Sunday, June 24

Continuing Education Courses

CE 1 (Sunday AM) 8:00 AM–12:00 Noon

Mechanism-Based Approaches to Cardiovascular Safety Assessment

Co-Chairs: **Brian Berridge, DVM, PhD, DACVP,** *GlaxoSmithKline, Raleigh, NC, and* **Michael Boyle, DVM, DACVP,** *NIEHS, Research Triangle Park, NC*

This session will explore current understandings of mechanisms of toxicity in the cardiovascular system and put that understanding in the context of how we do our nonclinical assessments. An introductory overview will bring the audience to a common level of understanding around cardiovascular form and function, potential cellular and molecular targets of toxicity, and bridge into the compromised target patient population. Subsequent sessions will explore contemporary and mechanistically-diverse areas of toxicity. Individual presentations will review our current level of understanding with respect to mechanisms of toxicity, review how current assessment paradigms address (or not) these mechanisms, and offer biomarker recommendations.

8:00 AM–8:05 AM **Introduction**

8:05 AM–8:25 AM **Introduction to the Cardiovascular System As a Target of Drug-Induced Toxicity**
Michael Boyle, DVM, DACVP, NIEHS, Research Triangle Park, NC

8:25 AM–9:05 AM **Cardiovascular Toxicity of Oncology Drugs**
Thomas Force, MD, Center for Translational Medicine, Temple University School of Medicine, Philadelphia, PA

9:05 AM–9:45 AM **Structural Cardiovascular Injury and Hemodynamically-Active Drugs: The Structure-Function Interface**
Heath C. Thomas, DVM, PhD, DACVP, GlaxoSmithKline Safety Assessment, King of Prussia, PA

9:45 AM–10:00 AM **Break**

10:00 AM–10:40 AM **Drug-Induced Mitochondrial Dysfunction and Cardiotoxicity**
Ingrid Pruimboom-Brees, DVM, PhD, DACVP, Novartis Pharma AG, Basel, Switzerland

10:40 AM–11:20 AM **Cardiomyocyte Calcium Handling and Cardiotoxicity**
Michael Quaile, PhD, GlaxoSmithKline Laboratory Animal Sciences, Research Triangle Park, NC

11:20 AM–12:00 Noon **Biomarkers of Cardiotoxicity—Challenges for Present and Future**
Eric Schultze, DVM, PhD, DACVP, FIATP, Lilly Research Laboratories, Indianapolis, IN

Career Development Workshop

Sunday, June 24
8:00 AM–12:00 Noon

Presentation Skills and Scientific Advocacy
(Free Event, registration required)

Co-Chairs: **Julie Johnson, DVM, PhD, DACVP,** *Abbott Laboratories, Abbott Park, IL, and* **Lyn Wancket, DVM,** *The Ohio State University, Columbus, OH*

Presented by Steven Cohen, Executive Vice President of ECG, The Communication Strategy Company, Englewood, NJ

Goals and Objectives

- Develop an appreciation for the differences between an adequate and an excellent presentation.
- Begin building the skills required to design an effective, high-impact scientific presentation with a strong rhetorical and persuasive structure and deliver it with confidence and clarity.
- Improve ability to deliver strong scientific advocacy.
- Understand the challenges of formal presentations, including US FDA Advisory Committee meeting presentations.

CE 2 (Sunday PM) 1:30 PM–5:00 PM

Nontraditional Applications of Clinical Pathology in Drug Discovery and Preclinical Toxicology

Co-Chairs: **Shashi Ramaiah, DVM, PhD, DACVP, DABT,** *Pfizer Global Research and Development Cambridge, MA, and* **Holly Jordan, DVM, PhD, DACVP,** *GlaxoSmithKline, Research Triangle Park, NC*

The objective of this unique clinical pathology course is to present and discuss contemporary examples of nonroutine applications of clinical pathology endpoints used in the drug development setting. Topics will be of interest to those with or without clinical pathology experience. Area experts will discuss bone turnover markers of laboratory animal species, clinical pathology of juvenile animals and nonroutine laboratory animal species and unique applications of the Advia Hematology platform.

1:30 PM–1:35 PM	**Introduction**
1:35 PM–2:20 PM	**Biomakers of Bone Metabolism in Preclinical Studies** *Thomas C. Register, PhD, Wake Forest School of Medicine, Winston-Salem, NC*
2:20 PM–3:05 PM	**Clinical Pathology of Pregnant and Juvenile Animals** *Anne Provencher Bolliger, DVM, MSc, DACVP, DECVP, FIATP, Charles River Laboratories, Sherbrooke, QC*
3:05 PM–3:25 PM	**Break**
3:25 PM–4:10 PM	**Clinical Pathology of Nonroutine Species** *Niraj K. Tripathi, BVSc, MVSc, PhD, DACVP, Covance Laboratories, Inc, Madison, WI*
4:10 PM–5:00 PM	**Unique Applications of the Advia Hematology Analyzer** *Denise Bounous, DVM, PhD, DACVP, Bristol Myers Squibb Company, Princeton, NJ, Nancy Everds, DVM, DACVP, Amgen Inc, Seattle, WA, and Florence Poitout, DVM, DACVP, DECVP, Charles River, Senneville, QC*

CE 3 (Sunday PM) 1:30 PM–5:00 PM

American College of Toxicology—Sponsored: Drug Development 101

Co-Chairs: **Hanan Ghantous, PhD, DABT,** *US FDA, Silver Spring, MD, and* **Lorrene Buckley, PhD, DABT,** *Eli Lilly and Company, Indianapolis, IN*

Drug development is a term used to define the entire process of bringing a new drug or device to the market. It is an integrated, multidisciplinary endeavor which includes drug discovery chemistry and pharmacology, nonclinical safety testing, manufacturing, clinical trials, and regulatory submissions. This workshop will overview the contributions of each area, with a focus on safety assessment, and some of the challenges that can arise. The workshop will also cover the information that should be included in INDs and NDAs submitted to US FDA as well as advice on how to write a good IND/NDA.

1:30 PM–1:35 PM	**Introduction**
1:35 PM–2:15 PM	**What Goes in, What Goes on, What Comes out: An Overview of CMC Development** *Eric C. Jensen, PhD, Eli Lilly and Company, Indianapolis, IN*
2:15 PM–2:55 PM	**The Role of Toxicology in Drug Development** *Lorrene Buckley, PhD, DABT, Eli Lilly and Company, Indianapolis, IN*
2:55 PM–3:25 PM	**Break**
3:25 PM–4:05 PM	**Introduction to Clinical Trials** *Yodit Belew, MD, US FDA, Silver Spring, MD*
4:05 PM–4:45 PM	**Regulatory Submissions and the Review Process** *Mark W. Powley, PhD, US FDA, Silver Spring, MD*
4:45 PM–5:00 PM	**Wrap Up**

CE 4 (Sunday PM) 1:30 PM–5:25 PM

The Placenta As an "Immune Organ" and Its Relevance in Toxicological Studies

Co-Chairs: **Eberhard Buse, PhD, Prof. Dr.rer.nat,** *Convance Laboratories Gmbh, Muenster, Germany, and* **Darlene Dixon, DVM, PhD, DACVP,** *NIEHS, Research Triangle Park NC*

The immune system plays a key role in host protection against potential pathogens, as well as foreign (nonself) proteins and altered cells with tumorigenic potential. The foreign fetal nonself proteins cause an immunologic materno-fetal conflict which has to be resolved in the placenta. The maternal rejection apparatus and the primarily fetal tolerance mechanisms involve delicate and well-controlled immune processes which take place, in large part, in the placenta.

1:30 PM–1:35 PM **Introduction**

1:35 PM–2:10 PM **Nonhuman Primate (NHP, Cynomolgus Monkey) Placenta and Its Immune Equipment**
Eberhard Buse, PhD, Prof, Dr.rer.nat, Covance Laboratories GmbH, Müenster, Germany

2:10 PM–2:45 PM **Changes in the Peripheral Immune Response during Pregnancy**
M.M. Faas, PhD, University Medical Center Groningen, Groningen, Netherlands

2:45 PM–3:05 PM **Break**

3:05 PM–3:40 PM **Local Adaptation of the Maternal Immune System in Human Pregnancy**
Jan Ernerudh, MD, Linköping University, Linköping, Sweden

3:40 PM–4:15 PM **The Human Placenta for Toxicology Assessment**
Udo Markert, Dr.med.habil, University Hospital Jena, Jena Germany

4:15 PM–4:50 PM **The Placenta and Toxicology**
Kurt Benirschke, MD, DACVP, University of California at San Diego, San Diego, CA

4:50 PM–5:25 PM **Pathologic Assessment of the Placenta**
J. Mark Cline, DVM, PhD, DACVP, Wake Forest University, School of Medicine, Winston-Salem, NC