

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).

7:30 AM	Continental Breakfast
8:00 AM	Course in Session
10:00 AM	Break
10:15 AM	Course in Session
12:00 NOON	Course Concludes <i>Lunch on own for Morning CE Course participants.</i>

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).

1:00 PM	Course in Session
3:00 PM	Break
3:15 PM	Course in Session
5:00 PM	Course Concludes
5:00 PM	Welcoming Reception <i>Rooftop Terrace—This hour and half reception will be an opportunity to see old friends and make new acquaintances.</i>
6:30 PM	All SPS Hosted Functions Adjourn

Scientific Sessions and Other Events

Tuesday, September 23

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

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

Program

SEPTEMBER 22–25, 2008

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 *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 *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.

- 2:15 PM **Use of Embryonic Stem Cell Derived Cardiomyocytes for Determination of Cardiac Cytotoxicity**
Silke Schwengberg, Axiogenesis AG
- 2:30 PM **Apex-to-Base Dispersion is Greater Than Transmural Dispersion of Repolarization in an Intact Isolated Rabbit Heart Model**
Nicolas Guérard, Novartis Pharma AG
- 2:45 PM **Differences in ECG Intervals and Restitution Parameters in the Conscious Sling-Trained Canine Model of Short QT Syndrome**
Anusak Kijawornat, Q Test Labs, LLC, The Ohio State University
- 3:00 PM **Break**
Exhibit Hall

3:30 PM

A. Translational

Session Chair: Ian MacKenzie

Ballroom D

EEG: Relevance in the Evaluation of Sedation and Seizure Risk

Speaker: Joseph Arezzo, PhD, Albert Einstein College of Medicine, Bronx, NY, United States

B. Emerging Technologies

Session Chair: Anthony Bahinski

Ballroom AB

Session Overview

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 *in vivo* 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.

Genetically Modified Animals and Safety Testing

Speaker: Sandra J. Engle, PhD, Pfizer, Inc., Groton, CT, United States

Enabling Targeted siRNA Delivery *In Vivo* Using Dynamic PolyConjugate Technology

Speaker: David L. Lewis, PhD, Mirus Bio Corporation, Madison, WI, United States

Novel *In Vivo* Models—KO Rat Models

Speaker: Alexandre Fraichard, PhD, MBA, genOway, Lyon, France

C. Integrated Systems Physiology

Session Chair: Ted Baird

Ballroom C

Neural Regulation of the Gastrointestinal Tract

Speaker: Gary M. Mawe, PhD, University of Vermont, Burlington, VT, United States

Mechanisms of Visceral/Cardiac Pain Perception

Speaker: Robert D. Foreman, PhD, Department of Physiology, University of Oklahoma Health Sciences Center, Oklahoma City, OK, United States

4:00 PM **Exhibit Hall Closed**

5:00 PM **All SPS Functions Adjourn**

Wednesday, September 24

7:30 AM **Continental Breakfast**
Exhibit Hall

8:00 AM

A. Translation: Issues in Personalized Medicine

Session Chair: Dusty Sarazan

Ballroom D

Mommies Cry Too: A Personal Story of Surviving Post Partum Depression Medication and an Unknown Cytochrome P450 Deficiency

Speaker: Carolyn Brink, (<http://www.mommiescrytoo.com>)

The Science Behind the Story: CYP450 Polymorphisms in Patients

Speaker: Steven Wrighton, PhD, Eli Lilly and Co., Indianapolis, IN, United States

Program

SEPTEMBER 22–25, 2008

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

9:30 AM

Break

Exhibit Hall

10:00 AM

A. Translational

Session Chair: Dusty Sarazan

Ballroom AB

Intent and Current Utilization of ICH S7B Guidelines: Phrma 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 "Everthing 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
Aliaksandr 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

Intergration 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

Program

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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

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
Ballroom AB

12:00 NOON Annual Meeting Adjourns