Sunday September 27

Diplomate in Safety Pharmacology (DSP) Certification Exam
9:00–16:30—Club C (1st Floor)
Preregistration for the exam was required by September 1. The next DSP certification exam will be held in Vancouver, British Columbia in September 2016.

Monday September 28

Morning Continuing Education Courses
Morning courses include a continental breakfast and refreshments during the break (for AM CE course attendees only).

7:30–8:00—Continental Breakfast
Course books will be available in the room for those with valid CE tickets.

AM1: Human Stem Cell Derived Cardiomyocytes: Emerging Technology to Guide Cardiac Safety Decisions during Preclinical Drug Development
8:00–12:00
Club B
Co-Chairs: Gary Gintant, PhD, AbbVie, North Chicago, IL, United States, and Stefan Braam, PhD, Pluriomics, Leiden, The Netherlands

The goal of the course is to provide attendees with an overview of basic principles and practical utility of stem cell derived cardiomyocytes in safety pharmacology. In this session the attendees will familiarize themselves with assays and technologies using these cells and implementation strategies in drug development. Speakers are experts from academia, technology companies and safety pharmacology professionals and regulatory agencies.

Speakers: Gary Gintant, PhD, AbbVie, North Chicago, IL, United States, Stefan Braam, PhD, Pluriomics, Leiden, The Netherlands, Liudmila Polonchuk, PhD, F. Hoffmann-La Roche, Ltd, Basel, Switzerland, Prof. Godfrey L. Smith, Clyde Biosciences, Glasgow, United Kingdom, Michael Clements, PhD, GE Healthcare, Cardiff, United Kingdom, and David Strauss, MD, PhD, US FDA, Silver Spring, MD, United States

AM2: Making “Sense” of Sensory System Safety Pharmacology
8:00–12:00
Club C
Co-Chairs: Matthew Abernathy, PhD, MPI Research, Inc, Mattawan, MI, United States, and Rachel L. Tapp, BS, MPI Research, Inc., Mattawan, MI, United States

An imperative element in the safety assessment of all new molecular entities is the response of the central and peripheral nervous system including cranial and peripheral sensory pathways. The requisite use of the functional observational battery and locomotor activity assessments by the current ICH Guideline directives (S7A) is considered to be the primary approach to the systematic monitoring of neurotoxic exposures. The essential context for the adoption of acceptable assessment techniques is that the potential behavioral changes should have been identified and reliable measures of these changes should be included in further testing, if needed. The current regulatory guidance limits non-clinical sensory system evaluation (sight, hearing, taste, smell, or touch) to those drugs of a known class with sensory system liability or use a non-traditional route of administration enabling contact with sensory epithelia. The existing tiered level of drug evaluation leaves most drugs to enter the clinic with minimal information concerning the potential risk of sensory system liability. In the case where a sensory system deficit is detected in non-clinical or clinical studies, Tier II evaluations must be conducted to fully characterize the observed toxicity and identify a therapeutic safety margin. This continuing education course will focus on the core behavioral assays a safety pharmacologist can use to initially detect sensory system liabilities in standard IND enabling studies. The functional observational battery will be analyzed to highlight what behavioral endpoints may signal sensory system dysfunction or subclinical toxicity. Based on these findings, we will provide further understanding and potential strategies to address some of the more common types of sensory pathology observed, clinical manifestations, and available Tier II evaluations related to vision, hearing, and balance assessments.

Speakers: Carrie G. Markgraf, MD, PhD, Merck Research Laboratories, Kenilworth, NJ, United States, Ken Schafer, DVM, PhD, DACVP, FIATP, Vet Path Services, Inc., Mason, OH, United States, Serge A. Picaud, PhD, European Vision Institute, INSERM-UPMC Paris, Paris, France, Matthew Abernathy, PhD, MPI Research, Inc, Mattawan, MI, United States, and Jordi Llorens, PhD, Universitat de Barcelona L’Hospitalet de Llobregat, Spain

AM3: Safety Pharmacologist—A Role as Detectives in Drug Discovery and Early Drug Development
8:00–12:00
Club D
Co-Chairs: Tomas Mow, DVM, PhD, H. Lundbeck A/S, Copenhagen, Denmark, and Kristy D. Bruse, PhD, DSP, Integrated Physiology & Pharmacology Consulting, LLC, Poughkeepsie, NY, United States

The role of the Safety Pharmacologist: How has the Safety Pharmacologist role changed over the last ten years? To avoid costly late-stage failures, predictive safety assays and models have been implemented in earlier phases of the pharmaceutical R&D value chain. It is important that such a ‘frontloading paradigm’ is not only a ‘fail early strategy’. Since “sorting out” does not automatically secure identification of drug candidates with less safety liabilities. Such a ‘frontloading paradigm’ has to show the way toward ‘what will not fail’.

To do that safety assessment needs to be done in close collaboration with the other disciplines and should begin early by integrating information on the therapeutic target/patient population, chemistry, potency, selectivity, etc. To secure such a strategy the Safety Pharmacologist has often shown to be the one with the right background and has been used to work in the interplay between chemistry, pharmacology, ADME and toxicology.
There he/she has shown to be the key in deciphering liability signals during lead identification, lead optimization and candidate selection. The safety pharmacologist has often been the Program Manager’s “Best Friend”.

This course will share current de-risking strategies including use of in silico modeling, in vitro, ex vivo, and in vivo assessments including classical safety pharmacology studies - but also how to do safety assessment in efficacy, mini-toxicology or disease model studies. The program will include basic lectures within Cardiovascular, Respiratory and CNS liabilities and case stories. All with the focus on applicability of the assays and models in the “frontloading paradigm”.

Speakers: Tomas Mow, DVM, PhD, H. Lundbeck A/S, Copenhagen, Denmark, Kristy D. Bruse, PhD, DSP, Integrated Physiology & Pharmacology Consulting, LLC, Poughkeepsie, NY, United States, Ard Teisman, PhD, Janssen Pharmaceutica NV, Beerse, Belgium, and Will S. Redfern, PhD, FRSB, FBPhS, DSP, AstraZeneca, Cambridge, United Kingdom

Lunch Break
12:00–14:00
(afternoon course participants, please see below for boxed lunch information)

Afternoon Continuing Education Courses
Afternoon courses include a boxed lunch and afternoon refreshments during the break (for PM CE course attendees with valid tickets only)
13:00–14:00—Boxed Lunch
Course books will be available in the room for those with valid CE tickets.

PM1: In Silico Modeling of Proarrhythmia Risk
14:00–18:00

Club B
Co-Chairs: Frederick J. Sannajust, PhD, Merck Research Laboratories, West-Point, PA, United States, and Anne S.Y. Chain, PhD, Merck Research Laboratories, RAhayw, NJ, United States

Recently, there is a paradigm shift in cardiototoxicity evaluation in drug development. The new emphasis is placed on qualifying and quantifying drug-induced pro-arrhythmic risk of novel compounds rather than the traditional hERG assessments. Various working groups involving academicians, regulators and industry leaders have driven initiatives to propose and refine assays, decision algorithms, methodologies and clinical trial designs leading to the potential future replacement of the costly thorough-QT trials. The objective of this course is to present a selection of the latest approaches, research and findings in the evaluation of cardiac pro-arrhythmic risk during different stages of drug development.

Speakers: Anne S.Y. Chain, PhD, Merck Research Laboratories, RAhayw, NJ, United States, Jean-Pierre Valentin, PhD, DSP, UCB Biopharma, Braine l’Alleud, Belgium, Blanca Rodriguez, PhD, University of Oxford, Oxford, United Kingdom, Sara Dutta, PhD, US FDA, Silver Spring, MD, United States, Yoram Rudy, PhD, Washington University in St. Louis, St. Louis, MO, United States, Mariano Vazquez, PhD, Barcelona Supercomputing Center, Barcelona, Spain, and Gary Mirams, PhD, University of Oxford, Oxford, United Kingdom

PM2: EEG Waveform Recognition Workshop
14:00–18:00

Club C
Co-Chairs: Carrie G. Markgraf, MD, PhD, Merck Research Laboratories, Kenilworth, NJ, United States, and Mary Jeanne Kallman, PhD, DSP, Kallman Preclinical Consulting, Greenfield, IN, United States

This workshop is a hands-on opportunity to become familiar with the technology and software for generating and interpreting electroencephalograms (EEG) in nonclinical species. EEG is the gold standard for confirming seizure and for identifying sleep patterns and sleep disturbances. However, reading nonclinical EEG waveforms and distinguishing abnormal from normal patterns is not a widely taught skill. This hands-on workshop will give attendees a chance to work in small groups with an EEG expert to discuss and interpret real EEG data from multiple nonclinical species. A training certificate, indicating that the attendee has been trained in basic EEG reading and interpretation will be issued for those who complete the workshop.

Speakers: Carrie G. Markgraf, MD, PhD, Merck Research Laboratories, Kenilworth, NJ, United States, Joe N. Kornegay, DVM, PhD, Texas A&M University, College Station, TX, United States, Howard C. Becker, PhD, Charleston Alcohol Research Center, Medical University of South Carolina, Charleston, SC, United States, Simon Authier, DVM, MSc, MBA, PhD, DSP, CIToxLAB, Laval, QC, Canada, Josh Burton, BS, emka TECHNOLOGIES Inc., Falls Church, VA, United States, Jean-Gérard Napoleoni, emka TECHNOLOGIES Inc., Paris, France, and Christopher L. Douglas, Covance, Madison, WI, United States

PM3: Supplemental Safety Pharmacology
14:00–18:00

Club D
Co-Chairs: Greet Teuns, DVM, MSc, Janssen R&D, Beerse, Belgium, and Gouri Shankar Bhattacharyya, MBBS, MD, MRCP, PhD, Fortis Hospital, West Bengal, India

Supplemental Safety Pharmacology Studies, as stated in the S7A (section 2.8.2), are those studies that evaluate potential adverse pharmacodynamics effects on organ system functions which are not addressed by the core battery (CV, CNS, Resp) or by regular repeated dose toxicity studies.

This course will focus on safety pharmacology in metabolism pharmacology, renal safety pharmacology and on the use of diseased models in safety pharmacology.

Speakers: Andreas Herling, DVM, PhD, Research & Translational Medicine R&D DIAB Division, Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany, Jean-Pierre Valentin, PhD, DSP, UCB Biopharma, Braine l’Alleud, Belgium, and Robert L. Hamlin, DVM, PhD, DACVIM, DSP, QTest Labs and The Ohio State University, Columbus, OH, United States

Welcome Reception and Exhibition Opening
18:00–19:30

Exhibit and Poster Areas