PQRI Workshop: **MIDD Approaches in Pediatric Formulation Development**
February 28-29, 2024
Bios

Andreas Abend, Ph.D. Senior Principal Scientist Merck & Co., Inc. andreas_abend@merck.com 	**Andreas Abend** received his PhD degree in Organic Chemistry from the University of Karlsruhe in Germany. Prior to joining Merck and Co., Inc. as a Senior Project Chemist, Andreas spent 3 years as a Post-Doctoral Fellow at the University of Wisconsin's Enzyme Institute. He is currently a Senior Principal Scientist in the Biopharmaceutical Sciences group in MRL's Development Sciences and Clinical Supply Department. Throughout his career at Merck, Andreas provided analytical support to small molecule API and drug product development activities spanning all clinical phases. Over the last two decades, he and his team contributed to the more than a dozen new Market applications. Andreas is a member of Merck's Biopharmaceutical Advisory Team, co-chair of PQRI's BTC, and a member of IQ's Analytical Leadership Group. He presented at many national and international meetings, published several manuscripts on Clinically Relevant Dissolution specifications, photostability and impurity identification. In 2017 and 2019 he was a co-organizer of workshops at the Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) and he is currently co-organizing a PQRI workshop dedicated to pediatric formulation development (Nov. 2023).
Gilbert Burckart, Pharm.D. Associate Director for Pediatrics Office of Clinical Pharmacology Office of Translational Sciences | CDER US Food and Drug Administration gilbert.burckart@fda.hhs.gov 	**Dr. Gilbert Burckart** is presently Associate Director for Pediatrics, Office of Clinical Pharmacology, US FDA. Dr. Burckart has served on the faculties of four universities (Buffalo, Tennessee, Pittsburgh, Southern California) for 33 years prior to coming to the FDA. He was a Professor of Pharmacy, Pediatrics, and Surgery. He moved to the US FDA's Office of Clinical Pharmacology in 2008, where he heads the Pediatric Group in the Immediate Office, and is very involved in pediatric regulatory science and educational programs in the Office.

M. Petrea Cober, PharmD, BCNSP, BCPPS, FASPEN
Northeast Ohio Medical University
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M. Petrea Cober, PharmD, BCNSP, BCPPS, FASPEN, attended the University of Tennessee, College of Pharmacy in Memphis, Tennessee. She completed her Post Graduate Year 1 Pharmacy Residency at Penn State Milton S. Hershey Medical Center in Hershey, Pennsylvania, and her Post Graduate Year 2 Pharmacy Residency in Pediatrics at the University of Michigan Hospitals and Health System in Ann Arbor, Michigan. She has served as a Clinical Assistant Professor of Pediatric Pharmacotherapy and Clinical Pharmacist - Pediatric Surgery/Intestinal Failure Program at the University of Michigan (2005-2010) and as a Clinical Pharmacy Specialist - Neonatal Intensive Care Unit at Akron Children's Hospital, in Akron, Ohio (2010-2023). She is currently a Professor of Pharmacy Practice, was recently appointed Director of Workforce Development for the Office of Student Success and is the Director of Professional Development for the Office of Education at the Northeast Ohio Medical University, College of Pharmacy. Her didactic teaching is in the areas of pediatrics, women's health, and nutrition. Dr. Cober's expertise is in pediatric-neonatal pharmacotherapy, nutrition, ethanol lock therapy, and management of patients with intestinal failure. She was awarded the 2021 Stanley Serlick Award from the American Society for Parenteral and Enteral Nutrition recognizing her contributions to parenteral nutrition safety, the 2020 American College of Clinical Pharmacy Pediatrics PRN Outstanding Practitioner Award, and the 2021 NEOMED Liebelt-Wheeler Award for Faculty Excellence. She is currently the chair of the American Association of Colleges of Pharmacy, Pediatrics Pharmacy Special Interest Group, and the president elect of the Pediatric Pharmacy Association.

James E. Cummins, Jr., Ph.D.
Chief, Preclinical Microbicide and Prevention Research Branch
Division of AIDS
National Institute of Allergy and Infectious Diseases
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Dr. James Cummins, Ph.D. is currently the Chief of the Preclinical Microbicide and Prevention Research Branch in the Prevention Sciences Program within the Division of AIDS (DAIDS) at the National Institute of Allergy and Infectious Diseases (NIAID), an institute within the U.S. National Institutes of Health (NIH). As part of the DAIDS mission to develop highly effective HIV prevention strategies, Dr. Cummins leads a team that manages a portfolio of grants and contracts supporting the preclinical development of non-vaccine biomedical prevention products. Active grants in the portfolio support the development and optimization of the next generation of HIV prevention products – including sustained release/long-acting products and multi-purpose prevention strategies. Current contract resources fill key gaps in product development pathways by enabling the acquisition of critical data, development of essential methods, product manufacture and characterization, and completion of studies necessary to advance products into clinical trials. These funding mechanisms have supported the development of a range of formulation types and facilitated the advancement of 12 products into NIAID-sponsored clinical trials. More recently, Dr. Cummins has expanded the capabilities of his Branch to include support for the development of pediatric formulations for HIV treatment and prevention, including comorbidities such as tuberculosis.

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<td>**Prof Nikoletta Fotaki, MSc, Ph.D., FAAPS**
Professor
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<td>**Prof Nikoletta Fotaki** is a Professor of Biopharmaceutics at the University of Bath, UK. She graduated in Pharmacy from the National and Kapodistrian University of Athens in Greece and she holds an MSc in Toxicology and a PhD in Biopharmaceutics-Pharmacokinetics. Her expertise and research are focused on PBPK modeling/ PBBM, in vitro and in silico tools for predicting absorption in normal populations and in special populations, dissolution methods, IVIVCs and biowaivers. Her scholastic work includes more than 90 peer reviewed publications, one book, 10 book chapters, 87 published conference contributions and 2 patents. She is an AAPS Fellow and a member of the AAPS Board of Directors with leading roles in the OBAM and IVRDT AAPS Communities. She is also the chair of the Biopharmaceutics Group of APS and she is a member of a USP expert panel and of several scientific societies and has been an invited speaker at several conferences.</td>
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<td>**Daniel Gonzalez, PharmD, Ph.D.**
Clinical Pharmacologist
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<td>**Dr. Daniel Gonzalez** is a clinical pharmacologist in the Division of Clinical Pharmacology of the Department of Medicine at the Duke University School of Medicine, and a member of the Duke Clinical Research Institute. Gonzalez received his PharmD and PhD from the University of Florida College of Pharmacy in 2008 and 2012, respectively. He then completed a postdoctoral fellowship through the UNC-Duke Collaborative Clinical Pharmacology T32 Postdoctoral Training Program. Following completion of his post-doctoral training, Gonzalez served as a faculty member at the UNC Eshelman School of Pharmacy between 2014 and 2023 and transitioned to Duke University in 2023. His research interests include clinical pharmacology and applying mathematical modeling and simulation techniques to characterize the pharmacokinetics and pharmacodynamics of drugs, guide drug dosage selection, and improve drug safety. Gonzalez's research program is funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), and he has published >100 peer-reviewed publications and >40 abstracts. He has been the major advisor for 8 PhD students (4 completed, 4 in training) and 15 postdoctoral fellows.</td>
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<td>**David Good, Ph.D.**
Senior Director
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<td>**David** is Senior Director and Head of Exploratory Biopharmaceutics in Drug Product Development (DPD) at Bristol-Myers Squibb in New Brunswick, NJ. David currently leads teams accountable for PK modeling and biopharmaceutics as well as a team's responsible for drug delivery and formulation development. His professional interests include mechanistic pharmacokinetic modeling and simulation (PBPK, ADME) for designing small molecule and biologics formulations as well as PK studies (clinical & non-clinical). Additionally, David has chemistry and material science research interests and experience related to crystal form screening and the rational design of supersaturating drug forms. David received his doctoral degree in Pharmaceutics from University of Michigan.</td>
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<td>**David Harris, Ph.D.**
Principal Scientist
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david.harris@merck.com
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<td>**David Harris** is a formulation scientist with over 30 years experience in the development of new chemical entities. He has a Bachelor of Pharmacy degree from the University of Bath, and a Ph.D. in Pharmaceutics from the University of Manchester, both in the United Kingdom, and subsequently spent two years as a Post-Doctoral Fellow at the University of Wisconsin – Madison, in the laboratory of the late Prof. Joseph Robinson. Since then he has been employed in various roles in formulation development, first with Schering-Plough and subsequently with Merck & Co., Inc.

Dr Harris has extensive experience in pharmaceutical product development, spanning solid and liquid oral products, with particular interest in pediatric formulation development. He is an also an active member of the European Paediatric Formulation Consortium (EuPFI), in which he leads the Age-Appropriate Formulation workstream.</td>
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Sandra Klein, Ph.D.
Professor of Pharmaceutical Technology
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Sandra Klein is a pharmacist by training and obtained her license to practice pharmacy and her PhD from the University of Frankfurt, Germany. She was a Postdoctoral Fellow at Eastman Chemical Company in Kingsport, TN, USA and has been a Professor of Pharmaceutical Technology at the University of Greifswald, Germany since 2010. Since starting her PhD, she has been working on the development of biorelevant in vitro methods to assess the bioavailability of orally administered drugs and meanwhile has more than 20 years of experience with biorelevant dissolution assays. Her current research focuses on the development of biopredictive in vitro models to estimate the in vivo performance of drugs for different patient populations, as well as the development of oral dosage forms for special patient populations, particularly pediatric patients. The latter activities span the spectrum from formulations for poorly soluble drugs through taste-masked formulations to controlled-release dosage forms. Other research interests include the development of predictive and accelerated in vitro release methods for lozenges, vaginal and rectal delivery systems, and long acting injectables.

Sandra is a member of the American Association of Pharmaceutical Scientists (AAPS), the European Paediatric Formulation Initiative (EuPFI), the German Pharmaceutical Society (DPhG) and the International Association of Pharmaceutical Technology (APV). She is currently also the Vice President of the APV, an Expert Member of the USP Expert Panel on New Advancements in Product Performance Testing, an Expert Member of the conect4children (c4c) Formulations Expert Group, and Editor-in-Chief of Pharmazie, An International Journal of Pharmaceutical Sciences.

Viera Lukacova, Ph.D.
Chief Scientist
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Dr. Viera Lukacova is the Chief Scientist at Simulations Plus, Inc. Over the last nearly two decades, she has been contributing to the research and development of GastroPlus®, DDDPlus™, and MembranePlus™ software packages widely used throughout the pharmaceutical industry in early drug development, formulation, pre-clinical, and clinical research; with the main focus on mechanistic absorption and PBPK modeling.

She is also involved in modeling studies helping companies with their drug development programs in early discovery stage, formulation development, clinical pharmacology applications, and interactions with regulatory agencies. She authored a number of papers in computational chemistry, basic research of transport of small molecules through artificial membranes, and pharmacokinetic and pharmacodynamic modeling in peer-reviewed journals and served as a reviewer of publications in the same areas.

Andrea Moir, M.Sc.
Senior Scientist
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Andrea Moir is a Biopharmaceutics specialist within Pharmaceutical Technology & Development at AstraZeneca Macclesfield and has over 25 years' pharmaceutical industry experience in oral and complex parenteral drug product development. Andrea initially worked within the analytical function developing a focus on dissolution before moving into Biopharmaceutics. Within this role she has experience of the use of in vitro and in silico tools to supporting the development of oral age appropriate paediatric products. She is also a member of the CMC paediatric network within AstraZeneca.

Neil Parrott, M.Sc.
Distinguished Scientist in Modeling and Simulation
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Neil Parrott works in the translational modelling and simulation group which is part of the Predictive Modeling and Data Analytics Chapter of Roche Pharma Research and Early Development in Basel, Switzerland. Neil specializes in physiologically based pharmacokinetic (PBPK) modeling and its application to Roche projects from early discovery to the market. Neil has a particular interest in the applications of PBPK modelling for first in human PK prediction, to guide formulation development, to guide studies in special populations such as children and to help manage drug-drug interactions by integrating data from advanced in vitro systems. He is involved in various research activities to develop better PBPK models and is active in cross-industry consortia such as the International Consortium on Innovation and Quality in Pharmaceutical Development (IQ). Neil has published over 130 papers and has given numerous presentations at international conferences.

Hardikkumar Patel, Ph.D.
Biopharmaceutics Assessor
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Hardikkumar Patel, Ph.D. is currently a Biopharmaceutics assessor in the Office of New Drug Product (ONDP) in the Office of Pharmaceutical Quality (OPQ). His responsibilities include biopharmaceutics assessment of NDAs (original and supplement), ANDAs (original and supplement), INDs, and Pre-ANDAs. Before joining ONDP, Hardik was with the Office of Lifecycle Drug Products (OLDP) from 2014 to 2022 where he served as an ORISE fellow (2014 to 2017), a drug product assessor for oral drug products, and a drug product assessor for liquid-based drug products. He did his internships at GSK Consumer healthcare as a bench scientist during summer 2012 and summer 2013. Hardik has Ph.D. in Pharmaceutical Sciences and M.S. in Industrial Pharmacy from Long Island University, NY. He got his Bachelor of Pharmacy (B. Pharm) degree from Nirma University, India.

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<td>**Nikunjkumar Patel, Ph.D.**
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<td>**Dr. Patel** is a Senior Director of PBPK Consultancy Services in the Simcyp division of Certara.

Nikunj helps clients with advanced PBPK modelling to expedite internal decision making, support biowaivers via virtual bioequivalence assessments, and develop model-informed regulatory strategies for novel products, generic formulations, scale-up and post-approval changes (SUPAC), and justification of dissolution specifications.

He has more than 15 years' experience in computer-aided drug design and PKPD modelling, including 13+ years' experience focusing on PBPK modelling.</td>
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<td>**Julia Pinto, Ph.D.**
Supervisory Chemist
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<td>**Dr. Pinto** is currently a Supervisory Chemist in the Office of Pharmaceutical Quality (OPQ), FDA. She is also a member of CDER's Pediatric Research and Equity Act Committee. Her group supports the CMC review for all applications submitted to the Office of Neuroscience which includes the Division of Analgesia, Addiction and Pain, The Division of Neurology I and II and the Division of Pulmonary Products. Prior to joining the FDA in 2005, Dr. Pinto began her career as a medicinal chemist at Leukosite, Inc. (now Millennium Pharmaceuticals) and subsequently Serono Laboratories in Massachusetts. She received her Ph.D. in Organic Chemistry from Rutgers University in New Jersey followed by a Postdoctoral Fellowship at the Universite of Louis Pasteur in Strasbourg, France. Outside of work, Dr. Pinto enjoys time with her family, traveling, hiking and theater arts.</td>
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<td>**Stephan Schaller, Ph.D.**
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<td>**Stephan** is the Founder and Managing Director of ESQlabs GmbH, a biosimulation solutions and services CRO and holds a PhD in Computational Engineering. He has > 15 years of industry experience with a focus on Model-Based Drug Development (MIDD) and Next-Generation Risk Assessment (NGRA). His scientific career is focused on mechanism-based modeling approaches such as PBK, and QSP/T for decision-making support to R&D teams in the pharmaceutical and chemical industries. Stephan is the current chair of www.Open-Systems-Pharmacology.com, an initiative to democratize and develop open-source PBK and QSP/T tools for physiologically- and mechanism-based analysis of the toxicity/safety and efficacy of drug therapies and chemicals. Stephan is coordinator of the German comutational life-sciences project "OSMOSES" and a PI for kinetics (PBK/QIVIVE) in the EU research project ONTOX and the Crack-IT Mega-Challenge #40: the Virtual Dog (for non-clinical safety).</td>
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Daniel Schaufelberger, Ph.D. Head, Pediatric Center of Excellence NGT BioPharma Consulting LLC dschaufelberger@ngtbiopharmaconsultants.com 	**Daniel Schaufelberger, Ph.D.**, a pharmaceutical executive with over 30 years of experience in pharmaceutical development, including pediatric products. Daniel retired from Janssen R&D LLC (Johnson & Johnson) as Sr. Scientific Director, where he co-chaired the J&J internal Pediatric Formulation Network. He is currently the Head of the Pediatric Center of Excellence at NGT BioPharma Consulting LLC. He is a CMC consultant for NIH/NIAID/DAIDS and for WHO's Global Accelerator for Paediatric Formulation Development (GAP-f). Daniel holds a degree in pharmacy (ETH Zurich) and a doctorate from the University of Lausanne. He is a member of the Pediatric Working Group of the International Consortium (IQ) for Quality in Pharmaceutical Development and has been appointed formulation expert for the pan-European "Conect4Children" initiative. Daniel is a founding member of the society of "Paediatric Medicines and Health Initiative", based in Mumbai, India. In 2020, he joined Johns Hopkins University, School of Medicine, All Children's Hospital in St. Petersburg, FL as adjunct assistant Professor. Daniel is a speaker and moderator at domestic and international conferences with a focus and passion for "developing better medicines for children".
Valentina Shakhnovich, MD Ironwood Pharmaceuticals	
Fang Wu, Ph.D. Senior Pharmacologist DQMM | ORS | OGD | CDER US Food and Drug Administration fang.wu@fda.hhs.gov 	**Dr. Fang Wu** is a senior pharmacologist reviewer and scientific lead for oral Physiologically-based Pharmacokinetic modeling in Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs (OGD) in FDA. Dr. Wu has been with FDA for more than 11 years. She is responsible for using modeling and simulations tools for reviewing pre-abbreviated new drug applications (pre-ANDA) meeting packages, ANDA consults and controlled correspondences. Prior to joining DQMM, Dr. Fang Wu was a biopharmaceutics reviewer for more than 4 years and responsible for NDA and ANDA reviews. She has been a principal and co-principal investigator for multiple FDA research projects and involved in several guidance working groups and grant review panels.

Lynne Yao, M.D.
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Lynne Yao, M.D., is the Director, Division of Pediatric and Maternal Health (DPMH) in the Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER). Dr. Yao received a B.S. degree in Biology from Yale University, and an M.D. degree from the George Washington University School of Medicine. She is board certified in both Pediatrics and Pediatric Nephrology. Prior to joining FDA, Dr. Yao was the Director of Dialysis and Associate Pediatric Residency Program Director at the Inova Fairfax Hospital for Children in Fairfax, VA. She has been with the FDA since 2008 and has been DPMH Director since 2012. As DPMH Director, Dr. Yao oversees quality initiatives which promote and necessitate the study of drug and biological products in the pediatric population; and improve collection of data to support the safe use of drugs and biological products in pregnant and lactating individuals. She collaborates with numerous stakeholders both inside and outside of FDA to advance development of safe and effective therapies for children, and pregnant and lactating women.