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Conducted August 5, 2010 Organized by the CPTR Section
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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Conducted June 21, 2010 Sponsored by sanofi aventis Organized by the PPB Section
Four Part Series: ADME and Pharmacokinetics in Drug Discovery/Development
Part 2: Absorption, First Pass Effect, and Bioavailability
Conducted by Tycho Heimbach, Ph.D., Novartis Institutes for Biomedical Research
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Four Part Series: ADME and Pharmacokinetics in Drug Discovery/Development

Part 1: Introduction to Drug Absorption, Distribution, Metabolism, and Excretion Kinetics

Conducted by Rose Feng, Ph.D., University of Michigan

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Conducted May 11, 2010 Organized by the FDD Section

Excipient Variability and the Effect on Product Quality

Conducted by Brian Carlin, Ph.D., FMC Corporation

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Conducted May 11, 2010 Sponsored by a grant from AstraZeneca Organized by the PPB Section

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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Conducted April 29, 2010 Organized by the CPTR Section

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

Conducted by Srikumar Melethil, Ph.D., J.D., The University of Findlay (Ohio)

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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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Conducted April 1, 2010 Organized by the PPB Section

Transdermal Product Development

Conducted by Thomas S. Spencer, Ph.D., Becwar-Spencer Associates, LLC

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Conducted March 29, 2010 Organized by the APQ Section

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. Cory Kalvass, Ph.D., Abbott Laboratories

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Conducted March 18, 2010 Organized by the PPB Section

Enabling Discovery through Formulation

Conducted by John Skoug, Ph.D., and Yi Gao, M.S., Abbott Laboratories

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Conducted Feb 25, 2010 Organized by the CPTR Section

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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Conducted Dec 10, 2009 Organized by the PA&BC Focus Group
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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Conducted October 27, 2009 Organized by the PPDM Section
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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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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Conducted September 18, 2009 Organized by the RS Section
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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Conducted August 20, 2009 Organized by the CPTR Section

The Role of Target and Mechanism Biomarkers in Translational Research, Donald Mager, Ph.D.

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Conducted August 4, 2009 Organized by the PPB Section

Understanding the Physical World, Gordon Flynn, Ph.D.

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Conducted July 23, 2009 Organized by the Product Quality Research Institute

PQRI Webinar on Sulfonate Esters, Andrew Teasdale, Ph.D.

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Conducted June 25, 2009 Organized by the PPB Section

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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Conducted June 8, 2009 Organized by the RS Section

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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Conducted May 12, 2009 Organized by the PPB Section – Funded by AstraZeneca

Characterization of Solids by Thermal Methods, Yuchuan Gong, Ph.D., Abbott

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Conducted April 30, 2009 Organized by the APQ Section

Key Factors to Design Quality Stability Program for Drug Products and API, Kim Huynh-Ba, Pharmalytik

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Conducted April 14, 2009 Organized by the PPB Section - Sponsored by a grant from AstraZeneca

Salt Selection & Optimization for Pharmaceutical New Chemical Entities, Abu Serajuddin, Ph.D., St. John's University, Queens, NY

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Conducted March 3, 2009 Organized by the PPB Section; Sponsored by a grant from AstraZeneca
Solubility and Solubilization of Drug Substances, Samuel Yalkowsky, Ph.D., University of Arizona
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Conducted February 20, 2009 Sponsored by the APQ Section
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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Conducted January 22, 2009 Sponsored by the RS Section
Understanding Pharmaceutical Quality by Design, Lawrence X. Yu, Ph.D., U.S. Food and Drug Administration
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Conducted December 11, 2008 Sponsored by the APQ Section
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 Immunicity 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 they application are mentioned. Finally, proposal for "default"-dissolution method 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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