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
Department of Chemical Engineering
Cockrell School of Engineering

•Review two growth and development trends where (a) the economies of developing countries grow rapidly by knowledge transfer from developing countries and (b) economies of developed countries grow slowly by generating new knowledge.
•Review how these two trends are associated with (a) rapid shifting of the manufacture of drugs and the provision of drug development services to developing countries; and (b) slower sustained generation of drug-related knowledge by developed countries. The trends are likely to lead to the shrinkage of the presently massive differences in drug prices in different countries.

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)

Moderator: *Kay Holcombe*
Genzyme Corporation

4:50-5:20 PM

Facilitating Pharmaceutical Innovation: Expanding Opportunities and Removing Regulatory Roadblocks - Global Role of the FDA

Gerald F Masoudi
Attorney
Covington & Burling LLP

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*

Moderator: *Robert J Meyer, M.D.*
Merck & Co, Inc.

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.

TUESDAY CONTINUED

Moderator: *Terrance Ocheltree, Ph.D.*
ONDQA/OPS/CDER/FDA

9:15-9:45 AM
Why Can't Observational Studies Be More Like Randomized Trials? Observational Medical Outcomes Partnership (OMOP) and Other Lessons
Allen H Heller, M.D.
Vice President, Medical Science
Bayer Healthcare Pharmaceuticals
Visiting Fellow in Statistics, Harvard
•Describe the Observational Medical Outcomes Partnership (OMOP) and top line results of the 'outcomes of interest experiment.'
•Understand basic principles of observational study design based on the analogy with randomized trials.
ACPE UPN: 0067-0000-12-004-L04-P (.05 CEUs)

9:45-10:15 AM
Observational Medical Outcomes Partnership and Sentinel Pilot Program - Industry Perspective
Nancy C Santanello, M.D., M.S.
Vice President, Head of Epidemiology
Merck & Co. Inc.
•Understand how industry perceives the work from OMOP & FDA Sentinel Pilot.
•Understand industry contributions.

10:15-10:30 AM Break

Moderator: *Maria Rivas, M.D.*
Bayer Healthcare Pharmaceuticals Inc

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.

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 PM
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 Biologics-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

Theme: *Point Counterpoint Discussion: Legal and Business Considerations Impacting Biosimilars and Therapeutic Interchangeability*

Moderator: *Nancy Hutchinson, Ph.D.*
Novartis Pharmaceuticals Corporation

10:35-11:00 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

WEDNESDAY CONTINUED

•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*

Moderator: *Mehul Mehta, Ph.D.*
OTS/CDER/FDA

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)

Moderator: *Andrea Masciale, J.D.*
Janssen Pharmacueutical Companies of Johnson & Johnson

3:00-3:45 PM
Impact of Evolving Biosimilar Policy on Innovator Biologics Development
Michael Corbo, R.Ph., Ph.D.
Vice President & Chief Development Officer
Bioenhancement Development Unit in Worldwide Research & Development
Pfizer, Inc.
•Understand the challenges of conducting comparative clinical trials.
•Understand the issues of appropriate reference product selection.
ACPE UPN: 0067-0000-12-010-L04-P
(0.075 CEUs)

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

Moderator: *Lisa Shipley, Ph.D.*
Merck & Co, Inc.

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

Moderator: *Gerald J Yakatan, Ph.D.*
IriSys, Inc.

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

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Volker Fischer, Ph.D.
Senior Director, DMPK/Bioanalysis
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