Dear Colleagues:

It is my pleasure to invite you to attend SOT’s 54th Annual Meeting, March 22–26, 2015, at the San Diego Convention Center in San Diego, California. The Annual Meeting provides opportunities to learn from your colleagues about their latest scientific findings in the field of toxicology and related disciplines as well as from distinguished leaders who will expand your scientific horizons. In addition, the SOT Annual Meeting provides a venue for you to share your year’s work. For the science of toxicology, this is the premier meeting that should not be missed.

Ample networking time allows Annual Meeting attendees to meet potential collaborators and mentors, and with increasing attendance from scientists around the world, those interactions can take on a global scope. The Annual Meeting also offers a chance to pause to pay tribute to those scientists who have distinguished themselves in their field of expertise as the recipients of the Society’s most prestigious awards. I’m sure that all attendees also look forward to enjoying the company of friends and colleagues.

Finally, SOT attendees can take advantage of the ToxExpo, which is the world’s largest exposition of its kind. Hundreds of exhibits offer 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 showcasing the most leading-edge toxicology research. Please join me in San Diego for this meeting and help us to make the SOT 54th Annual Meeting an event to remember.

Sincerely,

Norbert E. Kaminski, PhD
2014–2015 SOT President

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Important Deadlines

Late-Breaking Abstract Submission
January 12, 2015

Early-Bird Registration
January 31, 2015

Housing Reservation
February 19, 2015

Standard Registration
February 28, 2015

Registration Cancellation
February 28, 2015

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Important Program Changes This Year
In an effort to conserve resources, the printed Program will be mailed
ONLY by request and may include a shipping fee. A new feature this year
is the Online Planner, a tool to build your schedule for the meeting from
your desktop in January, before the app is available, and then sync it to
the Mobile Event App in February once it’s launched. See page 2 for
more details.

Registration Express
Register by January 31, 2015, with full payment and you’ll receive
your name badge and tickets in the mail before the meeting.

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Follow @SOToxicology and @ToxExpo on Twitter
Tweet using #2015SOT and #toxexpo

Find up-to-date information at www.toxicology.org
The SOT 2015 Annual Meeting Mobile Event App

SOT will provide you, our guests, with an enhanced Mobile Event App. A new feature this year is the Online Planner, a tool to build your schedule for the meeting from your desktop in January, before the app is available, and then sync it to the Mobile Event App in February once it’s launched. Provided free of charge to attendees and exhibitors, the Mobile Event App will be available early February via the SOT website and app marketplaces. Through the Mobile Event App, you will be able 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 will allow you to:

- Connect with fellow attendees
- Build your own schedule and synchronize from the Online Planner to your iPad, tablet, and smartphone simply by logging in
  - Add individual presentations or entire sessions to your schedule
  - Add a specific session abstract to your schedule
  - Add your own items to your schedule
- View presentation details, abstracts, and ePosters
- Boolean search for items based on session title, abstract title, abstract keywords, thematic track, and author name or affiliation
- View and interact with speakers
- View the San Diego Convention Center map and San Diego city maps
- Navigate the real-time ToxExpo floor plan and search for products, specials, and exhibitors
- Contact exhibitors
- Integrate with ToXchange, Twitter, and Facebook

Online Planner Features:

- Boolean search schedule
- Separate speaker and abstract tabs
- Collapse/expand by day, hide abstracts
- Schedule export for iCal and PDF
- Schedule sync with Mobile Event App

Download the app early February from your favorite app marketplace and access the Online Planner beginning in January via the SOT website.
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 54th Annual Meeting to be held March 22–26, 2015, at the San Diego Convention Center in San Diego, California.

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 2015 Symposia, Roundtables, Workshops, and other special sessions are timely and highly informative and span a broad spectrum of topics to meet the diverse interests of membership.

We are very pleased to confirm the participation of Dr. J. Craig Venter as the Plenary Opening Lecturer. Dr. Venter is founder, chairman, and CEO of the J. Craig Venter Institute (JCVI), founder and CEO of Synthetic Genomics Inc., and a co-founder and CEO of Human Longevity Inc. Most notably, he led the private effort to map the human genome, publishing the results in 2001. In 2010, the J. Craig Venter Institute manufactured the entire genome of a bacterium, creating the first synthetic organism. Synthetic biology represents a technology that offers potential solutions to address global needs such as new sources of energy, new food and nutritional products, and next-generation vaccines. We look forward to a stimulating 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 Translational Impact Award, which will highlight significant contributions that impact toxicology and contribute to enhancing human health. The program is also enhanced by the annual MRC Lecture; this year we are fortunate to have Dr. Brigitta Stockinger, head of the MRC Division of Molecular Immunology, deliver this keynote. Also featured will be the Frontiers for Toxicology Symposium “Bugs to Drugs: The Microbiome in Human Health, Disease, and Therapeutics.” It is a busy scientific program, but it 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 returning to San Diego for the first time since 2006. The convention center is conveniently located downtown, adjacent to San Diego Bay and only minutes away from the airport. Several attractions within walking distance of the convention center include the USS Midway floating museum, the restaurants, pubs, and music of the Gaslamp Quarter, and PETCO Park, the home of the San Diego Padres. A visit to San Diego is not complete without stops to other superb, nearby destinations, such as the top-rated San Diego Zoo and Sea World, the Mediterranean-style seaside town of La Jolla, and the grand Victorian-style Hotel del Coronado facing the Pacific.

In addition to the more than 2,500 abstracts currently scheduled to be presented during the Annual Meeting, interested participants are welcome to submit late-breaking abstracts from December 5, 2014, through January 12, 2015. The submission fee for late-breaking abstracts will be $50, and abstracts accepted during this final submission phase will be programmed into poster sessions that will be presented on Thursday, March 26. These abstracts will not be included in the printed copy of The Toxicologist but will be available through the Annual Meeting app. Late-breaking abstracts should be submitted online at www.toxicology.org. We look forward to welcoming you to beautiful San Diego, California.

Warmest regards,

Peter L. Goering, PhD, DABT, ATS
SOT Vice President and
Scientific Program Committee Chairperson, 2014–2015
“Come run with the leadership and enjoy the fellowship of SOT”
—William Slikker Jr.
SOT 2012–2013 President

Register by February 13 to receive a commemorative t-shirt!

Please see page 42 for more details.
**Preliminary Program Content Reference Guide**

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

**Preliminary Program Overview**

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<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Program Overview (pages 6–9)</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 (pages 10–11)</td>
<td>All of the Annual Meeting sessions highlighted within the five themes are listed. 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 54th Annual Meeting the Society will highlight 73 Thematic Sessions and CE courses.</td>
</tr>
<tr>
<td>Special Events (pages 38–53)</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 54th 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 (pages 55–61)</td>
<td>These pages list the 2015 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 (pages 65–69)</td>
<td>This section lists the keynote and other special lectures and sessions for the 2015 Annual Meeting. Detailed information for these sessions will be available in the final Program.</td>
</tr>
<tr>
<td>Scientific Sessions (pages 70–105)</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 for Symposia, Workshops, Roundtables, Informational, Education-Career Development, and finally the Regional Interest session.</td>
</tr>
<tr>
<td>Exhibits (pages 107–114)</td>
<td>ToxExpo is the profession's largest trade show and best resource for the latest information in technology, equipment, and services. This section contains the current list of exhibiting companies and Exhibitor-Hosted sessions.</td>
</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 103).

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

**Featured Sessions (50–165 minutes)**—Keynote and other special lectures (page 65).

**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 101).

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

**Poster Sessions (180–210* minutes)**—Topic-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 105).

**Roundtable Sessions (80 minutes)**—These provide an overview of controversial subjects, followed by questions and discussion (page 97).

**Symposium Sessions (165 minutes)**—Cutting-edge science, emphasizing new areas, concepts, and data (page 70).

**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 81).

*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.

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Tweet using #2015SOT and #toxexpo
Scientific Program Overview

Sunday, March 22

7:00 AM to 7:45 AM

SUNRISE CONTINUING EDUCATION COURSE

1. New Horizons in Chemical Carcinogenesis: Advances in Mode of Action and Mechanism of Cancer Pathogenesis

8:15 AM to 12:00 Noon

MORNING CONTINUING EDUCATION COURSES

2. An Introduction to the Exposome
3. Demystifying Mixtures: From Study Design Selection to Risk Assessment Application
4. Safety Evaluation of CNS Administered Therapeutics—Study Design, Dose Routes, and Data Interpretation
5. The Future of Developmental and Reproductive Toxicology—Building a Bridge to the Animal Free Zone
6. The New World of Cancer Immunotherapy: Challenges in Bench to Bedside Translation
7. Toxicology and Regulatory Considerations for Combination Products

1:15 PM to 5:00 PM

AFTERNOON CONTINUING EDUCATION COURSES

8. Advances in Safety Assessment of Medical Devices
9. Interpretation of Cardiovascular Safety Data in Toxicology Studies
10. Is Synthetic Biology the Future of Toxicology?
11. Skeletal System Endocrinology and Toxicology
12. Strategies in Investigative Toxicology in a Pharmaceutical Setting

Monday, March 23

8:00 AM to 9:00 AM

PLENARY OPENING LECTURE

Life at the Speed of Light
Lecturer: J. Craig Venter, J. Craig Venter Institute

9:15 AM to 12:00 Noon

SYMPOSIUM SESSIONS

- New and Emerging Tobacco Products—Biomarkers of Exposure and Injury
- The Role of Connexin-Based Channels in Toxicity

WORKSHOP SESSIONS

- Environmental Exposures and Alzheimer’s Disease: Epidemiology, Mechanisms, and Future Strategies
- Friend or Foe—Challenges and Perspectives for Nonclinical Development of Antibody-Drug Conjugates
- Linking Early-Life Stages: The First Step toward LifeCourse Risk Assessment
- The US Tox21 Collaboration: Advances Made and Lessons Learned
- Toxicological Epigenomics: The Interface between the Environment and Human Health
- Transporters As Gatekeepers for Chemical Exposure in Reproductive Tissues

PLATFORM SESSION

- Disposition and Pharmacokinetics

9:30 AM to 12:30 PM

POSTER SESSIONS

- Alternatives to Mammalian Models I—Cardio, Neuro, Developmental
- Biotransformation and Cytochrome P450
- Developmental Neurotoxicology—In Vitro Screening
- Developmental Neurotoxicology—Nonmammalian Models
- Ecotoxicology
- Inflammation in Disease
- Inflammation: Methods and Mechanisms
- Liver
- Metals
- Nanotoxicology, General, Environmental, Metals
- Nonpharmaceutical Safety Assessment
- Persistent Organic Pollutants
- Pharmacogenomics and Genetic Polymorphisms
- Risk Assessment I
- Stem Cell Biology in Toxicology Research

12:00 Noon to 1:30 PM

RESEARCH FUNDING SESSION

Brown Bag Luncheon

12:10 PM to 1:30 PM

ROUNDTABLE SESSIONS

- Addressing Potential Age-Related Sensitivity to Neurotoxicity of Pyrethroids
- Confronting and Overcoming the Barriers to Sharing Toxicological Research Data for Risk Assessment in the 21st Century

INFORMATIONAL SESSION

- Toxicological Application of Studies Funded by California Stem Cell Research and Cures Act (Prop 71)

EDUCATION–CAREER DEVELOPMENT SESSION

- Adaptive Leadership: Anticipating, Initiating, and Responding to Change

12:30 PM to 1:20 PM

MERIT AWARD LECTURE

Lecturer: Günter Oberdörster, University of Rochester Medical Center
1:00 PM to 4:30 PM
POSTER SESSIONS
- Alternatives to Mammalian Models II—Skin, Eye, Liver
- Autoimmunity/Hypersensitivity
- Biological Modeling
- Biomonitoring and Exposure Assessment
- Cell Death and Apoptosis
- Developmental Neurotoxicology—Stem Cells
- Epidemiology
- Genetic Toxicology I
- Liver and Models
- Natural Products
- Ocular Toxicology
- Pharmaceutical Safety: Large Molecule Case Studies
- Pharmaceutical Safety: Small Molecule Case Studies
- Risk Assessment II

1:30 PM to 2:30 PM
MEET THE DIRECTORS
A Conversation with Linda Birnbaum and Jim Jones
Lecturers: Linda Birnbaum, NIEHS, and Jim Jones, US EPA

2:00 PM to 4:45 PM
SYMPOSIUM SESSIONS
- Cardio-Oncology Concerns Encourage Novel Approaches to Pharmaceutical Risk Assessment
- Immunostimulant Cancer Treatments: Toxicology Programs with an Autoimmune "Twist"
- Nrf2 Signaling Pathways in Model Systems: A Master Regulator of Neurotoxicity and a Potential Therapeutic Target
- Considering Pharmacokinetics As the Mechanistic Basis to Link Chemical Exposures to Adverse Outcome Pathways
- Regulatory Neurodevelopmental Testing: New Guiding Principles for Harmonization of Data Collection and Analysis
- The EDSP Screening Battery: A Work in Progress for Prioritizing Compounds for Quantitative Risk Assessment
- Understanding and Communicating Uncertainty in Hazard Assessment and Dose Response

WORKSHOP SESSIONS
- Evaluating and Quantifying Stress for Inclusion in Cumulative Risk Assessment
- Infant Formula Nutrition: Regulatory and Safety Evaluation of Ingredients
- Pulmonary Toxicity of Graphene Nanomaterials: An Emerging Concern in Manufacturing and Applications?

EDUCATION-CAREER DEVELOPMENT SESSION
- Challenges in the Life Cycle of a Toxicologist

PLATFORM SESSION
- 21st Century DART: Advances, Challenges, and Promises

4:45 PM to 6:00 PM
SOT/EUROTOX DEBATE
In Vitro Alternatives Are Ready to Be Implemented and Relied Upon for Human Safety Testing

Tuesday, March 24
8:00 AM to 8:50 AM
TRANSLATIONAL IMPACT AWARD LECTURE

9:00 AM to 12:00 Noon
SPECIAL SYMPOSIUM
- Frontiers for Toxicology Session: Bugs to Drugs: The Microbiome in Human Health, Disease, and Therapeutics

9:00 AM to 11:45 AM
SYMPOSIUM SESSIONS
- Alternative Models to Study Classical Toxicants: A Mechanistic View
- Immune Responses to Different Classes of Inhaled Particulates: Unique vs. Shared Responses and Mechanisms
- Local and Systemic Toxicity from Cobalt and Chromium-Containing Hip Prostheses

WORKSHOP SESSIONS
- Cigarettes, E-Cigarettes, and Hookah
- Clinical and Translational Toxicology
- Computational Toxicology and Data Integration I
- Endocrine Toxicology
- Food Safety, In Vivo
- Immunotoxicity II
- Inhalants and Cardiopulmonary
- Nanotoxicology, Carbon-Based Nanomaterials
- Neurotoxicology, Neurodegenerative Disease—Alzheimer's Disease and Others
- Neurotoxicology, Neurodegenerative Disease—Parkinson's Disease
- Particulate Matter
- Reproductive Toxicology I
- Reproductive Toxicology II
- Skin
- Toxicity of Chemical Mixtures

9:00 AM to 12:30 AM
POSTER SESSIONS
- Alternatives to Mammalian Models III
- Biomarkers
- Carcinogenesis I
- Educational Activities and Outreach
- Food Safety, In Vitro
- Gene Regulation and Signal Transduction
- Genetic Toxicology II
- Immunotoxicity I
- In Vitro Cardiovascular Safety
- Juvenile Toxicity
- Neurotoxicology, Metals—Lead and Others
- Neurotoxicology, Metals—Manganese
- Neurotoxicology, Metals—Mercury
- Oxidative Injury and Redox Biology
- Pharmaceutical Safety: Models and Methods
- Systems Biology and Toxicology

9:30 AM to 4:30 PM
POSTER SESSIONS
- Cigarettes, E-Cigarettes, and Hookah
- Clinical and Translational Toxicology
- Computational Toxicology and Data Integration I
- Endocrine Toxicology
- Food Safety, In Vivo
- Immunotoxicity II
- Inhalants and Cardiopulmonary
- Nanotoxicology, Carbon-Based Nanomaterials
- Neurotoxicology, Neurodegenerative Disease—Alzheimer's Disease and Others
- Neurotoxicology, Neurodegenerative Disease—Parkinson's Disease
- Particulate Matter
- Reproductive Toxicology I
- Reproductive Toxicology II
- Skin
- Toxicity of Chemical Mixtures

(continued on next page)
Scientific Program Overview (continued)

1:30 PM to 4:15 PM
SYMPOSIUM SESSIONS
- Incorporating In Vitro Pharmacokinetic Data and Tools into Toxicity Testing and Risk Assessments: State of the Science
- New Developments in the Management of Nerve Agent Poisoning
- Where the Metal Meets the Bone...

WORKSHOP SESSIONS
- Current Understanding of Immune-Mediated Adverse Drug Reactions
- In Vitro Microphysiological Systems—Developing Confidence in Predictive Ability

PLATFORM SESSIONS
- Investigating Mode of Action in Chemical Carcinogenesis
- Prudent Animal Usage in Pharmaceutical Safety Testing

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

Wednesday, March 25

8:00 AM to 9:00 AM
KEYNOTE MEDICAL RESEARCH COUNCIL (MRC) LECTURE
Environmental Influences on the Immune System via the Aryl Hydrocarbon Receptor
Lecturer: Brigitta Stockinger, MRC National Institute for Medical Research

9:00 AM to 11:45 AM
SYMPOSIUM SESSION
- Role of the Gut Microbiome in the Host Response to Xenobiotics

WORKSHOP SESSIONS
- An Experiment in Collective Wisdom Utilizing Real-Time Audience Input: Weight-of-Evidence Assessment for Chemical-Specific Modes of Action Utilizing Two Case Studies
- Application of High-Throughput In Vitro Assays in Assessing Small Molecule Safety
- Deciphering Clinical and Experimental Retinal Toxicology: An Eye on the Present and Future
- Evaluating Similarity across Related Complex Mixtures: The Challenge of Herbal Supplements

REGIONAL INTEREST SESSION
- Some Like It Hot: Impacts of Wildfires on Human Health

PLATFORM SESSIONS
- Applications of ToxCast/Tox21 Data: Confidence and Predictivity
- Emerging Concepts in Genotoxicity Assessment

9:00 AM to 12:30 AM
POSTER SESSIONS
- Animal Models of Disease
- Animal Models: Measurements, Validations, and Historical Data
- Animal Models: Methods
- Cardiovascular Toxicity and Hemodynamics
- Developmental Neurotoxicology
- Developmental Toxicology I
- Developmental Toxicology II
- Fetal Basis of Adult Disease
- General and Developmental Neurotoxicology of Therapeutic Agents and Drugs of Abuse
- Medical Devices: Risk Assessment and Test Methods
- Metals—As, Cd, Hg
- Nanotoxicology, In Vitro
- Regulation/Policy
- Risk Assessment III

9:30 AM to 4:30 PM
POSTER SESSIONS
- Animal Models of Disease
- Animal Models: Measurements, Validations, and Historical Data
- Animal Models: Methods
- Cardiovascular Toxicity and Hemodynamics
- Developmental Neurotoxicology
- Developmental Toxicology I
- Developmental Toxicology II
- Fetal Basis of Adult Disease
- General and Developmental Neurotoxicology of Therapeutic Agents and Drugs of Abuse
- Medical Devices: Risk Assessment and Test Methods
- Metals—As, Cd, Hg
- Nanotoxicology, In Vitro
- Regulation/Policy
- Risk Assessment III

12:00 Noon to 1:20 PM
ROUNDTABLE SESSIONS
- Should Respiratory Sensitizers Be Listed As Substances of Very High Concern (SVHC) under REACH?
- Will Generally Recognized As Safe (GRAS) Become an Endangered Species?

INFORMATIONAL SESSION
- Risk Communication and Management in the Era of Social Media and the Internet: Serving Society’s Needs with Accurate Information

EDUCATION-CAREER DEVELOPMENT SESSION
- What Toxicologist Do You Wanna Be? The Role of Toxicologists across Diverse Organizations

View featured speaker biographies, connect with other attendees, and create your own schedule using the enhanced 2015 Mobile Event App or the Online Planner—available from the SOT website.
See page 2 for details.
12:30 PM to 1:20 PM
DISTINGUISHED TOXICOLOGY SCHOLAR AWARD LECTURE
Lecturer: Ian Kimber, University of Manchester

1:00 PM to 4:30 PM
POSTER SESSIONS
- Bioinformatics
- Carcinogenesis II
- Chemical and Biological Weapons
- Computational Toxicology and Data Integration II
- Disposition and Pharmacokinetics: Drugs, Chemicals, and Transporters
- Epigenetics
- Kidney
- Neurotoxicology, In Vivo
- Neurotoxicology, General
- Neurotoxicology, Pesticides
- Pesticides
- Receptors
- RNA-Based Biomarkers

1:30 PM to 4:15 PM
SYMPOSIUM SESSIONS
- Adult Neurogenesis in Chemical-Induced Neurotoxicities: A New Frontier in Toxicological Mechanistic Investigations, Biomarker Research, and Therapeutic Targeting
- Advanced Approaches for Quantitative Risk Assessment Using Human Data with Applications across Disciplines

WORKSHOP SESSIONS
- Genomics of Nonrodent Mammalian Species and Impacts on Nonclinical Safety Evaluation of Pharmaceuticals and Clinical Translation
- Increasing Interest and Engagement in Toxicology and STEM Disciplines: The Multiple Modalities and Impact of Research and Internship Opportunities for High School and Undergraduate Students
- Integrating Gene Expression Profiling into High-Throughput Toxicity Testing
- Strengths and Weaknesses of Mouse Models in Studies of Immunological Effects of Drugs and Chemicals
- The Carcinogenicity of Outdoor Air Pollution: A Review of the IARC Evaluation of Outdoor Air Pollution and Particulate Matter in Polluted Air As Group 1 (Known) Human Lung Carcinogens and Possible Bladder Carcinogens
- Windfall or Pitfall: Is There a Need for Modification of Developmental and Reproductive Toxicology Studies When Endocrine Disruption Is the Mode of Action?

PLATFORM SESSION
- Inflammation in Disease Due to Environmental Exposures

4:30 PM to 5:20 PM
ROUNDTABLE SESSIONS
- Epigenetics and Chemical Safety Assessment: Are We Ready?
- The Future of Carcinogenicity Testing

EDUCATION-CAREER DEVELOPMENT SESSION
- Crafting High-Impact Manuscripts: The Process from Hypothesis through Review and Publication

Thursday, March 26
8:30 AM to 12:00 Noon
POSTER SESSIONS
- Late-Breaking Poster Session
  See page 68 for submission information.

9:00 AM to 11:45 AM
SYMPOSIUM SESSIONS
- Chromatin Structure, Genomics, and Transcriptional Responses to Environmental Insults
- Comprehensive Analysis of Nano Silver Toxicity Profiles: Known, Unknown, and Surprises!
- Epigenetics, Developmental Programming, and Immune Function: Where Do We Go from Here?
- Exposure Assessment in the 21st Century: Needs and Challenges Facing High-Throughput Exposure Modeling

WORKSHOP SESSIONS
- Microphysiological Models of the Developing Nervous System: Biologically Driven Assembly Inspired by Embryology and Translated to Human Developmental Toxicology
- Painting the Future of Repeat-Dose Systemic Toxicity Testing: Progress from the European SEURAT-1 Project

PLATFORM SESSION
- POPs—In Vitro, In Vivo, and Computational Modeling Studies

Satellite Meeting: Updates on 21st Century Toxicology Activities and Related Efforts: Invited Presentations and Open Microphone
Thursday, March 26 12:30 PM to 4:00 PM
Manchester Grand Hyatt
San Diego, Hillcrest
See page 25 for more information.
2015 CONTINUING EDUCATION COURSES AND SCIENTIFIC SESSIONS: THEMATIC APPROACH

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

Advancing Clinical and Translational Toxicology

- Autoimmunity/Hypersensitivity—Poster Session
- Cardio-Oncology Concerns Encourage Novel Approaches to Pharmaceutical Risk Assessment—Symposium Session
- Current Understanding of Immune-Mediated Adverse Drug Reactions—Workshop Session
- Deciphering Clinical and Experimental Retinal Toxicology: An Eye on the Present and Future—Workshop Session
- Environmental Exposures and Alzheimer’s Disease: Epidemiology, Mechanisms, and Future Strategies—Workshop Session
- Immunostimulant Cancer Treatments: Toxicology Programs with an Autoimmune “Twist”—Symposium Session
- Immunotoxicity I—Poster Session
- Immunotoxicity II—Poster Session

Approaches for Protecting Vulnerable Populations

- Addressing Potential Age-Related Sensitivity to Neurotoxicity of Pyrethroids—Roundtable Session
- Evaluating and Quantifying Stress for Inclusion in Cumulative Risk Assessment—Workshop Session
- Infant Formula Nutrition: Regulatory and Safety Evaluation of Ingredients—Workshop Session
- Inflammation in Disease Due to Environmental Exposures—Platform Session
- Linking Early-Life Stages: The First Step toward Lifecourse Risk Assessment—Workshop Session

The 2015 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.

- Inflammation in Disease—Poster Session
- Inflammation: Methods and Mechanisms—Poster Session
- Inhalants and Cardiopulmonary—Poster Session
- Local and Systemic Toxicity from Cobalt and Chromium-Containing Hip Prostheses—Symposium Session
- New and Emerging Tobacco Products—Biomarkers of Exposure and Injury—Symposium Session
- New Developments in the Management of Nerve Agent Poisoning—Symposium Session
- The New World of Cancer Immunotherapy: Challenges in Bench to Bedside Translation—Continuing Education Course (AM06)
- Where the Metal Meets the Bone…—Symposium Session

Use the enhanced 2015 Mobile Event App or the Online Planner to plan your schedule using the thematic track option. Navigating sessions for each theme is easy and convenient with these planning tools.
Epigenomic Influences in Toxicological Responses
• Chromatin Structure, Genomics, and Transcriptional Responses to Environmental Insults—Symposium Session
• Epigenetics and Chemical Safety Assessment: Are We Ready?—Roundtable Session
• Epigenetics, Developmental Programming, and Immune Function: Where Do We Go from Here?—Symposium Session
• Genomics of Nonrodent Mammalian Species and Impacts on Nonclinical Safety Evaluation of Pharmaceuticals and Clinical Translation—Workshop Session
• RNA-Based Biomarkers—Poster Session
• Toxicological Epigenomics: The Interface between the Environment and Human Health—Workshop Session

Safety Assessment Approaches for Product Development
• Advances in Safety Assessment of Medical Devices—Continuing Education Course (PM08)
• Alternative Models to Study Classical Toxicants: A Mechanistic View—Symposium Session
• Application of High-Throughput In Vitro Assays in Assessing Small Molecule Safety—Workshop Session
• Emerging Concepts in Genetic Toxicology Assessment—Platform Session
• Friend or Foe—Challenges and Perspectives for Nonclinical Development of Antibody-Drug Conjugates—Workshop Session
• Interpretation of Cardiovascular Safety Data in Toxicology Studies—Continuing Education Course (PM09)
• Is Synthetic Biology the Future of Toxicology?—Continuing Education Course (PM10)
• Medical Devices: Risk Assessment and Test Methods—Poster Session
• Ocular Toxicology—Poster Session
• Safety Evaluation of CNS Administered Therapeutics—Study Design, Dose Routes, and Data Interpretation—Continuing Education Course (AM04)
• Skeletal System Endocrinology and Toxicology—Continuing Education Course (PM11)
• Strategies in Investigative Toxicology in a Pharmaceutical Setting—Continuing Education Course (PM12)
• Strengths and Weaknesses of Mouse Models in Studies of Immunological Effects of Drugs and Chemicals—Workshop Session
• The Future of Carcinogenicity Testing—Roundtable Session
• The Future of Developmental and Reproductive Toxicology—Building a Bridge to the Animal Free Zone—Continuing Education Course (AM05)
• Toxicology and Regulatory Considerations for Combination Products—Continuing Education Course (AM07)
• Will Generally Recognized As Safe (GRAS) Become an Endangered Species?—Roundtable Session
• Windfall or Pitfall: Is There a Need for Modification of Developmental and Reproductive Toxicology Studies When Endocrine Disruption Is the Mode of Action?—Workshop Session

Strategies for Exposure and Risk Assessments
• Advanced Approaches for Quantitative Risk Assessment Using Human Data with Applications across Disciplines—Symposium Session
• An Introduction to the Exposome—Continuing Education Course (AM02)
• Confronting and Overcoming the Barriers to Sharing Toxicological Research Data for Risk Assessment in the 21st Century—Roundtable Session
• Considering Pharmacokinetics As the Mechanistic Basis to Link Chemical Exposures to Adverse Outcome Pathways—Workshop Session
• Demystifying Mixtures: From Study Design Selection to Risk Assessment Application—Continuing Education Course (AM03)
• Exposure Assessment in the 21st Century: Needs and Challenges Facing High-Throughput Exposure Modeling—Symposium Session
• Incorporating In Vitro Pharmacokinetic Data and Tools into Toxicity Testing and Risk Assessments: State of the Science—Symposium Session
• Investigating Mode of Action in Chemical Carcinogenesis—Platform Session
• Regulation/Policy—Poster Session
• Risk Assessment I—Poster Session
• Risk Assessment II—Poster Session
• Risk Assessment III—Poster Session
• The Carcinogenicity of Outdoor Air Pollution: A Review of the IARC Evaluation of Outdoor Air Pollution and Particulate Matter in Polluted Air As Group 1 (Known) Human Lung Carcinogens and Possible Bladder Carcinogens—Workshop Session
• The EDSP Screening Battery: A Work in Progress for Prioritizing Compounds for Quantitative Risk Assessment—Workshop Session
• Toxicogenomics Meets Regulatory Decision-Making: How to Get Past Heat Maps, Network/Pathway Diagrams, and “Favorite” Genes—Continuing Education Course (PM13)
• Understanding and Communicating Uncertainty in Hazard Assessment and Dose Response—Workshop Session
AbbVie
Abbott Park, Illinois

American Petroleum Institute
Washington, DC

AstraZeneca
Macclesfield, United Kingdom

Boehringer Ingelheim Pharmaceuticals, Inc.
Ridgefield, Connecticut

Bristol-Myers Squibb Company
Princeton, New Jersey

CANTOX
Mississauga, Ontario, Canada

Celgene Corporation
Summit, New Jersey

Charles River
Wilmington, Massachusetts

Chevron Corporation
San Ramon, California

Coca-Cola Company
Atlanta, Georgia

Colgate-Palmolive Company
Piscataway, New Jersey

Covance
Madison, Wisconsin

Dow Chemical Company
Midland, Michigan

Dow Corning Corporation
Midland, Michigan

The DuPont Haskell Global Centers for Health and Environmental Sciences
Newark, Delaware

Eli Lilly and Company
Indianapolis, Indiana

ExxonMobil Biomedical Sciences, Inc.
Annandale, New Jersey

Genentech, Inc.
South San Francisco, California

Gilead Sciences, Inc.
Foster City, California

GlaxoSmithKline
King of Prussia, Pennsylvania

The Hamner Institutes for Health Sciences
Research Triangle Park, North Carolina

Honeywell International, Inc.
Morristown, New Jersey

Huntingdon Life Sciences/Harlan
Huntingdon, Cambridgeshire, United Kingdom

Janssen Pharmaceutical Companies of Johnson & Johnson
Raritan, New Jersey

Metabolon, Inc.
Durham, North Carolina

Millennium: The Takeda Oncology Company
Cambridge, Massachusetts

MPI Research
Mattawan, Michigan

Organovo, Inc.
San Diego, California

Pfizer, Inc.
Groton, Connecticut

Procter & Gamble Company
Cincinnati, Ohio

Regeneron Pharmaceuticals, Inc.
Tarrytown, New York

RTC Research Toxicology Centre S.p.A.
Pomezia, Italy

Sanofi
Bridgewater, New Jersey

Sequani, Ltd.
Ledbury, Herefordshire, United Kingdom

SNBL USA, Ltd.
Everett, Washington

Syngenta Crop Protection, Inc.
Greensboro, North Carolina

Toxicology Excellence for Risk Assessment (TERA)
Cincinnati, Ohio

Western Slope Laboratory
Troy, Michigan

WIL Research Laboratories, LLC
Ashland, Ohio

WuXi AppTec
St. Paul, Minnesota

XRpro Sciences, Inc.
Cambridge, Massachusetts

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 (SOT) 54th Annual Meeting and ToxExpo, March 22–26, 2015, at the San Diego Convention Center in San Diego, California. 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 Plenary Lectures and other featured sessions, Symposia, Workshops, Roundtable discussions, Informational Sessions, and a Regional Interest Session, as well as Platform and Poster Sessions. The Society anticipates that more than 6,500 toxicologists from more than 50 countries will attend. The SOT Annual Meeting also includes the ToxExpo, which is the largest exhibition dedicated to toxicology and the biomedical sciences. The ToxExpo features 350 exhibitors who lead the industry in developing cutting-edge products, services, and technology to benefit the toxicology community. Exhibitors also have the opportunity to demonstrate their products and educate attendees about their services via Exhibitor-Hosted Sessions throughout the week.

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 (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.

In-Depth Analysis: The Scientific Program Committee has devised a thematic approach that encompasses five themes of topical interest:

- Advancing Clinical and Translational Toxicology
- Approaches for Protecting Vulnerable Populations
- Epigenomic Influences in Toxicological Responses
- Safety Assessment Approaches for Product Development
- Strategies for Exposure and Risk Assessments

Countless Networking Opportunities: With more than 6,500 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.

ToxExpo
The Toxicology Marketplace

SOT has the Numbers Exhibitors Want

6,500 scientists and industry experts attend the SOT Annual Meeting and ToxExpo. Take the opportunity to:

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

Highly Influential Audience

Over 70 percent of ToxExpo attendees are involved in purchasing decisions.

Online Marketplace at ToxExpo.com

ToxExpo exhibitors are a year-round resource online at ToxExpo.com, which provides unlimited visibility and exposure. ToxExpo.com is a resource for all the products and services necessary to toxicologists throughout the year.

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
- Biomarkers
- Biotechnology
- Carcinogenesis
- Cardiovascular Toxicology
- Clinical and Translational Toxicology
- Comparative and Veterinary
- Dermal Toxicology
- Drug Discovery Toxicology
- Epigenetics
- Ethical, Legal, and Social Issues
- Food Safety
- Immunotoxicology
- In Vitro and Alternative Methods
- Inflammation and Disease
- Inhalation and Respiratory
- Mechanisms

- Medical Devices
- Metals
- Mixtures
- Molecular Biology
- Nanotoxicology
- Neurodegenerative Disease
- Neurotoxicology
- Occupational and Public Health
- Ocular Toxicology
- Pharmacology
- Regulatory and Safety Evaluation
- Reproductive and Developmental Toxicology
- Risk Assessment
- Stem Cells
- Toxicologic and Exploratory Pathology

For more information on exhibiting at the largest toxicology exposition in the world, please visit ToxExpo.com, or contact Laura Helm at 703.438.3115 or email at laura@toxicology.org.
SOT Annual Meeting

A Global Audience: More than 20 percent of the attendees come from outside North America, some from 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, you pay $300 for early-bird registration, compared to an average cost of $461 for similar toxicology society meetings. Also, SOT has arranged air carrier discounts and has reserved SOT Annual Meeting attendee discount-rated rooms at various hotels in the San Diego area through the SOT hotel room block. If you need to provide your employer with additional justification for attending the SOT Annual Meeting, visit 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 attend.

ToxExpo

ToxExpo is the toxicology profession’s largest exposition, uniting attendees and exhibitors from around the world to exchange information on the latest products and services. More than 350 exhibitors display innovative technology and methods before more than 6,500 attendees. The benefits of ToxExpo extend far beyond the three-day event—resulting in beneficial partnerships for all parties.

Use the enhanced 2015 Mobile Event App to create a list of exhibitors with whom you want to connect 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 2015 ToxExpo hours:

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

ToxExpo is accessible to attendees and exhibitors throughout the calendar year by visiting www.ToxExpo.com. ToxExpo is a valuable tool for the policymaker, scientist, student, or anyone who is looking for the latest that toxicology has to offer.

An Invitation to International Attendees

Scientists from around the world are invited to register for the 54th Annual Meeting and ToxExpo in San Diego, March 22–26, 2015. Please note that individual invitations are not required for attendance. Because the meetings are open to toxicologists at this annual event, which is designed to showcase the year’s latest in research.

Visa Information

If your travels require a visa, note that the United States is advising applicants to apply at least three to four months in advance of their travel date. We suggest that you contact the United States Consulate in your own country regarding documentation and necessary information for your visit to the United States.

If for visa purposes you need a formal invitation letter, you may request an invitation by sending your name, address, and email address to the SOT Registration Department at tel: 703.438.3115, fax: 703.438.3113, or email: sothq@toxicology.org.

Here is 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.
- http://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. A survey is available that can be used to assist future travelers with the visa process.
- Make an Appointment—Before visiting 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/visa/temp/wait/wait_4638.html.
- Get Your Documents Ready—Organize your passport, applications, 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 San Diego 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.

Scoot Around
888.441.7575
www.scootaround.com

If you require more handicapped 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 31, 2015, will receive badges and registration materials in the mail. Attendees who already have their 2015 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” 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 Diego, 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.

First Aid and Emergency Services at the Convention Center

If an emergency should occur while at the San Diego Convention Center, proceed directly to the nearest house phone, located throughout the facility, and dial 5911 for security. You will be connected directly to the 24-hour manned security department at the convention center.

A First Aid room will be located in Box Office A, near Registration.

An emergency medical technician will be on duty:

Saturday ...............12:00 Noon–6:00 PM
Sunday ...............6:00 AM–8:00 PM
Monday ...............7:00 AM–8:00 PM
Tuesday ...............7:00 AM–8:00 PM
Wednesday ..........7:00 AM–8:00 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.

Green in San Diego

The San Diego Convention Center is committed to supporting and encouraging sustainable practices, including the hosting of environmentally-friendly “green” meetings in their building. Their highly successful conservation and recycling efforts have earned them LEED Silver Certification from the US Green Building Council and more than two dozen state and city awards for their eco-conscious initiatives over the past five years. They provide clients with energy-efficient facilities and venue. The convention center also has a long-standing recycling program that includes not only paper, but the collection of plastic, cardboard, and glass materials.

(continued on next page)
Global Gallery of Toxicology

A Worldwide Vision for Toxicology

Toxicology-related scientific societies from around the world are invited to display a poster showcasing their key information, accomplishments, strategic initiatives, and activities.

Attendees interested in collaboration and discussion are invited to the Global Gallery Monday, March 23, 11:45 am–12:15 pm, for a representative-attended poster session with all Global Gallery Participants.

In addition to the 28 2014 Global Gallery participating Societies, new participants for the 2015 Annual Meeting include:

- Bulgarian Society of Toxicology • Chinese Society of Toxicology • French Society of Toxicology •
- International Society for the Study of Xenobiotics • International Society of Exposure Science •
- Israeli Society of Toxicology • Japanese Society of Immunotoxicology • Korean Society of Toxicology •
- Scientific Liaison Coalition • Society for Risk Analysis • Swedish Society of Toxicology •

Posters will be displayed prominently in the ToxExpo Exhibit Hall.

(continued from previous page)

Outside of the San Diego Convention Center, the city of San Diego also is doing its part to be green, with its San Diego Area Green Business Project encouraging green practices among businesses in the region, by offering tools to implement more efficient and sustainable business operations.

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 such as the Welcome Reception. The Guest/Spouse Hospitality Room will be located in the San Diego Marriott Marquis and Marina Hotel.

Why wait until the rooms are gone?

Book your hotel reservation today!

Go to www.toxicology.org/ai/meet/am2015/housing.asp
or call SOT’s official housing company
Connections Housing, 800.262.9974 or 404.842.0000

The deadline is February 19, 2015
Housing Information

The Society of Toxicology has reserved and arranged for discounted room rates at various San Diego hotels—known as the SOT hotel room block. Booking a room in the room block is an important way to support the Society 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 Society meet its obligation to the hotel, avoid penalties, and keeps meeting registration prices down. Please assist the Society by making your hotel reservation using the Connections Housing online housing reservation system.

Hotel Reservation Information

All reservations for housing must be made through Connections Housing and not with the hotels directly. The deadline date for new housing reservations is February 19, 2015. Please choose only one option to make your reservation:

- Mail Housing Form to:
  Connections Housing
  950 Scales Road, Building 200, Suite 201
  Suwanee, GA 30024 United States
- Tel: 800.262.9974 (USA) or 404.842.0000 (Domestic and International)
- Fax: 404.601.7441 (Domestic and International)
- Hours of Operation:
  9:00 AM–7:00 PM (EST) Monday–Friday

Hotel Acknowledgement

A reservation acknowledgment will be emailed, faxed, or mailed via Connections Housing to you once your reservation has been booked. (You will not receive a confirmation from your hotel.) If you do not receive an acknowledgment within three (3) business days, please call Connections Housing.

Changes and Cancellations

The deadline date for new reservations is Thursday, February 19, 2015. You can make changes and/or cancellations online or by contacting Connections Housing at 404.842.0000 or 800.262.9974. All cancellations made within 72 hours prior to the day of arrival and no shows 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 by telephone. Faxed and mailed housing requests will take longer to process and your hotel selections may not be available.

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.

Poisoning of kids from liquid nicotine exposure spiking as e-cigarettes become more prevalent.

This is just one of the many topics and headlines being discussed daily by SOT on Facebook and Twitter.

Join the conversation today by liking us on Facebook (www.facebook.com/societyoftoxicology) or following us on Twitter (@SOToxicology).
## Hotel Accommodations

<table>
<thead>
<tr>
<th>Hotel Name</th>
<th>Rate</th>
<th>Address</th>
<th>Distance from Convention Center</th>
<th>Amenities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Embassy Suites San Diego</td>
<td>$249 single/$269 double</td>
<td>601 Pacific Highway, San Diego, CA 92101</td>
<td>5 blocks</td>
<td>Club: Hilton Honors</td>
</tr>
<tr>
<td>2) Hampton Inn Downtown</td>
<td>$185 single/$195 double</td>
<td>1531 Pacific Highway, San Diego, CA 92101</td>
<td>12 blocks</td>
<td>Club: Hilton Honors</td>
</tr>
<tr>
<td>3) Hard Rock Hotel</td>
<td>$269 single/double</td>
<td>207 5th Avenue, San Diego, CA 92101</td>
<td>2 blocks</td>
<td>Club: N/A</td>
</tr>
<tr>
<td>4) Hilton San Diego Bayfront</td>
<td>$269 standard/$289 deluxe</td>
<td>1 Park Boulevard, San Diego, CA 92101</td>
<td>1 block</td>
<td>Club: Hilton Honors</td>
</tr>
<tr>
<td>5) Hilton San Diego Gaslamp Quarter</td>
<td>$269 single/double</td>
<td>401 K Street, San Diego, CA 92101</td>
<td>4 blocks</td>
<td>Club: Hilton Honors</td>
</tr>
<tr>
<td>6) Hotel Solamar</td>
<td>$236 king/$249-2 queens</td>
<td>435 6th Avenue, San Diego, CA 92101</td>
<td>4 blocks</td>
<td>Club: Kimpton in Touch</td>
</tr>
<tr>
<td>7) Manchester Grand Hyatt</td>
<td>$273 single/double</td>
<td>1 Market Place, San Diego, CA 92101</td>
<td>3 blocks</td>
<td>Club: Hyatt Passport</td>
</tr>
<tr>
<td>8) Omni San Diego</td>
<td>$265 single/double</td>
<td>675 L Street, San Diego, CA 92101</td>
<td>3 blocks</td>
<td>Club: Select Guest</td>
</tr>
<tr>
<td>9) Residence Inn Downtown/Gaslamp</td>
<td>$234 one bedroom</td>
<td>356 6th Avenue, San Diego, CA 92101</td>
<td>3 blocks</td>
<td>Club: Marriott Rewards</td>
</tr>
</tbody>
</table>

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

Although we understand that making your reservations outside of the SOT hotel block can sometimes be more economical, it decreases the money available to the Society to carry out its strategic goals and may cause the Society to 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.
### 54th Annual Meeting and ToxExpo

## General Information

### 11) San Diego Marriott Gaslamp Quarter
- **Address:** 660 K Street, San Diego, CA 92101
- **Rates:** $220 single/$240 double
- **Club:** Marriott Rewards
- **Check-in:** 4:00 PM/Check-out: 12:00 Noon
- **Location:** 2 blocks from convention center
- **Parking:** Valet only parking: $40/night
- **Conveniences:** Free in-room Internet and fitness center

### 12) San Diego Marriott Marquis and Marina
- **Address:** 333 W. Harbor Drive, San Diego, CA 92101
- **Rates:** $289 city/$309 bay
- **Club:** Marriott Rewards
- **Check-in:** 4:00 PM/Check-out: 12:00 Noon
- **Location:** Adjacent to convention center
- **Parking:** Valet parking: $40/night
- **Conveniences:** 50% off guest room Internet, Free fitness center access

### 13) The US Grant Hotel
- **Address:** 326 Broadway, San Diego, CA 92101
- **Rates:** $239 single/double
- **Club:** Starwood Preferred Guest
- **Check-in:** 3:00 PM/Check-out: 12:00 Noon
- **Location:** 9 blocks from convention center
- **Parking:** Valet only parking: $39/night
- **Conveniences:** Free in-room Internet and fitness center

### 14) W San Diego
- **Address:** 421 W. B Street, San Diego, CA 92101
- **Rates:** $218 single/double
- **Club:** Starwood Preferred Guest
- **Check-in:** 4:00 PM/Check-out: 12:00 Noon
- **Location:** 12 blocks from convention center
- **Parking:** Valet only parking: $39/night
- **Conveniences:** Free in-room Internet and fitness center

### 15) Westin Gaslamp Quarter
- **Address:** 910 Broadway Circle, San Diego, CA 92101
- **Rates:** $229 single/double
- **Club:** Starwood Preferred Guest
- **Check-in:** 4:00 PM/Check-out: 12:00 Noon
- **Location:** 6 blocks from convention center
- **Parking:** Valet only parking: $40/night
- **Conveniences:** Free in-room Internet and fitness center

### 16) Westin San Diego
- **Address:** 400 W. Broadway, San Diego, CA 92101
- **Rates:** $229 single/double
- **Club:** Starwood Preferred Guest
- **Check-in:** 4:00 PM/Check-out: 12:00 Noon
- **Location:** 10 blocks from convention center
- **Parking:** Valet only parking: $40/night
- **Conveniences:** Free in-room Internet and fitness center

### 17) Wyndham San Diego Bayside
- **Address:** 1355 N. Harbor Drive, San Diego, CA 92101
- **Rates:** $189 single/double
- **Club:** Wyndham Rewards
- **Check-in:** 3:00 PM/Check-out: 12:00 Noon
- **Location:** 14 blocks from convention center
- **Parking:** Self parking: $24/Valet: $32/night
- **Conveniences:** Free in-room Internet and fitness center

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

**All hotels have Internet access. Hotel sales tax is currently 12.6%.**
Use the enhanced 2015 Mobile Event App to access a complete San Diego city guide including hotels, restaurants, attractions, nightlife, and shopping. A new feature this year is the Online Planner, a tool to build your schedule for the meeting from your desktop in January, before the app is available, and then sync to the Mobile Event App in February once it’s launched.
## Hotel Services

<table>
<thead>
<tr>
<th></th>
<th>Hotel</th>
<th>Rates</th>
<th>Blocks to Convention Center</th>
<th>Single/Double Rate</th>
<th>Restaurant</th>
<th>Complimentary Breakfast</th>
<th>Fitness Center</th>
<th>Swimming Pool</th>
<th>Business Center</th>
<th>Complimentary In-Room Internet</th>
<th>Room Service</th>
<th>Gift Shop</th>
<th>Overnight Self-Parking</th>
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<td>✓</td>
<td>✓</td>
<td></td>
<td>3 stars</td>
</tr>
</tbody>
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†Rates shown are for single and double occupancy; additional fees may apply for additional guests.

All hotels currently have Internet access, a business center, offer complimentary fitness center access, and have a tax rate of 12.6%. Please note: services offered, taxes, and fees associated with hotel services are subject to change and availability. Information listed is complete and accurate as of November 15, 2014.
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 San Diego Convention Center.

@SOT Center—Internet Access
SOT will provide computers you can use to access the Internet. These computers are available to attendees in the @SOT Center, located on the Lobby Level of the San Diego Convention Center.

Free Wireless Internet Access
As a service to Annual Meeting registrants, SOT will be providing free wireless Internet access throughout the San Diego Convention Center in all locations where SOT events are being held. Information on how to gain access to the wireless Internet will be made available in the final Program.

Media Support Services
SOT welcomes accredited representatives of media organizations to its Annual Meeting. Attending media representative receive complimentary registration for the meeting, and interviews can be arranged with SOT Council members, meeting speakers and presenters, and SOT general members. For more information, please contact:

Michelle Werts
SOT Headquarters: 703.438.3115
Email: michelle@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/am2015/forms.asp. Ancillary functions may be hosted only by SOT affiliates, exhibitors, supporters, or organizations otherwise associated with SOT. All ancillary functions are held outside of the convention center in nearby hotels. Ancillary meeting spaces book quickly—submit your request now! Only meeting requests made by December 12, 2014, will be listed in the Annual Meeting Calendar and the Program.

Networking Time
The Scientific Program Committee has dedicated time on Tuesday, March 24 for attendee networking. We encourage you to connect and engage with your colleagues at the Annual Meeting from 12:00 noon to 1:30 pm on Tuesday between sessions. Only networking events and Exhibit Hall activities are scheduled during this time. Head into ToxExpo to network with your colleagues and expand your network!

Poster Displays
Global Gallery of Toxicology
Toxicology societies from around the world are invited to participate in the Global Gallery of Toxicology. Now in its fifth year, posters of these sister societies will be prominently displayed during the meeting, showcasing their formation, key accomplishments, strategic initiatives, and activities. The 2015 Global Gallery poster session will be listed in the scientific program with a “Representative Attended” poster time from 11:45 am to 12:15 pm on Tuesday, March 23. Posters will be available for viewing at all times throughout ToxExpo. The goal of SOT and of all these societies is to increase the reliance of international decision-makers on the science of toxicology and to advance human health and disease prevention. For more information about participating in the Global Gallery, please contact Kevin Meritt at 703.438.3115 by January 6, 2015.

Scientific ePosters
SOT is pleased to offer our poster presenters the opportunity to share their research electronically as well as in their assigned poster sessions. Poster presenters will be able to upload their ePosters beginning in mid-February. ePosters will be available to meeting attendees through the Mobile Event App anytime during the meeting. Scientific ePosters will also be available through the app until May 11, 2015.

Scientific Poster Printing Services
SOT is pleased to offer our poster presenters a convenient printing 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 complete 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. The deadline to take advantage of this service is February 27, 2015.

To get more information you can contact Michael Graham with Shepard Exposition Services at 703.352.4900 or mgraham@shepades.com. The order form can also be found online on the SOT Annual Meeting website at www.toxicology.org/ai/meet/am2015/forms.asp.

San Diego Convention Center
The SOT 54th Annual Meeting and ToxExpo will be held at the San Diego Convention Center located at 111 W. Harbor Drive in downtown San Diego. This beautiful convention center sits right on sparkling San Diego Bay and across the street from its exciting downtown; it is considered one of the top ten convention venues in North America. The center’s most distinguishing feature is its Sails Pavilion, a 90,000-square-foot exhibit and special event area. The Sails Pavilion’s roof consists of distinctive Teflon-coated fiberglass
“sails” intended to reflect San Diego’s maritime history, as well as to advertise the center’s closeness to the San Diego shore.

San Diego General Information

San Diego is America’s eighth-largest city with over 1.3 million residents. San Diego sits on the coast of the Pacific Ocean in Southern California, immediately adjacent to the border with Mexico and south of Los Angeles. It is nicknamed “America’s Finest City”; with friendly locals, 70 miles of stunning coastline, world-class attractions and a relaxed atmosphere all its own, it’s easy to see how San Diego earned its nickname. For more information on things to do, where to eat, special events, etc., please visit www.meetmeinsandiego.com/sot.

Science in San Diego

Birch Aquarium at Scripps Institution of Oceanography
2300 Expedition Way
Tel: 858.534.FISH
www.aquarium.ucsd.edu

Tap into your inner oceanographer and learn about the creatures of the sea at Birch Aquarium at Scripps. Located in La Jolla, the aquarium is home to more than 3,000 specimens representing more than 380 species of fishes and invertebrates. Make sure to visit Tide-Pool Plaza, which features three living tide pools, where visitors can touch and learn about the pools’ inhabitants.

Reuben H. Fleet Science Center
1875 El Prado Balboa Park
Tel: 619.238.1233
www.rhfleet.org

The Reuben H. Fleet Science Center is home to the world’s first-ever IMAX® Dome Theater, which presents digital planetarium shows and IMAX movies daily. The center’s eight galleries contain 12 permanent exhibitions and often host major traveling exhibitions, giving visitors the opportunity to explore 100+ interactive all-ages exhibits that bring science to life.

San Diego Festival of Science and Engineering

The San Diego Festival of Science and Engineering www.lovestemsd.org is March 14–20 and culminates in EXPO DAY at Petco Park on Saturday, March 21. The Festival mission is to engage and encourage kids in science and engineering to inspire today’s students to become tomorrow’s science, technology, engineering, and math (STEM) innovators. Hundreds of community businesses and organizations present more than 35 interactive events with dynamic speakers throughout the county the week. This includes the Southern California SOT Regional Chapter who will have a booth at the EXPO. Bring the family. Volunteer. Enjoy the excitement of a giant science festival.

San Diego Natural History Museum
1788 El Prado Balboa Park
Tel: 619.232.3821
www.sdnhm.org

Founded in 1874, the San Diego Natural History Museum pays homage to its roots by keeping the focus of its exhibits on the Southern California region it calls home, both past and present day. The Museum often hosts multiple traveling exhibitions, so be sure to check the calendar before you go!

San Diego Zoo
2920 Zoo Drive
Tel: 619.718.3000
zoo.sandiegozoo.org

The world-famous San Diego Zoo is perhaps best known for its successful panda program, but there’s certainly much more to check out than those black and white giants! Located in the heart of Balboa Park, the Zoo is 100 acres in size and is home to more than 3,700 animals representing more than 650 species from around the world. As the first zoo to house its animals in habitats that mimic their natural environment, the zoo has been set up as a unique walking experience with regionally themed trails throughout rolling hills.

San Diego Zoo Safari Park
15500 San Pasqual Valley Road
Tel: 619.718.3000
www.sdzsafaripark.org

Get away from the hustle and bustle of downtown and visit San Diego Zoo Safari Park, a 1,800-acre wildlife reserve which boasts more than 2,600 animals. The park offers seven different safaris to choose from, or choose them all with the ultimate safari, so you don’t miss a thing! See one of the Safari’s Cheetah Ambassadors run at over 60 mph in the one-of-a-kind Cheetah Run. The Safari Park is a cutting-edge facility that lets you get up close and personal with animals in a completely different way from traditional zoos.

San Diego Area Activities

For things to do in San Diego, go to www.meetmeinsandiego.com/sot.

Balboa Park
1549 El Prado
Tel: 619.239.0512
www.balboapark.org

Encompassing 1,200 acres, Balboa Park is home to 15 museums, beautiful gardens, and the world-famous San Diego Zoo. Often referred to as the “Smithsonian of the West,” Balboa Park is the largest urban park in North America, bigger than even New York’s Central Park in size. Balboa Park is celebrating its 100th anniversary in 2015, with plenty of special events to mark the occasion!

 Cabrillo National Monument
1800 Cabrillo Memorial Drive
Tel: 619.557.5450
www.nps.gov/cabr/index.htm

A visit to San Diego’s only national park offers fantastic views that can stretch from Mexico to Los Angeles on a clear winter’s day. Visit the picturesque Old Point Loma Lighthouse, which has been restored to its original 1800s appearance and presents a peek into the daily life of a light keeper. South of the Lighthouse is the Kelp Forest Overlook, where visitors can spot Pacific gray whales during their migration season. On the western side of Point Loma, pools form during low tide in the rocky cavities; in them you may see colorful starfish, octopi, and a multitude of other creatures.

Follow @SOToxicology and @ToxExpo on Twitter Tweet using #2015SOT and #toxexpo

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

**Carlsbad Flower Fields**
5704 Paseo del Norte
Tel: 760.930.9123
www.theflowerfields.com

The Flower Fields® never set out to be an attraction, but this 50-acre working farm couldn’t keep spectators away from the stunning fields of ranunculus flowers planted on a hillside overlooking the California coastline. The Flower Fields’ bloom from early March to early May, giving visitors the incomparable opportunity to experience the rainbow rows of ranunculus flowers up close.

**Gaslamp Quarter**
614 5th Avenue
Tel: 619.233.5227
www.gaslamp.org/visitor-guide

San Diego’s Gaslamp Quarter comprises 16-square blocks immediately across from the San Diego Convention Center. A mix of Victorian-era buildings and modern skyscrapers house more than 100 of the city’s finest restaurants, pubs, nightclubs, and retail shops. The Quarter is loaded with cultural offerings that include theatres, art galleries, symphony halls, concert venues, museums, and Padres baseball.

**Hotel del Coronado**
1500 Orange Avenue
Tel: 619.435.6611
www.hoteldel.com

Spend a day enjoying sun, sand, and shopping at the iconic Hotel del Coronado, located on the beaches of Coronado Island. Built in 1888 and designated a National Historic Landmark in 1977, this red roofed building is the largest all wooden structure, in the country and is certainly the jewel of the “Crown City.”

**LEGOLAND® California**
One LEGOLAND Drive
Tel: 760.918.5346
www.california.legoland.com

Come see over 30,000 models created using over 60 million LEGO® bricks at LEGOLAND® California Resort. This family-friendly amusement park has more than 60 rides, shows, and attractions, including three rollercoasters. The resort is also home to LEGOLAND® Water Park and SEA LIFE® Aquarium.

**Old Town San Diego State Historic Park**
2415 San Diego Avenue
Tel: 619.291.4903
www.oldtownsandiego.org

Old Town San Diego, considered the birthplace of California, was founded in 1769 as the first permanent Spanish settlement on the West Coast. Today visitors to this state park can explore 17 unique historic attractions along with museums, art galleries, and the Old Globe Theatre. The district offers up free tours with docents and live entertainment, featuring mariachi bands and dancers in period attire. If you have a craving for tacos, Old Town has the highest concentration of Mexican restaurants in San Diego.

**Seaworld® San Diego**
500 Seaworld Drive
Tel: 800.257.4268
www.seaworldparks.com/seaworld-sandiego

The original Seaworld® opened in San Diego on March 21, 1964; 50 years later the park has expanded to several locations across the country and still entertains millions of visitors every year. Head to Shamu Stadium to catch one of their world-famous shows featuring orcas, but don’t forget your poncho in case you end up in the splash zone! In addition to traditional aquarium exhibits, the park also offers a variety of interactive experiences with marine animals, including dolphins.

**USS Midway Museum**
910 Harbor Drive
Tel: 619.544.9600
www.midway.org

Visit the USS Midway Museum, and watch as history comes alive when you explore the longest-serving US Navy aircraft carrier of the 20th century! Climb into one of the museums, 29 meticulously restored airplanes, try one of their two flight simulators, or stop and talk to one of the docents stationed throughout the ship.

**San Diego Golf Courses**

**Balboa Park Golf Course**
2000 Visalia Row
Tel: 619.358.8129 ext. 3
(12 minutes from the convention center)

This oceanside course provides beautiful views of yachts on sparkling blue waters. Coronado Municipal Golf Course is conveniently located just minutes from downtown San Diego. The 18-hole course measures 6,590 yards from the blue tees and is a par 72.

**Coronado Golf Course**
11480 N. Torrey Pines Road
Tel: 858.552.1662
(5 minutes from the convention center)

Located in La Jolla, Torrey Pines Golf Course sits on cliffs overlooking the Pacific Ocean and is widely recognized as a premier destination golf course, having played host to the US Open and many other PGA Tour events. Torrey Pines comprises two par-72, 18-hole courses, known as the North and South Courses. The course’s namesake is the Torrey Pine, a tree that only grows in the wild along this small stretch of the coastline in San Diego County and on Santa Rosa Island.

**Old Town San Diego**
2415 San Diego Avenue
Tel: 619.291.4903
www.oldtownsandiego.org

Old Town San Diego, considered the birthplace of California, was founded in 1769 as the first permanent Spanish settlement on the West Coast. Today visitors to this state park can explore 17 unique historic attractions along with museums, art galleries, and the Old Globe Theatre. The district offers up free tours with docents and live entertainment, featuring mariachi bands and dancers in period attire. If you have a craving for tacos, Old Town has the highest concentration of Mexican restaurants in San Diego.

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500 SeaWorld Drive
Tel: 800.257.4268
www.seaworldparks.com/seaworld-sandiego

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**USS Midway Museum**
910 Harbor Drive
Tel: 619.544.9600
www.midway.org

Visit the USS Midway Museum, and watch as history comes alive when you explore the longest-serving US Navy aircraft carrier of the 20th century! Climb into one of the museums, 29 meticulously restored airplanes, try one of their two flight simulators, or stop and talk to one of the docents stationed throughout the ship.

**Balboa Park Golf Course**
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Tel: 619.358.8129 ext. 3
(12 minutes from the convention center)

This oceanside course provides beautiful views of yachts on sparkling blue waters. Coronado Municipal Golf Course is conveniently located just minutes from downtown San Diego. The 18-hole course measures 6,590 yards from the blue tees and is a par 72.

**Torrey Pines Golf Club**
11480 N. Torrey Pines Road
Tel: 858.552.1662
(5 minutes from the convention center)

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San Diego Beaches

**Coronado Beach**
920 Ocean Avenue
(13 minutes from the convention center)

Often voted one of America’s best beaches by The Travel Channel, Coronado’s beaches sparkle with soft, white sand. You won’t find any big swells at this beach, making it great for families or just relaxing while soaking in the sun.

**La Jolla Shores**
8200 Camino Del Oro
(20 minutes from the convention center)

Watch the sun set from La Jolla Shores while you sit next to one of the firepits that dot this mile-long crescent beach. A favorite among beachgoers of all interests, this spot is popular for both swimming and surfing. With the Scripps Institute of Oceanography Pier at one end, you’re likely to spot some (friendly) marine life.

**Mission Beach**
3000 Mission Boulevard
(15 minutes from the convention center)

Mission Beach offers up a West Coast beach boardwalk experience. Two miles of sandy shores are right next to the carnival-like Belmont Park, where you can ride a rollercoaster or take a spin on a Tilt-A-Whirl.

**Ocean Beach**
5059 Newport Avenue
(14 minutes from the convention center)

Situated between the San Diego River and the hills of Point Loma, Ocean Beach is great for surfers who can catch one of the waves created by the jetties here. The beach is friendly for all types of beachgoers, even the four-legged kind!

**Pacific Beach**
4500 Ocean Avenue
(17 minutes from the convention center)

Pacific Beach is the iconic Southern California beach town. With three miles of boardwalk and a lively atmosphere, this is a great place to people watch or take a walk over to Crystal Pier where you can see great views of the coastline.

San Diego Fun Facts
1. San Diego is the birthplace of California. The first European exploration of the West Coast was by Juan Rodriguez Cabrillo, a Portuguese navigator sailing for Spain, who landed in San Diego on September 28, 1542.
2. The world’s oldest working ship, the Star of India, built in 1863, has her home port in San Diego.
3. The San Diego Zoo grew out of the exotic animal exhibitions abandoned after the 1915 Panama-California Exposition, which celebrated the opening of the Panama Canal.
4. From the early thirties up until the late seventies, San Diego was known as the “Tuna Capital of the World.”
5. The Hotel Del Coronado is the largest wooden structure in the country. Marilyn Monroe filmed “Some Like it Hot” at the hotel, which has hosted ten United States presidents, as well as the first state dinner held outside the White House in 1970. The resort also unveiled the world’s first electrically lighted, outdoor Christmas tree in 1904.
7. The San Diego International Airport is the busiest single-runway major airport in the nation and the second-busiest in the world after London Gatwick.
8. San Diego County has the largest number of farms (almost 7,000) in the US. San Diego County also produces the most avocados of any region in the country.
9. The La Jolla Playhouse and Old Globe Theatre of San Diego have sent more shows to Broadway than any other US city.
10. San Diego’s Geisel Library, in La Jolla, houses the world’s largest collection of original Dr. Seuss manuscripts. Dr. Seuss (Ted Geisel) was a one-time resident of La Jolla.

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 2015 satellite meetings will be held in and around the San Diego area. Proposals for a satellite meeting should be sent by email to heidi@toxicology.org to the attention of Peter L. Goering, SOT Vice President and Scientific Program Committee Chair. Requests approved by December 20, 2014, will be published in the Program. All requests must be received by January 18, 2015.

Updates on 21st Century Toxicology Activities and Related Efforts: Invited Presentations and Open Microphone

Thursday, March 26, 12:30 PM to 4:00 PM
Manchester Grand Hyatt San Diego, Hillcrest

Presented by:
The Center for Alternatives to Animal Testing and Human Toxicology Project Consortium

Purpose of the Meeting: If you’re planning to attend the SOT Annual Meeting in San Diego this March, please join the Center for Alternatives to Animal Testing (CAAT) and the Human Toxicology Project Consortium (HTPC) for our annual satellite meeting on 21st century toxicology. The satellite meeting provides an informal setting in which interested stakeholders can update each other on efforts to advance in vitro, pathway-based testing and related approaches. The meeting will feature a limited number of invited presentations but also leave ample time for an open microphone segment, in which participants are welcome to give brief presentations on germane topics, with or without slides. To register, please email Jamie DeRita at jderita1@jhu.edu.
The Toxicologist and Annual Meeting Program

The Toxicologist: The Official Record of the 2015 Annual Meeting Abstracts

*The Toxicologist* is an important scientific resource, as it is the official compilation of all accepted abstracts for the 54th 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 purchased for $40 by preordering via the registration form or on-site while supplies last.
- *The Toxicologist* PDF is available for download via the SOT website.
- Full abstracts can be accessed via the Mobile Event App or Online Planner available on the SOT website and app market places.

The Program: The Official Guide to the SOT 2015 Annual Meeting and ToxExpo

The *Program* is the official guide to all the activities of the 2015 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 overview of all the Continuing Education course offerings. The *Program* details the schedule of events by name and lists all the special events, including the 2015 award recipients, 2015 Honorary member, SOT Endowment Fund 2014 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 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-Hosted Sessions.

- The *Program* PDF is available for download via the SOT website (early February).
- Copies of the *Program* can be picked up on-site. In an effort to better use resources, the printed *Program* will be mailed ONLY by request (within the US and Canada only). If you wish to receive your printed *Program* before the meeting (request made by February 28), 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).

The Late-Breaking Abstract Supplement to *The Toxicologist* will be available to download as a PDF via the SOT website in early March. The late-breaking abstracts will also be searchable in the Mobile Event App and Online Planner.

*(Please see complete details on page 68,)*
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 inside the ToxExpo Exhibit Hall. It 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

Supporting Opportunities

Annual Meeting support 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, support 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. Supporters are listed in publications related to the Annual Meeting, including the Preliminary Program, the Program, pre- and post-meeting newsletters, and the ToxExpo Directory.

In addition, Annual Meeting supporters are listed on the SOT Annual Meeting website and Mobile Event App, essential sources of information for all registrants. During the Annual Meeting, visual acknowledgments, which group supporters by level of contribution, are prominently displayed, as well as in the SOT presentations in all session rooms. In appreciation for their support of the Society, supporters at the Silver Level and above are invited to the SOT President’s Reception. Five levels of support 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)

Please see www.toxicology.org for more details.

Transportation

Air Transportation

Preferred Carrier Airfare Discounts

SOT has established discounted rates through Southwest and United 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.

Southwest Airlines

Tel: 800.435.9792
www.swabiz.com
SOT Discount Code: 99150833

SOT’s conference attendees will receive a discount and bonus Rapid Reward points from Southwest Airlines through our SWABIZ” account. Southwest Airlines is offering a 15% discount off Anytime and Business Select® fares and a 5% discount off select Wanna Get Away® fares for travel to and from the conference. Book your travel between now and March 1, 2015, to take advantage of the discounted rates. (Discounts are available for travel March 15, 2015, through March 31, 2015.)

United Airlines

Tel: 800.426.1122 (a service fee will apply)
www.united.com
SOT Discount Code: ZSSM52928

United Airlines is offering up to a 10% discount off fares for attendees traveling to San Diego for the SOT Annual Meeting. The discount is valid March 16–April 1, 2015. You may book your ticket at www.united.com (to receive an additional 3% discount and have service fees waived); in the offer code box, type ZSSM52928 to receive the discount.

You may also book your reservation by calling United Meetings at 800.426.1122; however, a service fee will apply. International attendees should call their local United Airlines reservations office or email groupmeetings@united.com with their preferred itinerary and discount codes.

San Diego International Airport (SAN)

San Diego International Airport, also known as Lindbergh Field, is a public airport operated by the San Diego County Regional Airport Authority, and is located three miles northwest of downtown San Diego.

If you are booking through a travel professional, please give them the following information: Agreement Code: 552928, Z Code: ZSSM.

SOT Travel Provider—ATC Travel Management

ATC Travel is the official travel management firm for SOT’s 54th Annual Meeting. To take advantage of their services and savings, visit www.atcmeetings.com/sot, or call toll-free 800.458.9383 Monday through Friday, 8:30 am–7:00 pm (Eastern Standard Time) and ask to speak to anyone on our SOT-dedicated team, or email reservations@atcmeetings.com. To obtain the maximum discounted fares, call at least 60 days prior to departure. Please note that depending on your reservation method, ATC Travel Management charges a $10 online service fee or a live agent reservation fee. Before contacting ATC Travel Management, 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 Diego
- 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)

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

General Information

Follow @SOToxicology and @ToxExpo on Twitter
Tweet using #2015SOT and #toxexpo

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

Ground Transportation—From the Airport
Ground transportation is located curbside at each of the three terminals.

Taxi Cabs
There are multiple companies that provide taxi cab services for San Diego International Airport. After disembarking from your plane and picking up any checked bags, follow the signs leading to the transportation plazas. A transportation coordinator will place you in the first available taxi, unless you specify otherwise. All taxi rates are based per trip, not per person. Most taxi charges run about $17 to downtown.

Shuttle Services
SuperShuttle and Execucar provide the easiest and most cost-effective ground transportation service between San Diego International Airport and all other major hotels in the downtown area. Shuttles depart from 9:00 am to 9:00 pm daily for downtown hotels every 15 minutes.

Hertz
800.654.2240 (US and Canada); 405.749.4434
www.hertz.com
Discount Number: CV#04X50003
Hertz is the official car rental company for the 54th SOT Annual Meeting. SOT discounted rates begin at $39 per day. These special group rates are good one week before and after the SOT Annual Meeting. To reserve your car online go to www.hertz.com. You may also call Hertz directly at the numbers listed above. Be sure to mention the SOT Hertz discount number CV#04X50003.

Public Transportation—Getting around Town
Metropolitan Transit System
The Metropolitan Transit System (MTS) offers fast and convenient service from the airport to the convention center. MTS operates the San Diego Trolley (www.sdmts.com/trolley/trolley.asp). In addition to the trolley, The Flyer, MTS bus route 992, directly services the airport and the downtown area.

Please visit www.sdmts.com/home1.asp for information on various routes, fares and schedules.

Convention Center Location and Parking
The San Diego Convention Center has a large parking garage conveniently located underneath the center on Harbor Drive between First Avenue and Fifth Avenue. The daily rate is $15 with no in-and-out privileges or overnight parking allowed.

San Diego Convention Center
111 West Harbor Drive, San Diego, CA 92101
Metered street parking is available in areas surrounding the San Diego Convention Center at a rate of $1.25 per hour. Parking meters are enforced 8:00 am–6:00 pm, Monday through Saturday, unless otherwise noted.

Check the San Diego website for more information on parking at www.visitsandiego.com.

Overnight Parking
Gaslamp City Square Garage
461 4th Avenue, San Diego, CA 92101
Entry Location:
4th Avenue between Island Avenue and J Street
Due to city zoning restrictions, overnight parking is not permitted in San Diego Convention Center parking garages.

Please check the SOT Hotel Accommodations and Services on pages 17–21 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 Diego 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 ideas. 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 name when you have travel plans in place.

Weather
San Diego has a Mediterranean climate, typical of much of California. Days are frequently warm, with pleasantly cool evenings. The average high temperature for March is 66°F. For an up-to-date, detailed weather forecast, visit the National Weather Service Forecast Office at www.wrh.noaa.gov/sgx.
Enhance Your Annual Meeting Experience

Participate in Regional Chapter, Special Interest Group, and Specialty Section Meetings/Receptions.

Component group meetings and receptions offer an excellent opportunity to network at the SOT Annual Meeting. If you’re a component group member, be sure to attend your Regional Chapter, Special Interest Group, or Specialty Section meeting/reception to connect and engage with your peers. It’s a great time to catch up with long-time friends and colleagues, or make new ones!

Are you interested in joining a Regional Chapter, Special Interest Group, or Specialty Section? Attend a component group networking meeting/reception at the Annual Meeting. There’s no better way to meet, network, and decide on joining a component group. You’ll be glad you did!

Component group meetings/receptions may be found on pages 49–53 of this Preliminary Program. For a full and complete listing, visit the SOT website, Online Planner, Mobile Event App, and the 54th Annual Meeting Program.
Registration

Registration for the Annual Meeting is available now. Register by January 31 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 by mail to SOT Headquarters.

Online Registration

SOT members and nonmembers are invited to register for the 2015 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 Headquarters
(Faxes require credit card payment)
Fax: 703.438.3113

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.

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 28, and it will be mailed to you in early March (in the US and Canada only). The Program will also be available for download via the SOT website in early February and for pick up on-site. See pages 26 and 33 for more details about the Program and The Toxicologist.

Badges and event tickets will be mailed in advance if you register by January 31, 2015. When you arrive at the San Diego Convention Center, please go to the registration area located on the Lobby Level of the San Diego Convention Center to pick up your registration materials that were not mailed (i.e., Program, the ToxExpo Directory, and other supplementary materials). You must present your 2015 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 must be 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 31, 2015
• Standard Registration: February 28, 2015
• Final Registration after: February 28, 2015

DO NOT mail your registration form to SOT if it will arrive after March 19, 2015. SOT will accept Annual Meeting registrations until March 19. After March 19, 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 19, 2015, you can easily pick up your badge at the “BADGE PICK UP” registration counter.

Registration Discount for Nonmembers

JOIN SOT AND SAVE!

Special offer to nonmember 2015 Annual Meeting attendees: apply for membership by May 1, 2015, and, when accepted, SOT will waive your 2015 dues. See page 32 for membership 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, and rental cars 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.

If the person the guest is accompanying is already registered, he or she must use the Guest Registration Form and send it to SOT Headquarters along with a copy of the regular registrant’s confirmation.

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 San Diego Marriott Marquis and Marina Hotel.

(continued on page 34)
**Registration Form**  
SOT 54th Annual Meeting • March 22–26, 2015

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### Registration Fees:

<table>
<thead>
<tr>
<th>I’m Already Registered</th>
<th>Early-Bird Registration (Received by Jan. 31)</th>
<th>Standard Registration (Feb. 1 to Feb. 28)</th>
<th>Final Registration (After Feb. 28*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOT Member</td>
<td>$300</td>
<td>$360</td>
<td>$420</td>
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<tr>
<td>Nonmember**</td>
<td>$640</td>
<td>$700</td>
<td>$760</td>
</tr>
<tr>
<td>SOT Retired/Emeritus Member</td>
<td>$70</td>
<td>$120</td>
<td>$170</td>
</tr>
<tr>
<td>Postdoctoral SOT Member</td>
<td>$85</td>
<td>$135</td>
<td>$185</td>
</tr>
<tr>
<td>Postdoctoral Nonmember**</td>
<td>$170</td>
<td>$220</td>
<td>$270</td>
</tr>
<tr>
<td>Graduate Student Member</td>
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<td>$115</td>
<td>$165</td>
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<tr>
<td>Graduate Student Nonmember**</td>
<td>$130</td>
<td>$180</td>
<td>$230</td>
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<td>Undergraduate Student (Copy of Student ID Required)</td>
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<td>High School Student (Copy of Student ID Required)</td>
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<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>SOT Affiliate</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Press</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Guest/Spouse (Nonscientist)</td>
<td>$70</td>
<td>$85</td>
<td>$100</td>
</tr>
</tbody>
</table>

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### Method of Payment:

All registrations submitted by hard copy or fax will be processed online by SOT staff.

- Check or Money Order # __________________________
  (PAYABLE TO “SOCIETY OF TOXICOLOGY”)

- Government Purchase Order # __________________________
  (US GOVERNMENT PO FORM MUST BE ATTACHED)

- Credit Card:  
  - Credit Card #: __________________________
  - Expiration Date: __________________________
  - Cardholder’s Printed Name: __________________________

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**By registering for the SOT Annual Meeting you agree to the terms and conditions outlined in the registration policies on page 34.**
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 7,800 members from nearly 60 countries worldwide. SOT members are drawn from academic institutions, industry, and government service, among other areas, 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.
- Access the official journal of SOT, Toxicological Sciences, online and/or choose to receive in print.
- Utilize Career Resources such as the SOT Job Bank and register for Mentor Match as a mentor or mentee.
- Qualify for exclusive SOT member awards—from Graduate Student Travel Support and Research Training to Postdoctoral Fellowships, Traveling Lectureships, SOT Awards, and more!
- Plus... Choose to join one or more of 27 Specialty Sections, 18 Regional Chapters, or 6 Special Interest Groups that provide a variety of networks for exchanging information and collaborating with peers. **Note**: Graduate Student and Postdoctoral members may join one Specialty Section and one Special Interest Group at no additional cost.

Plus...

Choose to join one or more of 27 Specialty Sections, 18 Regional Chapters, or 6 Special Interest Groups that provide a variety of networks for exchanging information and collaborating with peers. **Note**: Graduate Student and Postdoctoral members may join one Specialty Section and one Special Interest Group at no additional cost.

Membership Fees:

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

**Reduced Dues and Membership Dues Assistance for Scientists from Developing Countries**

Dues for Full and Associate developing countries membership are $50 and include membership in one Special Interest Group and one Specialty Section as well as online access to ToxSci. Dues for Student and Postdoctoral membership are $10 and include membership in one Special Interest Group and one Specialty Section. Student and Postdoctoral members may also qualify for a dues waiver through the Membership Dues Assistance Program.

Visit the SOT website at www.toxicology.org to learn more.

Join or upgrade your membership using the easy online membership application at www.toxicology.org.
CONTINUING EDUCATION COURSES:

- Yes, I would like to attend the following CE courses. (Only meeting registrants may enroll in a CE course.)
  - Early-Bird Registration (Received by Jan. 31)
  - Standard Registration (Feb. 1 to Feb. 20)
  - Final Registration (After Feb. 20)
  - # of Courses

<table>
<thead>
<tr>
<th>Course Description</th>
<th>Early-Bird</th>
<th>Standard</th>
<th>Final</th>
<th># of Courses</th>
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<td>$150 each</td>
<td>$185 each</td>
<td>$220 each</td>
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<td>SOT Retired/Emeritus Member</td>
<td>$110 each</td>
<td>$145 each</td>
<td>$180 each</td>
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<tr>
<td>Nonmember</td>
<td>$300 each</td>
<td>$335 each</td>
<td>$370 each</td>
<td>x</td>
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<tr>
<td>Postdoctoral (SOT Member/Nonmember)</td>
<td>$90 each</td>
<td>$125 each</td>
<td>$160 each</td>
<td>x</td>
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<tr>
<td>Graduate or Undergraduate Student (SOT Member/Nonmember)</td>
<td>$45 each</td>
<td>$80 each</td>
<td>$115 each</td>
<td>x</td>
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<tr>
<td>Press</td>
<td>$ 0 each</td>
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<td>$ 0 each</td>
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- Yes, I would like to attend the Sunrise CE Mini-Course (includes continental breakfast)
  - SOT Member/Affiliate
  - SOT Retired/Emeritus Member
  - Nonmember
  - Postdoctoral (SOT Member/Nonmember)
  - Graduate or Undergraduate Student (SOT Member/Nonmember)
  - Press

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 student or postdoctoral registrant and would like to attend the complimentary Student/Postdoctoral Mixer on Sunday, 7:30 pm - 9:00 pm. (Ticket required)
- Yes, I would like to attend the Mentoring Breakfast on Monday, 6:15 am - 7:45 am, as a mentee. (Limited seating and ticket required)
- Yes, I am a student or postdoctoral member registrant and would like to attend the complimentary Trainee Discussion Select one only: (Limited seating and ticket required)
  - Dr. J. Craig Venter (Opening Plenary) on Monday, 10:00 am - 11:00 am
  - Dr. Brigitta Stockinger (MRC) on Wednesday, 9:30 am - 10:30 am
- Yes, I am a student or postdoctoral registrant and would like to attend the In Vitro Lecture and Luncheon on Monday, 12:00 noon – 1:20 pm. (Ticket required)
- Yes, I am a postdoctoral registrant and would like to attend the Postdoctoral Luncheon on Tuesday, 12:00 noon – 1:15 pm. (Limited seating and ticket required)

PRINT MATERIALS:

In an effort to conserve 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 early March (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 28, 2015).

2015 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 $40 per copy (available while supplies last).

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

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<td>1. Academia</td>
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<td>a. Analytical</td>
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<td>3. Contract Research</td>
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<td>c. Hardware</td>
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<td>4. Government</td>
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<td>d. Software</td>
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<td>5. Military</td>
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<td>e. In Vitro</td>
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<td>6. Private Industry</td>
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<td>f. Lab Animal</td>
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<td>7. Other</td>
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<td>g. Neurotoxicology</td>
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<td>h. Pathology</td>
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<td>i. Quality Assurance</td>
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<td>j. Wildlife Toxic.</td>
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<td>11. Health and Safety</td>
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<td>12. Mgmt. Corporate</td>
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<td>61. Radioactive Isotope</td>
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<td>27. Clinical &amp; Transl. Tox.</td>
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<td>28. Comparative and Vet.</td>
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<td>30. Drug Discovery Tox.</td>
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<td>32. Ethical, Legal, and Social Issues</td>
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<td>33. Food Safety</td>
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<td>34. General Tox.</td>
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<td>57. Stem Cells</td>
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<td>58. Other</td>
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There will be no refunds for cancellations received at SOT Headquarters after February 28, 2015.

SOT will accept faxed registration forms until March 19. Online registration will be open until March 26. On-Site registration forms will be available at the Annual Meeting Registration Desk.
Registration

(continued from page 30)

**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 31, 2015. If your registration is received after January 31, you can pick up your badge and tickets at the "BADGE PICK UP" registration counters on-site. You do not need to enter the regular registration line.

**Cancellation Refund Policy**

All requests for cancellations and/or refunds must be received in writing at SOT Headquarters by February 28, 2015. These refunds will be processed, less a $50 cancellation fee, following the Annual Meeting. Refund requests received after February 28, 2015, will not be processed.

**Exhibitors**

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

**Americans with Disabilities Act (ADA)**

The San Diego 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.

2015 SOT Annual Meeting Policies

By registering for the 2015 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 telephone and fax numbers, and email 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—registrant name and affiliation shared.

SOT Annual Meeting registrants are prohibited from:

- Inviting children under the age of 15 and guest/spouse registrants into the ToxExpo Exhibit Hall. (Session chairs must provide consent for the guest/spouse or child to attend sessions.)
- Soliciting in the ToxExpo Exhibit Hall unless they are an approved exhibitor. SOT and ToxExpo retain the right to have removed from the exposition any company that has not duly contracted for exhibit space.
- Taking photographs or other electronic capture of scientific sessions in meeting rooms or the ToxExpo without the consent of the session chair and the presenter(s)/author(s).
- Photographing colleagues against the backdrop of scientific posters on display without the express consent of the presenting author(s).
- Photographing exhibit booths.
- Speaking on a cell phone while attending scientific sessions.

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.
High School Poster Exposition

Tuesday, March 24, 2015 • ToxExpo

High school students with a project related to toxicology are invited to submit an abstract for the High School Poster Exposition. The SOT K–12 Subcommittee organizes the Exposition and arranges for an SOT mentor for each student.

More information can be found on the Annual Meeting website in the Special Events: Education and Outreach section or by contacting bettye@toxicology.org.

The Southern California Chapter of SOT (SCCSOT) invites interested SOT members and Annual Meeting attendees to arrive early and

VOLUNTEER TO ASSIST WITH K–12 EDUCATION OUTREACH ACTIVITIES.

SCCSOT will be participating in EXPO DAY, a mind-blowing day of hands-on Science, Technology, Engineering, and Math, on Saturday, March 21, 2015, 10:00 am to 5:00 pm.

We need your help with this exciting day of toxicology activities and opportunities for students to talk with toxicologists. Please also invite local high school students to participate!

Contact: bettye@toxicology.org

www.lovestemsd.org
Job Bank

www.toxicology.org/jobbank

YOUR EMPLOYMENT AND RECRUITMENT RESOURCE

Job Seekers—Find Your Next Opportunity
Employers Are Looking for Candidates through the SOT Job Bank

• Every SOT member can utilize the SOT Job Bank as a job seeker free of charge.
• SOT members can log in to instantly browse posted positions.
• Post your resume and activate your profile to be seen by potential employers.
• Review the positions posted by major corporations, academic institutions, government agencies, and private research organizations; positions are available at all experience levels.
• 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 select employers for additional information on available positions.
• 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
The SOT Job Bank Is the Ideal Place to Streamline Your Hiring 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 for which you are looking.
• 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

SOT Society of Toxicology
Career Resource and Development Services

Streamline Your Job Search: Use SOT Job Bank Services

Free Job Search for SOT Members!
The SOT Annual Meeting, with over 6,500 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, the SOT online Job Bank prepares you to take full advantage of the on-site Job Bank Center in San Diego.

Job Bank
Access Available Any Time, Anywhere
The online Job Bank includes positions available at corporations, academic institutions, government agencies, and private research organizations. Last year over 100 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 Corporate 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 active employers or candidates

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 San Diego Convention Center in 130 (Office) and 131 B-C (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 appreciate and acknowledge 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. Employers may reserve interview rooms ahead of time or at the meeting on a first-come, first-served basis.

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 encouraged, and interested Job Seekers and Employers are welcome to come to the Job Bank Office to ask questions and learn more. For additional information, contact Kevin Merritt at SOT Headquarters: 703.438.3115 ext. 1601 or email: careerresources@toxicology.org.

Mentor Match
Online Mentoring Program
The Society of Toxicology recognizes the importance of mentoring in the scientific and professional development of its members. The objective of the 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/mentormatch.
Society of Toxicology Honors and Awards

AWARDS CEREMONY • Sunday, March 22, 2015 • 5:15 PM to 6:30 PM • San Diego Convention Center

SOT Awards

Achievement Award
Vishal S. Vaidya, PhD
Harvard Medical School, Boston, MA

Arnold J. Lehman Award
Richard A. Becker, PhD, DABT
American Chemistry Council, Washington, DC

Distinguished Toxicology Scholar Award
Ian Kimber, OBE, BSc, MSc, PhD, FSB, FBTS, ATS
University of Manchester, Manchester, Cheshire, United Kingdom
Distinguished Toxicology Scholar Award Lecture—
Wednesday, March 25, 12:30 PM to 1:20 PM

Education Award
Theodore A. Slotkin, PhD
Duke University Medical Center, Durham, NC

Enhancement of Animal Welfare Award
Marcel Leist, PhD
University of Konstanz, Konstanz, Germany

Merit Award
Günter Oberdörster, DVM, PhD
University of Rochester Medical Center, Rochester, NY
Merit Award Lecture—
Monday, March 23, 12:30 PM to 1:20 PM

Public Communications Award
Andrew D. Maynard, PhD
University of Michigan Department of Environmental Health Science,
Ann Arbor, MI

Translational Impact Award
Jefferey Burgess, MD, MS, MPH
University of Arizona, Tucson, AZ
Translational Impact Award Lecture—
Tuesday, March 24, 8:00 AM to 8:50 AM

Undergraduate Educator Award
Mindy F. Reynolds, BS, PhD
Washington College, Chestertown, MD

Board of Publications for the Best Paper in Toxicological Sciences Award
Temporal Concordance Between Apical and Transcriptional Points of Departure for Chemical Risk Assessment
Russell S. Thomas, Scott C. Wesselkamper, Nina Ching Y. Wang, Q. Jay Zhao, Dan D. Petersen, Jason C. Lambert, Ila Cote, Longlong Yang, Eric Healy, Michael B. Black, Harvey J. Clewell III, Bruce C. Allen, and Melvin E. Andersen

Honorary Membership
Shawn Douglas Lamb
Executive Director, Society of Toxicology,
Reston, VA
Supported Grants, Fellowships, and Awards

Global Senior Scholar Exchange Program

Sunisa Chaiklieng, Dr Biol Hum
Khon Kae University, Muang, Thailand

Host: Norbert E. Kaminski, PhD
Michigan State University, East Lansing, MI

Deepak Dhakal, MS
Trihbarun University, Patan, Nepal

Host: Aaron Barchowsky, PhD
University of Pittsburgh, Pittsburgh, PA

Best Postdoctoral Publication Awards

Presented at the Postdoctoral Assembly Luncheon on Tuesday

John Clarke, PhD
University of Arizona, Tucson, AZ


Yong Ho Kim, PhD
US Environmental Protection Agency, Research Triangle Park, NC


Christina Powers, PhD
US Environmental Protection Agency, Ann Arbor, MI


Colgate-Palmolive Grant for Alternative Research

Alfredo Miranda de Goes, BSc, MSc, PhD
Universidade Federal de Minas Gerais, Belo Horizonte, MG, Brazil

Lei Li Kerr, PhD
Miami University, Oxford, OH

Colgate-Palmolive Postdoctoral Fellowship Award in In Vitro Toxicology

Fabian A. Grimm, PhD
Texas A&M University, College Station, TX

Syngenta Fellowship Award in Human Health Applications of New Technologies

Alok Ranjan, BS
Texas Tech University Health Sciences Center, Amarillo, TX

Colgate-Palmolive Award for Student Research Training in Alternative Methods

Prajakta Shimpi, MS
University of Rhode Island, Kingston, RI
SOT Undergraduate Student Awards

Pfizer SOT Undergraduate Student Travel Awards

Scott Freeburg
Kenyon College
Gambier, OH

Sloane K. Miller
University of North Carolina at Chapel Hill
Chapel Hill, NC

Latisha Pryor
Fort Valley State University
Oglethorpe, GA

Yssa Rodriguez
St. Mary's University
San Antonio, TX

Nicole Sidebotham
Oregon State University
Corvallis, OR

Anna Wojcicki
University of Minnesota
Minneapolis, MN

Weelic Chong
Oberlin College
Oberlin, OH

Kathryn Fulda
Washington College
Chestertown, MD

Samantha Hall
Duke University
Durham, NC

Emily Daniel
William Jewell College
Liberty, MO

Alexander Jones
Purdue University
West Lafayette, IN

Gifty A. Dominah
Oberlin College
Oberlin, OH

Megan M. Koenecke
Kenyon College
Gambier, OH

Zuania I. Cordero Badillo
University of Puerto Rico
Rio Piedras
San Juan, PR

Samantha Hall
Duke University
Durham, NC

SOT Developing Country Travel Awards

The SOT/AstraZeneca/SOT Endowment Fund/IUTOX Travel Awards for several individuals from developing countries selected in December 2014 will be honored at the Awards Ceremony.

Outstanding Graduate Student Leadership Committee 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 22.

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.

Most of the SOT Endowment named funds provide travel support for students and postdoctoral to participate in the Annual Meeting. To learn more visit: www.toxicology.org/endowment.
Special Events

Recognition and Special Events
All activities will be held at the San Diego Convention Center in San Diego, California, unless otherwise noted.

Full details on the Special Events will be available in the Program, on the website, and via the Mobile Event App and Online Planner.

Committee on Diversity Initiatives Reunion
Saturday, March 21, 7:30 PM to 8:30 PM
Hosted by:
Committee for Diversity Initiatives
Please connect with the Committee on Diversity Initiatives (CDI) as we celebrate the Undergraduate Education Program and the people who make it successful. The CDI Reunion will provide a great opportunity for former students, organizers of the program, and volunteers to gather and celebrate 26 years of success in encouraging the next generation of scientists. Please welcome and network with this year's undergraduate student participants and Gehring Diversity Student Travel Awardee. Dessert, coffee, and tea will be served, so please mark your calendars and start the 54th Annual Meeting with a fun and interactive evening at the CDI Reunion.

Awards Ceremony Music
Sunday, March 22, 4:45 PM to 5:15 PM
Performed by
Amy Lynn Kanner
Amy Lynn Kanner will perform for SOT Annual Meeting attendees prior to the SOT Award Ceremony. Amy’s passion is playing the harp. She is also a composer and recording artist—her CD, “Garden of Delights,” features performances on multiple instruments.

Amy is also a physician and a graduate of the International Harp Therapy program—utilizing the unique resonance of the harp to create an atmosphere of relaxation and respite for both patients and health care staff.

Awards Presentation
Sunday, March 22, 5:15 PM to 6:30 PM
Please join the Awards Committee, in conjunction with Council, the Board of Publications, and the Education Committee as we honor scientists who have distinguished themselves with presentation of Awards at our prestigious SOT Awards Ceremony (pages 38–40). Also conferred at this ceremony are a number of grants, fellowships, and awards for cutting-edge and novel research. Please refer to the Awards and Fellowships section of the SOT website for complete details at www.toxicology.org/awards.

Welcome Reception
Sunday, March 22, 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 22, 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 wear your membership anniversary pin.

SOT Mentoring Breakfast
Monday, March 23, 6:15 AM to 7:45 AM
(Reservation Required)
Endorser(s):
Career Resource and Development Committee
Postdoctoral Assembly
Graduate Student Leadership Committee
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 forth annual Mentoring Breakfast.

(continued on next page)
The Mentoring Breakfast is for SOT members at any career stage—from graduate students and 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. Note that mentor information will be provided after the Annual Meeting, and only mentees should attend the breakfast.

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

Global Collaboration Coffee
Monday, March 23, 9:30 AM to 11:30 AM
The SOT Council invites all Global Gallery participants and representatives of societies from around the world to the Global Collaboration Coffee. Invites also include SOT Special Interest Group leaders, IUTOX Executive Committee members, SOT Councilors, 2015 Global Senior Scholars, and their hosts, and the 2015 recipients of the SOT/AstraZeneca/SOT Endowment Fund/IUTOX Travel Awards. 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 a “Representative Attended” poster time from 11:45 am to 12:15 pm on Monday, March 23. See page 16 for more information about the Global Gallery of Toxicology.

Brown Bag Luncheon
Monday, March 23, 12:00 Noon to 1:30 PM
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.

In Vitro Toxicology Lecture and Luncheon for Students
Alternative In Vitro Approaches for Predicting the Health Impacts of Nanomaterials
Monday, March 23, 12:00 Noon to 1:20 PM (Ticket Required)
Chairperson(s): Richard Pollenz, University of South Florida, Tampa, FL; Emily G. Notch, Western New England University, Springfield, MA, and Daniel J. Spade, Brown University, Providence, RI.
Lecturer: James C. Bonner, North Carolina State University, Raleigh, NC
Supported by:
An educational grant from the Colgate-Palmolive Company
Hosted by:
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 for $10 (non-refundable) via the Annual Meeting registration. Dr. Bonner will present an introduction to the topic, challenge participants to discuss specific questions at their tables, and then participants will report responses. More information can be found on page 44.

Past Presidents’ 5K Fun Run/Walk
Tuesday, March 24, 7:00 AM
Embarcadero Marina Park
When you pack for SOT 2015, don’t forget your running shoes so you can join us for the fifth annual Past Presidents’ 5K Fun Run/Walk! Open to anyone interested, this event is a great opportunity to meet old friends and make new acquaintances in a casual environment, joining SOT’s Past Presidents in showing support for SOT. Whether you’re in it for some friendly competition or would rather take a leisurely stroll, this event’s emphasis is on camaraderie and will bring together runners and walkers of all levels and paces. Come join us—we look forward to seeing you!

Register by February 13 to receive a complimentary souvenir t-shirt; visit the Special Events section of the SOT Annual Meeting website to register. Registration is only $20, and all proceeds will go toward the SOT Endowment Fund.
Research Funding Information Room

Tuesday, March 24 and Wednesday, March 25, 9:30 AM to 4:30 PM

Hosted by:
Career Resource and Development 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.

Postdoctoral Assembly Luncheon

Tuesday, March 24, 12:00 Noon to 1:15 PM
(Ticket Required)

Chairperson(s): Colleen McLoughlin, National Institute for Occupational Safety and Health, Morgantown, WV.

Hosted by: Postdoctoral Assembly

To encourage increased participation and networking among postdoctoral scholars, this year the Postdoctoral Assembly (PDA) Board has planned the PDA Luncheon to be more casual than a seated lunch. Finishing up a discussion from your morning poster session? Leaving early to run off to set up a poster or attend another meeting? That’s no problem, come stop in when you can! You can enjoy a buffet lunch and move around the room to mingle with others, including PDA officers, Postdoctoral Representatives, and SOT Councilors. This is the time for postdocs to relax, celebrate achievements, and have fun.

At 12:30 pm there will be a short program including recognition of the Best Postdoctoral Publication Award recipients and postdocs who receive awards from SOT Regional Chapters, Special Interest Groups, and Specialty Sections. PDA officers for 2015–2016 will share their vision for the future. Door prizes are always a big hit and add to the fun of the event. Postdocs should reserve a ticket for $10 when they register for the Annual Meeting.

Undergraduate Educator Network Meeting

Tuesday, March 24, 2:15 PM to 3:30 PM

Chairperson(s): Mindy F. Reynolds, Washington College, Chestertown, MD.

Endorser(s):
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 24, 4:30 PM to 6:00 PM
(SOT Members Only)

Members are invited and encouraged to attend the 54th SOT Annual Business Meeting. The agenda includes discussion of plans for 2015–2016, a financial summary, and a review of the 2014–2015 SOT activities.

Tox ShowDown

Tuesday, March 24, 7:30 PM to 9:00 PM
San Diego Marriott Marquis and Marina

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

Hosted by: 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. Three teams—The Endocrine Distruptors, The Free Radicals, and the Toxic Metabolites—will compete at answering questions concerning toxicology not only in its scientific context, but as it relates to society, the arts, and culture.

Supported 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.
Special Events

Student and Postdoctoral Scholar Events

Student/Postdoctoral Scholar Mixer

Sunday, March 22, 7:30 PM to 9:00 PM

(Ticket Required)

Hosted by:
Graduate Student Leadership Committee

The Graduate Student Leadership Committee hosts this opportunity for students and postdoctoral scholars to gather, meet new colleagues, and 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.

Chat with an Expert

Monday, March 23 to Thursday, March 26

Time Varies by Group

(Meet at the Chat with an Expert Poster in the Registration Area)

Hosted by:
Graduate Student Leadership Committee

The purpose of Chat with an Expert is to provide students and postdoctoral scholars with 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 Poster before proceeding to the meeting location. This program also includes opportunities for postdocs to host informal meetings. Details for each group meeting will be sent to participants in advance of the meeting.

Poster Tours for Trainees

Monday, March 23 to Wednesday, March 25

Time Varies by Group

(Meet at the Poster Tour Board in the Registration Area)

Hosted by:
Postdoctoral Assembly

The Postdoctoral Assembly organizes Poster Tours for Trainees for graduate students and postdoctoral scientists to participate in a one-hour guided poster tour with an expert toxicologist. These small group tours provide the opportunity for trainees to take part in critical evaluation of cutting-edge toxicology methods and research findings and network with an expert toxicologist. Options for graduate students and postdocs to sign up for specific times and topics will be available via the Annual Meeting website.

Trainee Discussion with Plenary Lecturer: Dr. Venter

Monday, March 23, 10:00 AM to 11:00 AM

(Ticket Required; SOT Student and Postdoctoral members only, limited seating)

Chairperson(s): Colleen E. McLoughlin, CDC-NIOSH, Morgantown, WV.

Lecturer: J. Craig Venter, J. Craig Venter Institute, San Diego, CA.

Dr. Venter will meet informally for discussion with graduate students and postdoctoral scholars after his Plenary Opening Lecture (see page 65). 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 23, 12:00 Noon to 1:20 PM

(Ticket Required)

Chairperson(s): Richard Pollenz, University of South Florida, Tampa, FL, Emily G. Notch, Western New England University, Springfield, MA, and Daniel J. Spade, Brown University, Providence, RI.

Lecturer: James C. Bonner, North Carolina State University, Raleigh, NC

Supported by:
An educational grant from the Colgate-Palmolive Company

Alternative In Vitro Approaches for Predicting the Health Impacts of Nanomaterials

Monday, March 23, 10:00 AM to 11:00 AM

(Ticket Required)

Chairperson(s): Colleen E. McLoughlin, CDC-NIOSH, Morgantown, WV.

Lecturer: J. Craig Venter, J. Craig Venter Institute, San Diego, CA.

Dr. Venter will meet informally for discussion with graduate students and postdoctoral scholars after his Plenary Opening Lecture (see page 65). Room size is limited and participants register for a ticket with their Annual Meeting registration.

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 illustrate how these test methods benefit animal welfare by refining, reducing, and eliminating 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 for $10 (nonrefundable) via the Annual Meeting registration. Dr. Bonner will present an introduction to the topic, challenge participants to discuss specific questions at their tables, and then participants will report responses.

The development of in vitro alternative approaches to test chemical toxicity and reduce the need for in vivo rodent testing continues to be a key area of focus for toxicologists. While traditional toxicology methods have relied heavily on animal studies, high-throughput screening approaches to generate toxicological data are becoming increasingly available for the safety assessment of chemicals. The emergence of the nanotechnology revolution has made the
demand for alternative testing more urgent than ever to address a rapidly expanding number and variety of engineered nanomaterials.

Nanotechnology is anticipated to bring societal benefits in the areas of medicine, engineering, electronics, and energy. However, it is also inevitable that some nanomaterials will present risks for disease in humans exposed occupationally or as a result of exposure to consumer products that incorporate nanomaterials. As the number of different types and modifications of nanomaterials in research, development and commercialization continues to grow exponentially, a reliable and robust scientific approach to screen nanomaterial toxicity will require in vitro cell systems that can predict disease in mice and humans in vivo. A promising new toxicological paradigm for nanomaterials will be discussed, using carbon nanotubes as a case study, which utilizes alternative test strategies to reduce reliance on animal testing through the use of in vitro cell-based model systems. The most appropriate types of in vitro systems for predicting specific types of disease (e.g., cancer, fibrosis, asthma) will be addressed for hazard assessment of nanomaterials at various stages of synthesis, product development and overall life cycle.

Postdoctoral Assembly Luncheon

Tuesday, March 24, 12:00 Noon to 1:15 PM
(Ticket Required)

Chairperson(s): Colleen McLoughlin, National Institute for Occupational Safety and Health, Morgantown, WV.

Hosted by: Postdoctoral Assembly

To encourage increased participation and networking among postdoctoral scholars, this year the Postdoctoral Assembly (PDA) Board has planned the PDA Luncheon to be more casual than a seated lunch. Finishing up a discussion from your morning poster session? Leaving early to run off to set up a poster or attend another meeting? That’s no problem; come stop in when you can! You can enjoy a buffet lunch and move around the room to mingle with others, including PDA officers, Postdoctoral Representatives, and SOT Councilors. This is the time for postdocs to relax, celebrate achievements, and have fun. At 12:30 pm there will be a short program including recognition of the Best Postdoctoral Publication Award recipients and postdocs who receive awards from SOT Regional Chapters, Special Interest Groups, and Specialty Sections. PDA officers for 2015–2016 will share their vision for the future. Door prizes are always a big hit and add to the fun of the event. Postdocs should reserve a ticket for $10 when they register for the Annual Meeting.

Undergraduate Student Meeting

Tuesday, March 24, 4:00 PM to 5:00 PM

Chairperson(s): Mindy E. Reynolds, Washington College, Chestertown, MD.
Endorser(s):
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.

Trainee Discussion with Medical Research Council (MRC) Lecturer: Dr. Stockinger

Wednesday, March 25, 9:30 AM to 10:30 AM
(Ticket Required; SOT Student and Postdoctoral members only, limited seating)

Chairperson(s): Kathryn E. Page, University of California Berkeley, Berkeley, CA.
Lecturer: Brigitta Stockinger, MRC National Institute for Medical Research, London, United Kingdom.

Dr. Stockinger will meet informally for discussion with graduate students and postdoctoral scholars after her Keynote MRC Lecture (see page 65). Room size is limited and participants register for a ticket with their Annual Meeting registration.

Education-Career Development Session

Crafting High-Impact Manuscripts: The Process from Hypothesis through Review and Publication

Wednesday, March 25, 4:30 PM to 5:50 PM

Chairperson(s): Caitlin Murphy, University of Texas-Austin, Austin, TX, and Karin Streifel, University of California Davis, Davis, CA.
Endorser(s):
Board of Publications
Career Resource and Development Committee
Postdoctoral Assembly

Hosted by: Postdoctoral Assembly

See full description and other Education-Career Development Sessions page 103.

Publications are an essential component for a successful career across all sectors of toxicology including industry, academia, and government. Although mentors provide informal guidance, students and postdoctoral fellows rarely receive formal training on how to develop a high impact manuscript. A complete understanding of the publication process will benefit junior scientists in formulating research plans, preparing manuscripts, developing manuscript submission strategies, and effectively serving as a reviewer—all important elements in a successful career. This session is designed to provide early-career toxicologists with insight into the publication process from the journal’s perspective. Speakers will focus on: (1) how to craft a high impact manuscript; (2) the role of the associate editor: strategies of selecting reviewers, the expectations of a reviewer and responding to reviewers’ comments; (3) maintaining scholarly productivity in non-academic careers; and (4) publishing in top-tier journals.
Special Events

Education Outreach Activities and Events

High School Poster Exposition
Tuesday, March 24

Chairperson(s): Marie Meagher Bourgeois, University of Southern Florida, Tampa, FL.

Endorser(s):
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 30, 2015. This display recognizes student effort and provides the high school students who have engaged in research with scientific meeting experience. Meeting attendees are invited to drop by to visit with these outstanding potential future toxicologists. More information is available on the SOT Annual Meeting website.

Undergraduate Education Program
Saturday, March 21 to Monday, March 23
Convention Center

Chairperson(s): Kristini Miles, Kimberly-Clark Corporation, Roswell, GA.

Hosted by:
Committee for Diversity Initiatives (CDI)

For schedule details go to www.toxicology.org/ai/meet/am2015/edout.asp.

Saturday, March 21
Open to CDI Travel Awardees.

• 5:15 PM–7:25 PM—Opening Program
• 7:30 PM–8:30 PM—CDI Reunion
Open to anyone previously involved with CDI programs.
• Recognition of the 2015 Perry J. Gehring Diversity Student Travel Award Recipient

Sunday, March 22
Open to CDI Travel Awardees and undergraduates who register through Annual Meeting registration.

• Welcome from SOT President Norbert Kaminski
• Toxicology Lectures
• Interactive Presentation

Monday, March 23
Open to CDI Travel Awardees.
• Students Attend Annual Meeting Sessions with Their SOT Mentors and Small Groups
• In Vitro Lecture and Luncheon for Students
• Program Wrap-Up
Official Journal of the Society of Toxicology

Toxicological Sciences

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For more information visit toxsci.oxfordjournals.org

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

Follow @SOToxicology and @ToxExpo on Twitter
Tweet using #2015SOT and #toxexpo
**4th Annual**

**Tox ShowDown**

Tuesday, March 24, 7:30 PM–9:00 PM
San Diego Marriott Marquis and Marina Hotel

**Calling All Meeting Attendees:**
**Contestants Still Needed!**

Tox ShowDown is a quiz game pitting three teams of toxicologists—The Endocrine Disruptors, The Free Radicals, and The Toxic Metabolites—against each other to see who really knows the most when it comes to toxicological fact and fancy. No ticket is required. Come and watch your peers let their hair down to mark the halfway point of the Annual Meeting.

**Join Us for an Evening of “Tox Trivia” and Fun!**
If you’d like to be a contestant, contact the GSLC Secretary Meghan Cromie or Phil Wexler.

*Hosted by: Graduate Student Leadership Committee (GSLC)*


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**Tuesday, March 24, 2015**

*7:00 AM*

“Come run with the leadership and enjoy the fellowship of SOT”
—William Slikker Jr.
SOT 2012–2013 President

Register by February 13 to receive a commemorative t-shirt!

Please see page 42 for more details.
**RC, SIG, and SS Receptions**

**Regional Chapter Meetings/Luncheons or Receptions**

Monday, March 23, through Wednesday, March 25, Various Times and Locations (Refer to the Annual Meeting Program, Mobile Event App, or Online Planner for more details.)

Many of the SOT Regional Chapters meet during the SOT Annual Meeting.

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allegheny-Erie and Michigan Regional Chapters Joint Reception</td>
<td>Monday, March 23</td>
<td>4:30 PM to 6:00 PM</td>
</tr>
<tr>
<td>Central States Regional Chapter Meeting/Breakfast</td>
<td>Monday, March 23</td>
<td>7:00 AM to 8:00 AM</td>
</tr>
<tr>
<td>Lone Star and South Central Regional Chapters Joint Reception</td>
<td>Tuesday, March 24</td>
<td>5:00 PM to 7:00 PM</td>
</tr>
<tr>
<td>Mid-Atlantic Regional Chapter Meeting/Luncheon</td>
<td>Monday, March 23</td>
<td>12:00 Noon to 1:30 PM</td>
</tr>
<tr>
<td>Midwest and Ohio Valley Regional Chapters Joint Reception</td>
<td>Monday, March 23</td>
<td>5:00 PM to 6:00 PM</td>
</tr>
<tr>
<td>National Capital Area and North Carolina Regional Chapters Joint Reception</td>
<td>Monday, March 23</td>
<td>5:30 PM to 7:30 PM</td>
</tr>
<tr>
<td>Northern California Regional Chapter Meeting/Reception</td>
<td>Tuesday, March 24</td>
<td>7:30 PM to 9:30 PM</td>
</tr>
<tr>
<td>Pacific Northwest Regional Chapter Meeting/Reception</td>
<td>Monday, March 23</td>
<td>5:30 PM to 7:30 PM</td>
</tr>
<tr>
<td>Regional Chapter Collaboration and Communication Meeting</td>
<td>Wednesday, March 25</td>
<td>12:00 Noon to 1:30 PM</td>
</tr>
<tr>
<td>Southeastern Regional Chapter Meeting/Reception</td>
<td>Monday, March 23</td>
<td>6:00 PM to 10:00 PM</td>
</tr>
<tr>
<td>Southern California and Mountain West Regional Chapters Joint Reception</td>
<td>Tuesday, March 24</td>
<td>6:00 PM to 9:00 PM</td>
</tr>
</tbody>
</table>

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

Monday, March 23, through Wednesday, March 25, Various Times and Locations (Refer to the Annual Meeting Program, Mobile Event App, or Online Planner for more details.)

Each of the six Special Interest Groups will hold a meeting/reception during the 2015 SOT Annual Meeting at various local locations. All current and prospective SOT Special Interest Group members are encouraged to attend.

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Association of Chinese in Toxicology/Korean Toxicologists Association in America Special Interest Groups Career Workshop 1: Current US Job Market for Toxicologists</td>
<td>Tuesday, March 24</td>
<td>7:30 AM to 9:00 AM</td>
</tr>
<tr>
<td>American Association of Chinese in Toxicology Special Interest Group Career Workshop 2: Opportunities for Toxicologists in China</td>
<td>Tuesday, March 24</td>
<td>4:00 PM to 5:30 PM</td>
</tr>
<tr>
<td>Association of Scientists of Indian Origin Special Interest Group Meeting/Reception</td>
<td>Monday, March 23</td>
<td>7:00 PM to 9:00 PM</td>
</tr>
<tr>
<td>Association of Scientists of Indian Origin Special Interest Group Lunch and Learn</td>
<td>Tuesday, March 24</td>
<td>12:00 Noon to 2:00 PM</td>
</tr>
<tr>
<td>Hispanic Organization of Toxicologists Special Interest Group Officers Meeting</td>
<td>Monday, March 23</td>
<td>6:45 AM to 8:00 AM</td>
</tr>
<tr>
<td>Hispanic Organization of Toxicologists Special Interest Group Reception</td>
<td>Tuesday, March 24</td>
<td>6:30 PM to 9:00 PM</td>
</tr>
</tbody>
</table>

(continued on page 51)
### Special Events

#### Special Interest Group Meetings/Luncheons or Receptions (continued)

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Korean Toxicologists Association in America Special Interest Group</td>
<td>Monday, March 23</td>
<td>7:00 PM to 9:00 PM</td>
</tr>
<tr>
<td>Meeting/Reception</td>
<td></td>
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</tr>
<tr>
<td>Special Interest Group Collaboration Group Meeting</td>
<td>Monday, March 23</td>
<td>12:00 Noon to 1:30 PM</td>
</tr>
<tr>
<td>Special Interest Group Global Hot Topic Event: Global Drug Development and Natural Products, End of an Era or an Endless Frontier?</td>
<td>Wednesday, March 25</td>
<td>7:00 AM to 8:00 AM</td>
</tr>
<tr>
<td>Women in Toxicology Special Interest Group Executive Board Meeting</td>
<td>Tuesday, March 24</td>
<td>7:45 AM to 8:45 AM</td>
</tr>
<tr>
<td>Women in Toxicology Special Interest Group Meeting/Reception</td>
<td>Wednesday, March 25</td>
<td>4:30 PM to 6:30 PM</td>
</tr>
</tbody>
</table>

#### Specialty Section Meetings/Luncheons or Receptions

**Monday, March 23, through Wednesday, March 25, Various Times and Locations** *(Refer to the Annual Meeting Program, Mobile Event App, or Online Planner for more details.)*

Each of the 27 SOT Specialty Sections will hold either a luncheon or early evening meeting/reception during the 2015 SOT Annual Meeting. All current and prospective SOT Specialty Section members are encouraged to attend.

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological Modeling Specialty Section Meeting/Reception</td>
<td>Wednesday, March 25</td>
<td>6:00 PM to 7:30 PM</td>
</tr>
<tr>
<td>Biotechnology Specialty Section Meeting/Reception</td>
<td>Wednesday, March 25</td>
<td>6:00 PM to 7:30 PM</td>
</tr>
<tr>
<td>Carcinogenesis Specialty Section Meeting/Reception</td>
<td>Monday, March 23</td>
<td>6:00 PM to 7:30 PM</td>
</tr>
<tr>
<td>Cardiovascular Toxicology Specialty Section Meeting/Reception</td>
<td>Tuesday, March 24</td>
<td>6:00 PM to 7:30 PM</td>
</tr>
<tr>
<td>Clinical and Translational Toxicology Specialty Section Meeting/Reception</td>
<td>Wednesday, March 25</td>
<td>6:00 PM to 7:30 PM</td>
</tr>
<tr>
<td>Clinical and Translational Toxicology Specialty Section Officers Meeting</td>
<td>Monday, March 23</td>
<td>6:30 AM to 8:00 AM</td>
</tr>
<tr>
<td>Comparative and Veterinary Specialty Section Meeting/Luncheon</td>
<td>Monday, March 23</td>
<td>6:00 PM to 7:30 PM</td>
</tr>
<tr>
<td>Dermal Toxicology Specialty Section Meeting/Reception</td>
<td>Wednesday, March 25</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Dermal Toxicology Specialty Section Officers Meeting</td>
<td>Monday, March 23</td>
<td>6:30 AM to 8:00 AM</td>
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<tr>
<td>Drug Discovery Toxicology Specialty Section Meeting/Reception</td>
<td>Tuesday, March 24</td>
<td>6:00 PM to 7:30 PM</td>
</tr>
<tr>
<td>Ethical, Legal, and Social Issues Specialty Section Meeting/Luncheon</td>
<td>Wednesday, March 25</td>
<td>12:00 Noon to 1:00 PM</td>
</tr>
<tr>
<td>Food Safety Specialty Section Meeting/Reception</td>
<td>Tuesday, March 24</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Food Safety Specialty Section Officers Meeting</td>
<td>Monday, March 23</td>
<td>6:30 AM to 8:00 AM</td>
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<tr>
<td>Immunotoxicology Specialty Section Meeting/Reception</td>
<td>Tuesday, March 24</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Immunotoxicology Specialty Section Officers Meeting</td>
<td>Monday, March 23</td>
<td>6:30 AM to 8:00 AM</td>
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*(continued on page 53)*
## Council

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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<tbody>
<tr>
<td>Norbert E. Kaminski</td>
<td>President</td>
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<tr>
<td>Peter L. Goering</td>
<td>Vice President</td>
</tr>
<tr>
<td>John B. Morris</td>
<td>Vice President-Elect</td>
</tr>
<tr>
<td>Leigh Ann Burns Naas</td>
<td>Secretary</td>
</tr>
<tr>
<td>Denise Robinson Gravatt</td>
<td>Treasurer</td>
</tr>
<tr>
<td>George P. Daston</td>
<td>Treasurer-Elect</td>
</tr>
<tr>
<td>Lois D. Lehman-McKeeman</td>
<td>Past President</td>
</tr>
<tr>
<td>Aaron Barchowsky</td>
<td>Councilor</td>
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<tr>
<td>Lorrene Buckley</td>
<td>Councilor</td>
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<tr>
<td>Myrtle A. Davis</td>
<td>Councilor</td>
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<tr>
<td>Ofelia A. Olivero</td>
<td>Councilor</td>
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<tr>
<td>Ivan Rusyn</td>
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<tr>
<td>John A. Wisler</td>
<td>Councilor</td>
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<tr>
<td>Ivan Rusyn</td>
<td>Councilor</td>
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<tr>
<td>John A. Wisler</td>
<td>Councilor</td>
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</table>

## Continuing Education Committee

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
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<tbody>
<tr>
<td>Qiyu Jay Zhao</td>
<td>Chair</td>
</tr>
<tr>
<td>Gary O. Rankin</td>
<td>Co-Chair</td>
</tr>
<tr>
<td>Gayathri Chadalapaka</td>
<td>Member</td>
</tr>
<tr>
<td>Kimberly A. Henderson</td>
<td>Member</td>
</tr>
<tr>
<td>Michael F. Hughes</td>
<td>Member</td>
</tr>
<tr>
<td>Saber M. Hussain</td>
<td>Member</td>
</tr>
<tr>
<td>William B. Mattes</td>
<td>Member</td>
</tr>
<tr>
<td>Monica A. Otieno</td>
<td>Member</td>
</tr>
<tr>
<td>James Wagner</td>
<td>Member</td>
</tr>
<tr>
<td>Galen Miller</td>
<td>Postdoctoral Representative</td>
</tr>
<tr>
<td>Sanket Gadhia</td>
<td>Student Representative</td>
</tr>
</tbody>
</table>

## Scientific Program Committee

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peter L. Goering</td>
<td>Chair</td>
</tr>
<tr>
<td>John B. Morris</td>
<td>Co-Chair</td>
</tr>
<tr>
<td>William D. Atchison</td>
<td>Member</td>
</tr>
<tr>
<td>Jeanine L. Bussiere</td>
<td>Member</td>
</tr>
<tr>
<td>Michael J. Carvan III</td>
<td>Member</td>
</tr>
<tr>
<td>Brian J. Day</td>
<td>Member</td>
</tr>
<tr>
<td>Mary Beth Genter</td>
<td>Member</td>
</tr>
<tr>
<td>B. Bhaskar Gollapudi</td>
<td>Member</td>
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<tr>
<td>Paul C. Howard</td>
<td>Member</td>
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<tr>
<td>Donald R. Mattison</td>
<td>Member</td>
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<tr>
<td>Barry S. McIntyre</td>
<td>Member</td>
</tr>
<tr>
<td>David Ross</td>
<td>Member</td>
</tr>
<tr>
<td>Timothy P. Reilly</td>
<td>Member</td>
</tr>
<tr>
<td>Lisa M. Sweeney</td>
<td>Member</td>
</tr>
</tbody>
</table>
### Special Events

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

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
<th>Time</th>
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<tbody>
<tr>
<td>In Vitro and Alternative Methods Specialty Section Meeting/Luncheon</td>
<td>Wednesday, March 25</td>
<td>12:00 Noon to 1:00 PM</td>
</tr>
<tr>
<td>In Vitro and Alternative Methods Specialty Section Officers Meeting</td>
<td>Monday, March 23</td>
<td>6:30 AM to 8:00 AM</td>
</tr>
<tr>
<td>Inhalation and Respiratory Specialty Section Meeting/Reception</td>
<td>Monday, March 23</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Mechanisms Specialty Section Meeting/Reception</td>
<td>Wednesday, March 25</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Medical Device and Combination Product Specialty Section Meeting/Reception</td>
<td>Tuesday, March 24</td>
<td>6:00 PM to 7:30 PM</td>
</tr>
<tr>
<td>Metals Specialty Section Meeting/Reception</td>
<td>Tuesday, March 24</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Molecular and Systems Biology Specialty Section Meeting/Reception</td>
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<td>Nanotoxicology Specialty Section Meeting/Reception</td>
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<td>Neurotoxicology Specialty Section Meeting/Reception</td>
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<td>Neurotoxicology Specialty Section Officers Meeting</td>
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<tr>
<td>Occupational and Public Health Specialty Section Meeting/Luncheon</td>
<td>Tuesday, March 24</td>
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<tr>
<td>Ocular Toxicology Specialty Section Meeting/Reception</td>
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<td>Regulatory and Safety Evaluation Specialty Section Brown Bag Luncheon Session: Global Regulatory Toxicology: First Stop EU</td>
<td>Tuesday, March 24</td>
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<td>Regulatory and Safety Evaluation Specialty Section Meeting/Reception</td>
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<td>Regulatory and Safety Evaluation Specialty Section Officers Meeting</td>
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<tr>
<td>Reproductive and Developmental Toxicology Specialty Section Meeting/Reception</td>
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<td>Reproductive and Developmental Toxicology Specialty Section Officers Meeting</td>
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<td>Risk Assessment Specialty Section Meeting/Reception</td>
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<td>Risk Assessment Specialty Section Officers Meeting</td>
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<tr>
<td>Specialty Section Collaboration and Communication Group Meeting</td>
<td>Monday, March 23</td>
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<tr>
<td>Stem Cells Specialty Section Meeting/Reception</td>
<td>Wednesday, March 25</td>
<td>6:00 PM to 7:30 PM</td>
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<tr>
<td>Toxicologic and Exploratory Pathology Specialty Section Meeting/Luncheon</td>
<td>Monday, March 23</td>
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**CEd-Tox**

**Continuing Education Courses Online**

CEd-Tox offers a great, affordable way to expand your professional development or stay current in the field of toxicology, all year long. Forty-one diverse CE courses from past SOT Annual Meetings are now available, including slide presentations and audio. **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](http://www.toxicology.org/cedtox.asp).

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

### Dermal Toxicology:

### Drug Discovery Toxicology:
- The What, When, and How of Nonclinical Support for an IND Submission (2013)*

### Food Safety:

### 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* Toxicology 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)*
- Inhalation Studies: Challenges and Complexities (2014)

### Mechanics:
- Computational and Experimental Aspects of microRNAs in Toxicology (2014)

### Medical Device:
- Combination Products: Toxicology and Regulatory Challenges (2014)

### Metals:
- Toxic Effects of Metals (2013)*

### Mixtures:
- Toxicology and Risk Assessment of Chemical Mixtures (2011)*

### Molecular and Systems 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)

### Neurotoxicology:
- The Practice and Implementation of Neural Stem Cell-Based Approaches to Neurotoxicology (2013)

### 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:
- Current Trends in Genetic Toxicology Testing (2014)
- 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:
- Basic Principles of Risk Assessment (2013)*
- Best Practices for Developing, Characterizing, and Applying Physiologically-Based Pharmacokinetic Models in Risk Assessment (2011)
- Epidemiology for Toxicologists: What the Numbers Really Mean (2014)

### 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)

*English Language Transcription Available*
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 22, 2015, at the San Diego 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.

New Horizons in Chemical Carcinogenesis: Advances in Mode of Action and Mechanism of Cancer Pathogenesis

Chairperson(s): James E. Klaunig, Indiana University, Bloomington, IN, and Udayan M. Apte, University of Kansas Medical Center, Kansas City, KS.

Endorser(s):
- Carcinogenesis Specialty Section

The ability of chemicals to cause cancer is an endpoint with a deep impact on public health. Understanding the mode of action of chemical carcinogens is critical for risk assessment of the chemicals. The mechanisms by which chemicals can cause cell transformation and neoplastic growth have been central to the discipline of toxicology. It is now apparent that the previous simplistic view that chemicals interact with DNA, inducing a mutation which results in the formation of a neoplasm, is incomplete. Chemical modulation of metabolism, nuclear receptors, gene expression, DNA repair processes, immune surveillance, inflammation, cell-to-cell communication, and changes in target cell function and structure, and their ability to activate stem/progenitor cells, contribute to the formation of preneoplastic cells and their progression to the malignant state. The multitude of changes in the target cell and its microenvironment must be considered in applying mode of action analysis to potential carcinogenic human risk. Besides the estrogen, CAR, PPAR, and AHR receptors, other nuclear receptors, including HNF4a, TR, Nur77, and LXR, previously not associated with cancer pathogenesis, appear to play a critical role in the formation and progression of cancer. While the role of these receptors in metabolic processes and differentiation has been known, new studies indicate these proteins are central in cancer pathogenesis via either their canonical or non-canonical actions driven by chemical exposure. This course will review our current level of understanding of chemical carcinogenesis as well as discussing some new frontiers that have implications in cancer pathogenesis from chemical exposure.

- New Horizons in Chemical Carcinogenesis: Advances in Mode of Action and Mechanism of Cancer Pathogenesis. James E. Klaunig, Indiana University, Bloomington, IN, and Udayan M. Apte, University of Kansas Medical Center, Kansas City, KS.
An Introduction to the Exposome

**AM02**  
*Strategies for Exposure and Risk Assessments*

**Chairperson(s):** Gary W. Miller, Emory University, Atlanta, GA, and Martyn T. Smith, University of California Berkeley, Berkeley, CA.

**Endorser(s):**  
Mixtures Specialty Section  
Postdoctoral Assembly  
Risk Assessment Specialty Section

The exposome has been defined as the totality of our exposures throughout our lifetime. Such a definition defies measurement, making it less than useful as a scientific construct. More recently, the concept of the exposome has evolved to represent a measurable entity that encompasses our complex exposures and how our bodies respond to such exposures. The addition of the biological response component to the definition of the exposome positions the field of toxicology to make major contributions to the field. By providing an intellectual foil to the genome-centric framework in biomedical research, the exposome has the potential to elevate the importance of the environment in health and disease. This course will introduce the attendees to the concept of the exposome, explain how it can be used to advance toxicological research by providing a clear translational output, and explain some of the innovative approaches being used to measure the exposome. In order for the exposome to become a useful concept it will be necessary to: (1) capture and quantify the complex exposures, (2) identify and quantify the diverse biological responses, and (3) integrate these disparate datasets with advanced conceptual thinking and innovative bioinformatic and mathematical approaches. This course was designed to address these three objectives in an informative and interactive setting.

- **The Exposome: Introduction and Implications for Toxicology.** Gary W. Miller, Emory University, Atlanta, GA.
- **The Blood Exposome.** Martyn T. Smith, University of California Berkeley, Berkeley, CA.
- **Exposome Bioinformatics: EWAS and Beyond.** Chirag J. Patel, Harvard Medical School, Boston, MA.

Demystifying Mixtures: From Study Design Selection to Risk Assessment Application

**AM03**  
*Strategies for Exposure and Risk Assessments*

**Chairperson(s):** Jane Ellen Simmons, US EPA, Research Triangle Park, NC, and Cynthia V. Rider, NIEHS, Research Triangle Park, NC.

**Endorser(s):**  
Mixtures Specialty Section  
Occupational and Public Health Specialty Section  
Risk Assessment Specialty Section

Assessing chemical mixture toxicity is often considered an intractable problem. Difficulty increases for complex mixtures as much of their composition is typically unknown. Although mixtures toxicology and risk assessment (RA) are more complex than for single chemicals due to potential interactions, significant advances have been made in recent years. As a number of experiments are designed poorly from a mixtures perspective, this course will provide coherent strategies for design, analysis of mixtures experiments for robust conclusions, and data that are useful in mixtures RA. Key principles and concepts underlying modern mixtures toxicology, RA, legislation, policy, and guidance in the United States and other nations will be reviewed. Guidance based on data quality will be provided for application of either whole mixture or component-based RA approaches. Whole mixture RA discussions will include recent research on methods to determine whether mixtures are sufficiently similar such that toxicity information for one mixture can be used to estimate the toxicity of another. Most mixtures RAs are component-based and a number of approaches will be illustrated—highlighting key differences. Those include the hazard index (HI), target organ HI, interaction weighted HI, and index-chemical based (relative potency factor and toxic equivalency factor) approaches. This course emphasizes recent advances and will be of value to experimentalists wanting to conduct mixture studies meaningful for evaluation of risk or safety, and risk assessors who evaluate mixtures data and apply mixtures RA methods.

- **Regulatory Drivers and Available Resources.** Moiz Mumtaz, CDC, ATSDR, Atlanta, GA.
- **Berenbaum and Beyond: Concepts and Theories Underlying Mixtures Research and Cumulative Risk Assessment.** Cynthia V. Rider, NIEHS, Research Triangle Park, NC.
- **Designing the Good, Eliminating the Bad and the Ugly.** Jane Ellen Simmons, US EPA, Research Triangle Park, NC.
- **Data Quality Assessment and Whole Mixture Assessments (Mixture of Concern, Sufficiently Similar Mixture, Group of Similar Mixtures).** Glenn Rice, US EPA, Cincinnati, OH.
- **Component-Based Additivity Approaches: Benefits and Uncertainties.** Richard Hertzberg, Emory University, Atlanta, GA.
of large molecules, cells, and other novel therapies directly to the central
inability of large molecules to bypass the blood-brain barrier. Delivery
treated by traditional systemic delivery methods, partly because of the
Many diseases affecting the central nervous system (CNS) are inadequately
treated by traditional systemic delivery methods, partly because of the
is targeted to pathologists, toxicologists, administrators, and regulatory
of results, and considerations for special endpoints in the studies. The course
is targeted to pathologists, toxicologists, administrators, and regulatory
personnel who may need to design, conduct, or review these complicated but
increasingly worthwhile investigations.

- Development of CNS Administered Biologics: Overview, Challenges,
  and a Case History. Brian R. Vuillemenot, Genentech, Inc., South
  San Francisco, CA.  
- Procedures of Intrathecal Drug Delivery and CSF Sampling in Juvenile
  Nonhuman Primate Studies. Sven H. Korte, Covance Laboratories GmbH, Muenster, Germany.  
- Intraparenchymal CNS Delivery. Robert B. Boyd, Northern Biomedical
  Research, Inc., Spring Lake, MI.  
- Morphologic Assessment of Studies Involving Direct Delivery to the
  CNS. Mark T. Butt, Tox Path Specialists, LLC, Frederick, MD.  
- Translation of Nonclinical Intrathecal Data to the Clinic. Teresa L.
  Wright, Shire, Lexington, MA.  

In this new age of predictive toxicity, adverse outcome pathways, and
replacements for traditional testing designs, the world of developmental and
reproductive toxicology is the final frontier. The sheer complexity of a devel-
oping mammalian embryo/fetus coupled to, and dependent upon, maternal
care to follow the prespecified path toward normal development still holds
many mysteries. In the past several years, there have been breakthroughs
in our thinking of developmental and reproductive toxicology alternative
assays that now take what was once inconceivable to something that is
merely on the horizon. The course focus will be to explore several different
examples utilizing novel model system approaches to predict reproductive
and developmental toxicity endpoints. The course will include an introduc-
tory overview on the history of this area and the unique challenges upon
finding alternatives for reproductive and developmental assays. Fundamental
developmental processes including the roundworm, C. elegans, as a model
organism for prediction of germline toxicities, will be presented. The course
will explore alternative vertebrate models and gain insights on the opportuni-
ties and challenges with the popular zebrafish as an alternative model for
evaluating developmental toxicity and novel downstream safety assessment
applications. The course will conclude with presentations on how different
alternative assays such as whole embryo culture, zebrafish, and embryonic
stem cells can be coupled together to develop a fingerprint to predict develop-
mental toxicity, and a presentation about how the interrogation of different
developmental pathways can be combined with computational approaches
to develop virtual developmental and reproductive toxicity platforms, such
as the virtual embryo. Scientists at multiple levels (graduate students to
very experienced scientists) in academia, government, or industry who are
interested in learning the current state of the science for developmental and
reproductive toxicity assessment are encouraged to attend this course. Course
learning objectives are: (1) The current state of the science for different
approaches in understanding potential for developmental and reproduc-
tive toxicity; (2) unique challenges and opportunities that exist within
the developmental and reproductive toxicity assessment area compared to other
disciplines within toxicology; (3) the pros and cons of utilizing single model
species tools versus combining multiple species for predictive assays; and (4)
steps that are underway for the longterm replacement of these studies with
approaches in bioprofiling combined with computational modeling.

- Introduction and Overview. Reza J. Rasoulpour, Dow AgroSciences,
  Indianapolis, IN.
Continuing Education

• Utilizing C. elegans As a Predictive Model for Germline Disruption. Patrick Allard, University of California Los Angeles, Los Angeles, CA.

• Alternative Development Toxicity Assessment Using Zebrafish—Routine Safety Assessment and Applications. Douglas Fort, Fort Environmental Laboratories, Stillwater, OK.

• Combining Rodent Whole Embryo Culture, Zebrafish, and Embryonic Stem Cell Assays to Generate Predictive Signatures. Karen Augustine, Bristol-Myers Squibb Company, Pennington, NJ.

• Building Cellular Pathways for the Future—The Virtual Embryo. Thomas B. Knudsen, US EPA, Research Triangle Park, NC.

The New World of Cancer Immunotherapy: Challenges in Bench to Bedside Translation

AM06 CE BASIC

Advancing Clinical and Translational Toxicology

Chairperson(s): Rodney Prell, Genentech Inc., South San Francisco, CA, and Rafael A. Ponce, Amgen, Seattle, WA.

Endorser(s):

Biotechnology Specialty Section
Immunotoxicology Specialty Section

The concept of harnessing the immune system to eradicate cancer has been a long-term goal in immunology and oncology. After years of disappointment, the field of cancer immunotherapy (CIT) has gained a strong foothold with the recent approval of two immunotherapies (ipilimumab and sipuleucel-T), and encouraging data emerging from clinical trials testing checkpoint inhibitors, chimeric antigen T cells, oncolytic vaccines, and other modalities. This intensifying effort to identify new CIT targets and/or develop new modalities will illustrate the challenges. Unique clinical challenges of developing CIT molecules, and the regulatory perspective on the need for nonclinical, clinical, and regulatory scientists to partner to ensure patient safety when developing CIT molecules, will also be presented.

• Introduction into the Transformative World of Cancer Immunotherapy. Rodney Prell, Genentech Inc., South San Francisco, CA.

• Developing Novel Nonclinical Models to Improve CIT Drug Development. Keith A. Bahjat, Providence Cancer Center, Portland, OR.

• Ipilimumab Nonclinical Safety Assessment: Lessons Learned. Helen G. Haggerty, Bristol-Myers Squibb, New Brunswick, NJ.

• Clinical Perspective: Approaches and Challenges to CIT Development. Willem Overwijk, MD Anderson Cancer Center, Houston, TX.

• Approaches and Challenges for Cancer Immunotherapy from a Regulatory Perspective. Stacey Ricci, US FDA, Silver Spring, MD.

Toxicology and Regulatory Considerations for Combination Products

AM07 CE BASIC

Safety Assessment Approaches for Product Development

Chairperson(s): Jon N. Cammack, AstraZeneca Biologics, Gaithersburg, MD, and Chandramalika (Molly) Ghosh, US FDA, Silver Spring, MD.

Endorser(s):

Drug Discovery Toxicology Specialty Section
Medical Device and Combination Product Specialty Section
Regulatory and Safety Evaluation Specialty Section

Therapeutic and diagnostic products that combine drugs, devices, and/or biological elements are termed, and regulated by the US FDA, as combination products. Technological advances continue to merge product types and blur the historical lines of separation between traditional drugs, biologics, and medical devices. Further, the increasing use of absorbable platforms adds another level of complexity to the development and regulation of certain combination products. US FDA's medical product centers, the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH), are utilizing evolving collaborative efforts in order to address the regulatory challenges of combination products. Because combination products involve components that would normally be developed and regulated under different types of processes and policies, and frequently submitted to different US FDA centers, these products raise challenging development, regulatory, and review management questions. Differences in these pathways for each combination product type can impact the processes for all aspects of product development and management, especially preclinical testing, but also clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, and post-approval modifications. The 2014 Sunrise Combination Products CE course introduced the emerging topic; the 2015 CE course will provide in-depth detail on the evolving regulatory processes in developing a successful preclinical evaluation program. In addition to examples of product develop-
The course will conclude with a presentation that provides practical guidance on the derivation of exposure limits for leachable chemicals released from medical devices. Presentations will provide an overview of the biocompatibility test methods recommended by ISO 10993, US Pharmacopeia, and ASTM and will include examples of test failures and how to resolve them without compromising patient safety. The course will begin with a broad overview of the approaches used to evaluate the biological safety of medical devices. Following the introductory talk, there will be presentations on two high profile and toxicologically important topics, the potential health risks associated with the use of metallic hip implants and approaches to evaluating the biological safety of plastic dental materials. One challenge in conducting toxicological risk assessments of compounds released from medical device materials is when there are no adequate toxicity data for these compounds. The course will conclude with a presentation that provides practical guidance on the derivation of exposure limits for leachable chemicals released from medical devices when only limited toxicity data are available. This course should be of broad interest to toxicologists and health care professionals involved in evaluating patient risks to new treatment modalities, and in particular to toxicologists involved in evaluating the safety of medical devices and combination products containing drugs or biologics.

- **Methods in Assessing the Biocompatibility of Medical Devices.** Niranjan S. Goud, Boston Scientific Corporation, Spencer, IN.
- **Derivation of Tolerable Intake Values for Compounds with Limited Toxicity Data.** Ron Brown, US FDA, Silver Spring, MD.

### Interpretation of Cardiovascular Safety Data in Toxicology Studies

**PM09 CE ADVANCED**

**Safety Assessment Approaches for Product Development**

**Chairperson(s):** John J. Kremer, Covance Laboratories Inc., Madison, WI, and Hong Wang, Genentech, Inc., South San Francisco, CA.

**Endorser(s):**
- Cardiovascular Toxicology Specialty Section
- Drug Discovery Toxicology Specialty Section
- Regulatory and Safety Evaluation Specialty Section

The value of integrating cardiovascular (CV) safety evaluation into general toxicology studies has been increasingly recognized in drug development for both pharmaceutical and biotechnology-derived products. These combined study approaches offer a unique opportunity to gain a holistic understanding of drug-related functional, biochemical, and morphological changes in the context of proper pharmacokinetic/pharmacodynamic (PK/PD) data. Past courses have focused on the best practices including study design and execution for integrating CV endpoints into toxicology studies. This course will provide a comprehensive and detailed discussion on the interpretation of CV findings as part of a toxicology study. For example, how are CV functional data interpreted (e.g. heart rate, blood pressure, electrocardiogram, contractility) as compared to traditional endpoints (e.g. pathology). Is a physiological finding (e.g. a decrease in contractility) a primary effect or a compensatory effect to other changes? Is it due to a direct CV effect or secondary to drug-related toxicity? How/when should a CV finding be interpreted as a “hazard” versus “adverse”? What are the potential mechanisms for toxicity? How do I utilize the holistic data to design the next steps? How does surgically implanted instrumentation affect or potentially confound a pathology evaluation? The course will start with outlining the questions and focus on how these assessments are used and interpreted in this emerging paradigm of combined CV/toxicology studies. The target audience consists of toxicologists who may have limited exposure to CV or safety pharmacology data or are looking to expand their knowledge in this area. By the end of this symposium, the audience should better understand the considerations...
and strategies in integrating CV/toxicology studies as well as real-world case studies (or best practices) for interpretation of these data for drug safety assessment.

• Study Design Considerations to Improve Cardiovascular Safety Assessment. John J. Kremer, Covance Laboratories Inc., Madison, WI.

• Hemodynamic Data: Toward Maximal Information Extraction. Bari Olivier, Michigan State University, East Lansing, MI.

• Pathologist Viewpoint on Mapping Physiological Data to Other Indices of Toxicity Including Histopathology. Wendy Halpern, Genentech, Inc., South San Francisco, CA.

• Doxorubicin in NHPs: A Case Study in Using Multiple Parameters to Assess CV Function As Part of a Toxicology Study. Michael Engwall, Amgen, Thousand Oaks, CA.

Is Synthetic Biology the Future of Toxicology?

PM10 CE ADVANCED

Safety Assessment Approaches for Product Development


Endorser(s):

In Vitro and Alternative Methods Specialty Section

One frequent critique of traditional in vitro study design is lack of functional correlation between a submerged cellular monolayer and a full organ or tissue system. However, scientists do agree that during preliminary toxicological screening, when little is known regarding the behavior of a new molecule, simple in vitro models coupled with basic toxicological endpoints are critical for generating a baseline response and determining future actions. Currently, a significant discrepancy exists between in vitro and in vivo correlations. One approach to bridge this gap is through the development of enhanced in vitro systems that more closely mimic an accurate physiological environment. When examining a physiological system, two key components to be addressed are: (1) the three dimensional aspect of an organ or tissue and the cell to cell communication that occurs within this structure; and (2) the dynamic environment that flows in and around the tissue, arising from the cardiovascular system. Early improvements in traditional in vitro designs explored co cultures that included immune cells, the addition of dynamic media flow, and three dimensional matrices (though limited studies have combined multiple of these variables). The focus of the course is to evaluate the current trends in synthetic biology that are advantageous to enhanced in vitro design. One major focus will be on current organ-on-a-chip research, which incorporates cell to cell communication coupled with dynamic flow of media or air, depending on cell type. In addition, since inhalation is a predominant route of toxicological exposure, this course will explore the design of an artificial nose that represents inhalation and the ability of a compound to cross the olfactory bulb in an effort to predict a neurotoxicity risk.

• Introduction. Saber M. Hussain, US Air Force, Wright-Patterson AFB, OH.


• Developing Microengineered Models of Liver Toxicology. Salman R. Khetani, Colorado State University, Fort Collins, CO.

• Microvascular Systems on a Chip. Kapil Pant, CFD Research Corporation, Huntsville, AL.

• Development of Artificial Respiratory Device for Nanomaterial Toxicity. Lei Kerr, Miami University, Miami, OH.

Skeletal System Endocrinology and Toxicology

PM11 CE BASIC

Safety Assessment Approaches for Product Development

Chairperson(s): Alan M. Hoberman, Charles River Laboratories, Horsham, PA, and Susan Y. Smith, Charles River Laboratories, Senneville, QC, Canada.

Endorser(s):

Clinical and Translational Toxicology Specialty Section

Immunotoxicology Specialty Section

Reproductive and Developmental Toxicology Specialty Section

The skeleton has traditionally been considered within the framework of two tenets: A hard structure for protection of the organism, and a major reservoir for the maintenance of serum calcium. Bone remodeling, the process of remaking our skeleton every decade, reinforces that structure/function correlate. However, emerging evidence suggests the skeleton is intimately related to other organ systems, including but not limited to organs involved in energy metabolism, reproductive system, immune system, central nervous system, and muscle, through paracrine, endocrine, and neural networks. The goal of this course is to explore these interactions further and highlight the importance of including skeletal evaluations in juvenile and standard toxicology studies and their relevance to humans and clinical trials. In addition, an overview of bone biology and the appropriate techniques for assessment of changes in bone will be provided. The presentations will focus on bone biology, its growth during infancy and childhood, and the regulatory systems involved in the maintenance of bone quality during adulthood; the techniques available for bone evaluations in toxicology studies; why bone has recently been accepted as an endocrine system and what the functions of hormones secreted from bone are; and the complex relationships unfolding between bone and the different biological systems, and the implications in drug development.

• Primer on Bone Biology: Cells, Matrix, and Mineral in Skeletal Modeling and Remodeling. Marc D. McKee, McGill University, Montréal, QC, Canada.

• State of the Art Assessment of Bone Tissue in Preclinical Studies. Aurore Varela, Charles River Laboratories, Montréal, QC, Canada.

• Bone As an Underappreciated Endocrine System. Clifford Rosen, Maine Medical Center Research Institute and Tufts University, Scarborough, ME.

• The Cross Talk between Bone and Other Biological Systems. Rana Samadfam, Charles River Laboratories, Montréal, QC, Canada.
Strategies in Investigative Toxicology in a Pharmaceutical Setting

PM12 CE BASIC

Chairperson(s): Damir Simic, Janssen R&D (Johnson & Johnson), Spring House, PA, and Mausumee Guha, Medivation—Toxicology, San Francisco, CA.

Endorser(s):
Drug Discovery Toxicology Specialty Section
Molecular and Systems Biology Specialty Section
Risk Assessment Specialty Section

Investigative toxicology is a broad discipline encompassing multiple tools and strategies to help generate and test hypotheses as part of target safety assessments and derisking efforts in support of discovery and development programs. In most pharmaceutical and biotechnology companies, investigative toxicology exists as either a stand-alone lab, or the function is embedded within various support groups. Discovery and development programs that call upon investigative toxicology to manage safety liabilities and facilitate understanding of toxicity issues face a number of challenges. These include adequate communication across stakeholders, steep learning curves, identification of clear deliverables that require resource prioritization, and constantly shifting interests. This “best practices” session will highlight steps for how to overcome such challenges by focusing on three key functions: (1) designing a testable hypothesis, (2) communication of the meaningful experimental findings, and (3) proposing rationales and decision processes for the timely resolution of the issue(s). Specifically, best practices will be highlighted in relation to the stage of the program within the R&D pipeline. The presenters will focus on optimal investigative toxicology strategies applicable during target safety evaluation, lead optimization, pre-IND, IND, late stages of the compound development, and life cycle management, with case examples. The utility of tools such as genomics, RNAi, metabolomics, in vitro assays and informatics for the integration of supportive data (e.g. clinical chemistry, histopathology, TK, and biomarkers), and application of communication tools such as MindMaps will be discussed. Finally, a regulatory perspective on the utility, impact, and practical considerations of submitting investigative toxicology studies to regulatory authorities to assess clinical risk will be presented.

- A Roadmap to Effective Investigative Toxicology Safety Assessment, De-Risking, and Communication. Damir Simic, Janssen R&D (Johnson & Johnson), Spring House, PA.
- Investigating Mechanisms of Toxicity of Pharmaceuticals during Late Stage Development and Life Cycle Management. Mausumee Guha, Medivation—Toxicology, San Francisco, CA.
- A Regulatory Perspective on Investigative Toxicology. Janice A. Lansita, Tox Strategies, Baltimore, MD.

Toxicogenomics Meets Regulatory Decision-Making: How to Get Past Heat Maps, Network/Pathway Diagrams, and “Favorite” Genes

PM13 CE ADVANCED

Chairperson(s): Frederick J. Rusyn, Texas A&M University, College Station, TX, and Russell S. Thomas, US EPA, Research Triangle Park, NC.

Endorser(s):
Biological Modeling Specialty Section
Molecular and Systems Biology Specialty Section
Risk Assessment Specialty Section

Toxicogenomics is a mature field which provides invaluable information on the molecular events preceding or accompanying toxicity; however, most traditional use of gene expression and other ‘omic data in toxicology is largely the same as it was ten years ago: the mode-of-action analysis, classification/prediction, and biomarker discovery. As the technological advances keep driving costs down and information content and reproducibility up, the toxicogenomics data has begun to be used more widely in the human health assessments of chemicals, and will likely be one of the crucial information sources for next-generation of risk assessment decisions. Given the general familiarity of the toxicologists with high-dimensional transcriptional profiling data and major traditional ways in which such data are analyzed, presented, and interpreted, this course is designed to demonstrate how the toxicogenomics data can become a key element in hazard identification, dose-response analysis and selection of scientifically-justifiable uncertainty factors. By superimposing the opportunities that are now afforded by both traditional and high-throughput genomics data onto the human health assessment paradigm, this course will be informative to the risk assessment practitioners and the toxicology research community, and increase the scientific impact of the fundamental toxicology studies.

- Gene Expression Profiling for Regulatory Decision-Making: Many Genes or Many Samples? David Gerhold, NIH, Bethesda, MD.
- Hazard Identification and Toxicogenomic Data: Read-Across Using High-Dimensional Biological Data. Ivan Rusyn, Texas A&M University, College Station, TX.
- Gene Expression and Genetic Variability. Fred A. Wright, North Carolina State University, Raleigh, NC.
Meet the Editor-in-Chief of *Toxicological Sciences*
Gary W. Miller
SOT Pavilion
Monday–Wednesday
March 23–25

Stay Current During the 54th Annual Meeting and ToxExpo

During the 54th Annual Meeting and ToxExpo, Society of Toxicology reporters will provide up-to-date commentary on the 2015 Annual Meeting scientific sessions through the SOT *Communiqué* blog. Additionally, up-to-date news about the toxicological research, technology, and innovations of the Annual Meeting and ToxExpo will be available through SOT’s Facebook and Twitter feeds (@SOToxicology and @ToxExpo).

Want to join the conversations? Email marcia@toxicology.org to become an SOT reporter or use #2015SOT and #ToxExpo when posting to your own Facebook and Twitter accounts for all content related to the meeting.
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 Conferences 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](http://www.toxicology.org/cct).

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

- **FutureTox III: Transforming 21st Century Science into Risk Assessment and Regulatory Decision-Making**
  - November 19–20, 2015
  - Arlington, Virginia

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 sponsorship and/or endorsement by the Society of Toxicology.
Building for the Future

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

Since its inception in 2006, contributors to the Endowment Fund have:

- Underwritten more than 140 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 toxicology educators 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.

Your contribution is worth twice as much thanks to the 1-to-1 dollar match that the Society will make for all donations made prior to June 30, 2016, or until $400,000 in matching funds are expended.

Please help SOT continue to make a difference by becoming a contributor to the SOT Endowment Fund. For more information, visit www.toxicology.org/endowment.
Plenary Lectures

Plenary Opening Lecture
Life at the Speed of Light

Monday, March 23, 8:00 AM to 9:00 AM

Lecturer: J. Craig Venter, J. Craig Venter Institute, San Diego, CA.

J. Craig Venter, PhD, is regarded as one of the leading scientists of the 21st century for his numerous invaluable contributions to genomic research. He is Founder, Chairman, and CEO of the J. Craig Venter Institute (JCVI), a not-for-profit research organization with approximately 300 scientists and staff dedicated to human, microbial, plant, synthetic and environmental genomic research, and the exploration of social and ethical issues in genomics.

Dr. Venter is Founder and CEO of Synthetic Genomics Inc (SGI), a privately held company dedicated to commercializing genomic-driven solutions to address global needs such as new sources of energy, new food and nutritional products, and next-generation vaccines.

Dr. Venter is also a co-founder and CEO of Human Longevity Inc (HLI), a San Diego-based genomics and cell therapy-based diagnostic and therapeutic company focused on extending the healthy, high-performance human life span.

Dr. Venter began his formal education after a tour of duty as a Navy Corpsman in Vietnam from 1967 to 1968. After earning both a Bachelor’s degree in Biochemistry and a PhD in Physiology and Pharmacology from the University of California at San Diego, he was appointed professor at the State University of New York at Buffalo and the Roswell Park Cancer Institute.

In 1984, he moved to the National Institutes of Health campus where he developed Expressed Sequence Tags or ESTs, a revolutionary new strategy for rapid gene discovery. In 1992 Dr. Venter founded The Institute for Genomic Research (TIGR, now part of JCVI), a not-for-profit research institute, where in 1995 he and his team decoded the genome of the first free-living organism, the bacterium Haemophilus influenzae, using his new whole genome shotgun technique.

In 1998, Dr. Venter founded Celera Genomics to sequence the human genome using new tools and techniques he and his team developed. This research culminated with the February 2001 publication of the human genome in the journal Science. He and his team at Celera also sequenced the fruit fly, mouse, and rat genomes.

Dr. Venter and his team at JCVI continue to blaze new trails in genomics. They have sequenced and analyzed hundreds of genomes, and have published numerous important papers covering such areas as environmental genomics, the first complete diploid human genome, and the groundbreaking advance in creating the first self-replicating bacterial cell constructed entirely with synthetic DNA.

Dr. Venter is one of the most frequently cited scientists, and the author of more than 250 research articles. He is also the recipient of numerous honorary degrees, public honors, and scientific awards, including the 2008 United States National Medal of Science, the 2002 Gairdner Foundation International Award, the 2001 Paul Ehrlich and Ludwig Darmstädter Prize and the King Faisal International Award for Science. Dr. Venter is a member of numerous prestigious scientific organizations, including the National Academy of Sciences, the American Academy of Arts and Sciences, and the American Society for Microbiology.

Keynote Medical Research Council (MRC) Lecture
Environmental Influences on the Immune System via the Aryl Hydrocarbon Receptor

Wednesday, March 25, 8:00 AM to 9:00 AM

Lecturer: Brigitta Stockinger, MRC National Institute for Medical Research, London, United Kingdom.

The aryl hydrocarbon receptor (AhR), well known in the pharmacology/toxicology field for its role in mediating the toxicity of xenobiotics, has more recently attracted the attention of immunologists. The evolutionary conservation of this transcription factor and its widespread expression in the immune system point to important physiological functions that are slowly being unravelled. In particular, the emphasis is now shifting from the role of AhR in the xenobiotic pathway toward its mode of action in response to physiological ligands. The current focus in the field is on understanding the molecular interactions and functions of AhR in the immune system in steady state and in presence of infection and inflammation, particularly in barrier organs such as the skin, the gut, and the lung.

Dr. Stockinger obtained her PhD in biology at the University of Mainz, and did postdoctoral training in London, Cambridge (UK), and at the Cancer Research Institute in Heidelberg. In 1985 she became a member of the Basel Institute for Immunology. In 1991, she became a group leader in the Division of Molecular Immunology of the National Institute for Medical Research in Mill Hill. Her research initially focused on immune tolerance using T cell receptor transgenic mouse models. The current research focus of her laboratory is on T cell biology, understanding the development, differentiation, and function of peripheral CD4 T cell subsets, as well as the physiological functions of the aryl hydrocarbon receptor in the immune system. Dr. Stockinger obtained an ERC Advanced Investigator grant in 2009 to study physiological functions of AhR, and in 2013 was awarded a Wellcome Senior Investigator Grant that will continue and expand the investigation of AhR in innate and adaptive immune cells. She became a Fellow of the Academy of Medical Sciences in 2005, an EMBO fellow in 2008, and a Fellow of the Royal Society in 2013.
SOT/EUROTOX Debate

In Vitro Alternatives Are Ready to Be Implemented and Relied Upon for Human Safety Testing

Monday, March 23, 4:45 PM to 6:00 PM

Chairperson(s): John B. Morris, University of Connecticut, Storrs, CT, and Mumtaz Iscan, Ankara University, Ankara, Turkey.

SOT Debater: George P. Daston, Proctor and Gamble Company, Cincinnati, OH.

EUROTOX Debater: Maurice P. Whelan, European Commission Joint Research Centre, EURL ECVAM, Ispra, Italy.

Endorser(s):
- 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 significant toxicological importance. This year, our debaters will address the proposition: In Vitro Alternatives Are Ready to Be Implemented and Relied Upon for Human Safety Testing.

In vitro and other nonanimal test methods have been under development for many years as possible replacements for animal testing as the basis for human safety risk assessment. The need for these methods is acute, both because of legislative pressure, such as the European Union’s Cosmetics Regulation, which forbids the use of ingredients tested in animals after March 2013, and because of the growing discrepancy between the number of chemicals for further testing. The debaters will discuss the state of the science of alternative methods and whether they can be relied upon for supporting human safety assessments.

Regardless of framework differences and personal convictions, each scientific debate 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 in San Diego, California, this debate will again take place (with the debaters taking the reverse positions) in Porto, Portugal during the 51st Congress of the European Societies of Toxicology (2015 Eurotox Annual Congress), September 13–16.

Special Symposium Session

Frontiers for Toxicology Session

Bugs to Drugs: The Microbiome in Human Health, Disease, and Therapeutics

Tuesday, March 24, 9:00 AM to 12:00 Noon

Chairperson(s): David Ross, University of Colorado, Denver, CO, and Paul C. Howard, US FDA-NCTR, Jefferson, AR.

Endorser(s):
- Scientific Program Committee

The human microbiome represents a symbiotic ecosystem that plays a key role in host metabolism and physiology, and is incredibly diverse even between healthy individuals. Dysfunctional microbiomes in various host environments are being increasingly recognized in the pathogenesis of altered metabolic states and diseases, such as metabolic syndrome, obesity, diabetes, certain autoimmune disorders, atherosclerosis, autism, asthma, and allergies. In particular, the gut microbiome plays a role in metabolism and absorption of drugs, toxicants, environmental chemicals, and dietary components; these exposures also alter the microbiota species composition and microbiome.

Breakthroughs in analytical methods and tools have accelerated the understanding of the roles of the microbiome in human health and disease. Metagenomics represents a powerful approach to define the microbiota species composition in a given ecosystem through detection of their genes and gene products, and the role of altered microbiomes in disease. Vast microbiota diversity exists within and between humans, each population producing a large array of their own metabolites and products, which contributes to regulating the overall host biology within this symbiotic relationship. Metabolic profiling strategies, including new mass spectrometric and bioinformatics techniques, are being developed to analyze the microbial metabolome to generate chemical maps that describe the molecular connections and communications between host cells and microbes. Understanding microbiome-metabolome-host interactions will drive the identification of novel drug targets and development of new therapeutic interventions for many diseases.

Rapid advances linking microbiota, the microbiome, and metabolome and their role in health and disease represent an important frontier from a toxicological perspective. The goal of this session is to feature eminent scientists who have made important contributions and advances to current knowledge of the microbiome. Integrated areas that will be explored include metagenomic characterization of microbiomes in human and environmental (continued on page 69)
Submit Your Recent Scientific Research during a Late-Breaking Abstract Submission Phase

The Society is poised to have another successful Annual Meeting with currently more than 2,500 abstracts scheduled to be presented in San Diego, March 22–26, 2015.

We invite you to submit an abstract during a late-breaking abstract submission phase which will occur from December 5, 2014, through January 12, 2015. All abstracts will be submitted online. The cost to submit an abstract is $50.

All accepted abstracts will be programmed on Thursday, March 26, 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 qualifications for submitting an abstract 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.

• 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.

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

• 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-breaking abstract period may be appropriate.

• Given the Society’s current publishing deadline, the abstracts accepted will be provided as a PDF addendum and are searchable through the Mobile Event App and Online Planner.

We look forward to welcoming you to the Society’s Annual Meeting in San Diego, California.
(continued from page 67)
ecosystems, changes in the microbiome from birth to death and important applications to forensics, the molecular characterization of the microbiome and the challenges of linking large amounts of genome sequencing and mass spectrometric data, and the metabolic cross-talk between the host and the symbiotic microbiome and its influence on disease and therapeutic, personalized medicine interventions.

- **Introduction.** Peter L. Goering, Society of Toxicology Vice President; US FDA-CDRH, Silver Spring, MD.
- **Metagenomic Approaches for Understanding the Microbial Foundations of Complex Ecosystems.** Mark D. Adams, J. Craig Venter Institute, San Diego, CA.
- **Dynamics of the Human Microbiota.** Rob Knight, University of California San Diego, San Diego, CA.
- **A Community-Based Molecular GPS from Microbes to People—Implications for Forensics, Health Monitoring, and Therapeutics.** Pieter C. Dorrestein, University of California San Diego, San Diego, CA.

**Meet the Directors**

**A Conversation with Linda Birnbaum and Jim Jones**

**Monday, March 23, 1:30 PM to 2:30 PM**

Chairperson(s): Peter L. Goering, Society of Toxicology Vice President; US FDA-CDRH, Silver Spring, MD.

Lecturer(s): Linda S. Birnbaum, NIEHS, Research Triangle Park, NC, and Jim Jones, US EPA, Washington, DC.

This important session will provide an informal venue for meeting attendees to have a candid and open discussion with two key leaders of federal organizations with missions to protect and improve public and environmental health: Dr. Linda Birnbaum, Director, NIEHS, and Jim Jones, Assistant Administrator, US EPA Office of Chemical Safety and Pollution Prevention. The entire session will be devoted to a question-and-answer format concerning scientific directions and priorities for NIEHS and US EPA-OCSP, funding priorities and outlooks, and training opportunities. Dr. Birnbaum has served as the Director of the National Institute of Environmental Health Sciences and the National Toxicology Program since 2009. Jim Jones has served as OCSP Assistant Administrator since 2013, as Deputy Assistant Administrator from 2007–2011, and as Director, Office of Pesticide Programs from 2003–2007.

**Award Lectures**

**Merit Award Lecture**

**Monday, March 23, 12:30 PM to 1:20 PM**

Lecturer: Günter Oberdörster, University of Rochester Medical Center, Rochester, NY.

**Translational Impact Award Lecture**

**Tuesday, March 24, 8:00 AM to 8:50 AM**

Lecturer: Jeffrey Burgess, University of Arizona, Tucson, AZ.

**Distinguished Toxicology Scholar Award Lecture**

**Wednesday, March 25, 12:30 PM to 1:20 PM**

Lecturer: Ian Kimber, University of Manchester, Manchester, Cheshire, United Kingdom.
New and Emerging Tobacco Products—Biomarkers of Exposure and Injury

Advancing Clinical and Translational Toxicology

Monday, March 23, 9:15 AM to 12:00 Noon

Chairperson(s): Daniel J. Conklin, University of Louisville, Louisville, KY, and Judith T. Zelikoff, New York University, Tuxedo, NY.

Endorser(s):
- Cardiovascular Toxicology Specialty Section
- Inhalation and Respiratory Specialty Section

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act was signed into law, giving the US FDA the authority to regulate new and emerging tobacco-derived products. Subsequently, there is an obvious need to provide scientific data in order to inform US FDA's decision-making regarding these products. Thus, biomarkers of exposure, biomarkers of injury, and controlled, acute, and chronic, as well as longitudinal exposure studies, are being conducted to better define what exactly new and emerging tobacco-derived products do in a variety of preclinical and clinical settings. New and emerging tobacco- and nicotine-derived products come in a dizzying array of products including electronic cigarettes, smokeless tobacco (including snus, snuff, and gutkha), shisha for hookah/water pipes, dissolvable lozenges, and nicotine gels that contain, deliver, and/or generate a varied number of harmful or potentially harmful constituents (HPHCs), making it challenging to predict the biological effects of exposures based solely on traditional cigarette exposure studies. This symposium will provide a broad overview of ongoing studies attempting to identify biomarkers of exposure, biomarkers of injury, and acute and chronic effects in the cardiovascular, pulmonary, and reproductive organ systems resulting from exposures to new and emerging tobacco products and/or their HPHCs.

- Introduction. Daniel J. Conklin, University of Louisville, Louisville, KY.
- Biomarkers of Exposure to Tobacco Smoke and Emerging Tobacco Products. Neal Benowitz, University of California San Francisco, San Francisco, CA.
- Pulmonary Effects of Exposure to Tobacco Smoke and New Tobacco Products. Ilona Jaspers, University of North Carolina at Chapel Hill, Chapel Hill, NC.
- Reproductive/Developmental Effects of Exposure to New and Emerging Tobacco Products and to Nicotine Delivery Devices in a Mouse Model. Judith T. Zelikoff, New York University, Tuxedo, NY.
- Cardiovascular Effects of Exposure to Harmful and Potentially Harmful Constituents (HPHCs) of Tobacco Products. Daniel J. Conklin, University of Louisville, Louisville, KY.

The Role of Connexin-Based Channels in Toxicity

Monday, March 23, 9:15 AM to 12:00 Noon

Chairperson(s): Brad L. Upham, Michigan State University, East Lansing, MI, and Mathieu Vinken, Vrije Universiteit Brussel, Brussels, Belgium.

Endorser(s):
- Mechanisms Specialty Section
- Molecular and Systems Biology Specialty Section

Connexins and their channels control tissue homeostasis at three levels, all which involve separate mechanisms. First, they form gap junctions, composed of two hemichannels of neighboring cells, of which each hemichannel is composed of six connexin proteins. As such, these gap junctions mediate the traffic of small, hydrophilic molecules between cells, a flux called gap junctional intercellular communication (GJIC) that controls gene expression and physiological functions. Secondly, hemichannels can form a separate pathway for communication, between the intracellular compartment and the extracellular environment. Thirdly, connexin proteins can affect the homeostatic balance independent of their channel-forming activities by directly interfering with gene expression. Dysfunction of connexin channels have been implicated in many diseases including cancer, reproductive dysfunction, peripheral neuropathies, liver disease, cataracts, deafness, teratogenesis, cardiac arrhythmias, and skin diseases. In the first presentation, general features of connexin-based channels will be discussed, as well as their mechanistic involvement in liver disease and toxicity. In the second presentation, the critical role of gap junction in redox signalling will be addressed. In the third presentation, toxicant-induced disruption of gap junctional intercellular communication in uterine muscle, with implications for parturition, will be outlined. The fourth presentation will focus on the use of gap junction function as a biomarker for elucidating toxicant-induced mechanisms of tissue dysfunction using advanced genomic strategies. Overall, this symposium will address significant advances and recent novel concepts in connexin biology and their application to toxicology.

- Integrative Role of Gap Junctions in Redox Signaling. Brad L. Upham, Michigan State University, East Lansing, MI.
- Connexin Signaling in Liver Toxicity and Disease. Mathieu Vinken, Vrije Universiteit Brussel, Brussels, Belgium.
- Uterine Muscle Gap Junctions As Toxicant Targets. Rita Loch-Caruso, University of Michigan, Ann Arbor, MI.
- Gap Junction Function: A Biomarker for Elucidating Toxicant-Induced Mechanisms of Tissue Dysfunction. Pavel Babica, Masaryk University, Brno, Czech Republic.
Cardio-Oncology Concerns Encourage Novel Approaches to Pharmaceutical Risk Assessment

**Advancing Clinical and Translational Toxicology**

**Monday, March 23, 2:00 PM to 4:45 PM**

**Chairperson(s):** Myrtle A. Davis, National Cancer Institute; Rockville, MD, and Brian R. Berridge, GlaxoSmithKline, Research Triangle Park, NC.

**Endorser(s):**
- Cardiovascular Toxicology Specialty Section

Recent successes in prolonging the life of cancer patients with optimized use of traditional approaches and the addition of novel classes of drugs (e.g., tyrosine kinase inhibitors) has raised the visibility and interest in managing the cardiovascular sequelae of a number of these therapeutic regimens. These concerns have energized the development of the unique and emerging field of cardio-oncology. A number of recent workshops have explored significant gaps and opportunities for improving both clinical and nonclinical approaches. This symposium intends to explore the knowns, unknowns, and opportunities for improvement in nonclinical approaches to cardiovascular risk assessment of anticancer drugs. The ultimate goal of these discussions is to identify opportunities to further enhance translation of nonclinical approaches and enhance relevance to patient outcomes.

- **Introduction.** Brian R. Berridge, GlaxoSmithKline, Research Triangle Park, NC.
- **Clinical Challenges for Managing Cardiovascular Risk in Cancer Patients in an Era of Prolonged Life Expectancy.** Douglas Sawyer, Vanderbilt School of Medicine, Nashville, TN.
- **The Intersection of Pharmacology and Toxicology in an Age of Targeted Cancer Therapies.** Brian R. Berridge, GlaxoSmithKline, Research Triangle Park, NC.
- **Use of Human-Induced Pluripotent Stem Cell-Derived Cardiomyocytes As a Screen for Drug-Induced Cardiotoxicity.** Kyle L. Kolaja, Cellular Dynamics, Inc., Montclair, NJ.
- **Opportunities for Improving Clinical and Nonclinical Approaches to Managing Cardiovascular Risk in Cancer Patients.** Myrtle A. Davis, National Cancer Institute, Rockville, MD.

Immunostimulant Cancer Treatments: Toxicology Programs with an Autoimmune “Twist”

**Advancing Clinical and Translational Toxicology**

**Monday, March 23, 2:00 PM to 4:45 PM**

**Chairperson(s):** Lauren Black, Charles River; Laurel, MD, and Helen G. Haggerty, Bristol-Myers Squibb, East Syracuse, NY.

**Endorser(s):**
- Biotechnology Specialty Section
- Immunotoxicology Specialty Section

Stimulating cellular immunity is transforming the way cancer is treated. But agonists to “attack” pathways (or antagonists to “brake” pathways) have caused Severe Adverse Events in clinical trials. Drugs in this category include antibodies, novel proteins, or engineered T cells. Since targets may not be in healthy animals, each tox program has unique hurdles, and so experts will delve into pathway, model, and program details that enabled clinical trials despite known clinical hazards. For example, an agonist antibody against the costimulatory receptor 4-1BB (CD137) caused Grade 4 hepatic inflammation in patients. Additional mechanistic toxicology was conducted using mice and an antimurine CD137 mAb to inform patient risks. PD-1/PD-L1 is studied by many firms because cancer cells upregulate this path to evade immunity—but blocking this pathway poses liabilities of autoimmune and infectious diseases. MPDL3280A blocks PD-L1 and was studied mainly in mice and cynomolgus monkeys; however, integrated assessment led to a more conservative first-in-human starting dose than the standard NOAEL or HNSTD approaches. CEA and OX40 offer two other promising targets: preclinical studies employed translational immunopharmacologic (in vitro and in vivo) models to characterize the safety for a novel BiTE constructs against CEA and an agonist mAb to OX40. Recent oncology clinical trials have also studied T cells that have been genetically modified to express “new” T cell receptors (TCRs) or chimeric antigen receptors (“CARs,” essentially fragments of therapeutic mAbs). These “CAR-T” cells can recognize selected extracellular targets and kill target-expressing cells. Surprisingly, preclinical studies for these biologic immunostimulants have been underutilized. Together, these talks should paint a detailed landscape of biologic cancer immunotherapies, and challenges facing toxicologists.

- **Introduction.** Lauren Black, Charles River Laboratories, Laurel, MD.
- **“CAR-T” Cells—A Crash Course in Immunostimulant Safety Concerns.** Christopher Horvath, Bluebird Bio, Cambridge, MD.
- **Integrated Nonclinical Safety Evaluation of a PD-L1 Antagonist with Impacts on Dosing.** Rodney Prell, Genentech, South San Francisco, CA.
- **Balancing Safety and Efficacy of Novel Immune System Agonists to CEA and OX40 Targets.** Rakesh Dixit, MedImmune/AstraZeneca, Gaithersburg, MD.
- **Overcoming the Safety Challenges of a CD137-Agonist Immunono- Oncology Therapeutic.** Helen G. Haggerty, Bristol-Myers Squibb, East Syracuse, NY.
- **Thinking beyond General Toxicology Studies for Immunotherapeutics.** Whitney Helms, US FDA/CDER, Silver Spring, MD.
Nrf2 Signaling Pathways in Model Systems: A Master Regulator of Neurotoxicity and a Potential Therapeutic Target

Monday, March 23, 2:00 PM to 4:45 PM

Chairperson(s): Richard M. Nass, Indiana University School of Medicine, Indianapolis, IN, and Jeffrey A. Johnson, University of Wisconsin-Madison, Madison, WI.

Endorser(s):
Neurotoxicology Specialty Section

The nuclear respiratory factor 2 (Nrf2), a bZip transcription factor, plays a critical role in maintaining cellular redox homeostasis in normal physiology, and in initiating environment- or pathophysiology-associated stress response. The high conservation of Nrf2’s structure, target genes, and downstream signal transduction pathways across animal phyla, in concert with the emerging evidence that the transcription factor is a regulator of protein degradation, neurotoxicity, and cell death, suggests that exploring Nrf2-associated molecular pathways in invertebrate and vertebrate genetic models will have significant relevance to human toxicology. In this symposium, we describe novel insights and strengths, as well as limitations, of increasingly complex genetic models including the nematode, fly, fish, and rodents to identify the molecular pathways involved in Nrf2-associated neuronal protection, as well as the utility of Nrf2-mediated therapeutic targets. Dr. Richard Nass will describe his studies utilizing the nematode C. elegans to explore the genetic and molecular basis of Nrf2- and sirtuin-associated DA neuronal vulnerability. Dr. Leo Pallanck will discuss his studies using the genetic fruit fly model D. melanogaster to identify Nrf2-inducing compounds to inhibit PD-associated neurodegeneration. Dr. Evan Gallagher will describe his research utilizing the genetic zebra fish model D. rerio to elucidate the role of Nrf2 in maintaining sensory behaviors following cadmium exposure. Dr. Jeff Johnson will discuss his studies on how astrocytic Nrf2 activation inhibits PD-associated genetic- and chemical-induced neuropathology in rodents. Finally, Dr. Donna Zhang will discuss her studies involving the regulation of Nrf2 by E3 ubiquitin ligases in rodents and humans, and the opportunities this regulation provides for identifying novel therapeutic targets and leads.

- Introduction. Richard M. Nass, Indiana University School of Medicine, Indianapolis, IN.
- The Identification and Characterization of an SKN-1/Nrf2 Pathway Involved in Toxicant-Associated C. elegans Models of Parkinson’s Disease. Richard M. Nass, Indiana University School of Medicine, Indianapolis, IN.
- Identifying Neuroprotective Factors from Coffee and Tobacco. Leo Pallanck, University of Washington, Seattle, WA.
- Role of Nrf2 in Regulating Cellular Antioxidant Responses of Fish. Evan P. Gallagher, University of Washington, Seattle, WA.
- A Role for Astrocytic Nrf2 Activation in Neuroprotection. Jeffrey A. Johnson, University of Wisconsin-Madison, Madison, WI.
- The Molecular Mechanisms of Nrf2 Regulation beyond Keap1: Developing Therapeutics Targeting the “Correct” E3 Ubiquitin Ligase for Nrf2 Activation. Donna D. Zhang, University of Arizona, Tucson, AZ.

TUESDAY

Alternative Models to Study Classical Toxicants: A Mechanistic View

Tuesday, March 24, 9:00 AM to 11:45 AM

Chairperson(s): Kathryn E. Page, University of California Berkeley, Berkeley, CA, and Monica R. Langley, Iowa State University, Ames, IA.

Endorser(s):
Graduate Student Leadership Committee
Mechanisms Specialty Section
Postdoctoral Assembly

Alternatives to in vivo toxicity testing are increasingly necessary due to regulatory mandates (e.g., REACH legislation), cost and time constraints, as well as ethical considerations. Models are being used in government, industry, and academia to develop a system for chemical screening and prioritization framework, and to study the mechanistic action of compounds traditionally studied in vivo. Graduate and postdoctoral researchers will describe their studies of classical toxicants using cell-based and alternative animal models that demonstrate how in vitro systems can be developed to elucidate mechanistic action of classical toxicants. The first presenter will describe the evaluation of ToxCast compounds to characterize multidimensional developmental and neurotoxicological effects using zebrafish. The second speaker will describe his efforts studying the developmental effects of RyR-active PCBs using embryonic zebrafish as a novel in vivo model. The third presenter will discuss the use of C. elegans in a genetic screen assessing MeHg-associated dopaminergic neuron degeneration, highlighting involvement of SKN-1/Nrf2 and MRP-7. The fourth speaker will present the development of an in vitro ‘omics approach to identify pathways of developmental neurotoxicity, and discovery of gene expression and metabolite changes relating to pesticides, pharmaceuticals, and metals. The fifth presenter will discuss a novel in vitro model for ozone adaptation, analyzing expression of proinflammatory and oxidative stress genes and discovery of the role of histone acetylation in the epigenetic control of ozone adaptation. The final speaker will present a combined functional genomics approach, using S. cerevisiae and avian DT40 cells, to determine the genotoxic mechanism of DCVC as a contributor to TCE renal toxicity. Attendees will learn of alternative methods with presenters stressing the strengths of these models in studying mechanisms of toxicity, while providing a retrospective look at classic toxicants and where we are now.
Immobile Responses to Different Classes of Inhaled Particulates: Unique vs. Shared Responses and Mechanisms

Tuesday, March 24, 9:00 AM to 11:45 AM

Chairperson(s): Andrij Holian, University of Montana, Missoula, MT, and Seishiro Hirano, National Institute for Environmental Studies, Tsukuba, Japan.

Endorser(s):
Inhalation and Respiratory Specialty Section
Immunotoxicology Specialty Section
Nanotoxicology Specialty Section

Inhaled particulates, including silica, asbestos, particulate matter, and nanoparticles, induce pulmonary inflammation, lung fibrosis and, often, systemic disease. As these materials each range in size, shape, durability, composition, and surface properties, they are often evaluated for immunotoxic effects individually rather than collectively. Often they are considered “distinct” classes of toxicants, and information that could be used to advance the overall knowledge about immunotoxicity of inhaled particulates is not frequently exchanged or evaluated in the context of a single toxicant class, viz., particulates. Taking a more unifying approach, some common findings about immunotoxicities (and associated mechanisms) have begun to emerge. For example, with each class of material, an initial pulmonary response is induced that is mediated via the innate immune system and, in turn, drives an early inflammatory response. Similarly, an adaptive immune response is then triggered that appears to be responsible for the onset of systemic diseases/pathologies. Nevertheless, each of these four particulate classes is capable of inducing some unique pathologies; consequently, there are likely some innate/adaptive responses (and associated mechanisms) induced by each type of particulate that somehow also specifically differ. The purpose of this symposium is to bring together experts to discuss, utilizing new cutting-edge information obtained about the immunotoxicity of these materials, the uniqueness of the innate and adaptive immune responses to each of the different particulates. A final presentation will then review areas of commonality and uniqueness. Based on these presentations, the symposium will seek to build a consensus about particle immunotoxicology that will help accelerate research for all particles and improve cross fertilization of research.

Local and Systemic Toxicity from Cobalt and Chromium-Containing Hip Prostheses

Tuesday, March 24, 9:00 AM to 11:45 AM

Chairperson(s): Allister Vale, University of Birmingham, Birmingham, United Kingdom, and Jeffrey Brent, University of Colorado, Denver, CO.

Endorser(s):
Clinical and Translational Toxicology Specialty Section
Metals Specialty Section
Occupational and Public Health Specialty Section

Over 500,000 patients in the US have received a metal-on-metal hip prosthesis. Movement of loosened components in a failing prosthesis and friction between bearing surfaces can result in increased local and systemic metal concentrations, principally of cobalt and chromium. Metallic debris affects bone health through direct effects on bone cells and through indirect inflammatory signalling. These effects vary with the metal, its concentration, physical form, and valency. Cobalt and chromium localize at nuclear and perinuclear sites in osteoblasts, suggesting uptake through cell membrane transporters, and is modulated by P2 receptor blockade. Metallic debris induces a range of cellular responses by direct cytotoxicity mediated through...
activation of redox reactions or the substitution of other bivalent cations in biological pathways, and through cytokine induction that is potentiated by direct and indirect activation of inflammasome signaling. Clinical studies have demonstrated that cobalt causes cardiovascular, visual, auditory, and thyroid dysfunction; malnourished heavy drinkers, for example, develop cardiomyopathy. Eighteen patients with systemic toxicity in association with a metal-containing hip have been reported. The reported systemic features fell into three main categories: neuro-ocular toxicity [14 patients: peripheral neuropathy (six cases), sensori-neural hearing loss (seven), cognitive decline (five), ocular toxicity (six)], cardiotoxicity (11 patients), and thyroid toxicity (nine patients). Currently, there is no evidence that chelation with any antidote will exert a beneficial therapeutic impact on clinical outcome in patients with health problems associated with cobalt-containing hip prostheses.

- **Introduction.** Allister Vale, University of Birmingham, Birmingham, United Kingdom.
- **Hip Prostheses: What Toxicologists Need to Know.** Allister Vale, University of Birmingham, Birmingham, United Kingdom.
- **Adverse Local Tissue Responses to Metal.** Mark Wilkinson, University of Sheffield, Sheffield, United Kingdom.
- **Mechanisms of Cardiovascular, Neurological, and Thyroid Effects of Cobalt Toxicity.** Jeffrey Brent, University of Colorado, Denver, CO.
- **Systemic Toxicity following Insertion of a Cobalt- and Chromium-Containing Prosthesis: A Critical Review of Published Cases.** Sally Bradberry, City Hospital, Birmingham, United Kingdom.
- **Is There a Role for Chelating Agents in the Management of Adverse Health Effects in Patients with Cobalt- and Chromium-Containing Hip Prostheses?** Michael J. Kosnett, University of Colorado, Denver, CO.

**Incorporating In Vitro Pharmacokinetic Data and Tools into Toxicity Testing and Risk Assessments: State of the Science**

**Strategies for Exposure and Risk Assessments**

**Tuesday, March 24, 1:30 PM to 4:15 PM**

**Chairperson(s):** Barbara A. Wetmore, The Hamner Institutes for Health Sciences, Research Triangle Park, NC, and Warren Casey, NIEHS, Durham, NC.

**Endorser(s):**
- Biological Modeling Specialty Section
- In Vitro and Alternative Methods Specialty Section
- Risk Assessment Specialty Section

New technologies and in vitro testing approaches can be valuable additions to risk assessments that have historically relied on in vivo test results. Compared to animal testing, in vitro high-throughput screening (HTS) assays are efficient, less expensive, and provide insights into chemical mode of action. However, the relationship between the in vitro chemical concentration in the well to the chemical concentration in the target tissue or blood in vivo is dependent upon pharmacokinetic (PK) and other variables not captured in HTS assays. Incorporation of in vitro to in vivo extrapolation (IVIVE) modeling with HTS data provides a bridge to link in vitro concentrations eliciting activity out to external in vivo exposures required to achieve target tissue concentrations similar to those at which activity is observed. Since its introduction five years ago, several efforts have ensued to assess, utilize, and refine this strategy. A series of talks have been assembled that update on progress made and consider principles to guide data evaluation for reliability and utility in a risk assessment context. Correlation of in vitro estrogen receptor activity to in vivo exposures has provided promising risk predictions. Efforts to streamline clearance and PK predictions using in silico- and in vitro-derived parameter estimates have laid the groundwork for HT PK modeling. Incorporation of isozyme-specific clearance data with enzyme abundance data for sensitive populations during IVIVE has quantitated PK variability. Moreover, the European Union is taking steps to harmonize standards for in vitro human hepatic metabolic clearance measurement. While the progress made is promising, the ultimate challenge will be in its acceptance as an appropriate tool to inform chemical risk assessment.

- **Introduction.** Barbara A. Wetmore, The Hamner Institutes for Health Sciences, Research Triangle Park, NC.
- **A Rational Approach to Using In Vitro Data to Improve Health Risk Assessment.** John C. Lipscomb, US EPA, Cincinnati, OH.
- **In Vitro to In Vivo Extrapolation (IVIVE) Modeling Tools to Inform Chemical Dosimetry and Population Pharmacokinetic Variability.** Barbara A. Wetmore, The Hamner Institutes for Health Sciences, Research Triangle Park, NC.
- **Using Reverse Toxicokinetic Models to Correlate In Vitro and In Vivo Estrogen Receptor Activity.** Warren Casey, NIEHS, Durham, NC.
- **High-Throughput Toxicokinetics for Environmental Chemicals.** John F. Wambaugh, US EPA, Research Triangle Park, NC.
- **Development of EURL ECVAM Harmonised Standards for In Vitro Human Hepatic Metabolic Clearance Methods.** Sandra Coecke, European Commission Joint Research Centre, Ispra, Italy.
New Developments in the Management of Nerve Agent Poisoning

**Advancing Clinical and Translational Toxicology**

**Tuesday, March 24, 1:30 PM to 4:15 PM**

**Chairperson(s):** Allister Vale, University of Birmingham, Birmingham, United Kingdom, and Horst Thiermann, Bundeswehr Institute of Pharmacology and Toxicology, Munich, Germany.

**Endorser(s):**
- Clinical and Translational Toxicology Specialty Section
- Neurotoxicology Specialty Section
- Occupational and Public Health Specialty Section

Nerve agents have been employed by Iraq and Syria and were released by terrorists in Japan on 11 occasions in 1994–1995. These releases indicate that countries must be prepared to treat civilian as well as military casualties. This requires an understanding of the mechanisms of toxicity of these agents, the factors that influence their clinical impact and knowledge of potential treatments. Much research is underway to improve the current treatment regimens, which include an anticholinergic drug (e.g., atropine) to antagonize the effects of excess acetylcholine (ACh) at muscarinic effector sites, the use of an oxime to reactivate nerve agent-inhibited acetylcholinesterase (AChE), and an anticonvulsant benzodiazepine to prevent or stop nerve agent-induced seizures. A series of novel phenoxyalkyl pyridinium oximes that show efficacy in the brain have been tested and found to reduce brain AChE inhibition and attenuate seizures. The in-service (military) medical countermeasure provision is based on carbamate pretreatment; such an approach is not possible in the case of a civilian population who are also not likely to be wearing personal protective equipment (PPE). The concept of employing physostigmine, hyoscine, and HI-6 in a single autoinjector in the absence of any form of pretreatment may reduce incapacitation significantly. In addition, the potential of human recombinant butyrylcholinesterase (BChE), and an anticonvulsant benzodiazepine to prevent or stop nerve agent-induced seizures. A series of novel phenoxyalkyl pyridinium oximes that show efficacy in the brain have been tested and found to reduce brain AChE inhibition and attenuate seizures. The in-service (military) medical countermeasure provision is based on carbamate pretreatment; such an approach is not possible in the case of a civilian population who are also not likely to be wearing personal protective equipment (PPE). The concept of employing physostigmine, hyoscine, and HI-6 in a single autoinjector in the absence of any form of pretreatment may reduce incapacitation significantly. In addition, the potential of human recombinant butyrylcholinesterase (BChE), and an anticonvulsant benzodiazepine to prevent or stop nerve agent-induced seizures. A series of novel phenoxyalkyl pyridinium oximes that show efficacy in the brain have been tested and found to reduce brain AChE inhibition and attenuate seizures. The in-service (military) medical countermeasure provision is based on carbamate pretreatment; such an approach is not possible in the case of a civilian population who are also not likely to be wearing personal protective equipment (PPE). The concept of employing physostigmine, hyoscine, and HI-6 in a single autoinjector in the absence of any form of pretreatment may reduce incapacitation significantly.

- **Introduction.** Allister Vale, University of Birmingham, Birmingham, United Kingdom.
- **Nerve Agents: An Introduction to Nomenclature, Mechanisms of Action, Clinical Features, Overview of Current Treatment, and Past Releases.** Allister Vale, University of Birmingham, Birmingham, United Kingdom.
- **Therapeutic Problems of Central Effects of Nerve Agents.** John H. McDonough, US Army Medical Research Institute of Chemical Defence, Aberdeen, MD.
- **The Development of Novel Centrally Effective Oxime Reactivators for Organophosphate-Inhibited Acetylcholinesterase.** Janice E. Chambers, Mississippi State University, Mississippi State, MS.
- **Translation of Experimental Findings into Recommendations for the Treatment of Nerve Agent Poisoning.** Horst Thiermann, Bundeswehr Institute of Pharmacology and Toxicology, Munich, Germany.
- **New Approaches in the Therapy of Nerve Agent Poisoning.** Paul Rice, Dstl Porton Down, Salisbury, United Kingdom.

Where the Metal Meets the Bone...

**Advancing Clinical and Translational Toxicology**

**Tuesday, March 24, 1:30 PM to 4:15 PM**

**Chairperson(s):** Koren K. Mann, Lady Davis Institute for Medical Research, McGill University, Montreal, QC, Canada, and Linda H. Nie, Purdue University, West Lafayette, IN.

**Endorser(s):**
- Metals Specialty Section

Bone is well known for its function as a structural support; however, new evidence suggests that bone is important as the site for hematopoiesis, in regulating mineral metabolism, in controlling glucose levels, and as an internal source of toxic metal exposure. Furthermore, bone is a complex, multicellular tissue that evolves depending on age and gender. As we age, particularly among women, we are more prone to osteoporosis and bone fracture. Many metals accumulate within the bone. Such an accumulation can directly alter the structural architecture of the bone itself, while it also renders the bone a primary depot of toxic metals that can result in pathologic effects in a variety of tissues. This symposium invites the researchers working on metals in bone to discuss the nonoverlapping mechanisms by which diverse metals accumulate and alter the bone, the local and systemic consequences of metals in bone, and how we can better assess bone metals in humans. After a brief introduction, the first speaker will discuss tributyltin-mediated activation of nuclear receptors and ensuing effects on osteogenesis. The second speaker will discuss how tungsten accumulation in the bone enhances adipogenesis at the expense of bone formation. The third speaker will address manganese accumulation in bone serving as an internal source that may contribute to manganese-induced Parkinsonian disorders. The fourth speaker will address the utility of bone lead as a reliable dosimeter for lead toxicity. Finally, the last speaker will discuss novel noninvasive technologies to define bone metal concentrations. The session will be of interest to a broader audience and, in particular, to those engaged in toxicologic research related to bone diseases, osteoporosis, metal toxicities, neurotoxicology, and systems biology.

- **Introduction.** Koren K. Mann, McGill University, Montreal, QC, Canada.
- **Suppression of Osteogenesis by Organotins. Is It All About PPARγ?** Jennifer J. Schlezinger, Boston University School of Public Health, Boston, MA.
The Thematic Track information can be found on pages 10–11.

Symposia

- Tungsten Accumulates in the Bone and Enhances Adipogenesis, Potentially at the Expense of Bone Formation. Alicia M. Bolt, Lady Davis Institute for Medical Research, McGill University, Montreal, QC, Canada.
- Manganese (Mn) Accumulation in Bone: Relationship to Mn-Induced Neurotoxicity. Wei Zheng, Purdue University, West Lafayette, IN.
- Bone As a Target and Dosimeter for Lead Toxicity and Exposure. Joel G. Pounds, Pacific Northwest National Laboratory, Richland, WA.
- Noninvasive In Vivo Quantification of Metals in Human Bones. Linda H. Nie, Purdue University, West Lafayette, IN.

WEDNESDAY

Role of the Gut Microbiome in the Host Response to Xenobiotics

Wednesday, March 25, 9:00 AM to 11:45 AM

Chairperson(s): Andrew Patterson, Pennsylvania State University, University Park, PA, and Frank Gonzalez, National Cancer Institute, National Institutes of Health, Bethesda, MD.

Endorser(s):
- Mechanisms Specialty Section
- Mixtures Specialty Section
- Molecular and Systems Biology Specialty Section

A population of nearly 100 trillion dynamic and diverse microbiota inhabits the human gut. Unlike the genome of a single organism, the combined genomic content of the gut microbiome, known as the metagenome, can rapidly vary as a function of diet, location, host genetics, and a variety of other factors, including exposure to chemical toxicants. The gut microbiome, considered an additional, metabolically vital organ of the human body. With these critical functions in mind, the gut microbiota might themselves be considered an additional, metabolically vital organ of the human body.

- Introduction. Andrew Patterson, Pennsylvania State University, University Park, PA.
- Impact of Dietary Persistent Organic Pollutants on the Host-Microbiome Interaction. Andrew Patterson, Pennsylvania State University, University Park, PA.
- Role of the Intestinal Microbiota in Colorectal Cancer. Frank Gonzalez, National Cancer Institute, National Institutes of Health, Bethesda, MD.
- Ah Receptor Contributes to Host-Microbiome Homeostasis. Gary H. Perdew, Pennsylvania State University, University Park, PA.
- Contributions of the Human Gut Microbiome to Drug Metabolism. Peter J. Turnbaugh, University of California San Francisco, San Francisco, CA.
- Gut Microbiota, Low-Grade Inflammation, and the Metabolic Syndrome. Andrew Gewirtz, Georgia State University, Atlanta, GA.

Adult Neurogenesis in Chemical-Induced Neurotoxicities: A New Frontier in Toxicological Mechanistic Investigations, Biomarker Research, and Therapeutic Targeting

Wednesday, March 25, 1:30 PM to 4:15 PM

Chairperson(s): Wei Zheng, Purdue University, West Lafayette, IN, and Aaron B. Bowman, Vanderbilt University, Nashville, TN.

Endorser(s):
- Metals Specialty Section
- Neurotoxicology Specialty Section
- Stem Cells Specialty Section

Loss of neurons in selective brain region(s) and retina is the pathological characteristic of numerous neurodegenerative diseases such as Parkinson’s disease (PD), Alzheimer’s disease (AD), and retinitis pigmentosa, among others. Classic neurobiology states that postmitotic neurons lack the ability to divide and thereby replace themselves. However, recent studies provide strong evidence that neurogenesis in the adult brain may mitigate adult neuronal loss by sustaining nonmotor function in PD and slowing cognitive deterioration and memory loss in AD. During adult neurogenesis, new neurons are generated from two primary proliferative niches in the adult brain. The subventricular zone (SVZ), nurtured by the cerebrospinal fluid (CSF) in brain ventricles, provides neural stem cells (NSC) via the rostral migration stream (RMS) to other brain regions, while the subgranular zone (SGZ) in the hippocampus produces new granule neurons for dentate gyrus. New studies suggest that toxicant exposure can alter neurogenesis, leading to compromised plasticity and neuronal dysfunction and exacerbating neuronal vulnerability to environmental toxicants. This session brings together experts in this fast evolving research field with a particular focus on how neurotoxicant exposure alters the adult neurogenesis and developmental proliferation. The goal of this session is to synthesize perspectives of critical niche areas of adult neurogenesis and its toxicology, with a focus on mechanisms that will provide new clues for potential amelioration and therapeutic intervention. This session will be of interest to those engaged in neurotoxicology related to neurodegenerative diseases, development, metal and pesticide toxicities, and systems biology.

- Introduction. Wei Zheng, Purdue University, West Lafayette, IN.
- Introduction to Adult Neurogenesis. Aaron B. Bowman, Vanderbilt University, Nashville, TN.
• Manganese-Copper Interaction: Effects on Adult Neurogenesis and Stem Cell Migration. Wei Zheng, Purdue University, West Lafayette, IN.

• Pesticide Exposure Disrupts Adult Neurogenesis and Behavior: Role of Inflammation and ER Stress. Jason R. Richardson, Robert Wood Johnson Medical School, Piscataway, NJ.

• Alteration of Adult Hippocampal Neurogenesis following Deletion or Activation of the Aryl Hydrocarbon Receptor in TCDD-Induced Neurotoxicity. Sarah E. Latchney, University of Texas Southwestern Medical Center, Dallas, TX.

• Gestational Lead Exposure (GLE) Increases Retinal Progenitor Cell Proliferation, Neurogenesis, and Signaling in Children and Animals. Donald A. Fox, University of Houston, Houston, TX.

Advanced Approaches for Quantitative Risk Assessment Using Human Data with Applications across Disciplines

**Strategies for Exposure and Risk Assessments**

**Wednesday, March 25, 1:30 PM to 4:15 PM**

**Chairperson(s):** Deborah Proctor, ToxStrategies Inc., Rancho Santa Margarita, CA, and Annie Albin Lumen, US FDA/NCTR, Jefferson, AR.

**Endorser(s):**
- Occupational and Public Health Specialty Section
- Regulatory and Safety Evaluation Specialty Section
- Risk Assessment Specialty Section

Health risk and safety assessments developed from human data are typically complicated by confounding and covariates, yet there are obvious advantages to using human, rather than animal, data for risk assessment, particularly when attempting to assess risk or set safety thresholds among sensitive individuals and/or vulnerable populations and life-stages. Further, the cumulative effects of multiple stressors and the mixture of environmental exposures from multiple sources are of important public interest but not readily evaluated in animal models. Recent advances in risk assessment modeling of human data for food allergies, pharmaceutical safety assessment, and occupational and environmental health have been achieved to address sensitive subgroups, conduct dose-response modeling, and assess cumulative exposures and health risks in relevant disciplines. Although the data needs vary across disciplines, the requirement to quantitatively describe variability in human response to a public health challenge is necessary across all. The objectives of this symposium are to review new approaches for risk assessment using human data and discuss case studies where these approaches have been applied, including biologically based pharmacokinetic modeling, dose-response modeling using smoothing splines, and probabilistic analysis to predict individual and population-level exposure-response relationships. The session aims to foster the use of innovative approaches across disciplines, focusing on risk assessment in sensitive/vulnerable subpopulations or sensitive life-stages, and discuss strategies for improved decision-making and risk management.

• **Introduction.** Deborah Proctor, ToxStrategies Inc, Rancho Santa Margarita, CA.

• **Evaluation of Food Allergen Exposure Risk Using Quantitative Risk Assessment Modeling.** Joseph L. Baumert, University of Nebraska-Lincoln, Lincoln, NE.

• **Comparison of Smoothing Spline Regression and Conventional Modeling Approaches for Quantitative Risk Assessments of Human Dioxin Exposure.** Chad M. Thompson, ToxStrategies, Inc., Katy, TX.

• **Application of a Probabilistic Framework to a Biologically Based Dose-Response Pregnancy Model to Evaluate Thyroidal Effects for Environmental Exposures to Perchlorate.** Annie Albin Lumen, US FDA/NCTR, Jefferson, AR.

• **Prediction of Patient Risk in Drug Development: Progress and Challenges for a “First in Class” Therapy.** Clifford Sachs, Janssen Research & Development, LLC, Spring House, PA.


**THURSDAY**

Chromatin Structure, Genomics, and Transcriptional Responses to Environmental Insults

**Epigenomic Influences in Toxicological Responses**

**Thursday, March 26, 9:00 AM to 11:45 AM**

**Chairperson(s):** Ivan Rusyn, Texas A&M University, College Station, TX, and Igor Pogribny, NCTR/US FDA, Jefferson, AR.

**Endorser(s):**
- Carcinogenesis Specialty Section
- Mechanisms Specialty Section
- Molecular and Systems Biology Specialty Section

Exposure to many environmental toxicants has been associated with epigenetic changes, which can affect gene expression patterns and likely contribute to disease or other phenotypes associated with exposure. The information on the mechanisms by which chemicals may impact gene expression is rapidly evolving, and recent discoveries show how exposures perturb the proteins and processes upstream of DNA methylation and other epigenetic marks. The transition from using epigenetic signatures of exposure as potential biomarkers to identifying their mechanisms allows for better characterization of the biology of how environmental insults are involved in establishing and maintaining gene expression patterns and chromatin state. The participation of the proteins that act as “readers,” “writers,” or “erasers” of the epigenetic code, depositing/removing epigenetic marks or binding to them and recruiting other proteins, as well as other factors such as noncoding
RNAs, chromatin remodeling complexes, intra- and intra-chromosomal interactions, and functional genomic elements, is now possible to elucidate using the latest genomic technologies. This symposium will explore how transcriptional regulation may be controlled by the developmental cues and/or environmental stimuli through a series of complex mechanisms which fall under the heading of epigenetic processes or modifications. Through a series of case studies, the basic mechanisms of the environmental control of epigenetic mechanisms will be illustrated. The linkages among exposure, genome, epigenome, and the host genetics will be addressed through data from in vivo and in vitro model systems.

- **Introduction.** Ivan Rusyn, Texas A&M University, College Station, TX.

- **Epigenetic Programmers Targeted during Developmental Reprogramming.** Cheryl Walker, Texas A&M University, Houston, TX.

- **Epigenetic Dysregulation by Oxidative Stress from Chemical Exposures.** Max Costa, NYU School of Medicine, Tuxedo, NY.

- **Transcriptional Effects of DNA Damage: Gene Expression Changes Associated with Tamoxifen Exposure in Humans and Nonhuman Primates.** Miriam C. Poirier, NIH/NCI, Bethesda, MD.

- **Genotoxic and Epigenotoxic Effects of Chemical Exposures: One Side of the Same Coin?** Igor Pogribny, NCTR/US FDA, Jefferson, AR.

- **Genetics Driving Epigenetics Associated with Altered Complex Phenotypes.** Terrence Furey, University of North Carolina at Chapel Hill, Chapel Hill, NC.

### Comprehensive Analysis of Nano Silver Toxicity Profiles: Known, Unknown, and Surprises!

**Thursday, March 26, 9:00 AM to 11:45 AM**

**Chairperson(s):** Srikanth S. Nadadur, NIEHS, Research Triangle Park, NC, and Linda S. Birnbaum, NIEHS, Research Triangle Park, NC.

**Endorser(s):**
- Inhalation and Respiratory Specialty Section
- Nanotoxicology Specialty Section

The fascinating optoelectronic and chemical properties of noble metal nanoparticles led to their significant application in nanotechnology and biomedicine. The silver nanoparticles have found widespread use in consumer products ranging from disinfectant, antifouling agents, and textiles, to nutraceuticals, biosensing, diagnostic imaging, and therapeutics. This widespread use of nano silver has potential to contribute to human health effects and raise environmental safety concerns. Hence, there is a need to develop an integrated and coordinated approach to gain a comprehensive understanding on the potential toxicity to better guide safe and sustainable use of nanotechnology. The toxicology data available to date on nano silver produced by diverse methods, physicochemical properties (size, shape, and surface coatings), and systems (in vitro, in vivo) used to investigate toxicity outcomes suggest the issue of dissolution of nanoparticles and silver ions and incomplete characterization data. As part of ongoing research efforts within the NIEHS Centers for Nanotechnology Health Implications Research Consortium, investigations are carried out to understand the biological interactions and response to silver nanomaterials of defined shape, structure and surface coating. These materials were commercially procured, extensively characterized, and investigated using cell culture systems (human, mouse, rat) representative of diverse organ systems and multiple rat and mouse models (wild type, knock out, collaborative cross strains, physiological states). The biological, physiological endpoints, and toxicokinetics from different routes of exposure indicated toxicity outcomes are dependent on the physicochemical properties, silver dissolution kinetics, cell culture system, or animal strains used. The presentations in this session will share with the scientific community the issues and scientific challenges in integrating this information into predictive health effects risk assessment models and the benefits of collaborative consortium efforts in addressing Nano EHS issues identified by NNI.

- **Introduction.** Srikanth S. Nadadur, NIEHS, Research Triangle Park, NC.

- **Improving In Vitro Assessment of Silver Nanoparticle Toxicity through Understanding of Ion Dissolution and Protein Corona Formation.** Jared M. Brown, University of Colorado, Aurora, CO.

- **Important Characteristics of Silver Nanoparticles and Particle Transformations in Biological Systems.** Donald R. Baer, Pacific Northwest National Laboratory, Richland, WA.

- **The Role of Genetics in the Susceptibility to Inhaled Nanoparticles.** Terry Gordon, New York University, Tuxedo, NY.
Epigenetics, Developmental Programming, and Immune Function: Where Do We Go from Here?

**Epigenomic Influences in Toxicological Responses**

**Thursday, March 26, 9:00 AM to 11:45 AM**

**Chairperson(s):** Berran Yucesoy, University of Cincinnati, Cincinnati, OH, and Victor J. Johnson, BRT Burleson Research Technologies Inc, Morrisville, NC.

**Endorser(s):**
- Immunotoxicology Specialty Section
- Inhalation and Respiratory Specialty Section
- Reproductive and Developmental Specialty Section

The epigenome is most vulnerable to dysregulation during the prenatal/fetal period as certain transient environmental influences can lead to persistent changes in epigenetic marks. These changes can adversely affect human development and health in childhood. Importantly, epigenetic changes that occur early during development may persist throughout life and, in some cases, may result in transgenerational impact on disease susceptibility. Many of the environmental factors that are implicated in infectious and noncommunicable disease risk are known to influence epigenetic programming of immune-related genes. This symposium is aimed at exploring the interaction between epigenetic, environmental, and developmental factors and their implications for childhood, life course, and transgenerational disease risk, and also for immune dysregulation and inflammation. In order to achieve this aim, the symposium will start with an overview of the central role of both microbial- and mammalian-generated epigenetic marks on immune development and dysfunction and will discuss related health risks and specific vulnerabilities. Next, the impact of prenatal and early postnatal environmental exposures on asthma and allergy risk will be discussed in the context of epigenetics, including alterations in DNA methylation, histone modifications, and microRNA expression of candidate genes. This will be followed by multigenerational and transgenerational outcomes of gestational arsenic exposure on tumor incidence in relation to epigenetic changes and the role of immune-related epigenetic regulation on tumor susceptibility. The symposium will end with a presentation discussing environmental epigenetics, the opportunity for development of epigenetic biomarkers of exposure and disruption of immune cell functions that are associated with disease development, and epigenetic potencies of individual pollutants. Novel, high-throughput technologies for examination of the epigenome as a whole will be leveraged to illustrate these concepts.

**Introduction.** Berran Yucesoy, University of Cincinnati, Cincinnati, OH, and Victor J. Johnson, BRT Burleson Research Technologies Inc, Morrisville, NC.

- Prenatal and Postnatal Environmental Exposures and Epigenetic Influences in Asthma and Allergy Risk. Rachel Miller, Columbia University, New York, NY.
- The Effects of Gestational Arsenite Exposure on the F2 Generation: Role of Epigenetics. Keiko Nohara, National Institute for Environmental Studies, Tsukuba, Japan.
- Early-Life Exposure to Environmental Pollutants and Epigenetic Programming of Immune-Related Diseases. Shuk-mei Ho, University of Cincinnati, Cincinnati, OH.

Exposure Assessment in the 21st Century: Needs and Challenges Facing High-Throughput Exposure Modeling

**Strategies for Exposure and Risk Assessments**

**Thursday, March 26, 9:00 AM to 11:45 AM**

**Chairperson(s):** Barbara A. Wetmore, The Hamner Institutes for Health Sciences, Research Triangle Park, NC, and Benjamin C. Blount, CDC, Atlanta, GA.

**Endorser(s):**
- Occupational and Public Health Specialty Section
- Regulatory and Safety Evaluation Specialty Section
- Risk Assessment Specialty Section

The release of Toxicity Testing in the 21st Century: A Vision and a Strategy generated a great deal of interest in assessing the utility of high-throughput (HT) in vitro assays in chemical hazard identification. Dosimetric adjustment of in vitro bioactivity data allows the derivation of oral equivalent doses that, on a mg/kg/day basis, provide a comparator to external exposure, allowing generation of putative margins of exposure (MOEs) that may then be employed in prioritization strategies. As federal HT hazard assessments transition to chemicals lacking exposure estimates, developing HT exposure prediction tools becomes increasingly important and is key to inserting risk relevancy into the process. While recent HT modeling efforts have yielded promise, they have concomitantly identified key needs that will require resolution to reduce model uncertainty. Biomonitoring data can play an important role in ground-truthing models, but ongoing surveys only offer limited data relevant for this task. This session will provide an update on the HT exposure modeling efforts currently underway, challenges identified, and additional needs to support realistic estimates of exposure variability, including identification of sensitive populations. This symposium will also provide perspective on the use of such tools in a regulatory setting.

**Introduction.** Barbara A. Wetmore, The Hamner Institutes for Health Sciences, Research Triangle Park, NC, and Benjamin C. Blount, CDC, Atlanta, GA.
Symposia

- The Impact of Rapid Bioactivity-Exposure-Based Prioritization on Chemical Safety. Steven M. Knott, US EPA, Washington, DC.
- Biomonitoring As an Exposure Assessment Tool in the Context of High-Throughput Screening (HTS): Concepts, Challenges, and Approaches. Lesa Aylward, Summit Toxicology, LLP, Falls Church, VA.
- Using Environmental and Biological Measurements to Develop Generalizable Relationships for Exposure Models. Ruthann Rudel, Silent Spring Institute, Newton, MA.
MONDAY

Environmental Exposures and Alzheimer’s Disease: Epidemiology, Mechanisms, and Future Strategies

Advancing Clinical and Translational Toxicology

Monday, March 23, 9:15 AM to 12:00 Noon

Chairperson(s): Jason R. Richardson, Robert Wood Johnson Medical School, Piscataway, NJ, and Anumantha Kanthasamy, Iowa State University, Ames, IA.

Endorser(s):
Neurotoxicology Specialty Section

Alzheimer’s disease (AD) is the most common neurodegenerative disease worldwide and is expected to increase three-fold over the next 40 years. To date, a massive amount of effort has focused on identifying genetic contributors to AD. Although there is a growing list of susceptibility genes that collectively contribute to AD, the largest GWAS study published on AD (>74,000 individuals) identified only 1 out of 19 loci as an individual strong contributor to AD. This finding has led to calls for studies to examine the potential influence of environmental and lifestyle factors on risk for AD. Given the wide-spread prevalence of AD and an ever-aging population, the role of environmental exposures in AD is a grossly understudied arena. This workshop brings together experts in the field of toxicology, neuroscience, and epidemiology to highlight the potential mechanisms by which environmental exposures contribute to AD. Experimental design and cutting-edge technologies relevant to discerning environmental influences on AD will also be discussed. The workshop contains presentations and a roundtable discussion that will address five primary questions: (1) What epidemiological strategies are likely to provide the most robust information on the association between AD and environmental exposures?; (2) What information can we apply to AD from experiences studying the role of environmental exposures in other neurodegenerative diseases?; (3) What is the role of environmental exposures in the etiology of AD?; (4) Do epigenetic alterations represent a mechanism by which environmental exposure contribute to AD?; (5) Does regulation of protein aggregation and transport of pathogenic proteins by environmental exposures contribute to the progression of AD?

- Introduction. Jason R. Richardson, Robert Wood Johnson Medical School, Piscataway, NJ.
- Environmental Exposures and AD: Developmental Origins and Role of Epigenetics. Nasser H. Zawia, University of Rhode Island, Kingston, RI.
- Role of the Divalent Metal Manganese in Protein Misfolding and Cell-to-Cell Transmission of Protein Aggregates via Exosomes in Cell Culture and Animal Models of Neurodegenerative Diseases. Anumantha Kanthasamy, Iowa State University, Ames, IA.
- Pesticide Exposure As a Risk Factor for AD: Evidence in Mice and Man. Jason R. Richardson, Robert Wood Johnson Medical School, Piscataway, NJ.

Friend or Foe—Challenges and Perspectives for Nonclinical Development of Antibody-Drug Conjugates

Safety Assessment Approaches for Product Development

Monday, March 23, 9:15 AM to 12:00 Noon

Chairperson(s): Mary Jane Hinrichs, MedImmune, Gaithersburg, MD, and Joerg Bluemel, MedImmune, Gaithersburg, MD.

Endorser(s):
Biotechnology Specialty Section
Regulatory and Safety Evaluation Specialty Section

The development of antibody-drug conjugates (ADC) has gained considerable momentum in recent years following the successful market introduction of two novel ADC molecules, T-DM1 (Kadcyla®) and brentuximab vedotin (Adcetris®). These molecules represent an exciting new class of oncology agents that combine highly potent cytotoxic small molecules (warhead) with targeted therapeutic proteins such as monoclonal antibodies. Due to the complexity of these molecules, ADC present unique challenges that encompass all aspects of nonclinical drug development, from the discovery process to translational issues such as patient selection. Despite the use of targeted delivery systems to deliver potent warheads, clinical development of ADC continues to be limited by toxicity. The purpose of this workshop is to bring together experts to discuss recent progress and challenges in the design and development of more efficacious ADC with improved tolerability. Specifically, recent data has shown that various aspects of ADC design play a major role in both the pharmacokinetic and toxicity profile of these molecules. The workshop will seek to explore how these factors can be used to engineer second-generation ADC with improved therapeutic indices.

- Development of Antibody-Drug Conjugates: Many Hopes But Also a Journey with Obstacles. Joerg Bluemel, MedImmune, Gaithersburg, MD.
- Analytical Challenges and Novel Techniques for Exposure Assessment of Antibody-Drug Conjugates. Ola Saad, Genentech, South San Francisco, CA.
- Nonclinical Safety Assessment of ADCs: Challenges and Opportunities. Simon Chivers, ADC Therapeutics, London, United Kingdom.
**Workshops**

**Linking Early-Life Stages: The First Step toward Lifecourse Risk Assessment**

**Approaches for Protecting Vulnerable Populations**

**Monday, March 23, 9:15 AM to 12:00 Noon**

**Chairperson(s):** Sally P. Darney, US EPA, Research Triangle Park, NC, and Harvey J. Clewell, The Hamner Institutes for Health Sciences, Research Triangle Park, NC.

**Endorser(s):**
- Reproductive and Developmental Toxicology Specialty Section
- Risk Assessment Specialty Section
- Scientific Liaison Coalition

Adverse health effects associated with chemical exposures are often greatest during periods of growth, differentiation, and development in embryonic, fetal, infant, and/or childhood life stages. Historically, risk assessment has considered the most critical and sensitive developmental window of exposure for each individual contaminant. However, a pregnant woman experiences exposures to a complex array of environmental contaminants and may transfer them to her fetus across the placenta and/or to her newborn through breast milk. Furthermore, mother and child will experience similar environmental exposures and modifying factors in their homes, schools and communities, all of which may impact subsequent physiology, disease susceptibility and lifelong health. To begin to address this complexity, we need ways to link exposures as they accrue and health outcomes as they emerge across time and life stages. This workshop will introduce lifecycle theory as applied to early-life stages, specifically to maternal and child health. Then experts in exposure and physiologically-based pharmacokinetic (PBPK) modeling will provide innovative approaches for predicting fetal and neonatal exposures based on the transfer of chemicals from pregnant women to their fetuses across the placenta and to their infants through breast milk, and for predicting biological effects of those exposures across life stages to adulthood. Drawing from a variety of data sources (human biomonitoring, longitudinal children’s health studies, exposure modeling, and biomarker discovery) case studies will demonstrate applications of lifecycle PBPK models to selected chemical classes. The workshop will conclude with an integrative panel discussion on how to apply lifecycle models in risk assessment. (DISCLAIMER: The views expressed in this abstract do not necessarily reflect US EPA policy).

- **Introduction.** Sally P. Darney, US EPA, Research Triangle Park, NC.
- **The Lifecourse Health Development Perspective on Chemical Exposures.** Neal Halfon, UCLA Center for Healthier Children, Families, and Communities, Los Angeles, CA.
- **PBPK Models for Human Pregnancy and Lactation Life Stages: A Case Study with PFOA and PFOS.** Harvey J. Clewell, The Hamner Institutes for Health Sciences, Research Triangle Park, NC.
- **Improving Infant Exposure and Health Risk Estimates: Using Serum Data to Predict Polybrominated Diphenyl Ether Concentrations in Breast Milk.** Satori Marchitti, US EPA, Athens, GA.
- **Pharmacokinetic Modeling of Lactational Exposure to Lipophilic Persistent Organic Pollutants (POPs): Applications in Epidemiology and Risk Assessment.** Marc-Andre Verner, Harvard School of Public Health, Boston, MA.
- **Lifestage Physiological-Based Pharmacokinetic (PBPK) Modeling of Metabolically Activated Compounds.** Jordan N. Smith, Battelle Memorial Institute, Pacific Northwest Division, Richland, WA.

**The US Tox21 Collaboration: Advances Made and Lessons Learned**

**Monday, March 23, 9:15 AM to 12:00 Noon**

**Chairperson(s):** Linda S. Birnbaum, NIEHS, Research Triangle Park, NC, and Robert J. Kavlock, US EPA, Washington, DC.

**Endorser(s):**
- **In Vitro and Alternative Methods Specialty Section**
- **Molecular and Systems Biology Specialty Section**
- **Regulatory and Safety Evaluation Specialty Section**

Launched in 2007, Tox21 is a multiagency collaborative effort among the National Institutes of Health’s National Institute of Environmental Health Sciences/National Toxicology Program and the National Center for Advancing Translational Sciences, the US Environmental Protection Agency’s National Center for Computational Toxicology, and the US Food and Drug Administration. The objective of this partnership is to shift the assessment of chemical hazards from traditional experimental animal toxicology studies to one based on target-specific, mechanism-based, biological observations largely obtained using *in vitro* assays, with the ultimate aim of improving risk assessment for humans and the environment. More specific goals are to identify patterns of compound-induced biological response to characterize toxicity/disease pathways, prioritize compounds for more extensive toxicological evaluation, and develop models predictive of adverse health effects in humans. By 2014, ~1800 compounds have been screened across ~700 assays in the ToxCast program, while a 10,000-compound library (which includes all ToxCast chemicals) was screened across a smaller, more focused set of nuclear receptor and stress response pathway assays. Tox21 is committed to full public accessibility and transparency and is releasing data through PubChem and other outlets. This workshop will summarize the progress and lessons learned from these studies; present an example prioritization scheme/prediction model; detail ongoing efforts to increase chemical characterization, biological coverage, and public outreach; and present the perspective of an end user of the data generated by Tox21 and similar efforts.

- **Introduction.** Linda S. Birnbaum, NIEHS, Research Triangle Park, NC.
- **The US EPA ToxCast Program: Moving from Data Generation to Application.** Russell S. Thomas, US EPA, Research Triangle Park, NC.
- **Tox21 Phase II: Testing the 10K Library in Quantitative High-Throughput Screening Assays.** Anton Simeonov, National Center for Advancing Translational Sciences, Rockville, MD.
Toxicological Epigenomics: The Interface between the Environment and Human Health

**Epigenomic Influences in Toxicological Responses**

**Monday, March 23, 9:15 AM to 12:00 Noon**

**Chairperson(s):** Shaun D. McCullough, US EPA, Chapel Hill, NC, and Dana Dolinoy, University of Michigan, Ann Arbor, MI.

**Endorser(s):**
- Mechanisms Specialty Section
- Molecular and Systems Biology Specialty Section
- Women in Toxicology Special Interest Group

An individual’s genetic makeup plays an important role in his or her response to toxicant exposure; however, polymorphisms in genes leading to susceptibility occur at a relatively low frequency. In addition to genetic makeup, epigenetic regulators, such as chromatin modifications, DNA methylation, and noncoding RNAs, function as critical and dynamic mediators of gene expression that shape the way that cells, tissues, and organisms respond to toxicant exposure. Toxicological epigenomics examines the role of these nongenetic mechanisms in the regulation of genes associated with toxicant response across the entire genome. By studying epigenetic mechanisms we will gain a better understanding of the molecular events underlying adverse health effects of toxicant exposure and improve our ability to predict susceptible populations. Further, the pliable nature of the epigenome allows for the use of epigenomics data to identify modifiable risk factors and develop models that will be used to limit the effects of toxicant exposure, thus promoting human health. This workshop will examine epigenomic mechanisms that are associated with exposures and outcomes by bringing experts together to discuss the interplay of epigenomics and toxicant exposure in the context of environmental health. We will explore questions such as: (1) How can animal models be utilized in toxicocoeugenics research? (2) How can human cross sectional, longitudinal, and clinical approaches best evaluate environmental effects on the epigenome and identify susceptible populations? (3) How can epigenomic data be applied in risk assessment? (4) How can toxicological epigenomics be applied to predict and mitigate the effects of toxicant exposure? Following this workshop, attendees will have a better understanding of how the epigenome influences the outcomes of toxicant exposure, how epigenomic studies can inform risk modification, and how epigenomics can be integrated into studies across many different aspects of toxicology.

**Introduction.** Shaun D. McCullough, US EPA, Chapel Hill, NC.

**Epigenomic Changes: A Major Mechanism Whereby the Environment Speaks to the Genome.** Ronald N. Hines, US EPA, Research Triangle Park, NC.

**Lifecourse Exposures and the Epigenome: Linking Epigenetic Alterations to Phenotypic Effects.** Dana Dolinoy, University of Michigan, Ann Arbor, MI.

**Genes, Genomes, and Genotoxicity: In Vivo Epigenetic Toxicology of 1,3-Butadiene.** Ivan Rusyn, Texas A&M University, College Station, TX.

**The Study of Impaired Systemic Immunity and Linked Epigenetic Modifications during Exposure to Polycyclic Aromatic Hydrocarbons in Ambient Air Pollution.** Kari Nadeau, Stanford University School of Medicine, Stanford, CA.

**Early-Life Environmental Influences on Epigenomics.** Carrie Breton, University of Southern California, Los Angeles, CA.

**Transporters As Gatekeepers for Chemical Exposure in Reproductive Tissues**

**Approaches for Protecting Vulnerable Populations**

**Monday, March 23, 9:15 AM to 12:00 Noon**

**Chairperson(s):** Lauren M. Aleksunes, Rutgers University, Piscataway, NJ, and Nathan J. Cherrington, University of Arizona, Tucson, AZ.

**Endorser(s):**
- Mechanisms Specialty Section
- Molecular and Systems Biology Specialty Section
- Reproductive and Developmental Toxicology Specialty Section

The passage of chemicals across the placenta and into the testes and ovaries is regulated by a number of physicochemical properties, as well as interactions with uptake and efflux transporters. In order to assess the risk for reproductive and developmental toxicities, it is critical to understand the mechanisms that restrict or enable entry to sensitive tissues. This workshop highlights the most recent knowledge of the interactions of drugs and chemicals with transport proteins in the placenta, ovaries, and testes. In the placenta, these proteins are found in syncytiotrophoblasts, extraembryonic membranes, and fetal endothelial capillaries. Recent work also demonstrates the basal and inducible expression of drug transporters in the ovaries. In the testes, drug transporters are expressed in Sertoli and germ cells in the semiferous epithelium. Emerging research from a number of laboratories demonstrates that transporters regulate the disposition of toxicants within the placenta, ovaries, and testes. Moreover, perturbations in the function of these proteins may alter drug responses and susceptibility to adverse events. The purpose of this workshop is to bring together experts in the fields of toxicology and reproduction to highlight the regulatory mechanisms that control chemical disposition in sensitive tissues. The workshop contains presentations and a roundtable discussion that will address the following questions: Which cell types are responsible for chemical transfer or extrusion in reproductive tissues? What physical and chemical properties of small molecules and biologics determine their disposition in the placenta, ovaries, and testes?
**Workshops**

What role do transporters play in the toxic responses of protected tissues? What are the advantages and disadvantages of preclinical animal models to recapitulate human chemical transfer? Do environmentally relevant concentrations of chemicals alter placental, ovarian, and testes barrier integrity?

- **The Placenta, Ovaries, and Testes: Hosts of Transporters, Home of the Next Generation.** Robert E. Chapin, Pfizer Global R&D, Groton, CT.
- **Gestational Age-Dependent Fetal Exposure to Xenobiotics: The Role of Placental Transporters.** Jashvant D. Unadkat, University of Washington, Seattle, WA.
- **Mechanisms That Reduce Transporter Function at the Blood-Placental Barrier.** Lauren M. Aleksunes, Rutgers University, Piscataway, NJ.
- **Impact of Phosphoramide Mustard Exposure on Ovarian Drug Transporter Expression.** Aileen Keating, Iowa State University, Ames, IA.
- **Uptake and Efflux Transporters at the Blood-Testis Barrier.** David M. Klein, University of Arizona, Tucson, AZ.

**Evaluating and Quantifying Stress for Inclusion in Cumulative Risk Assessment**

**Approaches for Protecting Vulnerable Populations**

**Monday, March 23, 2:00 PM to 4:45 PM**

**Chairperson(s):** Cynthia V. Rider, NTP/NIEHS, Research Triangle Park, NC, and Jane Ellen Simmons, US EPA, Research Triangle Park, NC.

**Endorser(s):**
- Mixtures Specialty Section
- Risk Assessment Specialty Section

The environmental justice movement has long recognized disproportionate exposure to chemical and nonchemical stressors in vulnerable populations. While chemical stressors are clearly defined, the term nonchemical stressor covers a broad landscape from physical (e.g., radiation, heat) to psychosocial (e.g., fear of violence). Here, we define nonchemical stressors as factors that stimulate a physiological stress response, with a particular focus on stressors that are relevant to people living in vulnerable communities. Both nonchemical and chemical stressors can contribute to multiple diseases (e.g., cardiovascular disease, asthma) that have higher incidence in vulnerable communities. However, there are many challenges to moving forward with quantitative risk assessments that accurately account for chemical and nonchemical stressors. Progress toward this goal requires focused research attention on developing and validating approaches for measuring the physiological effects of nonchemical stressors and interactions between chemical and nonchemical stressors. Additionally, advancement will require developing and evaluating case studies that adapt available approaches from epidemiology, toxicology, and risk assessment to estimate cumulative risk from chemical and nonchemical stressors. This workshop will bring together experts to discuss the latest science aimed at evaluating chemical and nonchemical stressors and incorporating them into cumulative risk assessments. Discussion will encompass a broad range of diseases (cardiovascular disease, neurodevelopmental delay), chemicals (air pollutants, metals), and stress types (maternal stress, chronic stress). Throughout the workshop, speakers will discuss promising approaches, knowledge gaps, and suggested future research. The concerted, multidisciplinary effort embodied in this workshop will help to shed light on the real impact of exposure to chemical and nonchemical stressors on health and disease in our most vulnerable communities. (This abstract does not reflect US EPA policy.)

- **Introduction.** Cynthia V. Rider, NTP/NIEHS, Research Triangle Park, NC.
- **Vulnerable Communities: At the Intersection of Chemical and Nonchemical Stressors.** Elena S. Craft, Environmental Defense Fund, Houston, TX.
- **Alters in CNS Effects of Lead and Methylmercury by Prenatal Stress and Early Behavioral Adversity.** Deborah A. Cory-Slechta, University of Rochester Medical School, Rochester, NY.
- **Quantifying “Stress” in Epidemiological Studies.** Diane B. Miller, CDC-NIOSH, Morgantown, WV.
- **A Framework for Examining Social Stress and Susceptibility to Air Pollution in Respiratory Health.** Jane E. Clougherty, University of Pittsburgh, Pittsburgh, PA.
- **Quantifying Chronic Stress Exposure for Cumulative Risk Assessment: Lessons Learned from a Case Study of Allostatic Load.** Amanda M. Evans, ORISE/US EPA, Cincinnati, OH.

**Infant Formula Nutrition: Regulatory and Safety Evaluation of Ingredients**

**Approaches for Protecting Vulnerable Populations**

**Monday, March 23, 2:00 PM to 4:45 PM**

**Chairperson(s):** A. Wallace Hayes, Harvard School of Public Health, Andover, MA, and Brinda Mahadevan, Abbott Nutrition, Columbus, OH.

**Endorser(s):**
- Food Safety Specialty Section
- Regulatory and Safety Evaluation Specialty Section
- Women in Toxicology Special Interest Group

Research continues to increase our understanding of human milk biology and its physiological functions in the newborn. This understanding has led to advancements in the safety and composition of formulas that ensure non-breastfed infants receive the nutrition needed for normal growth and development. Infant formulas marketed in the United States must meet specific federal requirements relative to composition, clinical merit, and quality. The purpose of the Infant Formula Act of 1980 and subsequent amendments is to ensure the safety and nutritional value of infant formulas—including minimum, and in some cases, maximum levels of...
Pulmonary Toxicity of Graphene Nanomaterials: An Emerging Concern in Manufacturing and Applications?

Monday, March 23, 2:00 PM to 4:45 PM

Chairperson(s): Jenny R. Roberts, NIOSH, Morgantown, WV, and Aaron Erdely, NIOSH, Morgantown, WV.

Endorser(s):
- Inhalation and Respiratory Specialty Section
- Nanotoxicology Specialty Section
- Occupational and Public Health Specialty Section

Graphene, a one-atom-thick monolayer of carbon, is an engineered nanomaterial (ENM) with physical and chemical properties that may offer application advantages over other carbonaceous ENMs, such as carbon nanotubes (CNT). As use of graphene nanomaterials (GNMs) in a variety of industries and manufacturing increases, the potential for respiratory exposure, particularly in the workplace, also rises. Unlike CNT, toxicity of GNMs has not been well defined. In addition, GNMs can vary in dimension, surface chemistry, number of layers, and other physico-chemical parameters, which in turn may affect toxicological potency of the material. The goal of this workshop is to present the most recent toxicological research findings in the field of GNMs and gain an understanding of the hazard and risk for exposure. The workshop will cover the physico-chemical characteristics and applications of a variety of GNMs, potential exposure in occupational settings, toxicity related to size and composition following various methods of pulmonary exposure in animal models, and comparative toxicity to well-defined carbonaceous ENMs. The outcome for the session is to establish whether GNM exposure poses a potential health hazard by providing an understanding of GNMs and conveying the most recent material science expertise and toxicological research related to respiratory exposure to various forms of GNMs.

- **Introduction.** Jenny R. Roberts, NIOSH, Morgantown, WV.
- **Physical and Chemical Properties of a Variety of Graphene Nanomaterials—Engineering Materials for Specific Applications.** Angelos Kyrlidis, Cabot Corporation, Billerica, MA.
- **Occupational Exposures along the Graphene Product Value Chain: Production, Formulation, and Use.** Christie M. Sayes, RTI International, Research Triangle Park, NC.
- **Particle Characterization and Toxicological Evaluation of Pulmonary Exposure to Graphenes of Different Sizes.** Jenny R. Roberts, NIOSH, Morgantown, WV.
- **A Five-Day Repeated Inhalation and 28-Day Post-Exposure Study of Graphene.** Il Je Yu, Institute of NanoProduct Safety Research, Hoseo University, Asan, Republic of Korea.
- **Comparative Inhalation Toxicities of Graphene and Other Carbonaceous Nanomaterials.** Robert Landsiedel, BASF Product Safety-Experimental Toxicology and Ecology, Ludwigshafen am Rhein, Germany.

TUESDAY

**Considering Pharmacokinetics As the Mechanistic Basis to Link Chemical Exposures to Adverse Outcome Pathways**

*Strategies for Exposure and Risk Assessments*

Tuesday, March 24, 9:00 AM to 11:45 AM


Endorser(s):
- Biological Modeling Specialty Section
- Molecular and Systems Biology Specialty Section

The Adverse Outcome Pathway (AOP) framework guides the formal characterization of the series of key events starting with chemical perturbation of a molecular initiating event (MIE) and resulting in an adverse outcome relevant for regulatory decision-making. AOPs should be chemical agnostic to allow general use in interpreting high-throughput assays developed based...
Workshops

on the MIE, but practical application of AOPs in risk assessment requires comparison between the concentration expected to result in an adverse outcome based on the extent of MIE stimulation and the biologically effective target tissue dose for a chemical. This requirement in turn speaks to the critical need to consider absorption, distribution, metabolism, and excretion (ADME) of a chemical, which may render an otherwise toxic chemical inaccessible to molecular targets in AOPs. Considerations of ADME not only link biological responses to chemical exposure, but are essential when extrapolating \textit{in vitro} assays to \textit{in vivo} conditions and across species and life stages. With the maturation of the AOP framework, this workshop seeks to open a dialogue within the Society on how to apply this same rigor to developing a framework that incorporates ADME events connecting environmental chemical exposure and AOP initiation. To provide the broadest array of perspectives on this problem, scientists from around the world have been invited to discuss toxicity pathways, adverse outcome pathways, pharmacokinetic modeling, and chemoinformatic tools. Following the presentations, there will be a discussion period to facilitate open discussion among workshop attendees on the state of the science in connecting ADME to AOP research. Participants should leave with a better appreciation of how ADME and AOPs together can improve toxicity predictions based on \textit{in vitro} measurements. The overarching goal of this workshop is to enhance the use of the AOP framework in chemical-specific risk assessment by better integrating knowledge and data between ADME and AOPs.

- \textbf{Toxicokinetic Aspects Contributing to Species Sensitivity.} Ksenia Groh, Eawag, ETH Zürich, Zürich, Switzerland.
- \textbf{The Role of Toxicokinetics and AOPs for the Zebrafish Embryo As a Predictive Model.} Stefan Scholz, Helmholtz Centre for Environmental Research-UFZ, Leipzig, Germany.
- \textbf{Translation of In Vitro Concentration-Response Relationships of Key Events to Human In Vivo.} George D. Loizou, Health & Safety Laboratory, Buxton, Derbyshire, United Kingdom.
- \textbf{An “ADME Module” in the Adverse Outcome Pathway Knowledgebase.} Yumei C. Tan, US EPA, Durham, NC.

\section*{Regulatory Neurodevelopmental Testing: New Guiding Principles for Harmonization of Data Collection and Analysis}

\textbf{Approaches for Protecting Vulnerable Populations}

\textbf{Tuesday, March 24, 9:00 AM to 11:45 AM}

\textit{Chairperson(s):} Abby Li, Exponent, San Francisco, CA, and Wayne Bowers, Health Canada, Ottawa, ON, Canada.

\textit{Endorser(s):}
- Neurotoxicology Specialty Section
- Regulatory and Safety Evaluation Specialty Section
- Reproductive and Developmental Toxicology Specialty Section

There is increasing concern worldwide about the potential for chemicals to affect neurodevelopment in children. In 2012, OECD published the extended 1-generation reproductive toxicity guideline 443, which will generate new auditory startle, motor activity, and morphometric data. Since these endpoints will have increased regulatory significance, their conduct and interpretation requires increased attention. New evaluations of older DNT studies conducted according to US EPA guidelines (including learning and memory) in global regions are also playing a larger role in children’s health risk assessment. Yet data from the same study has resulted in different risk assessments in different countries, leading to potential trade barriers. In addition, data are sometimes incompletely reported or analyzed, adding to inconsistencies in evaluations. These issues also apply to juvenile and pre-postnatal studies conducted for pharmaceuticals. Although various regulatory bodies have different risk management frameworks, this workshop will provide an opportunity to develop more harmonized scientific approaches for evaluating DNT data. One major reason for varying regulatory decisions based on the same data is expectations for variability of DNT data. Speakers from industry, academia, and government with regulatory neurotoxicology expertise will discuss inherent and controllable variability, suggest guiding principles for assessment of DNT data, and selection of benchmark response levels that take into account different variability. Speakers will address shortcomings in study conduct, data reporting, and analysis that are encountered by regulatory authorities, and will propose approaches to harmonize evaluation of data using different DNT endpoints as case studies. The workshop will end with discussion led by two discussants from industry and government. This session is especially timely as laboratories in different world areas are developing new capabilities to conduct the OECD 443 guideline and regulatory bodies place new emphasis on evaluation of DNT data for children’s health risk assessments.

- \textbf{Introduction.} Angela Hofstra, Syngenta Canada Inc, Guelph, ON, Canada.
- \textbf{Evaluating Data Variability for Neurobehavioural Measure: How Much Is Too Much?} Larry P. Sheets, Bayer CropScience, Stilwell, KS.
- \textbf{New Insights into Analysis of Highly Variable Data: Motor Activity As Case Study.} Wayne Bowers, Health Canada, Ottawa, ON, Canada.
• Introduction. Bethany R. Hannas, The Dow Chemical Company, Midland, MI.
• Challenges of Conducting and Interpreting Tier 1 EDSP Assays. Sue Marty, The Dow Chemical Company, Midland, MI.
• A Two-Tiered-Testing Decision Tree for Assays in the US EPA-EDSP Screening Battery: Using 15 Years of Experience to Improve Screening and Testing for Endocrine Active Chemicals. L. Earl Gray Jr., US EPA, Research Triangle Park, NC.
• Tier 1 Testing: Big Hopes for a Small Target. Gerald A. LeBlanc, North Carolina State University, Raleigh, NC.
• Species Extrapolations for EDSP—Are Species Adequately Evaluated in the EDSP. Glen Van Der Kraak, University of Guelph, Guelph, ON, Canada.

Understanding and Communicating Uncertainty in Hazard Assessment and Dose Response

Statistics for Exposure and Risk Assessments

Tuesday, March 24, 9:00 AM to 11:45 AM


Endorser(s):
Occupational and Public Health Specialty Section
Regulatory and Safety Evaluation Specialty Section
Risk Assessment Specialty Section

Hazard and risk assessment programs generally provide a single estimate as a final work product. These point estimates of human health hazard/risk associated with environmental exposures are regularly used by risk managers in regulatory decision-making in setting standards, determining emissions controls, setting occupational standards, and mitigating exposures to pollutants both nationally and internationally. Methodologies used to derive these point estimates vary, and many rely on upper bound or worst-case assumptions. Additionally, understanding of the components of these assessments, including the attendant uncertainty surrounding the point estimates and how this uncertainty impacts the estimates, is often limited, particularly in the summary information that is provided. Thus risk assessors, risk managers, and stakeholders are often challenged to understand all of the assumptions and uncertainties embedded in a hazard characterization. An improved approach to communication can help to fully convey the plausible range of risk estimates to risk managers. A better understanding of the uncertainties in these assessments will allow users a better sense of the overall confidence with which a risk value can be used and whether there is a proper balance between being protective and being predictive. This workshop session will explore different approaches and visual tools that have recently been developed to better communicate the uncertainties and confidence within hazard

Workshops

Workshops information can be found on pages 10–11

The Thematic Track

Workshops

The EDSP Screening Battery: A Work in Progress for Prioritizing Compounds for Quantitative Risk Assessment

Strategies for Exposure and Risk Assessments

Tuesday, March 24, 9:00 AM to 11:45 AM

Chairperson(s): Bethany R. Hannas, The Dow Chemical Company, Midland, MI, and Cynthia V. Rider, NTP/NIEHS, Research Triangle Park, NC.

Endorser(s):
Regulatory and Safety Evaluation Specialty Section
Reproductive and Developmental Toxicology Specialty Section
Risk Assessment Specialty Section

The US Environmental Protection Agency (US EPA) Endocrine Disruptor Screening Program (EDSP) has been evolving since its inception in 1998. The two-tiered program was initiated in response to a mandate by Congress to investigate the potential for pesticides and drinking water contaminants to have adverse effects on endocrine signaling. The collection of 11 assays included in EDSP Tier 1 were compiled to provide a standardized battery by which compounds could be screened for the potential to interact with estrogen, androgen, or thyroid (EAT) hormone signaling pathways. Compounds showing potential EAT activity in the Tier 1 battery are anticipated to undergo further, more comprehensive testing in EDSP Tier 2, which will provide dose-response data on adverse endpoints for use in quantitative risk assessment. Since 2009, when the US EPA issued the first set of testing orders for Tier 1 screening, 52 compounds have been screened through this battery of assays. Many challenges were encountered during this initial testing, including meeting assay performance criteria, interpreting data, and allocating time and resources for such a large-scale screening battery. One of the most significant and challenging questions that transpired following this first attempt at EDSP Tier 1 testing was, “Where do we go from here?” Addressing this question will be paramount in effectively implementing this program. Issues related to the dynamic process of optimizing the screening portion of the EDSP include challenges associated with Tier 1 screening, proposed approaches for streamlining the screening program, the future of the program as EDSP21, endocrine screening in nonmammalian species, and lingering questions on the aptness of the Tier 1 battery. Discussions focused on these topics are timely, with impending Tier 1 test orders on the horizon for List 2 compounds and upcoming decisions regarding the future for Tier 1 positive compounds as relates to moving into Tier 2 testing.

From SOPs to Reports to Evaluations: Learning and Memory As Case Study of How Missing Data and Methods Impact Evaluation.
Virginia C. Moser, US EPA, Research Triangle Park, NC.

Weight of Evidence (WOE) and Benchmark Dose (BMD) Analysis: Brain Morphometry and Startle Behavior As Examples.
Abby Li, Exponent, San Francisco, CA.

Discussion. Francis Bailey, Health Canada, Ottawa, ON, Canada, and Angela Hofstra, Syngenta Canada Inc, Guelph, ON, Canada.

Workshops

Scientific
assessments, such as IRIS. With each presented approach, specific examples will be provided so that we can move past discussion of the theoretical implementation and examine exactly what the approach would look like when used. In addition, US EPA will also be providing an update on the changes they have been making to help improve the communication of their findings within the IRIS program.

- **Introduction.** Nancy B. Beck, American Chemistry Council, Washington, DC.
- **Setting the Stage in Addressing Uncertainty, Variability, and Sensitivity.** Bette Meek, University of Ottawa, Ottawa, ON, Canada.
- **Unpacking Toxicity Assessments to Understand and Improve Confidence.** Roberta L. Grant, Texas Commission on Environmental Quality, Austin, TX.
- **Presenting Uncertainty in the Context of Biological Monitoring and Exposure Information.** William H. Farland, Colorado State University, Fort Collins, CO.
- **Improving Transparency and Prioritization of Data Needs in Hazard Value Development.** Christopher R. Kirman, Summit Toxicology LLP, Orange, OH.
- **Characterizing Uncertainty in Human Health Risk Assessment: An Agency Perspective.** Lynn Flowers, US Environmental Protection Agency, Washington, DC.
- **Facilitated Discussion on “Understanding and Communicating Uncertainty in Hazard Assessment and Dose Response.”** Lynn H. Pottenger, The Dow Chemical Company, Midland, MI.

**In Vitro Microphysiological Systems—Developing Confidence in Predictive Ability**

**Tuesday, March 24, 1:30 PM to 4:15 PM**

**Chairperson(s):** Suzanne C. Fitzpatrick, US Food and Drug Administration, College Park, MD, and Anthony Bahinski, Wyss Institute for Biologically Inspired Engineering at Harvard University, Boston, MA.

**Endorser(s):**

- **In Vitro and Alternative Methods Specialty Section**
- **Regulatory and Safety Evaluation Specialty Section**

Mechanically active “organ-on-a-chip” microdevices that reconstitute tissue-tissue interfaces critical to organ function can expand the capabilities of cell culture models and provide low-cost and more informative alternatives to animal toxicology studies. With simplified designs and careful choice of biocompatible device materials, they can be useful for high-content analysis and screening of cellular responses to drugs, chemicals, particulates, toxins, pathogens, or other environment stimuli relevant to pharmaceutical, cosmetic, and environmental applications. In 2011, President Obama announced that the National Institutes of Health will collaborate with the Defense Advanced Research Projects Agency (DARPA) and the US Food and Drug Administration to develop a chip to screen for safe and effective drugs far more swiftly and efficiently than current methods, and before they are tested in humans. It was clear to both US FDA and NIH that these models have the potential for more accurate modeling of physiological situations to answer fundamental basic science questions. As the science of in vitro microphysiological systems develops, it is also imperative that regulators communicate what they need to demonstrate confidence in the predictive capacity of these new and promising models. This workshop presents a pathway to full acceptance and use by first developing confidence in each of the different integral parts of the model and then combining them for a “context-of-use” evaluation of overall predictive ability to answer critical regulatory questions.

- **Introduction.** Anthony Bahinski, Wyss Institute for Biologically Inspired Engineering at Harvard University, Boston, MA.
- **Human Organs on Chips.** Anthony Bahinski, Wyss Institute for Biologically Inspired Engineering at Harvard University, Boston, MA.
- **Induced Pluripotent Stem Cells and Personalized Medicine: Are We Moving Towards a “Patient on a Chip”?** Clive Svendsen, Cedars Sinai Medical Center, Los Angeles, CA.
- **Characterizing and Validating Biological and Physiological Relevance of an In Vitro Microphysiological System.** John P. Wikswo, Vanderbilt University, Nashville, TN.
- **Defining an Appropriate Testing Paradigm for In Vitro Microphysiological Systems.** Yvonne Dragan, DuPont, Newark, DE.
- **Determining the Predictive Capability of In Vitro Microphysiological Systems to Answer Critical Regulatory Questions.** Suzanne C. Fitzpatrick, US Food and Drug Administration, College Park, MD.


**Safety Assessment Approaches for Product Development**

**Tuesday, March 24, 1:30 PM to 4:15 PM**

**Chairperson(s):** Pamela J. Spencer, The Dow Chemical Company, Midland, MI, and Martin L. Stephens, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD.

**Endorser(s):**

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

Historically, early identification and characterization of adverse effects of industrial chemicals was difficult because conventional toxicological test methods did not meet R&D needs (e.g., methods that are rapid, relatively inexpensive, and amenable to small amounts of test material). Consequently, undesirable toxicological effects were identified closer to commercialization, when few options for design changes existed and after significant investment.
of time, resources, and money. For example a 2-generation reproduction study costs more than $500,000, uses more than 3,000 rats, and takes 15 months to complete. Further time, money, and resources are consumed in efforts to “defend and save” products identified to have adverse effects. Today, rapidly evolving, next-generation safety assessment methodologies have the potential to transform how companies develop and commercialize new products and chemicals. New 21st century tools now make it feasible to incorporate toxicological assessments as early as the ideology stage of product development and to build in rules and criteria to guide the design of high-efﬁcacy/low-toxicity compounds. Toxicology as a tool for innovation affords beneﬁts for the company developing new products as well as for society. For companies, the earlier candidates with undesirable effects are identiﬁed and eliminated, the sooner limited resources can be redirected to those candidates with the highest likelihood of being a successful, sustainable alternative. The input of toxicologists early can inform test strategies and limit complex, costly, and lengthy studies to those few promising candidates, reducing post-market defense of products targeted for future deselection. For society, safer, healthier alternatives are commercialized and the risk of unknown health and environmental effects surfacing after product launch are reduced. Using 21st century toxicology methods as a preventive strategy to design out undesired human health and environmental effects offers beneﬁts to companies and society over the current paradigm. This session will provide a forum for collaboration among scientists working in complementary ﬁelds to discover common ground in the quest for safer chemicals by adopting an innovative, prevention-based framework to product safety assessment through strategic application of new 21st century methodologies. Case studies will be used to illustrate how to build successful strategies into product development.

- **Introduction.** Pamela J. Spencer, The Dow Chemical Company, Midland, MI.
- **A Framework for Designing Safer Chemicals.** Nicholas Anastas, US EPA, Boston, MA.
- **Chemical Design Principles and Screening Methodologies in Predicting Toxicity Liability to Guide Drug Discovery Candidate Selection.** Nigel Greene, Pfizer Inc., Groton, CT.
- **21st Century Toxicology: Tools for Innovation and Safer Chemical Design.** Thomas Hartung, Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD.
- **Innovative Toxicology: Matching Tools to Product Development Stage to Assess the Toxicity and Environmental Impact of New Products.** Randy Deskin, Deskin Associates LLC, Fort Myers, FL.

### 54th Annual Meeting and ToxExpo

**Scientific Workshops**

#### Current Understanding of Immune-Mediated Adverse Drug Reactions

**Advancing Clinical and Translational Toxicology**

**Tuesday, March 24, 1:30 PM to 4:15 PM**

**Chairperson(s):** Arno Siraki, University of Alberta, Edmonton, AB, Canada, and Alison Harrill, University of Arkansas for Medical Sciences, Little Rock, AR.

**Endorser(s):**

- Immunotoxicology Specialty Section

Immune-mediated adverse drug reactions (IM-ADRs) represent a significant incidence of patient morbidity and mortality, and they signiﬁcantly add to the cost of drug development. The most affected organs include the skin, liver, and blood, and such organs are known to initiate and shape immune responses. Despite major research efforts to investigate the mechanism behind IM-ADRs, our understanding of such reactions remains superficial. The role of drugs and how they are able to cause organ damage, whether by inducing or altering an immune response, is not well understood. At this workshop, research highlighting different mechanisms for how drugs initiate an immune response that leads to an IM-ADR will be discussed. This includes the formation of covalent adducts, the induction of danger signals to overcome immune tolerance, the “altered repertoire” hypothesis based on which drugs change the repertoire of self-peptides presented by HLA molecules, and the heterologous immunity model which provides an explanation for the low positive predictive value of most HLA associations of drug hypersensitivity. The presentations will highlight new advancements in the technology for early detection of IM-ADRs, *in vitro* assays, and the use of valid animal models.

- **Introduction.** Arno Siraki, University of Alberta, Edmonton, AB, Canada.
- **The Use of Animal Models in Investigating the Mechanism of Idiosyncratic Drug-Induced Hepatotoxicity.** Imir G. Metushi, La Jolla Institute for Allergy and Immunology, San Diego, CA.
- **Studies of the Role of Innate and Adaptive Immune Responses in Drug-Induced Liver Injury in Mice.** Cynthia Ju, University of Colorado, Aurora, CO.
- **Drug Hypersensitivity Caused by Alteration of the MHC-Presented Self-Peptide Repertoire.** Bjorn Peters, La Jolla Institute for Allergy and Immunology, San Diego, CA.
- **Current Science and Translational Opportunities in the Prediction and Prevention of Immunologically Mediated Adverse Drug Reactions.** Elizabeth Phillips, Vanderbilt University Medical Center, Nashville, TN.
Workshops

WEDNESDAY

An Experiment in Collective Wisdom Utilizing Real-Time Audience Input: Weight-of-Evidence Assessment for Chemical-Specific Modes of Action Utilizing Two Case Studies

Wednesday, March 25, 9:00 AM to 11:45 AM

Chairperson(s): Sean Hays, Summit Toxicology LLP, Lyons, CO, and Bette Meek, University of Ottawa, Ottawa, ON, Canada.

Endorser(s):
- Regulatory and Safety Evaluation Specialty Section
- Risk Assessment Specialty Section

This session is an exercise in using collective wisdom/audience participation to help inform the weight-of-evidence assessment for the mode of action (MOA) for two specific chemicals: 1,2,3-trichloropropane and tetrachloroethylene. The degree of confidence required for acceptance of a proposed MOA for a specific chemical will vary from individual to individual. As a result, chemical risk assessments that are published by regulatory agencies or individuals and MOA discussions are subject to criticism from individuals with a different viewpoint. Understanding this variation among individuals in the toxicology and risk assessment communities is an important factor for risk managers to understand and appreciate. This session will provide a forum to explore the degree of this variation in the level of confidence in chemical specific MOA arguments. Using proven technology for audience participation during scientific sessions and real-time analyses of results, the audience and speakers will explore how collective wisdom can inform the process of how MOA decisions are made, and how differing expertise impacts decisions. The presenters will discuss the technology used in this session, how individuals can provide insights on their expertise and experience, and the extent of weight of evidence in support of and against proposed MOA for 1,2,3-trichloropropane and tetrachloroethylene. Finally, the results of the collective wisdom exercise will be presented and findings from the exercise will be discussed by a panel of experts. Audience members should bring wifi-enabled devices to participate in real-time interaction with the presentation.

- Introduction. Sean Hays, Summit Toxicology LLP, Lyons, CO.
- Introduction to Collective Wisdom Technology. Christopher R. Kirman, Summit Toxicology LLP, Orange, OH.
- Weight of Evidence in MOA/AOP Analysis. Bette Meek, University of Ottawa, Ottawa, ON, Canada.
- Proposed Mode of Action and Weight of Evidence for 1,2,3-Trichloropropane Carcinogenicity Using a Human Relevance Framework. Colin M. North, ExxonMobil Biomedical Sciences, Inc., Annandale, NJ.
- Weight of Evidence of Proposed Modes of Action for Tetrachloroethylene-Induced Cancers. Michelle Deveau, University of Ottawa, Ottawa, ON, Canada.

- Collective Wisdom Findings and Discussion. Sean Hays, Summit Toxicology LLP, Lyons, CO.
- Panel Discussion. Annie M. Jarabek, United States Environmental Protection Agency, Research Triangle Park, NC.

Application of High-Throughput In Vitro Assays in Assessing Small Molecule Safety

Wednesday, March 25, 9:00 AM to 11:45 AM

Chairperson(s): Nigel Greene, Pfizer Inc., Groton, CT, and Russell S. Thomas, US Environmental Protection Agency, Research Triangle Park, NC.

Endorser(s):
- Drug Discovery Toxicology Specialty Section
- In Vitro and Alternative Methods Specialty Section

Social demands to ensure both public health and environmental safety from either planned or accidental exposure to existing or new molecular entities whilst still maintaining a flow of new and more effective medicines or the necessary commercial advances in personal products, requires both industry and regulatory authorities to identify and manage the risks presented by an increasingly large number of novel compounds. Often these hazard and risk assessments are made in the absence of high-quality toxicology data, and generating this data would take many years and millions of dollars for each compound under review. As a result, the scientific community has been seeking ways to prioritize these new and existing chemical entities according to their potential for adverse effects to either humans or the environment. The use and application of high-throughput in vitro assays offer significant advantages for both industry and regulator alike, but their application is not without its drawbacks. On the positive side, these types of approaches to hazard assessment are often fast and relatively cheap to run once they have been successfully implemented. In addition, these approaches offer a highly attractive public relations solution in view of the increasing demands to refine, reduce, or replace animals in laboratory experiments. However, questions still exist about their ability to adequately distinguish between toxic and nontoxic molecules and their effectiveness in ensuring public safety. This workshop will highlight recent experiences and learnings in the practical application of high-throughput in vitro assays across a broad scope of industry and regulatory agencies. The presentations will illustrate how in vitro assays are being applied to gain an understanding of which chemicals have the highest level of concern and can lead to a greater understanding of the mechanisms of action that can ultimately result in toxicity.

- Introduction. Nigel Greene, Pfizer, Inc., Groton, CT.
- Genetic Mapping of In Vitro Susceptibility to Cytotoxic Compounds—The 1000 Genomes High-Throughput Screening Study. Ivan Rusyn, Texas A&M University, College Station, TX.
Advancing Clinical and Translational Toxicology

Wednesday, March 25, 9:00 AM to 11:45 AM

Chairperson(s): Edward Chow, Allergan, Irvine, CA, and Donald A. Fox, The University of Houston, Houston, TX.

Endorser(s):
- Neurotoxicology Specialty Section
- Ocular Toxicology Specialty Section
- Toxicologic and Exploratory Pathology Specialty Section

The World Health Organization estimates that 285 million people worldwide are visually impaired or blind due to age-related macular degeneration (AMD), diabetic retinopathy, glaucoma, retinitis pigmentosa, or drug- and chemical-induced retinal degeneration. These retinopathies are characterized by progressive and regional/cell selective loss of anatomically or physiologically related neuronal function. Retinotoxicity is also an important issue during drug development as a result of both on- and off-target effects. New advances in noninvasive electrophysiological and imaging techniques at the cellular and micron level of resolution have enabled efficient time-course studies in man and animals and contributed to earlier detection/diagnosis and increased understanding of retinal toxicity in them. Basic and clinical science studies, utilizing advanced electrophysiological and imaging techniques, in developing and adult organisms, have elucidated interspecies similarities and differences in retinal anatomy, cell/molecular biology, cell signaling, pharmacology, physiology, pharmacokinetics, and metabolism that enable a more precise translation of animal retinotoxicity to man. The first four speakers in this symposium will present the latest information about these areas while the final speaker will address recent developments in retinal pigmented epithelium stem cell basic and clinical/translational research, including the toxicology evaluation that is required before initiating human trial for this latest technological advancement. Together, these speakers will provide the latest comprehensive information about retinotoxicology and describe a framework for predictive retinotoxicity of new drugs and environmental/industrial chemicals.

Introduction. Edward Chow, Allergan, Irvine, CA.


The Role of Blood-Retina Barrier Transporters in Retinal Toxicity. James Chastain, Alcon Research Ltd, Fort Worth, TX.

Toxicant-Induced and Off-Target Drug-Induced Retinotoxicity: Selective Cellular and Compartmental Sites and Mechanisms of Action. Donald A. Fox, The University of Houston, Houston, TX.

Retinal Pigment Epithelium: Disease and Drug-Induced Dysfunction. Craig Crosson, Medical University of South Carolina, Charleston, SC.

Stem Cells in Retinal Repair and Regeneration. Dennis Clegg, University of California Santa Barbara, Santa Barbara, CA.

Evaluating Similarity across Related Complex Mixtures: The Challenge of Herbal Supplements

Wednesday, March 25, 9:00 AM to 11:45 AM

Chairperson(s): Cynthia V. Rider, NTP/NIEHS, Research Triangle Park, NC, and Joseph M. Betz, ODS/NIH, Bethesda, MD.

Endorser(s):
- Food Safety Specialty Section
- Mixtures Specialty Section

Complex mixtures represent a significant public health concern and challenge to the risk assessment community. Whole mixture approaches are recommended by risk assessors because evaluating the “mixture of concern” necessarily accounts for the unidentified fraction and precludes the need to introduce the assumption of additivity among identified constituents (or define all interactions), as opposed to component-based approaches. However, assessing the safety or risk associated with every permutation of a complex mixture is an intractable problem. Therefore, methods for determining sufficient similarity of the mixture of interest to a well-characterized reference mixture are necessary. Herbal supplements provide a unique opportunity to make progress in this arena while addressing the important public health concern of herbal supplement safety. Herbal products on the marketplace often display a wide range of constituent concentrations that frequently differ from label claims. Significant research has been dedicated to characterizing the chemistry of these complex mixtures and comparing across related formulations using marker compounds and fingerprinting techniques in order to confirm appropriate source material and identify adulterated products. Progress has also been made in comparing similarity of biological responses across multiple herbal products and developing statistical methods for evaluating sufficient similarity. However, the whole picture—recommended approaches for evaluating chemical and biological sufficient similarity—has yet to emerge. In this session, speakers will discuss the latest science for evaluating chemical and biological similarity of related
products with a focus on herbal supplements. Developing recommended methods for comparing across herbal products will help in the evaluation of herbal supplements in the marketplace and could be readily extrapolated to other complex mixture scenarios (e.g., commercial formulations, environmental contaminant mixtures).

- **Introduction.** Cynthia V. Rider, NTP/NIEHS, Research Triangle Park, NC.

- **Framing the Issue: Is the Product You Are Consuming the Same As That Evaluated for Safety?** Joseph M. Betz, ODS/NIH, Bethesda, MD.


- **Fingerprinting Methods for Identification and Authentication of Botanical Supplements.** James Harnly, USDA, Beltsville, MD.

- **Moving forward on Complex Herbal Mixtures at the National Toxicology Program.** Cynthia V. Rider, NTP/NIEHS, Research Triangle Park, NC.

- **Steps toward Using Statistical Approaches for Determining Sufficient Similarity.** Chris Gennings, Mount Sinai, Richmond, VA.

### Genomics of Nonrodent Mammalian Species and Impacts on Nonclinical Safety Evaluation of Pharmaceuticals and Clinical Translation

- **Epigenomic Influences in Toxicological Responses**

  **Wednesday, March 25, 1:30 PM to 4:15 PM**

  **Chairperson(s):** Jing Yuan, Boehringer Ingelheim Pharmaceuticals Inc., Ridgefield, CT, and Hong Wu, Pfizer Inc., Groton, CT.

  **Endorser(s):**

  - Clinical and Translational Toxicology Specialty Section
  - Drug Discovery Specialty Section
  - Molecular and Systems Biology Specialty Section

  Inclusion of a nonrodent mammalian species is required in the safety assessment of pharmaceuticals according to ICH guidelines. The nonhuman primate has been commonly used for nonclinical safety assessment. In recent years, the minipig has emerged as a viable alternative of nonrodent species. The use of nonrodent species for testing aims at limiting the uncertainty in the risk extrapolation process from animal safety data to the human situation. The uncertainty mainly originates from species variation and population heterogeneity in various biological processes. While the use of small sample sizes for nonrodent species contributes to the observed variability or precision in a nonclinical safety study, any phenotypic variability observed is largely attributed to the genetic composition of testing animals. Therefore a better understanding of genetic variation and its subsequent impact on data interpretation from nonclinical safety studies in nonrodents is important. Comparative genomic studies in nonrodent species and humans will aid in better selection of relevant nonrodent species for safety assessment and better understanding of target organ toxicity mechanisms, which should lead to better translatability to humans. In this workshop, we will discuss the use of genetic and genomic data to support understanding of safety endpoints in nonrodent mammalian species, mainly nonhuman primates and minipig. The following issues will be included: (1) an overview of nonrodent mammalian species and genomic technologies used in nonclinical animal studies; (2) a series of case studies that illustrate the application of genetics and genomics in addressing toxicology issues, including species selection, immunomodulation, and target organ toxicity; (3) challenges and future perspectives of using genetic and genomic data to support safety assessment in nonrodent mammalian species; (4) a commentary from the regulatory perspectives on the application of genomics in clinical translation and challenges in regulatory submission.

- **Introduction.** Jing Yuan, Boehringer Ingelheim Pharmaceuticals Inc, Ridgefield, CT.

- **Transcriptional Program of Organ Development in the Göttingen Minipig from Young to Adult.** Tobias Heckel, Roche Pharmaceutical Research and Early Development, Basel, Switzerland.

- **Macaque Monkeys Are Vital Preclinical Models for Biomedical Research.** Roger Wiseman, University of Wisconsin-Madison, Madison, WI.

- **Genetics: The Underappreciated Factor in Drug Safety Assessment Using Cynomolgus Monkeys.** Karissa Adkins, Pfizer Inc., Groton, CT.

- **Geographic Origin-Dependent Genetic Variation in Nonhuman Primates and Impact for Toxicology Programs.** Olivier Grenet, Novartis Institutes of Biomedical Research, Basel, Switzerland.

- **Regulatory Experiences with Submission of Genomic Data for Human Risk Assessment.** John Leighton, US FDA, Silver Spring, MD.

### Increasing Interest and Engagement in Toxicology and STEM Disciplines: The Multiple Modalities and Impact of Research and Internship Opportunities for High School and Undergraduate Students

- **Wednesday, March 25, 1:30 PM to 4:15 PM**

  **Chairperson(s):** Richard S. Pollenz, University of South Florida, Tampa, FL, and William D. Atchison, Michigan State University, East Lansing, MI.

  **Endorser(s):**

  - Committee on Diversity Initiatives
  - Education Committee
  - Postdoctoral Assembly

  Only 40 percent of undergraduates who enter STEM disciplines graduate with a STEM degree. The loss is even greater for students from underrepresented groups. Thus, there is urgency at all educational levels to institute high-impact practices that will not only assure a strong pipeline within the STEM disciplines, but also produce qualified graduates with the skills to succeed in the job market and in graduate school. One of the most impactful practices to retain and prepare students interested in STEM disciplines is their strategic engagement in research experiences and internships. These
experiences can be targeted at middle and high school students to get them interested in specific disciplines and STEM careers, and then offered to undergraduates either in the summer or as part of their academic programs to encourage STEM persistence, career readiness, and matriculation to graduate school. Since these types of experiences are often tailored to the agency or institution and have different programming elements, this session will provide case studies of proven research and internship programs that have been offered to high school students, undergraduates, and graduate students in academia, government, and industry. Presentations will focus on the implementation and management of the programs, details of the training exercises, staffing needs, costs, and assessment practices that document the impact to the students. The session should be beneficial to all institutions and agencies interested in developing similar programs or building on their current programs. In addition, these types of initiatives not only provide engaged opportunities for students, but serve as demonstrated evidence of program development, mentoring activities, and outreach for those involved in implementing and administering the programs. The workshop will conclude with an unstructured panel discussion where attendees can network with the speakers and obtain details of how these programs may be scaled to fit their needs.

- **Introduction and Overview of Session.** Richard S. Pollenz, University of South Florida, Tampa, FL.
- **A Model One-Week Residential High School STEM Pre-College Engagement Program.** Richard S. Pollenz, University of South Florida, Tampa, FL.
- **Designing a Laboratory-Based Summer Program in Toxicology and Environmental Health Sciences for High School Students.** Lauren M. Aleksunes, Rutgers University, Piscataway, NJ.
- **Increasing Environmental Health Literacy: A Model for High School and Undergraduate Summer Internship Programs in Government.** Tammy R. Collins, NIEHS, Research Triangle Park, NC.
- **A Model for Undergraduate and Graduate Summer Student Programs in Industry.** Betty A. Pettersen, Pfizer Global Research and Development, Groton, CT.
- **“Bridge to the PhD in Biomedical Sciences”: A Program to Foster Engagement of Underrepresented Minority Students in Biomedical Research.** William D. Atchison, Michigan State University, East Lansing, MI.

### Integrating Gene Expression Profiling into High-Throughput Toxicity Testing

**Wednesday, March 25, 1:30 PM to 4:15 PM**

*Chairperson(s):* Chris Corton, US EPA, Durham, NC, and Scott S. Auerbach, NTP/NIEHS, Durham, NC.

*Endorser(s):*
- **In Vitro and Alternative Methods Specialty Section**
- **Mechanisms Specialty Section**
- **Molecular and Systems Biology Specialty Section**

Coordinated programs in high-throughput toxicity testing (HTT) (e.g., Tox21 and ToxCast screening programs) currently use assays that evaluate a limited number of potential molecular targets. Because of their complete coverage of the genome, microarrays have the potential to evaluate the underlying network of most, if not all, targets simultaneously. This workshop addresses the growing recognition in the toxicology community that technologies that measure global gene expression can be adapt for HTT. Significant advantages for integrating these technologies into HTT include simultaneous assessment of a greater diversity of potential chemical targets, linkage to ongoing large-scale efforts that examine gene expression changes after chemical and genetic perturbations in multiple *in vitro* systems (in particular, the Library of Integrated Network-based Cellular Signatures (LINCS) project), and the potential for using *in vitro* transcript profiling as a first step in HTT prior to more targeted *in vitro* assays. This workshop brings together a balanced representation of experts working in the field who will address challenges and provide solutions for using these global technologies in HTT and interpreting the results to inform risk assessment. The first speaker will present a comprehensive strategy for how expression profiling can be integrated into HTT, allowing the audience to understand the context of the following talks. The second and third speakers will describe two technologies (RASL-Seq and L1000 platforms) that have promising applications to HTT, highlighting how differences in platform performance can impact interpretation of chemical effects. The fourth speaker will discuss how transcript profiling results derived from cell cultures can be extrapolated to potential dose-relevant effects in the tissues of humans. The last speaker will describe the LINCS project as a model of HTT, in which transcript profiling of ~8000 chemicals was carried out across 17 cell lines. This workshop will be of broad interest to SOT members including scientists interested in the application of *in vitro* assays to regulatory decision-making.

- **Introduction.** Chris Corton, US EPA, Durham, NC.
- **Strategies for Integrating Transcript Profiling into High-Throughput Toxicity Testing.** Russell S. Thomas, US EPA, Research Triangle Park, NC.
- **A High-Throughput Gene Expression Approach to Identify Toxicity Mechanisms.** David Gerhold, NCATS, Rockville, MD.
- **Comparison of a Full-Genome Microarray with the L1000 Platform.** George Daston, Proctor and Gamble, Cincinnati, OH.
- **From Cell Lines to Tissues: Extrapolation of Transcriptional Effects to Human Tissues.** John F. Wambaugh, US EPA, Research Triangle Park, NC.
Workshops

- Using the Library of Integrated Network-Based Cellular Signatures (LINCS) to Characterize the Mechanism of Action of Small-Molecule Therapeutics. Aravind Subramanian, Broad Institute, Cambridge, MA.

Strengths and Weaknesses of Mouse Models in Studies of Immunological Effects of Drugs and Chemicals

**Safety Assessment Approaches for Product Development**

Wednesday, March 25, 1:30 PM to 4:15 PM

**Chairperson(s):** Courtney E.W. Sulentic, Boonshoft School of Medicine, Wright State University, Dayton, OH, and Bindu Nanduri, Mississippi State University, Mississippi State, MS.

**Endorser(s):**
- Immunotoxicology Specialty Section
- Regulatory and Safety Evaluation Specialty Section

Recent results with high-throughput datasets have raised new interest in discussions on the suitability of mice as models for immunology, inflammation, and immunotoxicology in humans. Mouse models are routinely used in immunotoxicology safety testing, efficacy testing for new drugs, and in basic immunology research. Recent studies from the Inflammation and Host Response to Injury, Large-scale Collaborative Research Program compared humans to mouse models with regard to trauma and sepsis, and raised questions about the validity of mice as a model to study acute inflammatory responses in humans (www.pnas.org/cgi/doi/10.1073/pnas.1222878110). This and other publications and original data from the presenters will provide an opportunity to discuss evidence for and against mice as suitable models for humans with regard to inflammation, immunology, and immunotoxicology. Data from industry and academia will be presented, along with evidence from various murine strains currently used in the study of acute inflammatory responses and immunity to attempt to identify key differences between mice and humans with regard to inflammatory and immune responses. Presenters will discuss how increased knowledge of these differences could increase the value of the mouse as an animal model for immunotoxicity studies.

- Introduction. Courtney E.W. Sulentic, Boonshoft School of Medicine, Wright State University, Dayton, OH.
- Mice As an Animal Model in Immunology: Regulatory and Industry Perspectives. Kenneth L. Hastings, Sanofi-Aventis, Bethesda, MD.
- A Reassessment of Mice As a Model for Sepsis in Humans. Stephen B. Pruett, Mississippi State University, Mississippi State, MS.
- Xenobiotic Effects on Immunoglobulin Expression in a Humanized Mouse Model. Courtney E.W. Sulentic, Boonshoft School of Medicine, Wright State University, Dayton, OH.
- Autoimmune-Prone versus Normal Mice As Models for Toxicant-Mediated Autoimmune Disease. Kathleen M. Gilbert, University of Arkansas for Medical Sciences, Little Rock, AZ.
- Comparisons of Immunological Changes in Burn Patients and Rodent Thermal Injury Models. Elizabeth Kovacs, Stritch School of Medicine, Loyola University, Chicago, IL.

The Carcinogenicity of Outdoor Air Pollution: A Review of the IARC Evaluation of Outdoor Air Pollution and Particulate Matter in Polluted Air As Group 1 (Known) Human Lung Carcinogens and Possible Bladder Carcinogens

**Strategies for Exposure and Risk Assessments**

Wednesday, March 25, 1:30 PM to 4:15 PM

**Chairperson(s):** George M. Woodall, US EPA, Research Triangle Park, NC, and Paul White, University of Ottawa, Ottawa, ON, Canada.

**Endorser(s):**
- Carcinogenesis Specialty Section
- Mixtures Specialty Section
- Risk Assessment Specialty Section

In October 2013, the International Agency for Research on Cancer (IARC), a specialized agency of the World Health Organization (WHO), evaluated outdoor air pollution and particulate matter (PM) in polluted air as Group 1 (known) human lung carcinogens. This workshop reviews and summarizes the key data from four disciplines (epidemiology, animal carcinogenesis, environmental mutagenesis, and human genotoxicity and epigenetic biomarkers) that were used to support the evaluation reached by IARC. This IARC Monograph (Vol. 109) follows an earlier set of monographs on the carcinogenicity of (a) polycyclic aromatic hydrocarbons and bitumin, (b) indoor air due to coal and biomass burning, and (c) diesel and gasoline emissions. These monographs, along with the outdoor air monograph, now provide an extremely comprehensive, timely, and integrated overview of all available research on outdoor air pollution. As noted in the outdoor air monograph, which is anticipated to be published in mid-2015, the working group concluded that there was sufficient evidence both in humans and animals for the carcinogenicity of outdoor air pollution and its associated PM, and there was strong mechanistic evidence from a wide variety of studies worldwide to support this conclusion. Four of the five speakers in this workshop were members of the IARC working group that made this evaluation. This session will wrap-up with a talk by the chair of the monograph who will note the lessons learned from this extensive analysis. He will also identify the future research directions and public health implications that emerge from this monograph and its remarkable data base. The views expressed in this abstract are those of the authors and do not necessarily reflect the views or policies of the US Environmental Protection Agency.

- Lung Cancer Epidemiology of Outdoor Air Pollution. Aaron J. Cohen, Health Effects Institute, Boston, MA.
Endocrine disruption (ED) has become an important topic of public concern. Despite increasing attention, little consensus exists about if/how low doses of ED chemicals affect homeostasis or even how these activities should be measured or regulated. Critics of current methodologies suggest that gaps in standard developmental and reproductive toxicity studies result in insufficient prediction of human safety in cases with an ED mode of action, arguing that nontraditional study designs and systems biology endpoints should be incorporated into regulatory decision-making. An increasing number of ED research and regulatory studies are now conducted using protocols modified to include ex vivo and in vitro assays, kinetic modeling, as well as ‘omic and epigenetic assessments. These enhancements may provide many new avenues for scientific discovery, but come at a price of increasing complexity. In this workshop, the strengths, weaknesses, and experimental pitfalls of these techniques will be presented and compared with conventional approaches to assess the consequences of ED. Advantages of such modifications for the detection and assessment of ED compounds will be weighed against their drawbacks using real-world example studies. The studies will first be presented, addressing what modifications were used and whether the “add on” parameters helped with hazard assessment. After each speaker has presented, the workshop will then conclude with a panel discussion session covering the good, the bad, and the ugly—which endpoints are useful and which are too complicated to make work, or generate uninterpretable data. The session will be of broad interest to academic, industry, regulatory, and consultant toxicologists concerned about the current status of ED testing and/or advances in nonclinical ED safety assessment.

**Workshops**

**Windfall or Pitfall: Is There a Need for Modification of Developmental and Reproductive Toxicology Studies When Endocrine Disruption Is the Mode of Action?**

**Safety Assessment Approaches for Product Development**

**Wednesday, March 25, 1:30 PM to 4:15 PM**

**Chairperson(s):** Bennard van Ravenzwaay, BASF SE, Ludwigshafen am Rhein, Germany, and L. Earl Gray Jr., US EPA, Research Triangle Park, NC.

**Endorser(s):**
- Molecular and Systems Biology Specialty Section
- Reproductive and Developmental Toxicology Specialty Section

Endocrine disruption (ED) has become an important topic of public concern. Despite increasing attention, little consensus exists about if/how low doses of ED chemicals affect homeostasis or even how these activities should be measured or regulated. Critics of current methodologies suggest that gaps in standard developmental and reproductive toxicity studies result in insufficient prediction of human safety in cases with an ED mode of action, arguing that nontraditional study designs and systems biology endpoints should be incorporated into regulatory decision-making. An increasing number of ED research and regulatory studies are now conducted using protocols modified to include ex vivo and in vitro assays, kinetic modeling, as well as ‘omic and epigenetic assessments. These enhancements may provide many new avenues for scientific discovery, but come at a price of increasing complexity. In this workshop, the strengths, weaknesses, and experimental pitfalls of these techniques will be presented and compared with conventional approaches to assess the consequences of ED. Advantages of such modifications for the detection and assessment of ED compounds will be weighed against their drawbacks using real-world example studies. The studies will first be presented, addressing what modifications were used and whether the “add on” parameters helped with hazard assessment. After each speaker has presented, the workshop will then conclude with a panel discussion session covering the good, the bad, and the ugly—which endpoints are useful and which are too complicated to make work, or generate uninterpretable data. The session will be of broad interest to academic, industry, regulatory, and consultant toxicologists concerned about the current status of ED testing and/or advances in nonclinical ED safety assessment.

**THURSDAY**

**Microphysiological Models of the Developing Nervous System: Biologically Driven Assembly Inspired by Embryology and Translated to Human Developmental Toxicology**

**Approaches for Protecting Vulnerable Populations**

**Thursday, March 26, 9:00 AM to 11:45 AM**


**Endorser(s):**
- In Vitro and Alternative Methods Specialty Section
- Neurotoxicology Specialty Section
- Reproductive and Developmental Specialty Section

Recent advances using human stem cells and other cells that can be ushered through differentiation and developmental maturation offer an unprecedented opportunity to develop predictive systems for toxicological assessment. The use of human cells is an advantage because there is no need to extrapolate across species, but even so, there may be the requirement that different cell types interact in a three-dimensional (3D) relationship in order to provide prediction of the intact human. For example, in the developing nervous system, multiple cell types including neurons, astrocytes, and oligodendrocytes, interact in the presence of growth factors, cytokines, and other hormones to function within a 3D spatial configuration that can reflect normal biological functioning in a predictive manner. The purpose of this
workshop is to take a close look at the novel approaches being applied for biologically driven assembly, in which exploiting the capacity of an embryo to build tissues and organs from scratch, and the multicellular response dynamics in biologically driven assembly are facilitating “human-on-a-chip” microscale systems and other cellular-complex culture models for evaluating developmental neurotoxicity. The individual topics will address the progress that has been made concerning how the cellular microenvironment dictates tissue morphogenesis and the importance of 3D cellular architecture in cellular function; identification of signaling pathways that contribute to exogenously-induced developmental neurotoxicity; mini-brain organoid platforms to study complex cellular networks and disease models for drug development, toxicology, and medicine; and the requirement for quantitative outcome measures that are essential to the overall success of the organotypic culture approach in order for it to be predictive of the human situation. Standard approaches will be outlined with the use of positive and negative test agents to allow confirmation of the reproducibility of these in vitro test systems in different laboratory environments. The views expressed in this abstract do not necessarily reflect US EPA or US FDA policy.

- **Introduction.** Thomas B. Knudsen, US EPA, Research Triangle Park, NC.
- **Engineered Microphysiological Systems for Cell-Based Predictive Models of Developmental Neurotoxicity and Teratogenicity.** William L. Murphy, University of Wisconsin–Madison, Madison, WI.
- **Probing Signaling Pathways in Developmental Neurotoxicity with Human 3D Neospheres.** Ellen Fritsche, IUF Leibniz Research Institute for Environmental Medicine, Duesseldorf, Germany.
- **Biological and Medical Applications of a Brain-on-a-Chip.** Thomas Hartung, Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD.
- **Standards and Minimum Requirements for Validation of Complex Organotypic Culture Model Systems.** Robert E. Chapin, Pfizer Inc, Groton, CT.
- **Panel Discussion.** William Slikker Jr., NCTR, US FDA, Jefferson, AR.

**Painting the Future of Repeat-Dose Systemic Toxicity Testing: Progress from the European SEURAT-1 Project**

**Thursday, March 26, 9:00 AM to 11:45 AM**

**Chairperson(s):** Russell S. Thomas, US EPA, Research Triangle Park, NC, and Maurice P. Whelan, European Commission Joint Research Centre, Ispra, Italy.

**Endorser(s):**
- In Vitro and Alternative Methods Specialty Section
- Molecular and Systems Biology Specialty Section
- Regulatory and Safety Evaluation Specialty Section

In 2011, a public-private partnership between the European Commission and Cosmetics Europe funded the “Safety Evaluation Ultimately Replacing Animal Testing” (SEURAT-1) cluster of six research consortia with the goal of filling scientific knowledge gaps and accelerating the development of nonanimal test methods for repeat-dose toxicity testing. Replacement of repeated-dose testing with alternative approaches is a daunting task and will require a complete shift in paradigm towards a new definition of “adversity” defined at the molecular and cellular level, rather than by traditional apical endpoints. To demonstrate and evaluate the applicability of the alternative methods developed within the consortium, a series of cross-cluster case studies were initiated to (i) develop a series of adverse outcome pathways (AOPs) that can be used for designing integrated test systems, (ii) demonstrate various AOP-based systems for quantitatively predicting repeat-dose toxicity, and (iii) apply information from the predictive systems to a chemical safety assessment. The purpose of this workshop is to present, for the first time, the results and lessons learned from a complementary set of these case studies. The workshop will be of high interest to a broad audience, including industry representatives whose products are affected by the European Union ban on cosmetic animal testing, government regulators interested in in vitro alternatives to animal tests, and academic researchers investigating the mechanisms of chemical toxicity.

- **Introduction.** Russell S. Thomas, US EPA, Research Triangle Park, NC.
- **Predictive Power and Robustness of an AOP Construct for Bile Salt Export Pump Inhibition to Cholestatic Injury.** Mathieu Vinken, Vrije Universiteit Brussel, Brussels, Belgium.
- **Chemotypes for Mitochondrial Toxicity Prediction.** Mark T. Cronin, Liverpool John Moores University, Liverpool, United Kingdom.
- **AOP-Based Classification Model for Repeat-Dose Liver Toxicity.** Alfonso Lostia, European Commission, Joint Research Centre, Ispra, Varese, Italy.
- **Development of a Liver Co-Culture System for Evaluating Adverse Outcome Pathways Leading to Fibrosis.** Leo A. van Grunsven, Vrije Universiteit Brussel, Brussels, Belgium.
- **Case Studies on Using In Vitro Molecular Screening, ‘Omics, and Computational Models to Support a Quantitative Chemical Risk Assessment and Chemical Read-Across.** Andrew White, Unilever, London, United Kingdom.
MONDAY

Addressing Potential Age-Related Sensitivity to Neurotoxicity of Pyrethroids

Approaches for Protecting Vulnerable Populations

Monday, March 23, 12:10 PM to 1:30 PM

Chairperson(s): Thomas G. Osimitz, Science Strategies, Charlottesville, VA, and Anna B. Lowit, US EPA, Washington, DC.

Endorser(s):
- Biological Modeling Specialty Section
- Neurotoxicology Specialty Section
- Risk Assessment Specialty Section

The sensitivity of infants and children to pesticides has historically been evaluated via a combination of developmental toxicity, reproduction, and developmental neurotoxicity studies conducted in accordance with US EPA and OECD test guidelines. For pyrethroid insecticides, the collective results from these studies indicated no additional sensitivity of young rats and rabbits during development, thus obviating the need for an additional safety factor for infants and children (FQPA). The pyrethroid industry is investigating age-related pharmacodynamic (PD) and pharmacokinetic (PK) differences in sensitivity using model pyrethroids. Designed in accordance with the principles in Toxicity Testing in the 21st Century: A Vision and a Strategy (NAS, 2007) and with US EPA input, the research is providing age-related pyrethroid-specific PD and PK parameters for PBPK model development. This significantly enhances both neurotoxicity and children’s health risk assessment and provides new understanding of how focused research can be developed for the adverse outcome pathway framework for risk assessment.

- Current State of Knowledge with Respect to Pyrethroid Neurotoxicology—Basis for Concern about Age-Related Sensitivity. Larry P. Sheets, Bayer CropScience, Stilwell, KS.
- Targeted Evaluation of Age-Related Pharmacodynamics Using Mammalian CNS Neurolemma Preparations. John M. Clark, University of Massachusetts, Amherst, MA.
- Use of Acoustic Startle Responses to Assess Age-Related Pharmacodynamics. Charles V. Vorhees, Cincinnati Children’s Research Foundation, Cincinnati, OH.

Confronting and Overcoming the Barriers to Sharing Toxicological Research Data for Risk Assessment in the 21st Century

Strategies for Exposure and Risk Assessments

Monday, March 23, 12:10 PM to 1:30 PM

Chairperson(s): George M. Woodall, US EPA, Research Triangle Park, NC, and Gary W. Miller, Emory University, Atlanta, GA.

Endorser(s):
- Ethical, Legal, and Social Issues Specialty Section
- Inhalation and Respiratory Specialty Section
- Risk Assessment Specialty Section

The need for better data-sharing opportunities is a highlight of the NAS document Toxicity Testing in the 21st Century: A Vision and a Strategy, which included recommendations to develop the data management infrastructure “to enable broad data-sharing across academic, government, industry, and NGO sectors and institutions.” This applies equally to high-throughput assay results, in vivo animal studies, and human clinical and epidemiological studies. The need is critical in quantitative analysis, where raw data from individual subjects or groups provides greater power in an analysis than will summarized results. Substantial barriers block access to these toxicological research data. An effective strategy to identify and propose remedies to those barriers has yet to be formulated. The issues are multifaceted: the need to protect personally identifiable information versus protection of public health, intellectual property rights versus public access to data developed using public funds, publication of research findings by the originator of the data versus allowing more powerful analysis using data from multiple studies, and many others. The primary intent of this roundtable discussion is to begin a dialogue to define a proper balance between these competing needs and stakeholder perspectives, while at the same time enhance the science of toxicology, protect public health, and ensure scientific credibility. Panelists have been selected to represent one or more stakeholder group. Open dialogue with the audience will be encouraged to include the perspectives of the larger SOT community. The views expressed here are those of the authors and do not necessarily reflect the views or policies of the US Environmental Protection Agency.

- Using Limited-Access Data in Public Health Research. Arden Pope, Brigham Young University, Provo, UT.
- Perspectives from a Major Collector, Organizer, Preserver, Curator, and Disseminator of Data. Pertti J. Hakkinen, NIH, Bethesda, MD.
- Perspectives from a University Attorney on the Issues of Using Research Data. Paul H. Zigas, East Carolina University, Greenville, NC.

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Roundtables

WEDNESDAY

Should Respiratory Sensitizers Be Listed As Substances of Very High Concern (SVHC) under REACH?

Wednesday, March 25, 12:00 Noon to 1:20 PM

Chairperson(s): Jon A. Hotchkiss, The Dow Chemical Company, Midland, MI, and David Basketter, DABMEB Consultancy Ltd., Sharnbrook, United Kingdom.

Endorser(s):
- Immunotoxicology Specialty Section
- Inhalation and Respiratory Specialty Section
- Regulatory and Safety Evaluation Specialty Section

There is increasing regulatory pressure in Europe to list respiratory sensitizers as substances of very high concern (SVHC) based on “equivalent level of concern” criteria set out in REACH Article 57(f). This approach assumes that in certain cases, the negative impacts caused by sensitizers on the health and quality of life of affected individuals and on society as a whole are comparable to those elicited by carcinogens, mutagens, and reproductive toxicants (CMRs). Potential factors for comparison include seriousness of the effect, delayed onset and/or irreversibility of effects, potency, mode of action, impairment of life quality, or uncertainty about the dose-response relationships. As there are currently no applicable guidelines or generally accepted assays that can accurately identify respiratory sensitizers or distinguish between respiratory and dermal sensitizers, all materials with sensitizing potential may be considered for inclusion as SVHC. While all respiratory sensitizers may test positive in animal-based dermal sensitization assays, skin sensitizing agents do not elicit respiratory effects under normal circumstances and respiratory sensitizers are generally considered to pose a greater health concern. Current guidance recommends a weight-of-evidence approach based on human and animal data to identify a potential respiratory sensitizer; however, some regulatory authorities may accept any positive indication of sensitizing potential as evidence for inclusion as a SVHC. A SVHC is subject to authorization within the EU and may not be used unless an authorization is granted for their specific use. These proposed regulatory actions will likely have a profound impact on the sale and use of materials upon which safe exposure levels may be based.

Introduction. Jon A. Hotchkiss, The Dow Chemical Company, Midland, MI.


Respiratory Sensitizers Should Be Listed As SVHC Based on an Equivalent Level of Concern to CMR Substances. David Basketter, DABMEB Consultancy Ltd., Sharnbrook, United Kingdom.

- Respiratory Sensitizers Are Not Equivalent to CMR Substances and Should Be Evaluated on a Case-by-Case Basis. Jon A. Hotchkiss, The Dow Chemical Company, Midland, MI.
- Respiratory Sensitizers Have Measurable Response Thresholds upon Which Safe Exposure Levels May Be Based. Juergen Pauluhn, Bayer Pharma AG, Wuppertal, Germany.

Will Generally Recognized As Safe (GRAS) Become an Endangered Species?

Wednesday, March 25, 12:00 Noon to 1:20 PM

Chairperson(s): Ray A. Matulka, Burdock Group, Orlando, FL, and Emilia Lonardo, Grocery Manufacturers Association, Washington, DC.

Endorser(s):
- Ethical, Legal, and Social Issues Specialty Section
- Food Safety Specialty Section
- Regulatory and Safety Evaluation Specialty Section

The current legislative and regulatory framework provides for self-determination of Generally Recognized As Safe (GRAS) ingredients in food products, with voluntary notification of the GRAS determination to the US FDA. Recent reports by the federal General Accountability Office, the Pew Institute, and the Natural Resources Defense Council have been critical of the Generally Recognized As Safe (GRAS) process for use of food ingredients. Specifically, GRAS has come under fire as not having adequate safeguards in place to protect the public from inadequate safety behind a decision of GRAS, specifically as being susceptible to conflicts of interest and generally, too far outside of regulatory oversight, which might otherwise provide a higher degree of assurance of public safety. More recently, the GRAS status of partially hydrogenated oils (aka trans fats) has been revoked. Does this mark the start of a new era where the US FDA will have more oversight of the GRAS process? Will GRAS notification be required? Would this requirement increase the safety of food ingredients? This roundtable will provide an in-depth look at the history and future of GRAS determinations, where the GRAS process has worked, why the GRAS status of a few ingredients has been revoked, and how the process can be improved. Principles followed in the self-determination and notification processes of GRAS ingredients, safeguards that are in place to ensure the safety of GRAS ingredients, and proposed steps to increase transparency and rigor of the assessments will be discussed.

Introduction. Emilia Lonardo, Grocery Manufacturers Association, Washington, DC.

US FDA’s GRAS Notification Program: Considerations Regarding Oversight of Food Ingredient Safety. Antonia Mattia, US FDA, College Park, MD.


Epigenetics and Chemical Safety Assessment: Are We Ready?

**Epigenomic Influences in Toxicological Responses**

**Wednesday, March 25, 4:30 PM to 5:50 PM**

**Chairperson(s):** Igor Pogribny, US FDA-NCTR, Jefferson, AR, and Jay I. Goodman, Michigan State University, East Lansing, MI.

**Endorser(s):**
- Regulatory and Safety Evaluation Specialty Section
- Risk Assessment Specialty Section

Continuous exposure to certain natural and manmade chemicals might be a major cause of noncommunicable human diseases, including cancer. Evidence is accumulating indicating that some of the earliest events preceding the development of these pathological states involve perturbations of the cellular epigenome, including modifications at the 5-position of DNA-cytosine, histone modifications, and expression of noncoding RNAs. This suggests that despite a lack of conclusive information to clarify which epigenetic changes are involved directly in the pathogenesis of exposure-related disease and which are the results of the pathological state, they might be useful in safety assessment of chemicals, including pharmaceuticals. The application of epigenomic profiling technologies to chemical safety assessment has great potential for providing novel mechanistic insights into the molecular basis of long-lasting cellular perturbations, including increased susceptibility to disease and/or toxicity. However, a better understanding of some of the key questions, including the following: (i) can we design screening systems to identify epigenetic perturbations that are actual predictors of toxicity?; (ii) what type(s) of epigenetic alterations should be used as biomarkers of exposure?; (iii) can appropriate trans-species epigenetic biomarkers be identified?; (iv) how does the inter-individual variability of the epigenome affect risk assessment?; (v) can these biomarkers and evaluations improve the risk assessment process?; and (vi) what needs to be acquired prior to incorporation of an epigenetic evaluation into the overall chemical safety assessment process?

- **Introduction.** Igor Pogribny, US FDA-NCTR, Jefferson, AR.
- **Epigenetics and Chemical Safety Assessment: Are microRNAs Potential Biomarkers of Chemical Carcinogenesis?** Nigel J. Gooderham, Imperial College London, London, United Kingdom.
- **Investigating the Role of Epigenetics in Product Safety Assessment.** Reza J. Rasoulpour, Dow AgroSciences, Midland, MI.
- **Toward Incorporating Epigenetic Mechanism into Carcinogen Identification and Evaluation.** Zdenko Herceg, International Agency for Research on Cancer (IARC), Lyon, France.

The current carcinogenicity testing scheme was developed in the 1930s and has undergone modifications in the years since. However, considerable advances in biology and knowledge of cancer mechanisms have also occurred over this time, and our increased mechanistic understanding of cancer development and progression coupled with the need to increase the science base of risk assessment warrant a re-evaluation of cancer testing approaches. This roundtable will examine current and future cancer assessment. Specifically, the roundtable will address how improvements in the detection and identification of carcinogens and the utility of this information for human risk assessment should be incorporated into the evaluation of potential carcinogenic risk. For example, recent proposed changes to the ICH S1 cancer risk guidelines have sparked a discussion of the utility of the rodent bioassay. The format of the roundtable will consist of three speakers providing an overview of the current and anticipated future approaches to carcinogen testing. In addition, a panel consisting of the three speakers and three additional toxicologists involved with carcinogen testing from the academic, industry, and regulatory sectors will be convened and will address the future testing paradigm for cancer.

- **Introduction.** Yvonne Dragan, DuPont Company, Newark, DE.
- **The Future of Carcinogenicity Testing for Pharmaceuticals.** Frank D. Sistare, Merck, West Point, PA.
- **An NIEHS/NTP Perspective on the Future of Toxicity and Carcinogenesis Testing.** Linda S. Birnbaum, NIEHS, Research Triangle Park, NC.
- **Smarter Cancer Testing for Pesticide Chemicals.** Anna B. Lowit, US EPA, Washington, DC.
FutureTox III: Transforming 21st Century Science into Risk Assessment and Regulatory Decision-Making

November 19–20, 2015
Hilton Crystal City at Washington Reagan National Airport
Arlington, Virginia

Meeting Overarching Objectives:

- Advancing the cornerstones for high-throughput risk assessment
- Taking TT21C in vitro data and in silico models forward while reducing reliance on animal testing
- Exploring progress and identifying challenges in implementing the emerging “big-data” toolbox for regulatory decision-making

The conference will include plenary sessions (invited lectures), poster sessions (open presentations), and topical breakout groups.

For more information on this and other CCT meetings, please visit www.toxicology.org/cct.
MONDAY

Toxicological Application of Studies Funded by California Stem Cell Research and Cures Act (Prop 71)

Monday, March 23, 12:10 PM to 1:30 PM

Chairperson(s): Kyle L. Kolaja, Cellular Dynamics International, Montclair, NJ, and Arezoo G. Campbell, Western University of Health Sciences, Pomona, CA.

Endorser(s):
Northern California Regional Chapter
Southern California Regional Chapter
Stem Cells Specialty Section

In 2004, Proposition 71 was passed to support stem cell research in California. The California Institute for Regenerative Medicine (CIRM) was created to allocate funds to establish stem cell research in the state. This session highlights research funded through this initiative that is translatable to toxicology. The introduction will provide a brief overview of the goals and implementation of the various California-based stem cell research initiatives funded through CIRM. The ability to create induced pluripotent cells from adult somatic cells has revolutionized cell biology. The first presentation will focus on the quality manufacturing aspects of iPSC and highlight their application in a number of California/CIRM-funded projects that are translatable to toxicological research. The second presentation will feature the function of the Coriell Institute for Medical Research. This institute was funded by CIRM to establish a centralized resource of well-characterized iPSCs. Tissue samples from 3,000 subjects enrolled through seven California-based research groups serve as starting material for deriving iPSCs. Samples are collected from healthy controls and patients with Alzheimer’s disease, autism spectrum disorders, liver, cardiovascular, eye, and respiratory diseases. The Coriell-CIRM Biobank, residing at the Buck Institute for Research on Aging, ensures exceptional storage and distribution of high-quality iPSCs, which can provide a useful model for toxicological testing of environmental and pharmaceutical agents. The last presentation will cover the application of stem cells in a toxicology study with emphasis on how live cell imaging in conjunction with video bioinformatics software tools can be used to assess the effects of environmental chemicals on cells that model stages of prenatal development.

- Regional Impact of Research Initiatives Funding by the California Stem Cell Research and Cures Act (Prop 71). Joe Panetta, Biocom, San Diego, CA.
- The Importance of Quality, Quantity, and Purity in Stem Cell-Derived Tissues and Their Application in Research and Therapeutics. Kyle L. Kolaja, Cellular Dynamics International, Montclair, NJ.
- The Coriell-CIRM Human Pluripotent Stem Cell Biorepository—A Resource for Safe Storage and Distribution of High Quality iPSCs. Steven J. Madore, Coriell Institute for Medical Research, Camden, NJ.
- Using Embryonic Stem Cells to Assess Prenatal Toxicity of Environmental Pollutants. Prue Talbot, University of California Riverside, Riverside, CA.

WEDNESDAY

Risk Communication and Management in the Era of Social Media and the Internet: Serving Society’s Needs with Accurate Information

Wednesday, March 25, 12:00 Noon to 1:20 PM

Chairperson(s): Steven J. Hermansky, ConAgra Foods Inc., Omaha, NE, and Suzanne C. Fitzpatrick, US FDA, College Park, MD.

Endorser(s):
Food Safety Specialty Section
Regulatory and Safety Evaluation Specialty Section
Risk Assessment Specialty Section

Ample evidence exists that the source of chemical safety information for people today has shifted, at least in part, from traditional sources of textbooks, academia, and government authorities to bloggers, websites, and email. This has multiple implications for society as well as our science. Adapting to this new world of communication is critical. Unfortunately, communicating and engaging with the lay public is not addressed as part of graduate training and, therefore, even accomplished toxicologists who are effective scientific communicators find themselves underprepared. The good news is that tools and guidance to help communicate in this new world are rapidly evolving. Expanding the use of these tools and developing new methods requires effort by the risk assessment and risk communication communities. This begins by understanding the tools, learning the methods, and, occasionally, taking a risk by trying out these new communication techniques. Sharing experiences cross functionally will enable communication across the risk management community. Four individuals with varying risk management roles across society come together in this informational session to share their experience and insight into the new world of risk communication. A discussion panel will follow the completion of the formal presentations.

- Introduction. Suzanne C. Fitzpatrick, US FDA, College Park, MD.
- Using Social Media to Communicate Science and Risk: An Industry Perspective. Steven J. Hermansky, ConAgra Foods Inc., Omaha, NE.
- Developing a Successful Risk Communication Program by Leveraging Social Media—Consumer Reports: An NGO Perspective. Urvashi Rangan, Consumer Reports, Yonkers, NY.

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Adaptive Leadership: Anticipating, Initiating, and Responding to Change

Monday, March 23, 12:10 PM to 1:30 PM

Chairperson(s): Brinda Mahadevan, Abbott Laboratories, Columbus, OH, and Hollie I. Swanson, University of Kentucky, Lexington, KY.

Endorser(s):
- Career Resource and Development Committee
- Education Committee

The magnitude of change in organizations has grown tremendously over the past two decades. A hallmark of successful organizations and individuals is their ability to anticipate and respond to change or even initiate change to meet the demand of the moment. Our current workplace environment must address changes in organizational structure, economic factors, and increase in global competitiveness. As individuals, we encounter changes in family structures, personal expectations, career pathways, and trajectories to dynamically sense and respond with actions that are focused, fast, and flexible. A successful leader, team, or organization will evolve, through purposeful strategies that influence and respond effectively to unpredictable and shifting demands and world events. This session will be composed of four presentations that will focus on the changes currently facing the industry, government, contract research organization, and academic sectors. Within each presentation, organizational changes, leadership challenges, and the impact on the individual will be addressed. Each speaker will emphasize their sector-specific changes and unique adaptations to change. The speakers will thus provide practical advice and concrete examples on adaptive leadership that demonstrate a leader’s ability at all levels to effectively accomplish the initiatives every day.

- Introduction to Speakers. Brinda Mahadevan, Abbott Laboratories, Columbus, OH.
- Introduction to Session. Hollie I. Swanson, University of Kentucky, Lexington, KY.
- Undertaking a Range of Activities and Adapting to Changes for the Future in Academia As a Thought Leader, a Communicator, and Teacher. Hollie I. Swanson, University of Kentucky, Lexington, KY.
- The Lesson of the Oak Tree and the Reed: Adapting to Change in a Corporate Research Environment. Lois D. Lehman-McKeeman, Bristol-Myers Squibb Company, Princeton, NJ.
- The Impact of Change in the Government (US FDA) and Its Global Influence on Regulatory Science and Career Development. William Slikker Jr., US FDA-NCTR, Jefferson, AR.
- Fostering Change in Developing a Strong Interdependent Relationship between CROs and Pharmaceutical Companies. Shawn Heidel, Covance Inc., Greenfield, IN.

Challenges in the Life Cycle of a Toxicologist

Monday, March 23, 2:00 PM to 4:45 PM

Chairperson(s): Tina E. Levine, Retired, Arlington, VA, and William J. Brock, Brock Scientific Consulting LLC, Montgomery Village, MD.

Endorser(s):
- Career Resource and Development Committee
- Education Committee
- Women in Toxicology Special Interest Group

Toxicologists face different challenges at different stages of their career life cycle. This session will explore some of these challenges, and offer potential solutions to those challenges. Industry, academia, and government employ 47%, 21%, and 14% of toxicologists, respectively. For students and postdoctoral trainees applying for jobs in these sectors, the initial challenge in getting that first position is presenting oneself on paper and in person. The goal of the first presentation will be to demystify the US federal hiring process with specific emphasis on how to describe oneself on paper as a toxicologist in order to be considered for a government position. The second speaker will address early-career toxicology positions in industry, and how the roles and responsibilities of the entry-level toxicologist contribute to the developing career. For the mid-career toxicologist, the challenge is often how to keep progressing, whether to pursue a technical or managerial track, and whether to consider transitioning to peripheral disciplines. The mid-career toxicologist speaker will provide guidance on how to develop a broad skill-set to enhance career opportunities. The fourth speaker will address how work/life satisfaction can be attained in the context of careers in science, which are very often a way of life and far more than a job. The tools presented will assist attendees in identifying strategies that can have the biggest impact on their work/life satisfaction and in developing their own personal action plan, whatever their career stage. The final challenge for many toxicologists is how to transition to semi- or full retirement; many toxicologists continue to work either full or part-time as consultants. Some choose to pursue interests long deferred due to the demands of full-time work. The last presentation will explore challenges encountered by the toxicologist as “retirement” and the twilight of a career approach. At the end of the session, a panel discussion will convene to address specific issues that arise in the career of the attendees, and discuss strategies for advancing the toxicology career.

- Introduction. Tina E. Levine, Retired, Arlington, VA.
- The Nuts and Bolts of Getting Hired As a Government Toxicologist. Tina E. Levine, Retired, Arlington, VA.
- Taking the Leap: Myths and Realities of Starting Your Career As an Industry Toxicologist. Jeffrey S. Moffit, FORUM Pharmaceuticals, Inc., Watertown, MA.
- Improving Your Work/Life Satisfaction. Donna J. Dean, Association for Women in Science, Hedgesville, WV.
- Challenges for the Late-Career Toxicologist. William Allaben, University of Arkansas Medical Center, Little Rock, AR.
What Toxicologist Do You Wanna Be? The Role of Toxicologists across Diverse Organizations

Wednesday, March 25, 12:00 Noon to 1:20 PM

Chairperson(s): Sudheer Beedanagari, Bristol-Myers Squibb, East Brunswick, NJ, and Erica D. Bruce, Baylor University, Waco, TX.

Endorser(s):
- Association of Scientists of Indian Origin Special Interest Group Career Resource and Development Committee
- Graduate Student Leadership Committee

Participants across SOT, namely students and postdocs, who are geared up to transition into their full-time career paths of choice as toxicologists do not have a good understanding of what toxicologists do on a day-to-day basis while working in diverse industries/organizations. Although academic toxicology training programs across the globe are training the students well in the principles and concepts of toxicology, they come short in educating the students/postdocs on the role they play as toxicologists in real-world job scenarios across diverse industries/organizations. Based on these needs and to better equip our young toxicologists, an informational session/education-career development session that highlights or summarizes the different roles toxicologists play in the real-world job settings would be of immense value to students/postdocs in evaluating if their training/personality suits them better in a specific industry/organization over the others. Although it is impossible to cover all the organizations where toxicologists play an important role in one CRAD/informational session, we attempted to represent the major organizations where toxicologists are hired predominantly in the recent years. Each of the five speakers will be covering the following general topics as part of their 15-minute presentations: (1) How and why the speaker ended up with their respective current affiliated organization; (2) How they went about securing their first job; (3) The kinds of training/soft skills/interpersonal skills needed to find a job in their respective organizations; (4) The kind of career-growth opportunities an entry-level toxicologist will have with the organization or respective industry; (5) The ONE thing the speaker most likes about their job; (6) The ONE thing the speaker most hates about their job.

- **Role of Toxicologists in the Pharmaceutical/Biotechnology Industry.** Raja Mangipudy, Bristol-Myers Squibb Company, New Brunswick, NJ.
- **Role of Toxicologists in an Academic and/or Research Institute.** Erica D. Bruce, Baylor University, Waco, TX.
- **Role of Toxicologists in the Cosmetic Industry.** Thomas A. Re, L’Oreal USA, Clark, NJ.
- **Role of Toxicologists in a Federal Organization.** Chandramallika (Molly) Ghosh, US FDA, Silver Spring, MD.
- **Role of Toxicologists in the Nutrition Industry.** Brinda Mahadevan, Abbott Nutrition, Columbus, OH.

Crafting High-Impact Manuscripts: The Process from Hypothesis through Review and Publication

Wednesday, March 25, 4:30 PM to 5:50 PM

Chairperson(s): Caitlin Murphy, University of Texas at Austin, Austin, TX, and Karin M. Streifel, University of California Davis, Davis, CA.

Endorser(s):
- Board of Publications
- Career Resource and Development Committee
- Postdoctoral Assembly

Publications are an essential component for a successful career across all sectors of toxicology, including industry, academia, and government. Although mentors provide informal guidance, students and postdoctoral fellows rarely receive formal training on how to develop a high-impact manuscript. Therefore, trainees still have questions regarding the publishing process. A complete understanding of the publication process will benefit junior scientists in formulating research plans, preparing manuscripts, in developing manuscript submission strategies, and in effectively serving as a reviewer—all important elements in a successful career. This session is designed to provide early-career toxicologists with insight into the publication process from the journal’s perspective. Speakers will focus on (1) how to craft a high-impact manuscript; (2) the role of the associate editor, strategies of selecting reviewers, the expectations of a reviewer, and responding to reviewers’ comments; (3) maintaining scholarly productivity in nonacademic careers; and (4) publishing in top-tier journals. Each speaker will also highlight what led to some of his or her most significant publications. Attendees will learn the benefits of publishing in the Society of Toxicology’s journal, how this may help in their unique career path, and define the roles of key players of the publication process. As well, Dr. Marcia McNutt, the editor in chief of Science, will share her insights on what it takes to publish in high-impact journals. This discussion is pertinent to all junior-level toxicologists who are in the process of publishing, undergoing revisions, and reviewing manuscripts. This career-development session will provide the formal training to understanding the entire process of creating a high-quality manuscript.

- **Introduction to Crafting High-Impact Manuscripts: Questions from Trainees.** Caitlin Murphy, University of Texas at Austin, Austin, TX.
- **Crafting a High-Impact Manuscript.** Gary W. Miller, Emory University, Atlanta, GA.
- **The Role of Associate Editor.** Dana Dolinoy, University of Michigan, Ann Arbor, MI.
- **Maintaining Scholarly Productivity in Nonacademic Careers.** Lois D. Lehman-McKeeman, Bristol-Myers Squibb Company, Princeton, NJ.
- **Science on Science: Publishing in Top-Tier Journals.** Marcia McNutt, Science magazine, Washington, DC.
Scientific

Regional Interest Session

**WEDNESDAY**

**Some Like It Hot: Impacts of Wildfires on Human Health**

**Approaches for Protecting Vulnerable Populations**

**Wednesday, March 25, 9:00 AM to 11:45 AM**

**Chairperson(s):** Michael C. Madden, US EPA, Chapel Hill, NC, and Shelley DuTeaux, California Department of Public Health, Sacramento, CA.

**Endorser(s):**
- Occupational and Public Health Specialty Section
- Southern California Regional Chapter

Wildfires have health impacts derived from combustion emissions and contribute 20–30% of ambient particulate matter (PM). One recent report predicted longer wildfire seasons, smokeier fires, and the burning of a larger area of the Western US. Elevated PM levels have been linked to increased deaths and hospitalizations for several morbidity outcomes. Different types of wildfire vary by the type of wood being burnt (i.e., crown, brush, below ground); the fire type may induce different types of health effects. Using a primate model, monkeys exposed to Northern California (CA) wildfire had persistent changes in blood cell cytokine production. Additionally, gender-dependent changes in airway hyper-responsiveness and compliance were observed. Alterations in health effects observed in both Northern and Southern California communities from wildfires in the last ten years will be compared and contrasted to an Eastern US peat-fueled wildfire. These studies examined susceptibility factors (e.g., socioeconomic, pre-existing cardiopulmonary disease) that modulated the observed health effects. Native tribes in Northern California were particularly susceptible to exposure due to the geography of tribal lands. The effectiveness regarding mitigation strategies (e.g., filters, face masks) within the affected communities will be described. The guidance for mitigating adverse health effects, developed by an international working group, will be presented and addresses the highly sensitive/susceptible populations. The identification of potentially susceptible individuals and effectiveness of intervention strategies have implications for preventing adverse outcomes and decline in public health. The observations from these studies will be integrated into the current knowledge of ambient PM-associated health effects as to the uniqueness of the findings. This session will be of great interest to public health specialists, inhalation and cardiovascular toxicologists, and those in the California area.

[This abstract may not reflect official US EPA policy.]

- **Introduction.** Michael C. Madden, US EPA, Chapel Hill, NC.

- **The Nature of Wildfire Smoke Impacts in California: Acute Effects, Interventions, and Long-Term Sequelae.** Shelley DuTeaux, California Department of Public Health, Sacramento, CA.

- **Impact of Wildfires in San Diego County.** Wilma J. Wooten, County of San Diego, San Diego, CA.

- **Health Burden from Peat Wildfire in North Carolina.** Ana G. Rappold, US EPA, Research Triangle Park, NC.

- **Persistent Immune and Pulmonary Effects of Wildfire Smoke during Infancy: Findings from a Nonhuman Primate Cohort.** Lisa Miller, School of Veterinary Medicine, University of California Davis, Davis, CA.


- **Panel Discussion/Q&A.** Daniel L. Costa, US EPA, Research Triangle Park, NC.
ToxExpo is the exposition associated with the Society of Toxicology’s Annual Meeting—that takes place over three days. When the Annual Meeting is over, ToxExpo lives on with a robust website at ToxExpo.com.

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- A unique environment for researching products and services of exhibiting companies that will keep you informed of new cutting-edge science and technology.

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**ToxExpo Hours**

- **Monday, March 23**
  - 9:00 AM to 4:30 PM
- **Tuesday, March 24**
  - 8:30 AM to 4:30 PM
- **Wednesday, March 25**
  - 8:30 AM to 4:30 PM

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Exhibitor-Hosted Sessions

MONDAY

Safety Biomarkers in Preclinical Studies: A Clinical Pathology Perspective

Monday, March 23, 9:15 AM to 10:15 AM

Presented by:
MPI Research

This session will provide an overview of the current principles involved in the application of safety biomarkers in preclinical research studies focusing on study design strategies, organ system evaluation, and validation principles. Additionally, integration of biomarker data with other study endpoints (e.g., traditional clinical pathology and pathology) will be discussed.

Adapting Cell-Based Assays to 3D Culture Models

Monday, March 23, 10:45 AM to 11:45 AM

Presented by:
Promega Corporation

Complex 3D cell culture models stretch the limits of assays designed for measuring cytotoxicity endpoints from monolayers of cells. We will present factors to consider for designing and validating performance of cell-based assays measuring viability (as an endpoint and in real time) and upstream cell stress events leading to cytotoxicity.

Computational Approach to Managing Mutagenicity Risk for ICH M7 and Beyond

Monday, March 23, 10:45 AM to 11:45 AM

Presented by:
Lhasa Limited

Lhasa Limited, the world leader for knowledge and data sharing in chemistry and the life sciences, will present their views and expertise in utilizing an integrated in silico solution to comply with the ICH M7 guidelines. In addition, they will highlight where in silico solutions provide further evidence of drug safety.

The Immunology of Immunogenicity?

Monday, March 23, 10:45 AM to 11:45 AM

Presented by:
Huntingdon Life Sciences/Harlan

Immunogenicity is an occasional consequence of treatment with a broad range of biological products. The session will discuss some of the immunological mechanisms that result in immunogenicity and their relevance to clinical use of the therapeutic. The session is aimed at toxicologists keen to learn more about the subject.

Utilization of In Vitro Mechanistic and 3D Models to Improve the Prediction of Hepatotoxicity and Cardiotoxicity

Monday, March 23, 10:45 AM to 11:45 AM

Presented by:
Cyprotex

This presentation will cover recent developments in the field of in vitro prediction of cardiotoxicity and hepatotoxicity. It will focus on the development of 3D cell-based cardiac and hepatic systems and their applicability in mechanistic mitochondrial assays (Seahorse) and 3D high-content imaging.

Alternative Models Developing in KIT for Predictive Toxicology

Monday, March 23, 1:45 PM to 2:45 PM

Presented by:
Korea Institute of Toxicology

- Agenda 1. Tissue engineering for alternative toxicology
- Agenda 2. Predictive toxicology models based on the multiorgan interaction

Diabetes and Weaker Bones—Exploring the Connection

Monday, March 23, 1:45 PM to 2:45 PM

Presented by:
Charles River

Osteoporosis and increased fracture risk have been added to the long list of complications of diabetes. This session will explore skeletal function and underlying mechanisms of compromised bones in metabolic diseases and will highlight endpoints to be included in safety studies to monitor for all diabetic complications.

Solutions and Lessons Learned with Inhaled Compounds in the Pharmaceutical and Chemical Industries: Perspective and Insights from Key Opinion Leaders James Swenberg and Chet Leach

Monday, March 23, 1:45 PM to 2:45 PM

Presented by:
Lovelace Respiratory Research Institute

Case studies for the use of inhaled models of industrial chemicals and pharmaceutical development will be provided by keynote speakers James Swenberg, DACVP, DVM, PhD, and Chet Leach, PhD, DABT.
The Gut Microbiota As a Source of Variability in Animal Models

Monday, March 23, 1:45 PM to 2:45 PM
Presented by:
IDEXX Laboratories

Aaron Ericsson, DVM, PhD, will present data regarding differences in the gut microbiota of mice associated with different genotypes, commercial source, and variables related to husbandry; effects of the gut microbiota on host responses to non-specific stimuli; and cost-effective methods of monitoring and manipulating the gut microbiota of mice.

TUESDAY
Considerations and Challenges Associated with Medical Device Risk Assessment

Tuesday, March 24, 8:30 AM to 9:30 AM
Presented by:
WuXi AppTec

Risk assessments based on chemical characterization data and intended use have recently become an integral component in the overall evaluation of medical device biocompatibility. Using ISO 10993-17 as a framework, the basic principles of risk assessment can be applied to the evaluation of medical device extracts.

The Use of Human HepatoPac, an In Vitro Microliver Platform, for Predictive Toxicology

Tuesday, March 24, 8:30 AM to 9:30 AM
Presented by:
Hepregen Corporation

Current in vitro platforms to assess hepatotoxicity have been poor predictors of in vivo performance. HepatoPac is a highly predictive in vitro microliver platform demonstrated to improve sensitivity. It remains functional for several weeks, making it an ideal platform for “extended-horizon” scenarios, including chronic toxicity and DDIs.

Application of Color Calibration in Photomicrography for Toxicologic Pathology

Tuesday, March 24, 10:00 AM to 11:00 AM
Presented by:
Datacolor Inc.

In toxicologic pathology, it is critical that color in photomicrographs accurately represent those seen in the specimen. Consistency between images and image color rendering on computer monitors is essential for viewing and evaluating images. Several case studies will illustrate the importance of color calibration to assessments by toxicologic pathology.

In Vitro Hepatotoxicity Evaluation with Cryopreserved Human, Animal, and Transgenic Animal Hepatocytes

Tuesday, March 24, 10:00 AM to 11:00 AM
Presented by:
In Vitro ADMET Laboratories, LLC

Application of plateable cryopreserved single donor and pooled human hepatocytes, hepatocytes from multiple preclinical animal species, and transgenic knock-out and humanized mouse hepatocytes in hepatotoxicity evaluation will be discussed, with emphasis on early hepatotoxicity screening in drug development and the elucidation of species difference, individual difference, and toxicological pathways.

Less Compound, Less Cost—How to Succeed in Early-Phase Inhalation Programs

Tuesday, March 24, 10:00 AM to 11:00 AM
Presented by:
Huntingdon Life Sciences/Harlan

As the cost of drug development increases, companies have prioritized early readout of efficacy and toxicity to limit the cost of late-stage failure. This session will discuss and demonstrate approaches to test article conservation that can significantly reduce test article consumption while still providing high-quality data.
Overcoming Challenges during Preclinical Sample Collection to Minimize the Impact on Toxicological Data

Tuesday, March 24, 10:00 AM to 11:00 AM
Presented by: Algorithm Pharma

When conducting preclinical studies, maintaining sample integrity following collection is critical. Due to the complexity of pharmaceutical compounds, challenges that can impact data reliability may occur during and following sample collection. Potential issues include whole blood stability, anticoagulants, acid and preservatives, hemolyzed plasma, and co-administered medications.

Fully Automated and Easy-to-Use Solution for Your Cytochrome p450 Gene Expression Testing

Tuesday, March 24, 11:30 AM to 12:30 PM
Presented by: HTG Molecular Diagnostics

Drug-metabolizing enzymes and transporter induction can result in clinically meaningful drug interactions. Measuring gene expression has traditionally relied upon RNA extraction from treated hepatocytes followed by RT-qPCR. An alternative, potentially more efficient method for measuring gene induction is the multiplex HTG Edge quantitative nuclease protection assay (HTG Edge chemistry).

Making Cardiotoxicity Prediction Simple and Relevant: Human iPSC-Cardiomyocytes and Integrated Impedance- and Field Potential-Based Assays Enable Highly Predictive Cardiotoxicity Assessments across Multiple Mechanisms

Tuesday, March 24, 11:30 AM to 12:30 PM
Presented by: Cellular Dynamics International and ACEA Biosciences

Cardiotoxicity manifests through several distinct mechanisms. This workshop will present (1) novel and peer-reviewed data using human cardiomyocytes with impedance and electrophysiological testing that validates a simplified and highly predictive workflow for electrical, biochemical, and contractile based cardiotoxicity detection and (2) integration with the FDA's Comprehensive in vitro Proarrhythmia Assay (CiPA).

Models of Chemical, Biological, Radiological, Nuclear, and Explosive (CBRNE) Threats: Considerations for Drug Development under the Animal Rule

Tuesday, March 24, 11:30 AM to 12:30 PM
Presented by: Lovelace Respiratory Research Institute

CBRNE requires the integration of multidisciplinary teams to do strategic studies for developing new drugs to protect the public and soldier. The animal models are complex and heavily integrated with pharmacology and toxicokinetics to enable translation.

Improved Methods for In Vivo and In Vitro Thrombogenicity Testing for Medical Devices

Tuesday, March 24, 1:00 PM to 2:00 PM
Presented by: American Preclinical Services

Thrombogenicity testing is a critical component of the ISO 10993-4 testing required for medical devices. Refined methods for in vivo thrombogenicity assessment using fluoroscopic guidance and contrast-mediated flow visualization have been identified and will be discussed along with novel in vitro blood-loop methods that allow assessment of new materials.

Usefulness of Biomarkers in Support of Preclinical Studies

Tuesday, March 24, 1:00 PM to 2:00 PM
Presented by: Charles River

A host of new biomarker methods and platforms are being routinely developed and validated, increasing the reliance on biomarkers to evaluate the toxicity and/or efficacy of new drugs. This session will provide an overview of therapeutic area biomarkers and considerations for biomarker assay development in support of preclinical toxicology programs.
For all your indispensable medical breakthroughs, Alpha Genesis delivers. Count on us for the highest-quality nonhuman primate research models in the industry, available when you need them.
**Exhibitor-Hosted Sessions**

**Application Study: Human-Induced Pluripotent Stem (iPS) Cell Assay As a Tool for Compound Ranking Based on Human Developmental Toxicity Potential**

*Tuesday, March 24, 2:30 PM to 3:30 PM*

Presented by:
Stemina Biomarker Discovery, Inc.

A human stem cell-based predictive model of human developmental toxicity can be applied to rank compounds by their relative teratogenic potency. Testing in a series of retinoids will provide an example. This approach can be applied to compound series in the discovery phase, or as a bridging study to enable read-across assessment.

**WEDNESDAY**

**Application of Molecular Imaging and Radiochemistry in Drug Development**

*Wednesday, March 25, 9:15 AM to 10:15 AM*

Presented by:
MPI Research

Contemporary drug development is a lengthy process. Molecular imaging (MI) has become a solution to decrease development time via assessment of specific molecular targets. MI is a multidisciplinary field evaluating biological processes at the molecular and cellular levels *in vivo*. This session focuses on application of molecular imaging drug development.

**Consequences of Immunogenicity in Nonclinical Safety Studies**

*Wednesday, March 25, 9:15 AM to 10:15 AM*

Presented by:
Charles River

In nonclinical safety testing, biotherapeutics have the potential to induce an immune response. This session will cover the effects of immunogenicity responses to biotherapeutics, including the approach taken to determine immunogenicity involvement and the methods for predicting clinical immunogenicity. Nonclinical case studies on adverse immunogenicity events will be presented.

**Advances in In Vitro and In Silico Techniques: Regulatory Acceptance Worldwide**

*Wednesday, March 25, 12:15 PM to 1:15 PM*

Presented by:
Huntingdon Life Sciences/Harlan

Advances in *in vitro* and *in silico* estimation of toxicological endpoints have challenged traditional approaches to safety assessment. The acceptability of these new methodologies has been acknowledged by regulatory authorities worldwide. We discuss our experiences in using these techniques to achieve regulatory success in a range of product types.

**Sharpen the Focus of Your Toxicology Research Program Using Agilent’s Integrated Biology Omics Solutions**

*Wednesday, March 25, 1:45 PM to 2:45 PM*

Presented by:
Agilent Technologies

Agilent’s GeneSpring Multiomics Suite enables insights to be gained in underlying mechanisms of toxicity through the analysis and visualization of multiomic data and mapping of affected pathways. Come to our workshop to learn about how it is being used to advance understanding of mechanisms underpinning endocrine disruption.
TAKE A CLOSER LOOK

Visit us in booth 1801!

Follow @SOToxicology and @ToxExpo on Twitter
Tweet using #2015SOT and #toxexpo

Find up-to-date information at www.toxicology.org
Tox ShowDown is a quiz game pitting three teams of toxicologists—The Endocrine Disruptors, The Free Radicals, and The Toxic Metabolites—against each other to see who really knows the most when it comes to toxicological fact and fancy. No ticket is required. Come and watch your peers let their hair down to mark the halfway point of the Annual Meeting.

Join Us for an Evening of “Tox Trivia” and Fun!
If you’d like to be a contestant, contact the GSLC Secretary Meghan Cromie or Phil Wexler.

Hosted by: Graduate Student Leadership Committee (GSLC)
www.toxicology.org/al/meet/am2015/socialevents.asp

The Southern California Chapter of SOT (SCCSOT) invites interested SOT members and Annual Meeting attendees to arrive early and

VOLUNTEER TO ASSIST
WITH K–12 EDUCATION OUTREACH ACTIVITIES.

SCCSOT will be participating in EXPO DAY, a mind-blowing day of hands-on Science, Technology, Engineering, and Math, on Saturday, March 21, 2015, 10:00 am to 5:00 pm.

We need your help with this exciting day of toxicology activities and opportunities for students to talk with toxicologists.

Please also invite local high school students to participate!
Contact: bettye@toxicology.org

www.lovestemsd.org
### Deadline for Proposals for SOT 2016 Annual Meeting

Sessions: April 30, 2015

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**Why Submit a Proposal?**

1. To present new developments in toxicology
2. To provide attendees with an opportunity to learn about state-of-the-art technology and how it applies to toxicological research
3. To provide attendees with an opportunity to learn about the emerging fields and how they apply to toxicology

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### Session Types

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<th>Type</th>
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| **Continuing Education** | Emphasis on quality presentations of generally accepted, established knowledge in toxicology  
  Note: CE Courses will be held on Sunday. |
| **Symposia**          | Cutting-edge science, new areas, concepts, or data                           |
| **Workshops**         | State-of-the-art knowledge in toxicology                                     |
| **Roundtables**       | Controversial subjects                                                      |
| **Continuing Medical Education** | Emphasis on state-of-the-art knowledge to assist medical doctors, health professionals, and researchers in life-long learning for providing high-quality health care  
  Note: Any session type may be considered for CME. |
| **Historical Highlights** | Review of a historical body of science that has impacted toxicology          |
| **Informational Sessions** | Scientific planning or membership development                                |
| **Education-Career Development Sessions** | Sessions that provide the tools and resources to toxicologists that will enhance their professional and scientific development |
| **Regional Interest** | Central topics of relevance that describe public health and/or ecological problems of a particular region |

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Submit your proposal online at www.toxicology.org
Support Opportunities

are still available for the 2015 Annual Meeting. Your support serves as visible evidence of your organization’s commitment to the science of toxicology. In addition, your support provides an opportunity for you to increase overall awareness of your company to SOT members and more than 6,500 Annual Meeting attendees. As a supporter, your company will be featured in pre- and postmeeting newsletters, the ToxExpo Directory, premeeting publications, on-site meeting registration materials, the Mobile Event App, and the SOT website. In addition, acknowledgement signs will group supporters 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 support 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 Support, contact Laura Helm at SOT Headquarters: 703.438.3115 or email: laura@toxicology.org.

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See you in San Diego, California
March 22–26, 2015

www.toxicology.org