FINAL PROGRAM

Wednesday – Thursday, February 28-29,2024 **(Virtual Event)**

PQRI Workshop: Model-Informed Drug Development (MIDD) Approaches in Pediatric Formulation Development

Day 1: The role of biorelevant dissolution and physiologically based biopharmaceutics modeling (PBBM) in pediatric formulation development.

Day 1 –Wednesday, February 28, 2024 8:30 AM – 2:30 PM US ET	
8:15 - 8:30 AM	Pre-Workshop Check Connections (virtual)
Session 1: Background and Introduction	
8:30 - 8:35 am	***Welcome & Workshop Objectives*** Gilbert J. Burckart, Pharm.D., US Food and Drug Administration
8:35 - 9:05 am	***Patient Centric Pediatric Product Development: A Caregiver Perspective*** M. Petrea Cober, PharmD., BCNSP, BCPPS, FASPEN, Northeast Ohio Medical University, College of Pharmacy
9:05 - 9:25 am	***Overview: Challenges in Pediatric Drug Product Development and Potential for Using Biorelevant Dissolution Testing*** Hardikkumar Patel, Ph.D., M.S., US Food and Drug Administration
9:25 - 9:50 am	***Current Landscape of Pediatric Biorelevant In Vitro Dissolution Testing*** Sandra Klein, Ph.D., University of Greifswald
9:50 - 10:15 am	***Biorelevant Dissolution Enabling Pediatric Formulation Selection/Optimization*** Andrea Moir, AstraZeneca
10:15 - 10:30 am	*Break*
Session 2: Knowledge Gaps and Challenges in PBBM for Pediatric Oral Formulation Development	
10:30 - 11:00 am	***Pediatric Ontogeny Related to Pediatric Oral Drug Absorption*** Valentina Shakhnovich, MD, Ironwood Pharmaceuticals
11:00 - 11:30 am	***Current Approaches Towards Leveraging PBBM to Predict Performance of Pediatric Formulation Across Different Age Groups*** David Good, Ph.D., Bristol Myers Squibb
11:30 am – 12 pm	***PBBM* to *Assess* Food Effect in Pediatric Patients** Neil Parrott, M.Sc., F Hoffmann LaRoche
Session 3: Application of PBBM to Support Pediatric Oral Formulation Development	
12:00 - 12:30 pm	***Physiologically Based Pharmacokinetic Absorption Modeling for Bioequivalence Evaluation in Adult and Pediatric Populations*** Fang Wu, Ph.D., US FDA
12:30 - 1:00 pm	***Evaluation of Absorption-Mediated Drug-Drug Interactions in the Pediatric Population*** Daniel Gonzalez, PharmD, Ph.D., Duke University
1:00 - 1:15 pm	*Break*
1:15 - 2:15 pm	***Breakout*** *Registrants will breakout into concurrent breakout sessions to facilitate small group discussions*
2:15 – 2:30 PM	Reconvene after breakouts
2:30 pm	End of Day 1

Day 2: Gaps and Opportunities in the Assessment of Pediatric Product Quality

Day 2 – Thursday, February 29, 2024 - 8:45 AM – 2:30 PM US ET	
8:30 - 8:45 AM	Pre-Workshop Check Connections (virtual)
8:45 - 9:00 am	***Welcome & Workshop Objective- Day 2/ Review of Day 1 Breakouts*** Andreas Abend, Ph.D., Merck & Co., Inc.
Session 4: Current Trends in Formulation Development	
9:00 - 9:30 am	***Trends and Challenges with the Development of Pediatric Formulations after the Implementation of the Current Regulations: Industry Perspective*** David Harris, Ph.D., Merck & Co., Inc.
9:30 - 10:00 am	***Current Trends and Experience with the Development of New Pediatric Drugs after the Implementation of Regulations: Regulatory Perspective*** Lynne Yao, MD, U.S. Food and Drug Administration
10:00 - 10:30 am	***"In-use" Dosing Practices: Risks and Opportunities/Food-Drug Design Space*** Nikoletta Fotaki, Ph.D., University of Bath
10:30 - 10:45 am	*Break*
Session 5: Challenges in the Assessment of Pediatric Formulation Quality: In-use and Life-cycle Management	
10:45 - 11:15 am	***Current Regulatory Expectations of Assessing In-Use Stability of Solid Oral Dosage Forms to be Mixed with Foods Proposed in Product Label*** Julia Pinto, Ph.D., U.S. Food and Drug Administration
11:15 - 11:45 am	***Unique Elements of the Pediatric Quality Target Product Profile (QTPP)*** Daniel Schaufelberger, Ph.D., NGT BioPharma Consulting LLC
11:45 am – 12 pm	***Forging New Partnerships to Advance Pediatric Formulations Development: An Overview of NIH Resources Spanning the Formulation Development Lifecycle*** James E. Cummins, Jr., Ph.D, National Institutes of Health
12:00 – 12:15 pm	*Break*
Session 6: In-Silico Enabled Assessment of PK Performance and Pediatric Product Life Cycle Management	

12:15 - 1:00 pm	• ***In-silico Evaluation of Pediatric Formulations: Possibilities and Challenges***
	  ○ Viera Lukacova, Ph.D., Simulations Plus, Inc.
	• ***Open-Source Solutions for MIDD in Pediatric (Formulation) Development with Open-Systems-Pharmacology.org***
	  ○ Stephan Schaller, Ph.D., ESQlabs GmbH
	• ***Destination PBPK in Pediatric Product Life Cycle Management: "Are we there yet?"***
	  ○ Nikunj Patel, Ph.D., Certara Inc.
	• Q&A Panel

1:00 - 1:15 pm	*Break*
1:15 – 2:15 pm	***Breakout*** *Registrants will breakout into concurrent breakout sessions to facilitate small group discussions*
2:15 – 2:30 pm	Reconvene after breakouts
2:30 pm	End of Workshop

Workshop Faculty

Andreas Abend, Ph.D., Senior Principal Scientist, Merck & Co., Inc.
Gilbert Burckart, Pharm.D., Associate Director for Pediatrics, Office of Clinical Pharmacology, Office of Translational Sciences | CDER | US Food and Drug Administration
M. Petrea Cober, PharmD., BCNSP, BCPPS, FASPEN, Professor of Pharmacy Practice; Director of Workforce Development, Office of Student Success; Director of Professional Development, Office of Education, Northeast Ohio Medical University, College of Pharmacy
James E. Cummins, Jr., Ph.D, Branch Chief, Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health
Nikoletta Fotaki, MSc, Ph.D., FAAPS, Professor, University of Bath
Daniel Gonzalez, PharmD, Ph.D., Clinical Pharmacologist, Duke University School of Medicine
David Good, Ph.D., Senior Director, Bristol Myers Squibb
David Harris, Ph.D., Principal Scientist, Merck & Co., Inc.
Sandra Klein, Ph.D., Professor of Pharmaceutical Technology, University of Greifswald, Germany
Viera Lukacova, Ph.D., Chief Scientist, Simulations Plus, Inc.
Andrea Moir, MSc., Senior Scientist, AstraZeneca
Neil Parrott, M.Sc., Distinguished Scientist, F Hoffmann LaRoche
Hardikkumar Patel, Ph.D., M.S., Biopharmaceutics Assessor, ONDP | OPQ | CDER| FDA
Nikunjkumar Patel, Ph.D., Senior Director of PBPK Consultancy Services, Certara Inc.
Julia Pinto, Ph.D., Supervisory Chemist, OPQ | CDER| FDA
Stephan Schaller, Ph.D., CEO, ESQlabs GmbH
Daniel Schaufelberger, Ph.D., Head, Pediatric Center of Excellence, NGT BioPharma Consulting LLC
Valentina Shakhnovich, MD, Medical Director of Clinical Development, Ironwood Pharmaceuticals
Fang Wu, Ph.D., Senior Pharmacologist, DQMM | ORS | OGD | CDER| FDA
Lynne Yao, MD, Director, Division of Pediatrics and Maternal Health | OND | CDER | FDA

Workshop Organizing Committee

Andreas Abend, Merck, Chair – Workshop Organizing Committee
Mary Kate Bielinski, PQRI Secretariat
Gilbert J. Burckart, Pharm.D., US Food and Drug Administration
Andre Dallmann, Bayer
Dede Godstrey, PQRI Secretariat
Wenlei Jiang, US Food and Drug Administration
Sandra Klein, Greifswald University
Julia Pinto, US Food and Drug Administration
Giuseppe Randazzo, Association for Accessible Medicines (AAM)
Karen Thompson, Merck