

# **2008 AAPS Annual Meeting and Exposition Preliminary Program As of August 12, 2008**

**Sunday, November 16, 2008**

**4:30 pm – 6:30 pm  
AAPS Opening Session**

*Keynote Address*

*Challenges of Pediatric Drug Development*

Dr. William E. Evans  
Director and Chief Executive Officer  
St. Jude Children's Research Hospital

*When Adversity Breeds Opportunity: What My Relationship with Medicine Taught Me  
About Life*

Jessica Melore  
New Jersey Sharing Network

**7:00 pm – 8:30 pm  
AAPS Welcome Reception**

**Monday, November 17, 2008**

**8:00 am - 10:00 am**

**Roundtables – Funded by a grant from Merck Research Laboratories**

Bioavailability Enhancement During Lead Optimization: Enabling Discovery or  
Encouraging Attrition (PPB)

Establish Out-of-trend Limits Based on Quality by Design (APQ)

Working at Risk in Drug Product Development: Understanding, Measurement and  
Evaluation of Risk in Driving Decisions (FDD)

Open Debate on Metabolites Testing (PPDM)

**10:00 am – 12:00 pm**

**AAPS Plenary Session - Funded by a grant from Southern Research Institute**

***Challenges of Pediatric Drug Development***

*Searching for Genomic Biomarkers of Drug Risk in Children*

Dr. Bruce Carleton, Pharm.D., Director, Pharmaceutical Outcomes Programme  
Children's and Women's Health Centre of British Columbia

*Title to be Announced*

Gregory Kearns, Pharm.D., Ph.D.

Chair, Department of Medical Research and Chief, Division of Pediatric Pharmacology  
& Medical Toxicology, Children's Mercy Hospitals

**12:00 pm – 1:15 pm**

**Hot Topic**

**12:00 pm – 1:30 pm**

**AAPS Luncheon for Graduate Students and Postdoctoral Fellows**

**Funded by a Grant from Eli Lilly & Company**

**12:00 pm – 5:30 pm**

**AAPS Exposition**

**AAPS Career Center**

**1:00 pm – 5:00 pm**

**AAPS Contributed Papers Poster Session**

**2:00 pm - 4:00 pm**

**Roundtables – Platinum Level Sponsorship Level**

Critical Versus Non-critical – Classification in the Absence of a Biorelevant Method (RS)

PATability of Excipients (FDD, MSE, PPB)

Leachables and Extractables in Solid Dosage Forms (APQ)

Particle Size Analysis and Specification of Pharmaceutical Powders (FDD, PPB, MSE)

Student/PostDoc Outreach and Development (SPOD) Committee Roundtable

**2:00 pm - 4:30 pm**

**Symposia – Diamond Level Sponsorship**

Application of Bio-relevant USP IV Dissolution Method in Pharmaceutics Development (APQ)

Approaches to First-In-Human Formulation Development (FDD, PPB)

Why Absorption and Pharmacokinetic Models Are More Important in Future Drug Development? (PPB, CPTR)

The Exubera Case – Is There a Chance for Biopharmaceuticals for Inhalation? (BIOTEC)

Green Pharmaceutical Sciences (DDD)

SiRNAs as Pharmacological Tools and Therapeutic Agents: Challenges and Opportunities (PPDM)

**Tuesday, November 18, 2008**

**7:00 am - 8:15 am**

**Sunrise Sessions – Silver Level Sponsorship**

Clinical Applications of Pharmacogenetics (CPTR)

The ABC's of Drug Master Files (RS)

Rational Drug and Prodrug Design Via Computational Modeling (DDD)

PK/PD of Biologics: From Discovery to Successful Development (PPDM)

Quality Agreements (MSE)

Application of Design of Experiments to Analytical Method Development (APQ)

**8:00 am – 12:00 pm**

**Contributed Papers Poster Session**

**8:30 am - 11:00 am**

**Symposia – Diamond Level Sponsorship**

Drug Discovery and Drug Developability for Lead Optimization (PPB)  
Diabetes Disease Progression Modeling (CPTR)

**Graduate Award Symposia**

Graduate Award Symposium (PPDM & CPTR)  
Graduate Award Symposium (APQ)  
Graduate Award Symposium (PDD & PT)

**Poster Podium**

Graduate Research in Drug Design and Discovery (PDD)

**9:00 am - 11:00 am**

**Roundtables – Platinum Level Sponsorship Level**

Biosimilars/Follow-On-Proteins: The Latest Regulatory Position in the US and Europe  
Need for New Product Development Model in Generic Pharmaceutical Industry: Science Vs. First to File Opportunities (FDD, MSE)

Emerging Technologies: Liquid Fill Hard Capsule Technology in the Pharmaceutical Industry (FDD, MSE)

Regulatory Challenges and Perspectives of Handling Impurities Not Covered by ICH Q3A and Q3B (APQ)

**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**

**2:00 pm - 4:00 pm**

**Roundtables – Platinum Level Sponsorship Level**

Searching for the New Technologies for Immunogenicity Testing: Life After Demise of an ECL- Based Assay Platform (BIOTEC)

Quantitative Clinical Pharmacology Analyses: Communicating to Influence Decisions (CPTR)

Food Effect or No Food Effect: From Bench Findings to Reality (FDD, PPB)

*In Silico/In Vitro* Models for Compound Profiling (PPDM)

Challenges in Developing Inhalation and Nasal Products: Linking to Quality by Design (FDD, MSE)

**2:00 pm - 4:30 pm**

**Symposia – Diamond Level Sponsorship**

Technologies and Science Behind Enhancing Bio-availabilities of Poorly Soluble Compounds (APQ)

Sigma Receptors: Viable Therapeutic Targets for Medication Development (DDD)

25th Anniversary of Pharmaceutical Research: Impact on Drug Development and Roadmap to Future Innovations (PPB, MSE)

Emerging Technologies for Development of Oral Delivery Systems (FDD)

The Next Generation of Antibodies? – Engineered Antibody Fragments (BIOTEC)

AAPS/ACCP Joint Symposium

**4:45 pm – 6:15 pm**

**AAPS Exposition Cocktail Reception**

**Wednesday, November 19, 2008**

**7:00 am - 8:15 am**

**Sunrise Sessions – Funded by a grant from Algorithm Pharma**

Root Cause Analysis During Out of Specification Investigation: A Step-By-Step Procedure (APQ)

Generic Biologics - What you Always Wanted to Know but Were Afraid to Ask (RS)

Tumor Imaging and Targeted Drug Delivery (FDD, PPB)

Green Pharmaceutical Sciences: An Overview (DDD)

Accurate Prediction of Metabolic DDI - from Preclinical Discovery to Clinical Development (PPDM)

A Patent Primer for Pharmaceutical Scientists (RS)

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

**8:30 am - 11:00 am**

**Symposia - **Funded by a grant from AstraZeneca****

IVIVC/R for Solid Oral Dosage Forms: Objectives and Challenges (CPTR)

Challenges and Opportunities in the Implementation of PAT and Real-time Release in the Pharmaceutical Industry (RS)

Drug Substance and Drug Product Interface: A Critical Step Toward Quality by Design for Pharmaceutical Products (FDD, PPB, MSE)

Structure-Activity Relationship (SAR) in ABC Transporters (PPDM)

Modeling and Simulation Strategies for Evaluation of Drug Safety in Clinical Studies (CPTR)

**8:30 am – 11:00 am**

**Poster Podium**

*Parenteral Controlled Release Invited Poster Podium Session*

**9:00 am - 11:00 am**

**Roundtables – Platinum Level Sponsorship Level**

Incurred Sample Analysis: Experiencing the Workshop in 2008 (APQ)

The World Within and Beyond P-Gp: Do we Underestimate or Overestimate P-Gp? (PPB)

Outsourcing Drug Product Development to India and China (MSE)

Changing Models in Drug Development (DDD)

Identification and Validation of Biomarkers (PPDM)

**9:30 am – 4:30 pm**

**AAPS Exposition**

**AAPS Career Center**

**12:00 pm – 1:15 pm**

**Hot Topic**

**1:00 pm – 5:00 pm**

**Contributed Papers Poster Session**

**2:00 pm - 4:00 pm**

**Roundtables – Platinum Level Sponsorship Level**

Human Pharmacokinetics and Efficacious Dose Prediction from Preclinical Species Data: Approaches, Successes, and Challenges (PPDM)

*In Vitro* Bioequivalence Testing for Aerosol Products: From Today to Tomorrow (FDD)

The Impact of Kidney Disease/Renal Impairment on Drug Metabolism and Transport (CPTR)

Development and Maintaining a Biomarker Monitoring Program (APQ)

Transporters as Prodrug Carriers for Oral Drug Delivery (FDD, PPB)

**2:00 pm - 4:30 pm**

**Symposia – Diamond Level Sponsorship**

Outsourcing – Mechanisms and Case Studies for Development and Manufacturing at a Contract Facility (MSE)

CMC Aspects of First-In-Human Studies with Biopharmaceuticals (BIOTEC)

Combination Products - Scientific and Regulatory Challenges (FDD, MSE, PPM, RS)

High Energy Solids for Delivering Poorly Water-soluble Drugs: Opportunities and Challenges (FDD, PPB)

AAPS-PSJ Joint Symposium: Pharmaceutical and Biotech Products in the Race to Cure Cancer

**2:00 pm – 4:30 pm**

**Poster Podium**

Absorption & Transporter Focus Group

**Thursday, November 20, 2008**

**7:00 am - 8:15 am**

**Sunrise Sessions – **Funded by a grant from Merck Research Laboratories****

Pharmaceutical Co-crystals (FDD, PPB)

Dealing with Contamination and Carry Over in Analytical Research (APQ)

Analytical Method Development Based on QbD Principles (APQ)

Organic Cation Transporter Family: From Discovery to Clinical Impact (PPDM)

Biomarkers of Local Drug Delivery from Pulmonary Drug Products (FDD, PPB)

**8:30 am - 11:00 am**

**Symposia – Diamond Level Sponsorship**

BDDCS - At the Beginning of a New Era (PPDM)

Particle Formation in Protein Therapeutics: Mechanisms & Characterization (BIOTEC)

Celebrating the Nanotechnology R&D Act: Then, Now and the Future (CPTR, FDD, MSE, PPB)

Simultaneous Global Regulatory Submissions (RS)

Quality by Design and Its Role in Developing Analytical Methods (APQ, RS)

Advancing Technologies in Nutraceutical Research (FDD, MSE, PPB)

**9:00 am - 11:00 am**

**Roundtables – Platinum Level Sponsorship Level**

Quality by Design: Defining Clinically Relevant Design Goals (MSE)

Prodrug Approaches for Organ Specific Targeted Therapy (DDD)

*In Vitro* Oral Drug Transport Data: Approaches to Data Analysis and Modeling (PPB)

Effective Interactions from Pre-IND to IND and Beyond: “Getting Your Ducks in the Row” with the FDA (PPDM, RS)