Monday, September 19

Sponsored Presentations
07:00–08:00
See page 48

Welcome
08:00–09:30
Ballroom B

Keynote Plenary
08:30–09:30
Ballroom B

Safety Pharmacology across the Globe: Vision of Past, Present, and Future
Jean-Pierre Valentin, PhD, HDR, CBiol, FSBiol, FRCPath, DSP, UCB Pharma SA, Braine-l’Alleud, Belgium

The field of safety pharmacology emerged from concerns over significant gaps in the safety data that existed at the time, putting clinical trial subjects and patients at risk of pharmacodynamic toxicity. From this beginning, the field has evolved, but the risks remain of assuring the safety of novel targeted therapies over a lifetime of treatment of complex diseases. In addition to the clinical challenges, the field of safety pharmacology has emerged in a period where business models, regulatory landscape for risk tolerance, and societal challenges have evolved and molded how the field is practiced in the current day. Despite all of those challenges, safety pharmacology has demonstrated its positive impact on drug discovery and development by contributing to identification and elimination of hazards, and assessment, management, and mitigation of risks. Projecting the challenges of today into the near and long term future so that the field of safety pharmacology can be positioned for next 10 to 20 years, beyond a period where most of us will be around to influence that future, is what we would like to achieve. How do we project that future, what is the roadmap to advise future generations of safety pharmacologists, what principles can we share with them today that will be relevant for tomorrow? Let us consider these together and lay out a vision and path taking into account the past and present to model the future of safety pharmacology.

Exhibits and Posters Open
09:00–17:00
Exhibit Hall B

Break
09:30–10:00
Exhibit Hall B

Track A: Translational Cardiovascular Safety Pharmacology
10:00–12:00
Ballroom B

Co-Chairs: Robert J. Austin-LaFrance, Groton, CT, United States, Abby C. Collier, PhD, The University of British Columbia, Vancouver, BC, Canada, and Harushige Ozaki, Takeda Pharmaceutical Company Limited, Fujisawa, Kanagawa, Japan

In sum, the goal of all preclinical safety testing is the accurate and complete identification of effects resulting from administration of a test compound. The more accurate and complete the information, the better we are able to predict the risk associated with administration in humans. This session will examine current methods of evaluating the translational accuracy of various cardiovascular test systems, introduce emerging paradigms, and discuss their application in developing clinical risk profiles. Presentations will include consideration of various test platforms and their separate and combined contributions to a predictability index.

10:00–10:30
In Vitro Assays to Address and Predict Drug-Induced Effects on Contractility and Cardiomyocyte Damage
Amy Pointon, AstraZeneca, Macclesfield, United Kingdom

10:30–11:00
Translational Biomarkers of Cardiovascular Injury and Dysfunction
Michael C. Boyle, DVM, PhD, DACVP, DABT, Amgen, Inc., Thousand Oaks, CA, United States

11:00–11:30
Cardio-Functional Assessment of Effects of Tanezumab, Nerve Growth Factor Antibody, on Sympathetic Function: A Novel Translational Approach
Siddhartha Bhatt, PhD, Pfizer, Inc., Groton, CT, United States

11:30–12:00
The Late Sodium Current: Small but a Major Contributor to the Cardiac Action Potential
Marc Pourrier, PhD, IonsGate Preclinical Services Inc., Vancouver, BC, Canada
Advances in science related to the GPCR target family provided a wealth of drugs during the past decades. Better understanding of the structure of GPCRs and their function in physiological systems provides the pharmaceutical industry novel strategies and tools to develop more refined SAR-driven drug design, alternatives to the common approach to screen the receptors at their inactive state, and consider more predictive models with high clinical relevance. This session will provide a variety of state-of-the-art scientific contributions ranging from ligand-based physiological classification of GPCRs to connections between receptor heterogeneity and clinical outcome. Speakers will address the translational value of their research with a particular emphasis on safety aspects.

10:00–10:30  Structural and Spatiotemporal Determinants of G Protein-Coupled Receptor Functional Selectivity: Implication of Ligand-Biased Signaling for Drug Discovery
Michel Bouvier, PhD, Université de Montréal, Montréal, QC, Canada

10:30–11:00  Mas-Related G Protein-Coupled Receptors Have a Critical Role in Mast Cell Control of Pseudo-Allergic Reactions
Marianna Kulka, PhD, National Institute for Nanotechnology, Edmonton, AB, Canada

11:00–11:30  Structure-Based Discovery of Novel GPCR Ligands with New Biology
Brian K. Shoichet, PhD, University of California, San Francisco, CA, United States

11:30–12:00  Bitter Taste Receptors on Airway Smooth Muscle: New Therapeutic Targets and Evidence for a Previously Unrecognized Chemosensory System
Stephen B. Liggett, MD, University of South Florida, Tampa, FL, United States

Lunch Break, Networking, Exhibits
12:00–13:00  Exhibit Hall B

CSPT Rapid Fire Poster Presentations
12:30–13:30  Ballroom C

Please plan to eat lunch in the Exhibit Hall from 12:00–12:30.

These rapid fire poster presentations were selected from CSPT Posters and are 3–5 minutes each with additional poster viewing time/judging from 13:30–14:30.

Sponsored Presentations
12:30–13:30  See page 48

Poster Presentations, Poster Judging, Networking, Exhibits
13:00–14:30  Exhibit Hall B

13:00–14:00  Even Poster Numbers Present (SPS/JSPS)
13:00–14:00  All SPS Jr. Investigator Poster Contest Entries Present (Even and Odd)
13:30–14:30  All CSPT Posters Present and Trainee Presentation Competition Entries Judged (CSPT)
SPS Oral Communications 1–2

SPS Oral Communications 1: Isolated Organs, Disease Models, and *In Silico* Models Optimization

**14:00–15:15**  
**Ballroom B**  
**Co-Chairs:** Eric I. Rossman, PhD, GlaxoSmithKline, King of Prussia, PA, United States, and Frederick J. Sannajust, PharmD, PhD, Merck & Co., West Point, PA, United States

**14:00–14:15** Combined Cardiovascular, Respiratory, and Neurobehavioral Telemetry Model in the Conscious Rat: A Novel Approach to Study the Acute Physiological Effects of Caffeine and Chlorpromazine following Oral Administration  
Jason Payseur, et al. (Poster #136)

**14:15–14:30** Comparative Evaluation of *In Silico* Models to Assess Cardiac Pro-Arrhythmic Risk in Early Drug Development  
Pierre Morissette, et al. (Poster #132)

**14:30–14:45** Chronic Enalapril and Carvedilol Therapy in Beagle Dogs with Induced Chronic Ischemic Left-Ventricular Dysfunction: Effects on Angiotensin Responsiveness  
Beth Geist, et al. (Poster #181)

**14:45–15:00** Simulation of IQ-CSRC Prospective Study Using Integrated *In Silico* 2-Dimensional Transmural Human Ventricular Wedge Preparation Model  
Taeko Kubo, et al. (Poster #46)

**15:00–15:15** Investigating the Cardioprotective Role of Metformin during Sunitinib-Induced Cardiotoxicity by qRT-PCR Profiling of MicroRNAs Associated with Myocardial Injury  
Hardip Sandhu, et al. (Poster #167)

SPS Oral Communications 2: Ion Channels

**14:00–15:15**  
**Ballroom C**  
**Co-Chairs:** Robert J. Austin-LaFrance, Groton, CT, United States, and Hong Shi, MD, Bristol-Myers Squibb Company, Pennington, NJ, United States

**14:00–14:15** Temperature Effects on Kinetics of hERG Drug Block: Implications for *In Silico* Proarrhythmic Risk Prediction  
Monique Windley, et al. (Poster #116)

**14:15–14:30** Application of the Adverse Outcome Pathway (AOP) Approach for Cardiotoxicity Adverse Endpoints  
Helen Prior, et al. (Poster #110)

**14:30–14:45** Assessment of Positive and Negative Inotropic Compounds Using an Impedance-Based System with Human iPSC-Derived Cardiomyocytes under Controlled Pacing Conditions  
Xiaoyu Zhang, et al. (Poster #117)

**14:45–15:00** Successes and Challenges of Performing hERG Studies for CiPA  
Adam Hill, et al. (Poster #95)

**15:00–15:15** Analyzing Effects of Cardiac Fibroblasts on Aging Hearts Using 2D/3D Co-Culture Systems and Computational Simulation  
Tetsuro Wakatsuki, et al. (Poster #115)

Break, Exhibits, Poster Presentations, Poster Judging

**15:15–15:45**  
**Exhibit Hall B**

15:15–15:45 Odd Poster Numbers Present (SPS/JSPS)
15:15–15:45 All SPS Jr. Investigator Poster Contest Entries Present (Even and Odd)

Track A: Advances in Technologies—*In Vitro* and *In Silico* Models

**15:45–17:45**  
**Ballroom B**  
**Co-Chairs:** Najah Abi Gerges, PhD, AnaBioS Corporation, San Diego, CA, United States, Gerhard Multhaup, Dr. rer. nat., McGill University, Montréal, QC, Canada, and Takashi Yoshinaga, PhD, Eisai Co., Ltd., Tsukuba, Japan

The session will provide insight into the latest knowledge and development in the fields of cardiac safety science and bioimaging. Experts will give presentations on the *in silico* identification of drug-induced pro-arrhythmia, moving towards *in silico* drug trials in safety pharmacology and characterization of physiologically relevant 3D cardiac micro-tissues for drug safety testing, as well as a presentation focusing on the state-of-the-art imaging of live cells employing newly developed fluorogenic probes. We aim to show that these scientific innovations and developments could be of benefit for reducing attrition in drug development.

**15:45–16:15** An *In Silico* ECG Database of Drug Effects for Proarrhythmic Risk Assessment by Heart Simulator  
Jun-ichi Okada, PhD, The University of Tokyo, Chiba, Japan
16:15–16:45  Towards In Silico Drug Trials in Safety Pharmacology
          Blanca Rodriguez, PhD, University of Oxford, Oxford, United Kingdom

16:45–17:15  Human-Induced Pluripotent Stem Cell-Derived Cardiomyocytes (hiPS-CMs) in 2D vs. 3D for Drug-Induced Cardiac Risks: 20 Reference Drugs Using Ca²⁺ Transient Assay
          Hua Rong Lu, PhD, Janssen Pharmaceutica NV, Beerse, Belgium

17:15–17:45  Development of Fluorogenic Antioxidants to Monitor Reactive Oxygen Species in Live Cells
          Gonzalo Cosa, PhD, McGill University, Montréal, QC, Canada

Track B: Practical Pharmacology

15:45–17:45  Ballroom C

Co-Chairs: Bruce H. Morimoto, PhD, Celerion, Inc., Redwood City, CA, United States, and George K. Dresser, MD, PhD, FRCP(C), Western University, London, ON, Canada

The Practical Pharmacology session will highlight the clinical application of pharmacology and toxicology principles in the provision of health care to patients. We will be presenting clinical cases that highlight issues related to providing optimal therapeutics and toxicological care.

15:45–16:00  Pharmacokinetics As a Practical Tool for Individualized Patient Dosing
          P. Timothy Pollak, MD, PhD, FRCPC, University of Calgary, Calgary, AB, Canada

16:00–16:15  Pharmacokinetics As a Critical Factor Influencing Safe and Effective Drug Delivery
          P. Timothy Pollak, MD, PhD, FRCPC, University of Calgary, Calgary, AB, Canada

16:15–16:45  Of Mice and Men: Translational PET Imaging to Define Dose Occupancy
          Lisa A. Wells, PhD, Imanova, London, United Kingdom

16:45–17:15  Making Pharmacogenomic Results Matter to Patients and Clinicians: When are They Actionable?
          Bruce C. Carleton, PharmD, The University of British Columbia, Division of Translational Therapeutics, Vancouver, BC, Canada

17:15–17:45  Personalized/Pharmacogenomics of Oncology Therapy
          Wendy Teft, PhD, Western University, London, ON, Canada, and Richard B. Kim, MD, FRCPC, Western University, London, ON, Canada

Sponsored Presentations

18:00–19:00  See pages 48–49

Tuesday, September 20

Sponsored Presentations

07:00–08:00  See page 49

Keynote Plenary

08:30–09:30  Ballroom B

Using Big Data and Little Data to Understand Variable Drug Actions
          Dan M. Roden, MD, Vanderbilt University, Nashville, TN, United States

Initial studies to define mechanisms underlying variable response to drug therapy—the fundamental goal of the discipline of Clinical Pharmacology—focused on outlier patients or small study groups, i.e., “Little Data.” As the discipline turned to the genomic basis for variable drug actions, increasingly large datasets have been studied with drug phenotypes coming from large networks or electronic health records (EHRs), i.e., “Big Data.” These large resources, in turn, have provided the starting point for new discovery in genome science and in pharmacogenomics. This talk will describe some of these advances, and how there is an emerging focus back to individual subjects both in discovery as well as in recent efforts to use DNA datasets coupled to EHRs to implement pharmacogenomics.

Exhibits and Posters Open

09:00–17:00  Exhibit Hall B

Break

09:30–10:00  Exhibit Hall B
Track A: Translational Central Nervous System and Respiratory Safety Pharmacology

10:00–12:00 Ballroom B

Co-Chairs: Simon Authier, DVM, MSc, MBA, PhD, DSP, CiToxLAB, Laval, QC, Canada, Donald W. Miller, PhD, University of Manitoba, Winnipeg, MB, Canada, and Yuko Sekino, PhD, National Institute of Health Sciences, Tokyo, Japan

On the one hand, safety pharmacology is actively expanding with significant progress with in vitro drug safety screening models. On the other hand, safety pharmacology aims to predict clinical trial outcome and clinical data can be used to validate non-clinical drug safety screening tools. This session will explore central nervous system (CNS) and respiratory safety pharmacology models across the full spectrum from single cell assays to clinical concordance. Highlighting weaknesses of older safety testing paradigms but also exploring completely new methods to improve drug safety evaluations, the session will challenge safety pharmacology boundaries and open new horizons. CNS drug safety assays are typically under-represented in the in vitro arena and the session will present cutting edge applications in this emerging field.

10:00–10:30 Immunohistochemical Assay for Central Nervous System Synaptic Dysfunction Using Cultured Neurons
Tomoaki Shirao, MD, PhD, Gunma University, Maebashi, Japan

10:30–11:00 Microglia and Neuroinflammation As Therapeutic Targets in Drug Development for Central Nervous System Disorders
Tiina M. Kauppinen, PhD, University of Manitoba, Winnipeg, MB, Canada

11:00–11:30 Apneic Events—A Proposed New Target for Respiratory Safety Pharmacology
Dennis J. Murphy, PhD, DABT, DSP, Consultant, Chester Springs, PA, United States

11:30–12:00 Assessing the Predictive Value of the Rodent Neurofunctional Assessment for Commonly Reported Adverse Events in Phase I Clinical Trials
Samuel Jackson, PhD, National Centre for the Replacement, Refinement and Reduction of Animals in Research, London, United Kingdom

Track B: State-of-the-Art Methods in Pharmacology

10:00–12:00 Ballroom C

Co-Chairs: Maxim Soloviev, MD, PhD, DSP, Incyte Corporation, Wilmington, DE, United States, Brad Urquhart, PhD, Western University, London, ON, Canada, and Junko Kurokawa, PhD, Tokyo Medical and Dental University, Medical Research Institute, Bunkyo-ku, Tokyo, Japan

This session will focus on the description and application of state-of-the-art methods and techniques in pharmacology as they apply to drug safety and efficacy. Session topics include pharmacometabolomics, mass spectrometry-based imaging, and organ-on-a-chip, and will include not only “state-of-the-art technologies” but also “state-of-the-art thinking about data.” Pharmacometabolomics is the study of the metabolites in a system and how they affect drug efficacy and toxicity. This technique has been adapted as a new form of precision medicine in terms of personalizing drug therapy. Recent advances in mass spectrometry have enabled mass spectrometry-based imaging of organs or even entire preclinical animals. This powerful technique can aid in visualizing drugs, metabolites, or proteins to specific organelles within an organ. Microchips lined with human cells recapitulate the architecture of major organs such as the heart, kidney, liver, intestine, lungs, etc. These organs-on-chips can be used to assess the safety and efficacy of drugs. Non-standard approaches to data collection and interpretation will be discussed.

10:00–10:30 Human Microphysiological Systems at the Frontiers of Drug Discovery
Anthony Bahinski, PhD, MBA, FAHA, GlaxoSmithKline, King of Prussia, PA, United States

10:30–11:00 Next-Generation Molecular Histology: High Performance Mass Spectrometry for Metabolite, Lipid, and Protein Imaging
Jeffery Spraggins, PhD, Vanderbilt University, Nashville, TN, United States

11:00–11:30 Pharmacometabolomics
David Wishart, PhD, University of Alberta, Edmonton, AB, Canada

11:30–12:00 Comprehensive Prediction Method for Adverse Drug Reaction by Using System Pharmacology
Hiroshi Suzuki, PhD, University of Tokyo Hospital, Hongo, Bunkyo-ku, Tokyo, Japan

Lunch Break, Networking, Exhibits
12:00–13:00 Exhibit Hall B

CSPT Pharmacology Chairs’ Meeting
12:00–13:30 Room 10

Sponsored Presentations
12:30–13:30 See page 49

Exhibits and Poster Presentations
13:00–14:00 Exhibit Hall B

13:00–14:00 Odd Poster Numbers Present (SPS/JSPS/CSPT)
Paediatric and Fetal Clinical Pharmacology Session

13:30–15:00

Room 11

Co-Chairs: Colin Ross, PhD, The University of British Columbia, Vancouver, BC, Canada, and Michael Rieder, MD, PhD, Western University, London, ON, Canada

The inclusion of children in clinical trials is increasingly important, notably in that many drug regulatory agencies now require a paediatric plan during the process of drug approval. There are many challenges to studies in children as well as to drug discovery in children and the place of precision medicine in child health care. This symposium will address key issues in paediatric therapeutics related to drug discovery, regulation, and implementation of precision medicine for children.

13:30–14:00 Precision Medicine in Childhood Asthma
Anke-Hilse Maitland-van der Zee, PhD, Utrecht University, Utrecht, Netherlands

14:00–14:30 Pharmacogenomics of Adverse Drug Reactions and Repurposing of Drugs to Prevent ADRs
Colin Ross, PhD, The University of British Columbia, Vancouver, BC, Canada

14:30–15:00 Early Phase Drug Studies in Children: Challenges and Opportunities
Michael Rieder, MD, PhD, Western University, London, ON, Canada

# SPS Oral Communications 3–4

SPS Oral Communications 3: Behavioral Pharmacology and Central Nervous System

14:00–15:15 Ballroom B

Co-Chairs: Ted J. Baird, PhD, DSP, MPI Research, Mattawan, MI, United States, and Mary Jeanne Kallman, PhD, DSP, Kallman Preclinical Consulting, Greenfield, IN, United States

14:00–14:15 Evaluation of the Subjective Similarity of the GlyT1 Inhibitor Bitopertin to Five Drugs of Abuse Using Drug Discrimination Testing in the Rat
Theo Dinklo, et al. (Poster #74)

14:15–14:30 Rodent Big Brother: Optimal Positioning of the Subcutaneous RFID Microchip Transponder for 24/7 Home Cage Monitoring in Rats
Karen Tse, et al. (Poster #87)

14:30–14:45 Analysis of Calcium and Voltage Changes on Dopaminergic Neuronal Activity Relevant to Parkinson’s Disease with Kinetic Image Cytometry
Patrick McDonough, et al. (Poster #171)

14:45–15:00 Astrocyte-Derived Factor Increases the Level of Functional N-methyl-D-aspartate Receptors in Human Induced Pluripotent Stem Cell-Derived Neurons
Kaoru Sato, et al. (Poster #66)

15:00–15:15 Seizure Liability Assessments Using Hippocampal Brain Slices: Comparison of Multiple Preclinical Species
Michael Accardi, et al. (Poster #208)

SPS Oral Communications 4: hiPS-Cardiomyocytes in Safety Pharmacology

14:00–15:15 Ballroom C

Co-Chairs: Khuram W. Chaudhary, PhD, GlaxoSmithKline, King of Prussia, PA, United States, and Martin Traebert, PhD, Novartis Pharma AG, Basel, Switzerland

14:00–14:15 Comparison of Heart Rate Correction Formulas for Accurate Detection of Repolarization Changes in Spontaneously Beating hiPSC-Cardiomyocytes
Hong Shi, et al. (Poster #245)

14:15–14:30 Utilising FRAP to Assess Cx-43 Uncoupling in Spontaneously Beating Human Induced Pluripotent Stem Cell-Derived Cardiomyocytes (hiPS-CMs)
Caroline Archer, et al. (Poster #224)

14:30–14:45 Characterization of hERG Channel Modulators in Optically Paced Human iPSC-Derived Cardiomyocytes Using Ultra-widefield Optopatch
Vivian Hecht, et al. (Poster #232)

14:45–15:00 Variations of Drug Responses in Induced Pluripotent Stem Cell-Derived Cardiomyocytes from Healthy Japanese Volunteers
Atsuhiko Naito, et al. (Poster #65)

15:00–15:15 Pacing of Human iPSC Cell-Derived Cardiomyocytes (hiPSC-CMs) Is Effective for Detecting Chronic Arrhythmogenic Risk of Pharmaceutical Compounds
Tomoharu Osada, et al. (Poster #42)
**Track A: Translational Biomarkers: Bridging the Gap**

**Ballroom B**

Co-Chairs: *Mary Jeanne Kallman, PhD, DSP, Kallman Preclinical Consulting, Greenfield, IN, United States, Thomas K.H. Chang, PhD, The University of British Columbia, Vancouver, BC, Canada, and Katsuyoshi Chiba, PhD, Daiichi Sankyo Co., Ltd., Tokyo, Japan*

This symposium will focus on recent advances in the use of biomarkers to support safety evaluations. Biomarker efforts for the central nervous system, cardiovascular, respiratory, and renal functioning will be discussed. Early data from the ILSI/HESI Subcommittee on Translational Biomarkers of Neurotoxicity collaborative project to characterize the potential markers of neurotoxicity in biological fluids for several known neurotoxins will be shared. The rationale for the protocol for the collaborative study will be described. Additional presentations on cardiovascular, renal, and respiratory biomarker development will complement the neurotoxicity discussion. Participants from different global locations will contribute to the audience's understanding of difficulties in identifying biomarkers and the importance of biomarkers in the future regulatory and scientific environment.

15:45–16:15 **Brief History of the ILSI/HESI Subcommittee on Translational Biomarkers of Neurotoxicity and an Early Report of the Collaborative Biomarker Project**

*Syed Imam, PhD, NCTR/FDA, Jefferson, AR, United States, University of Texas Health Science Center, San Antonio, TX, United States, and University of Arkansas for Medical Sciences, Little Rock, AR, United States*

16:15–16:45 **Glial Fibrillary Acidic Protein (GFAP) and Related Astroglial Proteins As Biomarkers of Neurotoxicity**

*James O’Callaghan, PhD, CDC/NIOSH/HELD, Morgantown, WV, United States*

16:45–17:15 **Framework for Integrated Cardiovascular Risk Assessment: Utilization of Cardiac Biomarkers**

*Katsuyoshi Chiba, PhD, Daiichi Sankyo Co., Ltd., Tokyo, Japan*

17:15–17:45 **Clinical Interstitial Pneumonia-Related Respiratory Biomarkers**

*Don Sin, MD, MPH, The University of British Columbia and St. Paul’s Hospital, Vancouver, BC, Canada*

17:45–18:15 **Safety Risk Assessment and Mechanism-Based Drug-Induced Kidney Injury Biomarkers**

*André da Costa, PhD, UCB Biopharma Sprl, Braine-l’Alleud, Belgium*

**Track B: CSPT Trainee Oral Presentations**

**Ballroom C**

Chair: *Shinya Ito, MD, FRCPC, Hospital for Sick Children, University of Toronto, Toronto, ON, Canada*

15:45–16:00 **Genetic Variation in SLC16A5 Confers Protection from Cisplatin-Induced Ototoxicity in Adult Testicular Cancer Patients**

*Britt Drogemoller*

16:00–16:15 **Multifactorial Prediction of Anthracycline-Induced Cardiotoxicity in Childhood Cancer: 10 Years of Active Surveillance and Pharmacogenomics Studies at the Canadian Pharmacogenomics Network for Drug Safety**

*Folefac Aminkeng*

16:15–16:30 **Characterization of the Gut Microbiota, Metabolomics, and Drug Metabolism over Chronic Kidney Disease Progression**

*Emily D. Hartjes*

16:30–16:45 **Pharmacogenomic Prediction of Cisplatin-Induced Nephrotoxicity in Patients Treated for Childhood Cancer**

*Rodolfo Rivas*

16:45–17:00 **Genome-Wide Scan Identifies Association between an Interferon Regulatory Factor Variant and Interferon-Beta Induced Liver Injury in Multiple Sclerosis Patients**

*Kaarina Kowalec*

17:00–17:15 **Elucidating the Impact of Genetic Variation in Bile Acid Transporters on Bile Acid Signaling and Xenobiotic Transport**

*Laura Russell*
Wednesday, September 21

Poster Removal
08:00–10:00  Exhibit Hall B

Exhibits Dismantle
08:00–12:00  Exhibit Hall B

CSPT Annual General Meeting and Awards Presentation/Ceremony
08:00–09:45  Room 11
08:00–09:00  CSPT Annual General Meeting for Members
09:00–09:30  CSPT Piafsky Young Investigator Award Presentation
09:30–09:45  CSPT Awards Ceremony

SPS Annual Members’ Meeting and Awards Presentation/Ceremony
08:30–09:45  Ballroom C
08:30–09:15  SPS Annual Members’ Meeting and Awards Ceremony
09:15–09:45  SPS Distinguished Service Award Presentation

Break
09:45–10:00

Plenary: Global Regulatory Climate for Safety Pharmacology
10:00–12:00  Ballroom C
Co-Chairs: Carrie G. Markgraf, MD, PhD, Sunovion, Marlborough, MA, United States, Bruce C. Carleton, PharmD, The University of British Columbia, Vancouver, BC, Canada, and Shin-ichi Sekizawa, PhD, DVM, Pharmaceuticals and Medical Devices Agency, Chiyoda-ku, Tokyo, Japan

Increasingly, safety pharmacology is undertaken in a global regulatory climate. While S7A guides the overall aims of safety pharmacology, new topics arise as the science and drug development advance. This session will present the similarities and—importantly—differences between Health Canada, PMDA, and FDA policies and guidance on a range of topics critical to the successful use of safety pharmacology data in support of clinical testing. The revision to S7B, progressive licensing, the CiPA and JiCSA initiatives, the recent CNS AEs in a French Phase 1 trial, and use of the British health database AMED will be discussed by regulators and safety pharmacologists.

10:00–10:30  Comparing Similarities and Differences in Global Safety Pharmacology Regulatory Practices
Frederick J. Sannajust, PharmD, PhD, Merck & Co., West Point, PA, United States

10:30–11:00  Developments in the Canadian Framework for Adaptive Life-Cycle Regulation of Pharmaceuticals and Biologic Products
David Lee, BA, JD, Health Canada, Ottowa, ON, Canada

11:00–11:30  Electrophysiology Studies of iPS-Derived Cardiomyocytes As a Surrogate of QT Prolongation
Yasunari Kanda, PhD, National Institute of Health Sciences, Tokyo, Japan

11:30–12:00  Panel Discussion

Presidents’ Summary
12:00–12:30  Ballroom C

Meeting Adjourned
12:30