### Continuing Education Courses

**Monday, September 22**

Please note that participation in the Continuing Education course requires attendees to register for the courses. See Continuing Education Web page for course descriptions. www.safetypharmacology.org/am2008/ce.asp

**Morning Courses: CE(1), CE(2), CE(3), CE(4)**

Morning Courses include a continental breakfast and refreshments during the break. Morning Course Schedule (may vary depending on course).

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>7:30 AM</td>
<td>Continental Breakfast</td>
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<tr>
<td>8:00 AM</td>
<td>Course in Session</td>
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<tr>
<td>10:00 AM</td>
<td>Break</td>
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<tr>
<td>10:15 AM</td>
<td>Course in Session</td>
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<tr>
<td>12:00 NOON</td>
<td>Course Concludes</td>
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**Afternoon Courses: CE(5), CE(6), CE(7), CE(8)**

Afternoon Courses include a box lunch that can be picked up in the respective meeting room at 12:30 PM and refreshments during the break. Afternoon Course Schedule (may vary depending on course).

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>1:00 PM</td>
<td>Course in Session</td>
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<tr>
<td>3:00 PM</td>
<td>Break</td>
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<tr>
<td>3:15 PM</td>
<td>Course in Session</td>
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<tr>
<td>5:00 PM</td>
<td>Course Concludes</td>
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<tr>
<td>5:00 PM</td>
<td>Welcoming Reception</td>
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<tr>
<td>6:30 PM</td>
<td>All SPS Hosted Functions Adjourn</td>
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</table>

### Scientific Sessions and Other Events

**Tuesday, September 23**

- **7:30 AM** Continental Breakfast
  - Exhibit Hall
- **8:15 AM** Welcome and Announcements
  - Dr. Ian MacKenzie
  - President of the Safety Pharmacology Society
  - Ballroom AB
- **8:30 AM** President’s Keynote Address
  - Craig T. January
  - MD, PhD., F ACC University of Wisconsin -Madison
  - Discovery of hERG: Historical Perspectives and Contemporary Concerns
  - Ballroom AB
- **9:30 AM** Break
  - Exhibit Hall

**10:00 AM**

**A. Translational: Biomarkers**

**Session Chair: Mike Engwall**

**Ballroom D**

**ECG and Blood Pressure as Biomarkers—Orthostatic Hypotension**

**Speaker: Nancy Poy**, DVM, Pfizer, Groton, CT, United States

**Ultrasound as a Biomarker of Cardiovascular Function: Valves, Hypertrophy, and Vascular**

**Speaker: Brian Hoit**, MD, Professor of Medicine, Case Western Reserve and Department of Cardiology and Internal Medicine, Case Western Reserve University and University Hospitals of Cleveland, Cleveland, OH, United States

**Serum Chemistry Parameters as Cardiovascular Biomarkers**

**Speaker: David Watson**, PhD, Research Advisor Investigative Toxicology, Eli Lilly and Co., Indianapolis, IN, United States
B. Emerging Technologies

Session Co-Chairs: Anthony Bahinski and Craig January

Ballroom AB

Stem Cells Session Overview:
The field of stem cell research has been rapidly accelerating in the last several years. The development of validated human cell-based \textit{in vitro} safety screens has the potential to facilitate earlier attrition of compounds with unacceptable safety profiles. This session will focus on recent efforts to develop a new source of pluripotent stem cells from somatic tissue and on the development of \textit{in vitro} models using stem cell derived human tissue for drug safety evaluation.

Human Induced Pluripotent Stem (iPS) Cells: Implications for Drug Screening
Speaker: James S. Thomson, VMD., PhD, University of Wisconsin-Madison, Madison, WI, United States

Human Pluripotent Stem Cell-Derived Cardiomyocytes for Safety Pharmacology Applications
Speaker: Timothy J. Kamp, MD, PhD, University of Wisconsin-Madison, Madison, WI, United States

Human Embryonic Stem Cells Provide a Robust Source of Neural Cells for Drug Discovery and Toxicity
Speaker: Steven L. Stice, PhD, The University of Georgia and Aruna Biomedical Inc., Athens, GA, United States

C. Integrated Systems Physiology

Session Co-Chairs: Maxim Soloviev and Franz Hock

Ballroom C

Introduction to Chronobiology
Speaker: Björn Lemmer, MD, PhD, Professor and Director, Institute of Pharmacology and Toxicology, Ruprecht-Karls University, Heidelberg, Germany

Chronopharmacokinetics
Speaker: Björn Lemmer, MD, PhD, Professor and Director, Institute of Pharmacology and Toxicology, Ruprecht-Karls University, Heidelberg, Germany

Vascular Consequences of Sleep Disordered Breathing
Speaker: Barbara Morgan, PhD, PT, University of Wisconsin-Madison, Madison, WI, United States.

Mechanisms of Intermittent Hypoxia Induced Respiratory Plasticity: A Guide for Novel Therapeutic Approaches to Sleep Apnea?
Speaker: Gordon Mitchell, PhD, University of Wisconsin-Madison, Madison, WI, United States

12:00 NOON Lunch Break
The buffet lunch will be serviced in the Exhibit Hall.

Poster Viewing
All Attendees are encouraged to visit the Exhibit Hall to view the posters and learn about the latest technology and services available to the field of safety pharmacology.

Poster Presentation Judging

2:00 PM

A. Invited Oral Communications 1: What’s Happening in My Head? Drug Abuse and Seizure Liabilities

Ballroom AB

2:00 PM Overview of the Joint PhRMA-FDA Dialogue Session on Abuse Potential
Carrie Markgraf, Schering-Plough Research Institute

2:15 PM Strategy to Reduce Seizure Liability
Elizabeth Bell, AstraZeneca

2:30 PM Evaluation of Morphine Withdrawal Effects Using Telemetry
Paul Moser, Porsolt & Partners Pharmacology

2:45 PM Glp-Compliant Drug Self-Administration in the Non-Human Primate
David V. Gauvin, MPI Research

B. Invited Oral Communications 2: Predicting Liabilities—Part 1

Ballroom C

2:00 PM Correlation Between Ejection Fraction and DP/DT+ in Conscious Telemetered Dogs Dosed with Atenolol
Helen Prior, AstraZeneca, UK Ltd.
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<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker/Details</th>
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<tbody>
<tr>
<td>2:15 PM</td>
<td>Use of Embryonic Stem Cell Derived Cardiomyocytes for Determination of Cardiac Cytotoxicity</td>
<td>Silke Schwengberg, Axigenesis AG</td>
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<td>2:30 PM</td>
<td>Apex-to-Base Dispersion is Greater Than Transmural Dispersion of Repolarization in an Intact Isolated Rabbit Heart Model</td>
<td>Nicolas Guérard, Novartis Pharma AG</td>
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<td>2:45 PM</td>
<td>Differences in ECG Intervals and Restitution Parameters in the Conscious Sling-Trained Canine Model of Short QT Syndrome</td>
<td>Anusak Kijtawornat, Q Test Labs, LLC, The Ohio State University</td>
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<tr>
<td>3:00 PM</td>
<td>Break</td>
<td>Exhibit Hall</td>
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<td>3:30 PM</td>
<td><strong>A. Translational</strong></td>
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<td></td>
<td><strong>Session Chair: Ian MacKenzie</strong></td>
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<td>Ballroom D</td>
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<td><strong>EEG: Relevance in the Evaluation of Sedation and Seizure Risk</strong></td>
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<td><strong>Speaker: Joseph Arezzo, PhD, Albert Einstein College of Medicine, Bronx, NY, United States</strong></td>
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<td><strong>B. Emerging Technologies</strong></td>
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<td><strong>Session Chair: Anthony Bahinski</strong></td>
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<td>Ballroom AB</td>
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<td></td>
<td><strong>Session Overview</strong></td>
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<td>With increasing emphasis on mechanistic studies, the emergence of biotherapeutics and earlier involvement in the drug discovery process, there is an increasing need for novel <em>in vivo</em> models beyond the core battery of safety pharmacology assays. This session will focus on recent efforts to use RNAi and transgenic animals to provide early insights into target safety.</td>
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<td><strong>Genetically Modified Animals and Safety Testing</strong></td>
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<td><strong>Speaker: Sandra J. Engle, PhD, Pfizer, Inc., Groton, CT, United States</strong></td>
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<td><strong>Enabling Targeted siRNA Delivery In Vivo Using Dynamic PolyConjugate Technology</strong></td>
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<td><strong>Speaker: David L. Lewis, PhD, Mirus Bio Corporation, Madison, WI, United States</strong></td>
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<tr>
<td>2:15 PM</td>
<td><strong>Novel In Vivo Models—KO Rat Models</strong></td>
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<td><strong>Speaker: Alexandre Fraichard, PhD, MBA, genOway, Lyon, France</strong></td>
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<td>3:30 PM</td>
<td><strong>C. Integrated Systems Physiology</strong></td>
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<td><strong>Session Chair: Ted Baird</strong></td>
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<td>4:00 PM</td>
<td><strong>Ballroom C</strong></td>
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<td><strong>Neural Regulation of the Gastrointestinal Tract</strong></td>
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<td><strong>Speaker: Gary M. Mawe, PhD, University of Vermont, Burlington, VT, United States</strong></td>
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<td>4:00 PM</td>
<td><strong>Mechanisms of Visceral/Cardiac Pain Perception</strong></td>
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<td><strong>Speaker: Robert D. Foreman, PhD, Department of Physiology, University of Oklahoma Health Sciences Center, Oklahoma City, OK, United States</strong></td>
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<td>7:30 AM</td>
<td><strong>Wednesday, September 24</strong></td>
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<td>8:00 AM</td>
<td><strong>A. Translation: Issues in Personalized Medicine</strong></td>
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<td><strong>Session Chair: Dusty Sarazan</strong></td>
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<td><strong>Ballroom D</strong></td>
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<td><strong>Mommies Cry Too: A Personal Story of Surviving Post Partum Depression Medication and an Unknown Cytochrome P450 Deficiency</strong></td>
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<td><strong>Speaker: Carolyn Brink, (<a href="http://www.mommiescrytoo.com">http://www.mommiescrytoo.com</a>)</strong></td>
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<td><strong>The Science Behind the Story: CYP450 Polymorphisms in Patients</strong></td>
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<td><strong>Speaker: Steven Wrighton, PhD, Eli Lilly and Co., Indianapolis, IN, United States</strong></td>
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B. Emerging Strategies—Advancement in Modeling of Drug-Induced Torsades des Pointes

Session Co-Chairs: Alan Bass, Niels-Christian Ganderup, and Josh Burton

Ballroom AB

Progress Towards Advancement of Pre-Clinical Modeling for Drug-induced Torsades des Pointes
Speaker: Alan Bass, PhD, Schering-Plough, Kenilworth, NJ, United States

Ca²⁺ Handling by Ventricular Myocytes is a Predictor of Vulnerability to Torsade de Pointes in Drug-induced Long QT Type 2
Speaker: Guy Salama, PhD, University of Pittsburgh, Pittsburgh, PA, United States

Alternative Mechanisms of Drug-Induced QT Prolongation—Beyond hERG
Speaker: Jean-Pierre Valentin, PhD, AstraZeneca, Macclesfield, United Kingdom

Emerging Issues in Safety Pharmacology—Survey of Industry Identifying Consortia Projects
Speaker: Niels-Christian Ganderup, MSc Biology, Ellegaard Göttingen Minipigs, Dalmose, Denmark

C. Integrated Systems Physiology

Session Chair: Scott Mittelstadt

Ballroom C

Mechanisms of Platelet-Mediated Thrombosis
Speaker: John Folts, PhD, Coronary Thrombosis Research and Prevention Laboratory, University of Wisconsin, Madison, WI, United States

Central Mechanisms of Baroreflex Control of Blood Pressure
Speaker: Jeanne Seagard, PhD, Department of Anesthesiology, Zablocki Department of Veterans Affairs Medical Center, Medical College of Wisconsin, Madison, WI, United States

10:00 AM

A. Translational

Session Chair: Dusty Sarazan

Ballroom AB

Intent and Current Utilization of ICH S7B Guidelines: Pharma and FDA Perspectives
Speaker: Peter K. S. Siegl, PhD, Siegl Pharma Consulting LLC, Blue Bell, PA, United States and John E. Koerner, PhD, Division of Cardiovascular and Renal Products, U.S. Food and Drug Administration, Silver Spring, MD, United States

B. Emerging Strategies: Strategies for Combating Attrition in Discovery

Session Chair: Alan Bass

Ballroom D

Emerging Drug Safety: Combating Attrition in Discovery as a Way of Mitigating Failure in Development
Speaker: Alan S. Bass, PhD, Schering-Plough, Kenilworth, NJ, United States and Mark E. Cartwright, DVM, PhD, Drug Safety, Schering-Plough, Kenilworth, NJ, United States

Frontloading of Safety Pharmacology in Support of Selecting the Best Compounds for Development
Speaker: Silvana Lindgren, PhD, Safety Assessment, AstraZeneca R&D, Södertälje, Sweden

C. Integrated Systems Physiology

Session Chair: Dennis Murphy

Ballroom C

Ventilatory Control: Carotid Body Plasticity and Pharmacology
Speaker: Gerald Bisgard, DVM, PhD, University of Wisconsin, Madison, WI, United States

Effects of Gender and Age on Ventilatory Control
Speaker: Mary Behan, PhD, University of Wisconsin, Madison, WI, United States

11:00 AM

Safety Pharmacology Society Annual Meeting and Awards
Ballroom AB
12:30 PM  Lunch Break
The buffet lunch will be serviced in the Exhibits Hall.
Poster Viewing

All Attendees are encouraged to visit the Exhibit Hall to view the posters and to learn about the latest technology and services available to the field of safety pharmacology.

2:00 PM

A. Invited Oral Communications 3: "Ins and Outs" and "Everything in Between"

Ballroom AB
2:00 PM  Fast, Effortless, and Accurate Measurement of Glomerular Filtration Rate in Conscious Monkeys
Alain-Sticker Krongrad, Charles River Laboratories

2:15 PM  Urodynamics Telemetry: A Tool for Investigating the Urinary Bladder Function in Conscious Cynomolgus Monkey
Stéphane Milano, MDS Pharma Services

2:30 PM  Mouse: More Sensitive Than Rat or Guinea Pig for Assessing Respiratory Depressant Potential of Drugs
Sandra Picard, Porsolt & Partners Pharmacology

2:45 PM  The Smartpill for Gastrointestinal Monitoring in Dogs
Helen Penton, Charles River Laboratories Preclinical Services

B. Invited Oral Communications 4: Predicting Cardiovascular Liabilities—Part 2

Ballroom C
2:00 PM  A HESI Consortium Approach to Assess the Human Predictive Value of Non-Clinical Repolarisation Assays
Jean-Pierre Valentin, HESI

2:15 PM  Evaluation of the Pro-Thrombotic Effect of COX-2 Inhibitor in Dog Model of Arterial Thrombosis
Aliaksandru Bulhak, AstraZeneca R&D

2:30 PM  IKS: Another Cardiovascular Liability Besides hERG, and Use of a Novel IKS Blocker to Screen for IKS Blockade
Rob Towart, Johnson & Johnson PRD

2:45 PM  High Definition Oscillometry (HDO): A Novel Method for Non-Invasive Blood Pressure Measurements in Cynomolgus Monkeys
Andrea Mitchell, Covance Laboratories

3:00 PM  Break
Exhibit Hall

3:30 PM

A. Translation Track
Session Chair: Kristy Bruse

Ballroom AB
Predictivity Model/Frame—What are the Tools and How are They Used for Predicting Liability?

Speaker: Rob Wallis, PhD, Pfizer, Sandwich, United Kingdom

Panel Discussion—Predictivity and Personalized Medicine

Speakers: Rob Wallis, PhD, Pfizer, Sandwich, United Kingdom, Steven Wrighton, PhD, Eli Lilly and Co., Indianapolis, IN, United States, Peter K.S. Siegl, PhD, Blue Bell, PA, United States, and John E. Koerner, PhD, U.S. FDA, Silver Spring, MD, United States

B. Emerging Strategies—Integration of Toxicity and Safety Pharmacology Studies in Risk Assessment

Session Chair: Sharon Rowton and Alfred Botchway

Ballroom D
Integration of Functional Endpoints into Repeat-Dose Toxicity Studies

Speaker: Will Redfern, PhD, Safety Pharmacology UK, Global Safety Assessment, AstraZeneca R&D, Alderley Park, Cheshire, United Kingdom

Case Studies to Answer: Why You Would/Would Not Consider Cross Discipline Assessment

Speaker: Rich Alper, PhD, Pfizer Drug Safety Research & Development, Groton, CT, United States

CV, CNS, Respiratory: How to Use Established Models for Combined Risk Assessment

Speaker: Mary-Jeanne Kallman, PhD, Eli Lilly and Co., Greenfield, IN, United States
C. Integrated Systems Physiology

**Session Chair: Ted Baird**

Ballroom C

**Visual Electrophysiology in Pre-Clinical Testing**

*Speaker: James Ver Hoeve, PhD, University of Wisconsin-Madison, Madison, WI, United States*

**Long-Term Regulation of Blood Pressure**

*Speaker: Kim Hoagland, PhD, Merck & Co., Inc., West Point, PA, United States*

**Drug-Induced Activation of Immune Function: Mechanisms and Potential Adverse Effects**

*Speaker: Curtis Maier, PhD, GlaxoSmithKline Pharmaceuticals, King of Prussia, PA, United States*

4:00 PM    Exhibit Hall Closed
5:00 PM    All SPS Hosted Functions Adjourn

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**Thursday, September 25**

8:15 AM

**Introduction to Biologics**

*Session Chair: Tom Beck*

Ballroom AB

8:15 AM

**Introduction to Biologics**

*Speaker: Hugo Vargas, PhD, Amgen, Thousand Oaks, CA, United States*

This presentation will give an overview of the commonly encountered biologic molecules and touch on potential complexities these types of molecules present for safety pharmacology.

8:45 AM

**Point-Counter Point: Integration of Safety Pharmacology Endpoints in Toxicology Studies for Biologics Testing**

*Speakers: Derek Leishman, PhD, Lilly Research Laboratories, Greenfield, IN, United States and Noel Dybdal, PhD, Genentech, Southern San Francisco, CA, United States*

This discussion will present the advantages and disadvantages of incorporation of Safety Pharmacology endpoints into toxicology studies conducted with large molecules. Each speaker will present his or her view and critically evaluate the others views.

9:30 AM    Break
10:00 AM    **Biologics and Safety Pharmacology: A Regulatory Perspective**

*Session Chair: Gregory Friedrichs*

Ballroom AB

*Speaker: Michael S. Orr, PhD, DABT, Pharmacology Reviewer, U.S. Food and Drug Administration, Silver Spring, MD, United States*

11:00 AM    **Biologics and Safety Pharmacology: A Clinical Perspective**

*Session Chair: Carrie Markgraf*

Ballroom AB

*Speaker: Stephen Flach, PhD, Covance Madison, Madison, WI, United States*

11:45 AM    Closing Remarks

12:00 NOON    Annual Meeting Adjourns