee is relied upon by the mentor to provide active participation and input into the relationship. According to national polls, as well as SOT-specific surveys, one of the resounding topics of interest for developing scientists is mentoring from the broad perspectives of choosing the right mentor, down to developing the skills to become a sound mentor. Therefore, this session was designed to complement existing mentor matching opportunities offered through SOT. Speaker presentations will focus on: (1) the fundamentals of mentoring, including the different situations and roles in which the mentee-mentor dynamic may be encountered; (2) an introduction to the most commonly used mentoring techniques; (3) identifying characteristics of a strong mentor-mentee relationship; and (4) mentoring towards the future of science and the challenge to overcome more complex scientific problems. Speaker perspectives will address the mentorship role within academia, government, and industry. Attendees of this session will learn to identify a healthy mentor-mentee relationship and understand the benefits to each member of the collaboration. Mentoring topics discussed in this session will be applicable to scientists at every career stage through highlighting the basics behind a strong, mutually-beneficial mentoring relationship.

- Supervisors, Mentors, and Yodas: A Perspective on Their Role in Your Career Development. Nigel J. Walker, NIEHS, Research Triangle Park, NC.
- Approaches for Mentoring Graduate Students. Stephen H. Safe, Texas A&M University, College Station, TX.
- The Two-Way Street of Mentoring: Reflections on Career Development in a Chemical Industry Toxicology Laboratory. Edward W. Carnes, Dow Chemical Company, Midland, MI.
The Thematic Track information can be found on pages 10–11.

Education-Career Development Sessions

- The Future: Mentoring Interdisciplinary Scientists. Ofelia A. Olivero, NIH, Bethesda, MD.

WEDNESDAY

Regulatory Science and Risk Assessment: Lessons for Early-Career Scientists on What to Expect and How to Pursue This Career Path

Wednesday, March 13, 12:00 Noon to 1:20 PM

Chairperson(s): Betina J. Lew, The Procter and Gamble Company, Cincinnati, OH, and Jose A. Torres, Texas Southern University, Houston, TX.

Sponsor: Postdoctoral Assembly

Endorsed by: Career Resource and Development Committee Education Committee Risk Assessment Specialty Section

During academic training, postdoctoral and graduate students generally are not provided with opportunities for interacting with toxicologists who are involved in risk assessment and regulatory affairs. The educational training mainly focuses on basic sciences or solving mechanistic problems and thus lacks the practical aspects of risk assessment and regulatory preparation. This concern was discussed at the Education Summit in October 2011, which was organized by the Education Committee of the SOT. Dr. John Doull’s comment that, “toxicology is what we do, but risk assessment is why we do it,” shows the importance for trainees to become aware of both. Unfortunately, when it is time for the trainee to make the decision on what will be the next step in their careers, they are well prepared on what we do, but fall short on why we do it. The objectives of this session are to provide postdoctoral and graduate students with basic understanding of approaches in risk assessment and regulatory affairs in some of the sectors and to educate them about necessary preparative steps in this field. In this 80-minute Education-Career Development Session, trainees will become more familiar with the routine job of toxicologists outside of the academic setting. Further, there will be a panel discussion on steps that can be taken during graduate school and postdoctoral training to improve the preparation for a career in risk assessment and regulatory fields. Thus, the participants are expected to gain a basic knowledge of risk assessment and regulatory preparation in the life of a toxicologist and how to pursue this field.

- Risk Assessment in the Private Sector. Donald L. Bjerke, The Proctor & Gamble Company, Cincinnati, OH.


- Getting Ready for a Career As a Risk Assessor in a Global Environment. Andrew Maier, Toxicology Excellence for Risk Assessment, Cincinnati, OH.

- Regulations and Assessment for New Drugs by the US FDA. David Jacobson Kram, US FDA, Jefferson, AR.

Toxicological Writing for Industrial and Regulatory Audiences

Wednesday, March 13, 4:30 PM to 5:50 PM

Chairperson(s): Chidozie J. Amuzie, MPI Research, Portage, MI, and Michele La Merrill, Mount Sinai School of Medicine, New York, NY.

Sponsor: Career Resource and Development Committee

Endorsed by: Biotechnology Specialty Section Education Committee Graduate Student Leadership Committee Postdoctoral Assembly Risk Assessment Specialty Section

Excellence in scientific and technical writing leading to high-quality publications, a skill set developed and refined from graduate training through early career in toxicology, is one key trait that can lead to a successful career as a toxicologist. Some academic institutions have programs that support scientific and technical writing for their staff. However, the majority of toxicologists (80%) are employed outside academia, predominately within biopharmaceutical and chemical industries, government, and contract research organizations. Graduates from academic programs that train in writing might acquire skills related to preparation of dissertations, grant proposals, and manuscripts for scientific peer-reviewed journals. The skills acquired from this training, when existent, does not necessitate a smooth transition to a successful career outside academia. Thus early-career toxicologists are sometimes unaware of, or otherwise unprepared for, technical writing assignments that occur in industrial and regulatory toxicology. In addition, different writing skills are required for clear and concise communication of toxicological results to nontoxicologist stakeholders. Therefore, an interactive workshop that evaluates the challenges presented by, and the skills required for, toxicological writing outside academia will be of great use to the majority of graduate students, postdoctoral trainees, and early-career toxicologists. Four speakers from the pharmaceutical industry, the chemical industry, a government regulatory agency, and a contract research organization will review the type(s) of technical writing required within their setting. Notably, they will extensively highlight common mistakes and discuss valuable strategies and tools to avoid these mistakes through interactive exercises using provided writing examples.
Education-Career Development Sessions

- **Fundamentals of Technical Writing within the Pharmaceutical Industry.** Lorrene A. Buckley, Eli Lilly & Company, Indianapolis, IN.


- **Technical Writing in the Chemical Industry.** Richard W. Lewis, Syngenta, Bracknell, Berkshire, United Kingdom.

- **Writing a Toxicology Study Report: A Contract Research Organization Perspective.** Dennis J. Meyer, Charles River Labs, Reno, NV.

NOTES
Regional Interest Sessions

**MONDAY**

**Toxicological Challenges in Food Production in Texas and the Gulf Coast**

Monday, March 11, 9:15 AM to 12:00 Noon

*Chairperson(s):* Erica D. Bruce, Baylor University, Waco, TX, and Laura M. Plunkett, Integrative Biostrategies LLC, Houston, TX.

*Sponsor:* Lone Star Regional Chapter

*Endorsed by:* Food Safety Specialty Section

With recent media attention on episodes of food contamination and the impact of chemicals in the environment on the food supply (i.e., bacterial contamination of food, as well as the 2010 BP oil spill), public awareness of food safety issues has grown. This symposium will explore the topic of food safety as it relates to unique features of food production in Texas and the Gulf Coast. Texas is a major source of fresh fruit and vegetable production for both regional and countrywide consumption, while the Gulf Coast is a major source of fresh fish and seafood for many parts of the United States. Topics covered in the symposium will include recent legislative initiatives such as the Food Safety and Modernization Act of 2010, current regulatory oversight of food safety in the Gulf Coast region, and key public and/or worker health issues associated with food production in the region. The goal of the symposium is to describe the strengths and weaknesses of current regulations and practices to ensure a safe food supply as well as worker safety, and provide dialog for ways to address unique concerns related to food production in Texas and the Gulf Coast. Symposium speakers work in academia, for the United States government (US FDA), and an organization representing the interests of the public (Center for Science in the Public Interest), which will allow for discussion of the topics from a variety of perspectives.

- **Multiagency Response to Seafood Safety Concerns following the 2010 Deepwater Horizon Oil Spill.** Robert Dickey, US FDA, Dauphin Island, AL.
- **Seafood Safety Challenges for the Texas Gulf Coast.** David Plunkett, Center for Science in the Public Interest, Washington, DC.
- **Occupational Hazards in Texas Food Production.** Eva Shipp, Texas A&M School of Rural Public Health, College Station, TX.
- **Occupational Heat Stress in Agricultural Settings.** Jeffrey Levine, The University of Texas Health Science Center at Tyler, Tyler, TX.

**WEDNESDAY**

**Assessment of Environmental, Dietary, and Biological Risk Factors Impacting Liver Cancer Incidence in Texas**

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

*Chairperson(s):* Erica D. Bruce, Baylor University, Waco, TX, and Amelia Romoser, Texas A&M University, College Station, TX.

*Sponsor:* Lone Star Regional Chapter

*Endorsed by:* Food Safety Specialty Section, Hispanic Organization of Toxicologists Special Interest Group, Mixtures Specialty Section, Risk Assessment Specialty Section

The increasing incidence of primary liver cancer in Texas is a result of multiple risk factors, including environmental and dietary exposures to carcinogens, as well as biological factors, such as hepatitis C infection. Texas has the highest liver cancer mortality rate in the United States, affecting the Hispanic portion of the population most acutely. It is speculated that the increased incidence of primary liver cancer observed in these Hispanic communities is due to occupational exposures to pesticides, polycyclic aromatic hydrocarbons (PAHs), and dietary risk factors from contaminated maize. Current research and risk assessment in this field is focused on cancer epidemiology within these populations to determine those risk factors that are most hazardous to the community health of south Texas. Many pesticides used in farming and households are labeled as probable carcinogens and can cause many other negative health effects in people chronically exposed. Research and educational programs in Texas are striving to increase awareness of health effects from exposure and pesticide safety. PAHs are also known hepatic carcinogens, forming DNA adducts within the liver. Health effects observed in Texas from chronic PAH exposure through foods and poor air quality are being assessed. Additionally, mycotoxin occurrence is heightened in the southern portion of the state where drought conditions and excessive heat contribute to fungal growth on staple crops (i.e., maize). Specifically, aflatoxin and fumonisin exposures have been observed in various communities in San Antonio and along the Texas-Mexico border. These mycotoxins are known to both initiate and promote hepatocellular carcinoma. Understanding the risk factors for primary liver cancer in Texas is essential to developing future remediation, prevention, and treatment strategies, as well as identifying and establishing necessary changes in state regulations.

- **Liver Cancer Incidence Trends in Texas 1995–2009.** John Villanacci, Texas Department of State Health Services, Austin, TX.
Regional Interest Sessions

- **A Lay Health Worker-Based Intervention for Reducing Families’ Environmental Exposures.** L. Cizmas, Texas A&M University, College Station, TX.

- **Early Obesity and Risk of Hepatocellular Carcinoma in USA.** M. Hassan, The University of Texas MD Anderson Cancer Center, Houston, TX.

- **Biomarkers of Hepatocellular Cancer Risk and Diagnosis.** Regina M. Santella, Columbia University Mailman School of Public Health, New York, NY.

- **Mitigation of Aflatoxin Exposures Using a Clay-Based Enterosorbent.** Timothy D. Phillips, Texas A&M University, College Station, TX.

- **Risk Factors Influencing the Incidence of Liver Cancer in San Antonio.** Fernando Guerra, University of Texas Health Science Center San Antonio, San Antonio, TX.

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**NOTES**
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**ToxExpo.com is:**
- A 24/7 comprehensive online resource, searchable by company name or by product or service.
- A comprehensive approach to organizing the wealth of ideas and insights in cross-disciplinary areas of toxicology.
- The toxicology market place—your source for product information and resources to keep your lab competitive.
- The place where professionals will learn how to explore a rapidly changing science.
- A chance to think outside the box—find out how your work relates to research in other disciplines.
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**ToxExpo Hours:**

- **Monday, March 11**
  9:00 AM to 4:30 PM

- **Tuesday, March 12**
  8:30 AM to 4:30 PM

- **Wednesday, March 13**
  8:30 AM to 4:30 PM

**ToxExpo Time!**

In addition to the standard Exhibit Hall hours and poster presentation times, one hour of dedicated networking time has been allotted in the scientific program for attendees to visit with exhibitors.

ToxExpo Time will take place on **Tuesday, March 12**, from 12:30 pm–1:30 pm.
# 2013 Exhibitor Listing

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Exhibitor/Sponsor-Hosted Sessions

**MONDAY**

**Assessing Toxicity of the Hematologic System in Preclinical Safety Studies**

Monday, March 11, 9:15 AM to 10:15 AM

Presented by: MPI Research

This session will provide an overview of the current principles involved in the evaluation of the hematologic system focusing on techniques critical to accurate data interpretation. In addition, integration of hematology data with other study endpoints (e.g., microscopic pathology, in-life data, etc) will be discussed.

**Optical Coherence Tomography in Nonclinical Ocular Drug Development**

Monday, March 11, 9:15 AM to 10:15 AM

Presented by: Covance

Optical Coherence Tomography (OCT) is used to obtain high-resolution images of ocular tissues. The basic functionality of OCT, examples from several instrument models and lab animal species, and considerations for data acquisition, analysis, and interpretation will be discussed to demonstrate how this technique can be applied in nonclinical studies.

**Quantification of Cardioactive Drug Effects Using xCELLigence RTCA Cardio and Human iPS-Derived Cardiomyocytes**

Monday, March 11, 9:15 AM to 10:15 AM

Presented by: ChanTest Corp.

We evaluated xCELLigence Cardio instrument and stem cell-derived human cardiomyocytes (SC-hCMs) for sensitivity to compounds with broad mechanisms of action. Distinct impedance profiles were observed for drugs that modify contraction, acutely block hERG, inhibit channel trafficking, and cardiotoxicants, allowing us to correlate known cardiac activity with impedance profiles.

**Accurate Identification of DILI (Drug-Induced Liver Injury) and Non-DILI Drugs with Primary Cultured Human Hepatocytes**

Monday, March 11, 10:30 AM to 11:30 AM

Presented by: In Vitro ADMET Laboratories

Results of a highly specific and sensitive in vitro assay with primary human hepatocytes for the identification of drugs known to induce severe drug-induced liver injuries (DILI) will be presented. The assay may be useful in drug development for the selection of drug candidates with low propensity to cause DILI.

**Current Trends in Pharmaceutical Development**

Monday, March 11, 10:30 AM to 11:30 AM

Presented by: Harlan Laboratories

A first topic of this session will deal with the toxicity of surfactants, cosolvents and conventional vehicles used in formulating drugs before starting the regulatory preclinical safety development. The relevance of immunogenicity in preclinical trials after parenteral administration will also be discussed as a hot topic in the development of biopharmaceuticals.

**Monoclonal Antibodies for Oncology and Autoimmunity—Running Translatable Studies in Nonhuman Primates**

Monday, March 11, 10:30 AM to 11:30 AM

Presented by: Huntingdon Life Sciences

Monoclonal antibodies have proven clinical success in treating oncology and autoimmune disease. Ensuring that studies are performed in a regulatory- and ethically-compliant manner and the collected data easily translates to the clinic is of crucial importance. The talk will focus on NHP supply, immunotoxicity study design, microsampling and microanalysis.
Battelle’s CoLaborative Approach to Drug/Chemical Safety, Discovery, and Development

Monday, March 11, 11:45 AM to 12:45 PM

Presented by:
Battelle

Drug and chemical safety has recently received tremendous attention. Identifying risk early in development benefits public health and saves companies time and money. Dr. Michael Holsapple and colleagues will address how Battelle and its CoLaborative use systems biology to address these industry challenges.

More Predictive Efflux Transporter Evaluation Using Transporter Knockout Rats and Ceco-2 Cell Lines

Monday, March 11, 11:45 AM to 12:45 PM

Presented by:
Sigma Life Science

Sigma-Aldrich is the exclusive provider of novel in vivo and in vitro models—including Mdr1a, Bcrp, Mrp1, and Mrp2 knockout rats and Caco-2 Cells. Transporter knockout rats provide a more specific, definitive tool for efflux assays. We will discuss results from Mdr1a, Bcrp, and Mrp2 knockout rats.

Use of Cryopreserved Human Hepatocytes to Investigate Genetic Variability in Drug and Xenobiotic Metabolism and Toxicity

Monday, March 11, 11:45 AM to 12:45 PM

Presented by:
Celsis In Vitro Technologies

The session will describe the use of cryopreserved human hepatocytes to investigate genetic variation in a well-established genetic polymorphism (N-acetyltransferase 2) that is important in the metabolism and toxicity of numerous drugs and xenobiotics.

Cardiac Toxicity Assessment Using Stem Cell-Derived Cardiomyocytes

Monday, March 11, 1:00 PM to 2:00 PM

Presented by:
ACEA Biosciences, Inc.

Cardiac toxicity is a major concern in drug development. In this workshop, the utility of xCELLigence Cardio System with stem cell-derived cardiomyocytes for assessment of compound risk will be discussed. This cardio system provides a high-throughput, quantitative, and predictive assay that can be used earlier in drug discovery process.

New Approaches to Follow up GeneTox Positive Results

Monday, March 11, 1:00 PM to 2:00 PM

Presented by:
BioReliance Corporation

High false positive rates in mammalian in vitro genetox assays lead to a large number of costly and time consuming follow up in vitro genotoxicity studies. BioReliance has qualified techniques that investigate MOA and help resolve positive in vitro studies, including Pig-a, FISH/CREST, Big Blue, 3D Skin, 96-well Flow MN, and Comet.

ICP-MS Use and Validation for Toxicological Applications

Monday, March 11, 2:15 PM to 3:15 PM

Presented by:
Chemical Solutions Ltd.

Understanding key factors and performance characteristics of ICP-MS instrumentation as applied to testing of common elements of concern in toxicological work. Discussion will include the role of DRC and KED modules in lowering detection limits and eliminating interferences.
Exhibitor/Sponsor-Hosted Sessions

Skeletal Evaluations in Toxicology Studies: How and When?

Monday, March 11, 2:15 PM to 3:15 PM
Presented by: Charles River

With advancements in our understanding of signaling pathways, the skeleton is implicated as target tissue for compounds in development for diverse therapeutic areas, including diabetes, obesity, and cancer. Using case studies, this session will highlight techniques and endpoints that can be used to assess the skeleton in both adults and juveniles.

Zebrafish As a Predictive Model for Assessing Toxicity and Safety

Monday, March 11, 2:15 PM to 3:15 PM
Presented by: Phylonix

The zebrafish animal model is increasingly used to assess compound toxicity, safety, and efficacy. In this workshop, methods for performing assays in whole transparent animals will be described. In addition, results for compounds characterized in mammals will be presented.

Efficient Integration of Chromosomal Damage and Gene Mutation Endpoints into Repeat-Dose Toxicology Studies

Monday, March 11, 3:30 PM to 4:30 PM
Presented by: Litron Laboratories

Integration of genetic toxicology assays into general toxicology studies is increasingly important for drug/chemical safety programs. This session will cover two flow cytometric methods that measure chromosomal damage and gene mutation in blood samples and how these complementary assays can be practically executed in a 28-day repeat-dose study design.

Juvenile Safety Assessment in Göttingen Minipigs

Monday, March 11, 3:30 PM to 4:30 PM
Presented by: Ellegaard Göttingen Minipigs and Marshall BioResources

This presentation will describe the benefits of the Göttingen Minipig as an additional model in juvenile safety assessment studies; the physical and sensory development of piglets; and the potential for minipigs in evaluating the toxicity of certain compounds on the development of the nervous system, reproductive system, and immune system.

TUESDAY

Genetic Toxicity Assessment for the Modern Era: New Regulations, New Strategies, New Methods

Tuesday, March 12, 8:30 AM to 9:30 AM
Presented by: WIL Research

Guiding potential human therapies through genetic toxicology testing can be a complicated process in light of recent changes in the ICH guidelines and advances in assay designs (such as the comet Assay). Strategies that provide for efficient yet scientifically and regulatory compliant approaches to genetic toxicity assessment will be presented.

Moving towards Establishing Standardized Conditions for In Vitro Human Toxicity Testing

Tuesday, March 12, 8:30 AM to 9:30 AM
Presented by: Promega Corporation

More effective in vitro toxicity testing strategies are currently needed for predicting human toxicities. In this presentation the challenges and opportunities for meeting this demand will be discussed with a focus on advances in tissue culture technology and the corresponding establishment of standardized testing conditions, analysis, and acceptance criteria.

Why Do We Do What We Do? Pathology Endpoints in Repeat-Dose Toxicology Studies: A Review of Global Regulations

Tuesday, March 12, 8:30 AM to 9:30 AM
Presented by: Vet Path Services, Inc.

An overview of the pathology endpoints specifically outlined in regulatory guidances issued from North America, Europe, and Japan for pharmaceutical toxicology studies. The pathology endpoints are parameters from clinical pathology, organ weights, macroscopic, and cause of death. Endpoints will also be put in the context of published literature and best practices considerations.
Considerations for Developmental Immunotoxicity (DIT) in Preclinical Testing

Tuesday, March 12, 9:45 AM to 10:45 AM

Presented by:
Charles River

Developmental immunotoxicity testing (DIT) is required or recommended by regulatory agencies as part of safety assessments for chemicals and pharmaceuticals. A variety of assays/endpoints are available to evaluate DIT in rodent and nonrodent species. We will discuss study designs for DIT evaluation, including species, endpoints, data interpretation, and testing strategies.

Navigating the Scientific Regulatory Maze for an Agrochemical from Candidate Selection to Product Registration

Tuesday, March 12, 9:45 AM to 10:45 AM

Presented by:
Huntingdon Life Sciences

The process from selection to authorization of a new agrochemical molecule is costly and time consuming. A case study will be discussed which highlights how the iterative process of testing and risk assessment looks to understand complex interactions between the biology and chemistry in man and the environment.

Nonclinical Development of Biopharmaceuticals and Biosimilars—Lessons Learned

Tuesday, March 12, 9:45 AM to 10:45 AM

Presented by:
MPI Research

The increase in biopharmaceuticals in development has been impressive over the past 10 years. This talk will cover the differences in the nonclinical approach used for biopharmaceuticals compared to the traditional small molecule approach, evaluate study design aspects, and include lessons learned through the evaluation of completed biopharmaceutical nonclinical studies.

Carbonanotubes—A New Challenge in Toxicity Testing

Tuesday, March 12, 11:00 AM to 12:00 Noon

Presented by:
Fraunhofer ITEM

The session will focus on the state of the art and future of in vivo and screening tests with carbonanotubes. Innovative systems of aerosol generation will be presented as well as novel experimental data on the genotoxic and carcinogenic potential of carbonanotubes.

New Method for Procedure-Related Handling of Nonhuman Primates: Contribution to Improved Animal Welfare and Minimizing Variability in Data

Tuesday, March 12, 11:00 AM to 12:00 Noon

Presented by:
SNBL USA, Ltd.

Nonhuman primates (NHPs) are well-established animal models for nonclinical toxicology. Manual Restraint by Chair of NHPs increases data variability during routine studies. The Procedure Cage is an alternative to Chair Restraint. This presentation reviews data obtained using Procedure Cage and discusses the contribution to reduction in inter- and intra-animal data variability.

SEND Submissions to the US FDA: How Do I Get Ready for Prime Time?

Tuesday, March 12, 11:00 AM to 12:00 Noon

Presented by:
PointCross Life Sciences

The US FDA will soon mandate SEND formatted nonclinical study data submissions. Industry participants from a SEND Simulation Environment over the past few months will provide practical guidance for data conversion from source systems, files and PDF reports into a harmonized representation both for SEND compliance and scientific R&D use.
Exhibitor/Sponsor-Hosted Sessions

**Advanced Techniques in Quantitative Whole Body Autoradiography and Cryo-Imaging**

*Tuesday, March 12, 12:15 PM to 1:15 PM*

**Presented by:**
- XenoBiotic Laboratories

Quantitative Whole Body Autoradiography (QWBA) is widely used to provide tissue distribution data of a radiolabeled drug as part of a nonclinical ADME program. Advancements in Cryo-imaging and Quantitative Autoradiography (CIQA) along with 3D modeling techniques provide an innovative approach for observing site-specific localization of drug and drug-induced or naturally occurring abnormalities.

**Electric Cell-Substrate Impedance Sensing: A Label Free, Noninvasive Method of Cell Measurement**

*Tuesday, March 12, 12:15 PM to 1:15 PM*

**Presented by:**
- Applied Biophysics, Inc.

An overview of the use of impedance (both simple and complex) to detect cell morphological changes. Emphasis will be placed on the use of different AC frequencies to distinguish cell parameters. Various ECIS applications.

**Introducing the First Fully Digital Wireless Solution for Large Animal Research**

*Tuesday, March 12, 12:15 PM to 1:15 PM*

**Presented by:**
- Data Sciences International

PhysioTel™ Digital advances research by simplifying study execution, enhancing animal welfare, and improving data accuracy. A panel of scientists will share experiences and perspectives using the first fully digital implantable telemetry system in multiple animal models. Discussion will focus on new technology implementation to maximize lab space, time, and investment.

**Human-Induced Pluripotent and Embryonic Stem Cell-Derived Hepatocytes and Cardiomyocytes for Use in High-Content Toxicity Assessments**

*Tuesday, March 12, 1:30 PM to 2:30 PM*

**Presented by:**
- Cellectis Stem Cells

Cellectis stem cells’ human pluripotent stem cell-derived hepatocytes and cardiomyocytes exhibit specific markers and functional similarities to adult human cells. With high homogeneity, availability in multiwall plate formats, and with low batch to batch variations, makes the cells excellent *in vitro* tools for safety pharmacology and toxicity assessments.

**Integrated Testing Strategies for Skin Sensitization: Safety Assessment for Cosmetics**

*Tuesday, March 12, 1:30 PM to 2:30 PM*

**Presented by:**
- L’Oréal Research & Innovation

The session will focus on the state of the art and the future of *in vitro* and *in silico* tests used in safety assessment for cosmetics. Specific emphasis will be placed on the Integrated Testing Strategies for Skin Sensitization, its challenges, and development.

**Multiplex Detection of Drug-Induced Kidney Toxicity with New Bio-Plex Pro™ RBM Assays**

*Tuesday, March 12, 1:30 PM to 2:30 PM*

**Presented by:**
- Bio-Rad Laboratories

Developed in conjunction with the Predictive Safety Testing Consortium’s (PSTC) Nephrotoxicity Working Group, Myriad RBM’s urine-based quantitative multiplex protein assays for detecting, monitoring, and characterizing kidney toxicity are now available in kit form for use with the Bio-Plex® Suspension Array System. Analytical validation and application examples will be presented.
Implementing Systematic Review at the NTP

Tuesday, March 12, 2:45 PM to 3:45 PM
Presented by:
National Toxicology Program

The NTP has developed an approach to use systematic review methodology in reaching conclusions for literature-based evidence assessments. NTP scientists will discuss the approach for study identification, quality assessment, and integration of data across evidence streams (human, animal, in vitro) and demonstrate new web-based tools for graphical display of data.

The Use of HepatoPac™, an In Vitro Microliver Platform, for Mechanistic Toxicology Studies

Tuesday, March 12, 2:45 PM to 3:45 PM
Presented by:
Hepregen Corporation

HepatoPac is a highly predictive in vitro microliver platform that retains high functionality over several weeks. The model has been extensively validated and has been demonstrated to improve sensitivity in toxicity studies. This session will provide examples where HepatoPac has been successfully used to study mechanistic hepatotoxicity.

The Value of the Göttingen Minipig in the Development of New Biotherapeutics

Tuesday, March 12, 2:45 PM to 3:45 PM
Presented by:
Marshall BioResources and Ellegaard Göttingen Minipigs

This presentation discusses the Göttingen Minipig as a potential model in preclinical testing of biopharmaceuticals. Recent studies have demonstrated some similarity to human sensitivity to various biologically-derived compounds, including certain monoclonal antibodies. Sequencing of the Göttingen Minipig genome means genomic level target validation, and potential cross-reactivity, is now possible.

WEDNESDAY

Alternative Methods in Preclinical Toxicology: 3Rs in Practice

Wednesday, March 13, 9:15 AM to 10:15 AM
Presented by:
Charles River

Charles River is committed to the 3Rs (Replacement, Reduction, and Refinement) and continues to apply these principles in preclinical toxicology. In this session, we demonstrate novel aspects of applying these guiding principles in the use of candidate selection, microsampling and in vitro models, which provide significant gains in increased efficiencies.

Immunological Considerations of Intravenously Administered Drugs: Addressing Challenges in the Development of Intravenous Drugs Series

Wednesday, March 13, 9:15 AM to 10:15 AM
Presented by:
Covance

New regulatory guidelines require assessment of immune “function” for certain drug classes in the preclinical environment. Many challenges are associated with such assessment, particularly for intravenously administered drugs. This session discusses strategies for conducting intravenous studies and ways to avoid common pitfalls associated with managing immunological concerns.

Human Embryonic Stem (hES) Cells for Predictive Toxicology

Wednesday, March 13, 10:30 AM to 11:30 AM
Presented by:
Stemina Biomarker Discovery, Inc.

More predictive in vitro developmental toxicity screens are needed to provide early safety assessments. Human embryonic stem (hES) cells provide an all human system to predict developmental toxicity. Attendees will learn about Stemina’s new targeted, fast, highly predictive assay using specific biomarkers identified from a metabolomics-based developmental toxicity screen: devTOX.
Exhibitor/Sponsor-Hosted Sessions

IPA the Fast Path to Toxicity Targets of Interest

Wednesday, March 13, 10:30 AM to 11:30 AM
Presented by:
  Ingenuity Systems

Learn how IPA can help you quickly filter down to specific toxicity targets of interest, understand the related genetic and biomarker evidence, and create gene panels for phenotypes of interest. With IPA, you can discover plausible signaling cascades from predicted upstream regulators that can explain the gene expression changes in your transcriptional profiling experiments.

New Drugs for the Treatment of Inflammation and Chronic Viral Infection—Assessing the Safety of Drugs Designed to Modify TLR Pathways

Wednesday, March 13, 10:30 AM to 11:30 AM
Presented by:
  Huntingdon Life Sciences

Toll-like receptors play a major role in the innate immune system. Drugs that interact with TLRs have potential to treat a wide range of diseases. The talk will focus upon pathway biology, selection of relevant nonclinical species and performance of safety studies designed to collect clinically translatable readouts.

Application of QWBA and Short-Lived Isotopes in the Drug Development Paradigm

Wednesday, March 13, 2:15 PM to 3:15 PM
Presented by:
  MPI Research

Quantitative Whole-Body Autoradiography (QWBA) is a high-resolution tissue distribution assessment commonly used in preclinical drug development. QWBA is typically performed with long-lived isotopes. However, short-lived isotopes provide a solution to contemporize QWBA combining it with multiple imaging platforms, such as PET and SPECT, within a single study design.
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**Deadline for Proposals for SOT 2014 Annual Meeting Sessions: April 30, 2013**

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<th>Session Types</th>
<th>Why Submit a Proposal?</th>
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<td><strong>Continuing Education</strong>—Emphasis on quality presentations of generally accepted, established knowledge in toxicology</td>
<td>1. To present new developments in toxicology.</td>
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<td><em>Note: CE Courses will be held on Sunday.</em></td>
<td>2. To provide attendees an opportunity to learn about state-of-the-art technology and how it applies to toxicological research.</td>
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<tr>
<td><strong>Symposia</strong>—Cutting-edge science; new areas, concepts, or data</td>
<td>3. To provide attendees an opportunity to learn about the emerging fields and how they apply to toxicology.</td>
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<td><strong>Workshops</strong>—State-of-the-art knowledge in toxicology</td>
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<td><strong>Regional Interest</strong>—Central topics of relevance that describe public health and/or ecological problems of a particular region</td>
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Sponsorship Opportunities

are still available for the 2013 Annual Meeting. Your sponsorship serves as visible evidence of your organization's commitment to the science of toxicology. In addition, your sponsorship provides an opportunity for you to increase overall awareness of your company to SOT members and more than 7,300 Annual Meeting attendees. As a sponsor, your company will be featured in pre- and postmeeting newsletters, the ToxExpo Directory, premeeting publications, on-site meeting registration materials, and the SOT website. In addition, acknowledgement signs will group sponsors by levels of giving and will be displayed at many of the SOT functions during the Annual Meeting, as well as in the SOT presentation in all session rooms.

Your sponsorship will help the Society sustain low registration rates, which allows scientists at all stages of their career to attend. If you are interested in SOT Sponsorship, contact Tina Giovanini at SOT Headquarters: 703.438.3115 or email: tina@toxicology.org.

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Dear Colleagues:

I cordially invite you to attend SOT’s 52nd Annual Meeting, March 10–14, 2013, at the Henry B. Gonzalez Convention Center in San Antonio, Texas. 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 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 52nd Annual Meeting an event to remember.

Sincerely,

William Slikker Jr., PhD, ATS
2012–2013 SOT President

Important Deadlines

Early Bird Registration
January 25, 2013

Housing Reservation
February 8, 2013

Standard Registration
February 15, 2013

Registration Cancellation
February 15, 2013

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