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Criteria for FDA's Acceptance of Results from Pharmacometrics Approaches

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Glass Delamination: An Industry Challenge

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Clinical Pharmacology Strategies in the Development of Antibody Drug Conjugates:

The Next Generation of Oncology Agents. The T-DM1 Story

Conducted by Sandhya Ramanathan Girish, Ph.D., Genentech

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Cyclodextrins II: Their Pharmacokinetics, Safety/Toxicology and in vivo Performance

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Cyclodextrins I: Physicochemical Properties and in vitro Evaluation

Conducted by Thorsteinn Loftsson, Ph.D., University of Iceland

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Conducted March 25, 2011 Organized by the PPB Section

Funded by a grant from AstraZeneca

Practical Aspects of Amorphous Solid Dispersion Design and Development

Conducted by Feng Qian, Ph.D., Bristol-Myers Squibb Co.

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Conducted March 17, 2011 Organized by the API Manufacturing Technology Focus Group

Particle Characterization of API **Part 2**

Conducted by Ronald G. Iacocca, Ph.D., Eli Lilly and Company

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Conducted March 10, 2011 Organized by the API Manufacturing Technology Focus Group

Particle Characterization of API **Part 1**

Conducted by Ronald G. Iacocca, Ph.D., Eli Lilly and Company

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Conducted February 24, 2011 Organized by the AAPS Non-Clinical Dose Formulation Analysis Focus Group
Funded by a grant from MPI Research

White Paper Review: Non-Clinical Dose Formulation Analysis Method Validation and Sample Analysis

Conducted by Monica Lee Whitmire, MS, BS, BS, MT (ASCP), MPI Research

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Conducted February 10, 2011 Organized by the PPB Section; Sponsored by a grant from AstraZeneca
Characterization and Stabilization of Amorphous Pharmaceutical Solids

Conducted by George D. Zografi, Ph.D., University of Wisconsin-Madison

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Conducted January 26, 2011 Organized by the FDD Section; Sponsored by a grant from sanofi aventis
Physiological and Biochemical Barriers to Drug Delivery

Conducted by Xiaoling Li, Ph.D., University of the Pacific

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Strategies for Protein Formulation: Role of Pharmaceutical Sciences and the Development of Rapid Efficient Development Practices

Conducted by Nick Warne, Ph.D., Pfizer, Inc.

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Conducted December 9, 2010 Organized by the CPTR Section

Selected Case Studies on Application of PBPK Modeling in Preclinical and Clinical Studies

Conducted by Thierry Lavé, Ph.D., Pharm.D., F. Hoffmann-La Roche, Basel, Switzerland

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Ouch, There Goes My Blood-Brain Barrier:

How Inflammatory Pain in the Periphery Modulates Drug Delivery to the CNS

Conducted by Patrick T. Ronaldson, Ph.D., University of Arizona

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Conducted November 4, 2010 Organized by the PPDM Section

In vitro Hepatocyte Predictive Models for Hepatic Disposition of Drug Candidates

Conducted by Yurong Lai, Ph.D., Pfizer, Inc.

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Cell-based Permeability Measurements: Experimental Methods and Analysis

Conducted by Philip Burton, Ph.D., CeeTox

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Conducted October 21, 2010 Organized by the LBAB Focus Group of the Biotec Section
Free and Total Assays for Antibody Biotherapeutics and Targets
Conducted by Jean Lee, Ph.D., Amgen, Inc. and Lindsay King, Ph.D., Pfizer, Inc.
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Individualizing a Postdoctoral Position Based on Your Career Aspirations
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Solid API Stability
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Application of BCS in Regulatory Submissions
Conducted by Mehul U. Mehta, Ph.D., U.S., Food and Drug Administration
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Monoclonal Antibody Clinical Development
Conducted by Sandhya Girish, Ph.D., Genentech
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Mechanistic Models to Simulate Dose Response of IgE Suppression Following Dosing of Anti-IgE Monoclonal Antibodies
Conducted by Pascal Chanu, PharmD., Pharsight - A Certara Company
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Biometric Modeling
Conducted by Kiyo Sugano, Ph.D., Pfizer, UK
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Conducted July 29, 2010 Organized by the Drug Transport Focus Group of the PPDM Section
Membrane Transporters in Drug Development: A Report from the International Transporter Consortium: Decisions, Impact and Future Directions
Conducted by Lei Zhang, Ph.D., U.S. Food and Drug Administration
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Conducted July 22, 2010 Organized by the PPB Section
Four Part Series: ADME and Pharmacokinetics in Drug Discovery/Development
Part 4: PK/PD in Clinical Drug Development
Conducted by Steven Zhang, Ph.D., Bristol-Myers Squibb
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End of Phase 2A Meetings with the FDA: Past and Future
Conducted by Jogarao Gobburu, Ph.D., U.S. Food and Drug Administration
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Four Part Series: ADME and Pharmacokinetics in Drug Discovery/Development
Part 3: Distribution, Transporters, and Drug Delivery to Target Tissue
Conducted by Bill Smith, Ph.D., Pfizer and Xingrong Liu, Ph.D., Genentech
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Implementing New Standards: Bridging the Gap Between Data Mgmt. & Regulatory Affairs
Conducted by Shan Wang, President/CEO MedXview, Inc.
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Four Part Series: ADME and Pharmacokinetics in Drug Discovery/Development
Part 2: Absorption, First Pass Effect, and Bioavailability
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Part 1: Introduction to Drug Absorption, Distribution, Metabolism, and Excretion Kinetics
Conducted by Rose Feng, Ph.D., University of Michigan
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Excipient Variability and the Effect on Product Quality
Conducted by Brian Carlin, Ph.D., FMC Corporation
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Biopharmaceutics Classification System (BCS): Ten Years and Maturing
Conducted by Gordon L. Amidon, Ph.D., University of Michigan College of Pharmacy
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Pharmacokinetic and Pharmacodynamic Modeling of Biologics: Understanding New Complexities
Conducted by Bernd Meibohm, Ph.D., FCP, University of Tennessee Health Science Center
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Conducted April 22, 2010 Organized by the Indiana/Ohio Discussion Group and the IP Focus Group
Patent Issues in Drug Development: Perspectives of a Pharmaceutical Scientist-Attorney
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Conducted April 14, 2010 Organized by the Population PD/PD Focus Group of the PPDM Section
The Full Covariate Models and WAM Algorithm
Conducted by Marc R. Gastonguay, Ph.D, and Kenneth G. Kowalski, M.S.,
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Transdermal Product Development

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Setting Specifications for API and Pharmaceutical Products under QbD

Conducted by Eda Ross Montgomery, Ph.D., Vertex

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Conducted March 25, 2010 Organized by the Drug Transport Focus Group

Kinetic Considerations for the Quantitative Assessment of Efflux Activity and Inhibition

Conducted by J. Corey Calvass, Ph.D., Abbott Laboratories

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Factors Affecting the PK / PD of Liposomal and Nanoparticle Agents

William C. Zamboni, Pharm.D., Ph.D., University of North Carolina

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Ocular Drug Delivery

Ashim K. Mitra, Ph.D., University of Missouri – Kansas City

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Protein Aggregation and Immunogenicity

Harald Kropshofer, Ph.D., F. Hoffmann La Roche, Basel, Switzerland

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Optimizing the Physicochemical Properties of Clinical Candidates during Drug Discovery

Edward Kerns, M.S. and Li Di, Ph.D., Pfizer

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Conducted October 29, 2009 Organized by the CPTR Section

Use of PK/PD Modeling for Starting Dose Selection in First-in-Human Trials in Biologics

Balaji Agoram, Ph.D., Pfizer

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Mouse Models for Functional Analysis of Microsomal Cytochrome P450

Xinxin Ding, Ph.D., Wadsworth Center, NYS Department of Health

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Nanotechnology in Drug Discovery and Development

Roy Haskell, Ph.D., Bristol-Myers Squibb

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Application of Materials Science to Solid Dosage to Design Form Design and Process Development
Bruno Hancock, B.Pharm., Ph.D., MRPharmS, Research Fellow, Pfizer Inc., Groton CT
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Conducted October 8, 2009 Organized by the Ligand Binding Assay Bioanalytical Focus Group of BIOTEC Section
Application of Multifactorial DOE for the Ligand Binding Lab
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Transgenic Mouse Models of Drug Transporters: Insights to Drug Disposition and Efficacy Richard Kim, M.D., University of Western Ontario.
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Development, Evaluation, and Application of in Vitro/in Vivo Correlations, Patrick Marroum, Ph.D., US FDA.
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Polymorphism and Pharmaceuticals, Stephen Byrn, Ph.D.
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The Role of Target and Mechanism Biomarkers in Translational Research, Donald Mager, Ph.D.
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Understanding the Physical World, Gordon Flynn, Ph.D.
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PQRI Webinar on Sulfonate Esters, Andrew Teasdale, Ph.D.
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Mechanical Property Characterization Methods for Pharmaceutical Solids, Gregory Amidon, Ph.D.
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Conducted June 10, 2009 Organized by the Sterile Products Focus Group
ABCs of Sterile Manufacturing and Related Challenges, Michael Akers, Ph.D.
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How to Get Your Newly Discovered Drug Candidate into Human Clinical Trials in the U.S., Dr. Nancy Motola and Mr. Paul Alessandro
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Conducted May 27, 2009 Organized by the PPDM Section
Understanding and Measuring Target Site Concentration, Drs. Hartmut Derendorf, Ralph Clinckers, and William Couet
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Characterization of Solids by Thermal Methods, Yuchuan Gong, Ph.D., Abbott
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Key Factors to Design Quality Stability Program for Drug Products and API, Kim Huynh-Ba, Pharmalytik
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Salt Selection & Optimization for Pharmaceutical New Chemical Entities, Abu Serajuddin, Ph.D., St. John's University, Queens, NY
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Solubility and Solubilization of Drug Substances, Samuel Yalkowsky, Ph.D., University of Arizona
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Validating Analytical Methods Based on Current ICH Guidance and USP/Industry Standards (APQ Module 5)
Saji Thomas, Ph.D., Par Pharmaceuticals
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Understanding Pharmaceutical Quality by Design, Lawrence X. Yu, Ph.D., U.S. Food and Drug Administration
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Accelerated Stability Assessment Program (ASAP): Using Science to Set Expiry Dating for Solid Drug Product
Ken Waterman, Ph.D., Pfizer This is APQ Module 4:
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Conducted December 4, 2008 Sponsored by the PPDM Section
Linking Drug Effects to Target Site Concentrations by Microdialysis
Conducted by Elizabeth CM de Lange, Ph.D. and Margareta Hammarlund-Udenaes, Ph.D.
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Conducted December 3, 2008
Aggregation of Therapeutic Proteins: Causes, Control, Consequences and Challenges
Conducted by John Carpenter, Ph.D.
Presented by the Protein Aggregation and Immunity Focus Group

SUMMARY: Aggregation is an important consideration in the development of biologics. Control of this phenomena requires a good understanding of the underlying mechanisms and the characterization of the aggregates formed. The presentation will cover the causes of aggregation of therapeutic proteins, fundamental factors governing protein aggregation, the approaches to reduce aggregation, the potential safety issues related to aggregates and some of the analytical challenges for protein aggregates and particles.

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Conducted October 2, 2008 (APQ Module 3)

Predictive Dissolution Methods

Conducted by Erika Stippler, Ph.D.

SUMMARY: This webinar gives a broad overview on dissolution testing. It gives a short description of the importance of the test in the evaluation of the performance of dosage forms. The factors which should be considered in case of development of a predictive dissolution method are discussed. Dissolution apparatus available and their application are mentioned. Finally, proposals for "default"-dissolution methods are given for the different dosage forms.

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Conducted July 29, 2008 (APQ Module 2)

Fundamental Statistics Applied to Analytical Laboratory

Conducted by Abbie Gentry, Ph.D.

Presented by the APQ Section Click here for complete details and link to registration. Click here to download PDF.

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Conducted April 28, 2008 (APQ Module 1)

Control of Impurities in Drug Substance and Drug Product

Conducted by Christopher M. Riley, Ph.D.

Presented by the APQ Section.

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Conducted February 29, 2008:

Polymer Nanomaterials for Drug Delivery

Conducted by Professor Alexander Kabanov, College of Pharmacy, University of Nebraska Medical Center, Omaha

Funded by a grant from AstraZeneca. Presented by the Modified Release Focus Group.

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Conducted May 4, 2007

Zen and the Art of Preformulation

Conducted by Neelima Phadnis, Ph.D., Neurogen

Funded by a grant from AstraZeneca. Presented by the PDD Section.

SUMMARY: Advances in science and technology have contributed towards a growing arsenal of methodologies for studying molecules and their interactions in systems of pharmaceutical interest. The screening process- preformulation, leverages available methodologies to support a wide array of activities at various stages of a typical industrial R&D program. To a relative newcomer in an industrial setting, the business approach to the screening process may appear complex. This talk will familiarize the audience with different approaches to industrial preformulation programs, summarize the evolution of the field, current thinking and potential areas of growth in the next few years.

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Conducted June 7, 2007

Lipid-based Systems for Oral Drug Delivery

By David Hauss, Ph.D., Bristol Myers Squibb Co.

Funded by a grant from AstraZeneca. Presented by the PDD Section.

SUMMARY: Approximately 40% to as much as 70% of new chemical entities entering drug development pipelines today suffer from low aqueous solubility. The poor and variable gastrointestinal absorption afforded these compounds by conventional formulations can be complicated by a significant, positive food effect, potentially resulting in unexpected toxicity while making development more costly and difficult. The use of lipid-based formulations for developing oral dosage forms for these challenging compounds will be reviewed.

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