International Conference on Drug Development (ICD^2)
February 27-29, 2012 • Barton Creek Conference Center - Austin, TX

Mission: To offer the most informative and up to date conference in the science and regulation of global drug development.

Theme: Fostering Innovation and Translational Research in Support of Public Health and Economic Growth

Subtheme: Moving the FDA into the XXI Century - Advancing Regulatory Science into Medicines - Balancing Pharmaceutical Innovation Drug Safety and Economic Growth

MONDAY, FEBRUARY 27
2:30-3:00 PM
Welcome/Opening Remarks
Salomon Stavchansky, Ph.D.
Alcon Centennial Professor of Pharmaceutics
The University of Texas at Austin

M. Lynn Crismon, Pharm.D., Dean
James T. Deluisio Regents Chair
Behrens Inc. Centennial Professor
The University of Texas at Austin

Theme: Facilitating Pharmaceutical Innovation: Expanding Opportunities and Removing Roadblocks
Moderator: Samuel D Maldonado, M.D., MPH, FAAP
Johnson & Johnson

3:00-3:50 PM
Advancing Science into Medicines, Diagnostic and Devices - Balancing Pharmaceutical Innovation Drug Safety and Economic Growth
Adam Heller, Ph.D.
Ernest Cockrell, Sr. Chair Emeritus in Engineering
The University of Texas at Austin

Moderator: Kay Holcombe
Genzyme Corporation

Theme: Drug Safety - Quality of Medicines (QbD) and Impact of Pharmacovigilance

3:50-4:20 PM
The Past, Present, and Future of Pharmaceutical Innovation
Kenneth I Kaitin, Ph.D.
Director and Professor
Tufts Center for the Study of Drug Development
Tufts University School of Medicine
• To understand the economic, regulatory, and scientific challenges affecting pharmaceutical innovation today.
• To examine new R&D models and approaches for product development.
ACPE UPN: 0067-0000-12-001-L04-P (.05 CEUs)

4:20-4:50 PM
Innovative Legislation for Special Populations - Pediatrics-BCPA, PREA, ICH-E-11
Stephen P Spielberg, M.D., Ph.D.
Deputy Commissioner for Medical Products and Tobacco
US Food & Drug Administration
• Understand impact of incentives to drive drug development where traditional funding does not work.
• Understand international harmonization of regulations.
ACPE UPN: 0067-0000-12-002-L04-P (.05 CEUs)

5:20-5:50 PM
Translational Medicine - Innovative Approach to Cross-Discipline Drug Discovery
Lloyd B Klickstein, M.D., Ph.D.
Translational Medicine Head
New Indications Discovery Unit
Novartis Institutes for BioMedical Research
• Understand the strategy for identification of drug indications.
• Initial review of principles guiding the translational medicine approach to drug development.
ACPE UPN: 0067-0000-12-003-L04-P (.05 CEUs)

5:50-6:30 PM Panel Discussion

6:30-7:15 PM Welcome Reception

7:30 PM Dinner - Hill Country Dining Rm

TUESDAY, FEBRUARY 28
7:30 AM Breakfast

Theme: Drug Safety - Quality of Medicines (QbD) and Impact of Pharmacovigilance

8:30-9:15 AM
Implementation of the Sentinel Pilot Program-Lessons Learned from the Pilot Program - FDA Perspective
Janet Woodcock, M.D.
Director CDER
US Food & Drug Administration
• Develop a better understanding of the Sentinel Program and FDA’s involvement, as well as the many partners involved. Where we are now and where we plan to go.
11:00-11:30 AM
Quality by Design-FDA Lessons Learned and Challenges for International Harmonization
Christine M. V. Moore, Ph.D.
Acting Director
ONDQA/CDER/FDA
US Food & Drug Administration
- Describe how Quality by Design principles relate to pharmaceutical development and manufacturing.
- Describe major FDA initiatives in implementation of QbD.
ACPE UPN: 0067-0000-12-005-L04-P (0.05 CEUs)

11:30-12:00 PM Panel Discussion

12:00 PM Lunch

Afternoon Free for Recreation

7:00 PM Dinner - Foothills Room in Hill Country Dining Rm
Moderator: Volker Fischer, Ph.D.
Abbott Laboratories

8:30-9:30 AM
Microengineered Hydrogels for Stem Cell Bioengineering and Tissue Regeneration
Ali Khademhosseini, Ph.D.
Associate Professor
Harvard-MIT Division of Health Sciences and Technology
- Learn about controlling cell-microenvironment interactions by using patterned hydrogels to direct the differentiation of stem cells.
- Describe the fabrication and the use of microscale hydrogels for tissue engineering by using a ‘bottom-up’ and a ‘top-down’ approach.
ACPE UPN: 0067-0000-12-006-L04-P (0.1 CEUs)

WEDNESDAY, FEBRUARY 29

7:30 AM Breakfast
Theme: Challenges and Opportunities in the Science and Regulation of Biosimilars-Quality of Medicines-A Round Table Discussion
Moderator: Chuck Hoiberg, Ph.D.
Pfizer, Inc.

8:30-9:30 AM
Update of CDER Regulatory Science Initiatives-Challenges in the Science, and Regulation of Innovative and Complex Drug Delivery Systems for Drugs and Biologicals-Roles of FDA in Global Harmonization - Biosimilars User Fees
Janet Woodcock, M.D.
Director CDER
US Food & Drug Administration
- Learn about the various initiatives that CDER is involved currently and the plans for future avenues.

Moderator: Joanne Palmisano, M.D., FACP - Boehringer Ingelheim Pharmaceuticals, Inc.

9:30-10:20 AM
Worldwide Experience with Developing Biosimilars and Potential Impact on Patient Access and Health Care Cost
Mark A McCamish, M.D., Ph.D.
Head Global Biopharmaceutical Development
Sandoz International GmbH Novartis Biosimilars
- Biosimilars have been introduced outside the US and already improved patient access and achieved cost savings.
- Regulatory processes developed for assessing comparability of originator products pre- and post-manufacturing changes are the basis for evaluating Biosimilars.
ACPE UPN: 0067-0000-12-007-L04-P (0.075 CEUs)

10:20-10:35 AM Break

10:35-11:00 AM
Theme: Point Counterpoint Discussion: Legal and Business Considerations Impacting Biosimilars and Therapeutic Interchangeability
Moderator: Nancy Hutchinson, Ph.D.
Novartis Pharmaceuticals Corporation

10:30-11:00 AM
Completion of a QbD Filing for a Novel Monoclonal Antibody: Lessons Learned and Future Implications
Brian Kelley, Ph.D.
Vice President, Bioprocess Development
Genentech, Inc.
- Understand how a set of risk assessments addressing product attributes, process and control system could be designed to support a Qbd filing.
- See opportunities for current and future applications to use platform knowledge, specifically for monoclonal antibody products.
ACPE UPN: 0067-0000-12-006-L04-P (0.1 CEUs)

10:30-11:00 AM
Theme: Challenges and Opportunities in the Science and Regulation of Biosimilars-Quality of Medicines-A Round Table Discussion
Moderator: Chuck Hoiberg, Ph.D.
Pfizer, Inc.

10:30-11:00 AM
Legal/Regulatory Challenges & Opportunities for the BioPharma Industry arising from FDA’s Establishment of Standards for Biosimilarity & Interchangeability
John M. Engel, J.D.
Founding Partner & Managing Partner Engel & Novitt, LLP
Apply a working understanding of the statutory provisions and evolving regulatory standards by which competing biological products in the U.S. would be determined by FDA to be “biosimilar” and/or “interchangeable.”

Critically evaluate the broader legal and regulatory implications for biopharma generally and biosimilars in particular of such FDA determinations, esp. with respect to pre- and post-approval demonstrations of biologic comparability, biologic naming, inadvertent biologic substitution, and track and trace for biologics.

**11:00-11:25 AM**
**Legal Considerations to Establish Biosimilarity and Therapeutic Interchangeability**
**Richard F Kingham**
Partner, Covington & Burling LLP
- Understand the legal requirements for approval of biosimilar products in the United States and the European Union.
- Understand the procedures for making determinations as to interchangeability of biosimilar and reference products in the United States and the European Union.
ACPE UPN: 0067-0000-12-008-L04-P (0.025 CEUs)

**11:25-11:50 AM**
**Legal Considerations to Establish Biosimilarity and Therapeutic Interchangeability**
**Kurt R Karst, J.D.**
Hyman, Phelps & McNamara, P.C.
- Understand the legal framework for biosimilar approval.
- Understand some of the various legal considerations/issues that will likely arise in the context of biosimilar approvals.

**11:50-12:30 PM**
**Legal Considerations-Round Table Discussion**

**12:30-1:45 PM Lunch**
**Theme: Global Development and Commercialization of Biosimilars**

**1:45-2:10 PM**
**USP Global Role on Biosimilars - Documentary Standards and Monographs**
**Tina S Morris, Ph.D.**
Vice President, Biologics and Biotechnology
United States Pharmacopeia
- Understand the importance of public standards for biological medicines and USP’s role.
- Have a comprehensive overview of the approaches USP is taking in providing quality standards for the assessment of all biological medicines.

**2:10-2:30 PM**
**USP Global Role on Biosimilars - Potency Assays and Reference Materials**
**Walter W Hauck, Ph.D.**
Senior Scientific Fellow
United States Pharmacopeia
- Understand contributions USP is making to practice of bioassays.
- Understand what USP is doing in developing reference materials for biological medicines.

**2:30-3:00 PM**
**GPhA Perspectives on Biosimilars - What Initiatives Can Industry Take to Foster and Transform the Development of Biosimilars?**
**Ralph G Neas**
President and CEO, GPhA
- Understand the importance of making biogenerics available to the public at the earliest opportunity.
- Biogenerics are essential to the sustainability of the healthcare system and to the economy.
ACPE UPN: 0067-0000-12-009-L04-P (0.05 CEUs)

**3:00-3:45 PM**
**Impact of Evolving Biosimilar Policy on Innovator Biologics Development**
**Michael Corbo, R.Ph., Ph.D.**

**3:45-4:15 PM**
**Use of Data Generated with Foreign Comparator Reference Product for Safety and Efficacy Evaluation for US Submissions**
**Sumant Ramachandra, M.D., Ph.D.**
Senior Vice President of Research & Development and Medical Affairs
CSO Hospira, Inc.

**4:15-4:30 PM Break**

**4:30-5:00 PM**
**Development of Methodologies to Ensure Product Quality of Innovator Drugs-Biologics, Biosimilars, and Generic Drugs**
**Dr. Stefan Schlatter**
Associate Director Cell Culture Development
Boehringer Ingelheim Pharma GmbH & Co. KG
- Understand the current challenges of progress development from a CMOs perspective.
ACPE UPN: 0067-0000-12-011-L04-P (0.05 CEUs)

**5:00-5:30 PM Panel Discussion**

**6:30-8:00 PM Dinner - Foothills Room in Hill Country Dining Rm**

**8:15 PM FDA Panel Discussion**
2012 ICD2 Program Planning Committee

Jennifer Bosworth, Pharm.D.
Interim Director, Pharmacy CE
The University of Texas at Austin
College of Pharmacy

Linda S. Carter
Regulatory Scientist
Hyman, Phelps and McNamara

Michael A. Dorato, Ph.D., DABT
Global Vice President, Discovery Services
Covance Laboratories, Inc.

Volker Fischer, Ph.D.
Senior Director, DMPK/Bioanalysis
Global Pharmaceuticals R&D
Abbott

Charles P. Hoiberg, Ph.D.
Executive Director
Pfizer, Inc.

Kay Holcombe
Senior Policy Advisor
Genzyme

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Senior Clinical Consultant
Biologics Consulting Group, Inc.

Nancy Hutchinson
Head, Drug Regulatory Affairs North America
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Kenneth I. Kaitin, Ph.D.
Director and Research Professor
Tutts Center for the Study of Drug Development
Tutts University

John A. Kerzan
Sr. Client Manager, DMPK/cGMP
Covance Laboratories

Steven Kozlowski
Supervisory Medical Officer
DHHS/FDA/CDER/OPS/OBP

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Vice President
Global Regulatory Sciences, US and Regulatory Policy
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Pediatric Drug Development Center of Excellence
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Andrea Masciale, J.D.
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