

2009 AAPS Annual Meeting and Exposition Preliminary Program

As of 5/14/09

Sunday, November 8, 2009

4:30 pm – 6:15 pm

AAPS Opening Session - Diamond Level Sponsorship

Keynote Address

6:15 pm – 7:30 pm

AAPS Welcome Reception

Monday, November 9, 2009

8:00 am - 10:00 am

Roundtables – Funded by a grant from Algorithmic Pharma

Myths and Misconceptions in the Value of Early Phase 1 Studies to Predict Risk of QT Prolongation - CPTR

Evaluation of the Regression Type in LC-MS/MS Bioanalytical Methods - APQ

Biotherapeutics and Modulation of Drug Transporters - PPDM

Optimization of Systemic Exposure in Preclinical and Clinical Development: "Success Stories" of Proven Methods for Challenging Drug Candidates - What You Did Not Already Know! - PPB

Role of Excipient Impurities in Drug-excipient Interactions – FDD

10:00 am – 12:00 pm

AAPS Plenary Session - Diamond Level Sponsorship

12:00 pm – 1:15 pm

Hot Topic

12:00 pm – 5:30 pm

AAPS Exposition

1:00 pm – 5:00 pm

AAPS Contributed Papers Poster Session

AAPS Career Center

APQ (Analysis and Pharmaceutical Quality) Section
CPTR (Clinical Pharmacology and Translational Research) Section
FDD (Formulation Design and Development) Section
PPB (Physical Pharmacy and Biopharmaceutics) Section
RS (Regulatory Sciences) Section

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2:00 pm - 4:00 pm

Roundtables – Platinum Level Sponsorship Level

Nanoparticles - Are They Ever Going to Amount to Anything? - FDD

Strategies for the Determination of a Robust Cut Point in Immunogenicity Assays: Impact of Immunogenicity White Paper - BIOTEC

Navigating the New Rules Regarding Patent Law: Decodifying “Obviousness”, “Limited Claims” and How it Affects New Composition of Matter Patents - DDD

IVIVC for Establishing Clinically Relevant Specifications - APQ

2:00 pm - 4:30 pm

Symposia – **Funded by a grant from Catalent Pharma Solutions**

The Modeling and Simulation Frontier: Multi-Level, Multi-Scale, Multi-Attribute, Adaptable, and Extensible, Discrete Event Models – CPTR

Regulatory Significance of Critical Quality Attributes and Critical Process Parameters in Successful Product Development and Commercialization – RS

AAPS/ACCP Joint Symposium – Strategic Biomarkers for Treating Diseases in Younger Children Safely and Effectively (CPTR & PPDM)

Novel Sustained Release Formulations with Lipid Excipients – FDD

Process Analytical Technologies in API Manufacturing – APQ

Leaner Development Strategies to Enrich Drug Pipeline – BIOTEC

Tuesday, November 10, 2009

7:00 am - 8:15 am

Sunrise Sessions – Silver Level Sponsorship

The Story of the Three Bears: Too Big, Too Small, Just Right! Size Issues in Drug Development – CPTR

Practical Considerations in Using Excipients for Drug Testing in Early Toxicology Studies – FDD

Sterile Filtration - Principles and Case Studies – MSE

Solve your Problems in a Smarter Way: Use Design of Experiments – PPB

The Blood Brain Barrier – DDD

8:00 am – 12:00 pm

Contributed Papers Poster Session

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8:00 am – 5:00 pm
Career Center

8:30 am - 11:00 am

Symposia – Diamond Level Sponsorship

Freeze-Drying of Biologics/small Molecules: Case Studies that Touch on Formulation, Process and Packaging Challenges – MSE

Impact of the Variability of Ligand Binding PK Assays on the Outcome of Comparability Assessments for Follow-on Biologics – BIOTEC

Application of Nanoparticulate Technology in the Development of Oral Dosage Forms: Impact on Drug Product Performance – PPB

Grad Student Research Achievement Awards

–APQ

–PPDM /CPTR

–Graduate Symposium in Drug Delivery & Pharmaceutical Technologies (FDD, MSE, PPB)

–DDD

9:00 am - 11:00 am

Roundtables – Platinum Level Sponsorship Level

Impact of Changing Regulations on Post-approval CMC Changes: US and EU Perspectives – RS

Critical Role of CMC-project Management in the Drug Development Process – MSE

How to Face and Successfully Defend FDA and Other Regulatory Audits – APQ/RS

Latest Developments of Drug Targeting to Cancer Stem Cells – BIOTEC

To Test or Not to Test? Risk Assessment Approaches for Human Metabolites – PPDM

9:30 am – 6:15 pm

AAPS Exposition

AAPS Career Center

12:00 pm – 1:15 pm

Hot Topic

Student/PostDoc Outreach and Development (SPOD) Committee Roundtable

1:00 pm – 5:00 pm

Contributed Papers Poster Session

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2:00 pm - 4:00 pm

Roundtables – **Funded by a grant from Catalent Pharma Solutions**

Inclusion of Women in Clinical Trials and Drug Development - How Far Have We Gone – CPTR

Bioequivalence Requirements: Challenges in Global Drug Development and Harmonization– RS

Stability Evaluations Using Alternate Accelerated Conditions – RS, APQ

The Pros and Cons of Development Approaches to Poorly Soluble Compounds (In-house Development and Manufacture vs. Outsourcing) – MSE

Characterization of Amorphous Pharmaceutical Solids and Solid Dispersions – PPB

2:00 pm - 4:30 pm

Symposia – Diamond Level Sponsorship

Leveraging Prior Quantitative Knowledge in Guiding Pediatric Drug Development – CPTR

Challenges and Application of Dissolution for Testing Nutraceuticals, Natural Products and Traditional Medicines – APQ

Reactive Metabolites in Drug Discovery and Development: How Can We Handle the Risk? – PPDM

Pros and Cons of Emerging Methods in Population PK and Exposure/response Analysis – PPDM

State of the Art Approaches to Drug Design: Case Studies of Successful Applications of Drug Design Techniques to Identify Clinical Candidates – DDD

New Frontiers in Biologics: Advances & Challenges in PEGylation and Alternatives to PEGylation – BIOTEC

4:45 pm – 6:15 pm

AAPS Exposition Cocktail Reception

Wednesday, November 19, 2009

7:00 am - 8:15 am

Sunrise Sessions – Silver Level Sponsorship

Minimizing the Guesswork of Early Human Dose Predictions: Application of PK Prediction methodologies Including PBPK – PPDM

Rational Design of a Freeze-Dried Formulation for a Biologic – BIOTEC

Pharmacogenetics: Methods and Clinical Application – CPTR, PPDM

Innovative Colonic Drug Delivery Systems with a Case Study in Formulation and Temporal Gastrointestinal Transit Analysis – FDD

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Today, Tomorrow and Beyond: Approaches and Challenges in Modeling Pharmacodynamic Effects with Long Time Delays – PPDM

8:00 am – 12:00 pm
Contributed Papers Poster Session

8:00 am – 5:00 pm
Career Center

8:30 am - 11:00 am
Symposia - Funded by a grant from AstraZeneca

What Can the Pharmaceutical Industry Learn About Process Development and Manufacturing from Other Businesses? – MSE

Pharmacoproteomics: Targeted Absolute Quantitative Proteomics in ADME – PPDM

Pharmacokinetic-Pharmacodynamic Aspects of Inhaled Lung-Targeted Agents – FDD, PPDM

The Influence of Excipient Functionality on Quality by Design for Drug Product – RS & FDD

Extrapolation Preclinical Data to Predict Human Pharmacokinetics: Understanding and Practice – PPB

9:00 am - 11:00 am
Roundtables – Platinum Level Sponsorship Level

Translational Challenges in PK/PD/TD of Biotechnology-Derived Products – CPTR

ISR Failure Investigation: Avoiding and Resolving Through Investigation – BIOTEC

Facilitating the Transition to Model-Based Drug Development – PPDM

Repurposing Old Drugs for New Uses – DDD

Intestinal Delivery of Lipidic Drug Complexes and Conjugates: Case Studies – FDD

Impact of Pharmacogenomics on Drug Development: an Industrial Perspective – BIOTEC

9:30 am – 4:30 pm
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Alcohol Dose Dumping for Extend Release Solid Oral Dosage Products – APQ

Comparator Products – Untold Stories – RS & APQ

Salts, Cocrystals, Polymorphs/solvates, Nanoparticles, or Amorphous: How to Pick the Winner – PPB

Tumor Targeting Using Nanotechnology-Based Drug Delivery Systems – PPB

In Vivo Animal Models for Prediction of Drug-Drug Interactions – PPDM

2:00 pm - 4:30 pm

Symposia – **Funded by a grant from SanofiAventis**

Using Quality-by-Design Principals to Establish Pharmaceutical Equivalence and Bioequivalence of Advanced Dosage Forms – RS

With Scientific and Risk-based Approaches, Can QbD Reduce Industry's Stability Burden? – APQ

Toxicological Considerations in Early Drug Discovery: Avoiding Failures by Applying Rational Drug Design – DDD

Mechanism-Based PK/PD Modeling: Its Role in Discovery and Early Development of Biologics – PPDM

The Graying Globe - Drug Development in the Elderly – CPTR, PPDM

Microdialysis Role in the Development and Optimization of Drug Topical Delivery – PPB, APQ, PPDM, RS

Thursday, November 12, 2009

7:00 am - 8:15 am

Sunrise Sessions – Silver Level Sponsorship

Physiologically Based Pharmacokinetic Modeling: Concepts and Applications in Drug Discovery and Development – PPDM

Humanized Transgenic Transporter Models - Update on State of the Art – PPDM

Modeling Ophthalmic Drug Delivery and Disposition – FDD

Non Clinical Dosage Form Release Testing - GMP or GLP? – APQ

Protein-Based Vaccines – BIOTEC

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Using Modeling and Simulations to Safely Adjust Dose Regimens for Obese Patients – CPTR

Impact of Unstable Metabolites During Drug Quantitation in Regulated Bioanalysis – APQ

The Role of ATP Binding Cassette Transporters in Tissue Defense and Organ Regeneration – PPDM

Advances in the Injectable Combination Products – FDD

Excipient Variability: Why some Lots Pass and others Fail – PPB

Hot Melt Extrusion: a Novel Oral Solids Processing Technology – FDD

9:00 am - 11:00 am

Roundtables – Platinum Level Sponsorship Level

Evaluating Fit-for-Purpose Models. Consensus or Controversy – CPTR, PPDM

First Time in Human Dosing – Gimmicks, Luck and Science – PPDM

What Can Computational Design Do for Drug Discovery and Development? Current State of the Art – DDD

Role of Models in Design Space (Mini Symposium) – MSE

Predicting Oral Drug Absorption: Fiction and Facts – PPB

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