

FDA/MCERSI Hybrid Workshop:
**Clinical Pharmacology Guidances Advancing Drug Development and
Regulatory Assessment: Role and Opportunities Workshop**

Speaker & Panelist Biographies

Session 1 – Opening & Overview



Issam Zineh, PharmD MPH, FCP, FCCP is Director of the Office of Clinical Pharmacology (OCP) at the U.S Food and Drug Administration (FDA). He has held various leadership positions at FDA including Associate Director for Genomics in OCP (2008-2012) and Co-Director of the CDER Biomarker Qualification Program (2009-2015) and serves on the CDER Medical Policy Council. He is a recognized expert in the fields of drug development and evaluation, clinical pharmacology, pharmacotherapy, and precision medicine. As Director of OCP, Dr. Zineh leads a staff of over 280 regulatory, research, program/project management, and administrative staff in FDA's efforts to enhance drug development and promote regulatory innovation through clinical pharmacology and experimental medicine.



Peter Stein, MD is the Director of CDER's Office of New Drugs (OND). OND is responsible for the regulatory oversight of investigational studies during drug development and decisions regarding marketing approval for new (innovator or non-generic) drugs, including decisions related to changes to already marketed products. OND provides guidance to regulated industry on a wide variety of clinical, scientific, and regulatory matters. A nationally-recognized leader in pharmaceutical research and development, Dr. Stein joined CDER in 2016 as the OND Deputy Director. Before coming to FDA, he served as Vice President for late-stage development, diabetes, and endocrinology at Merck Research Laboratories. He also served as Vice President, head of metabolism development at Janssen. He has more than 30 years of academic, clinical, and industry experience. Dr. Stein holds a bachelor's degree in history from the University of Rochester in New York and a medical degree from University of Pennsylvania. He trained at Yale University and Yale-New Haven Hospital in internal medicine and in endocrinology and metabolism.



Kathleen M. Giacomini, PhD is the current Dean of the University of California, San Francisco School of Pharmacy. Of multi-ethnic ancestry, Kathy has been recognized for her commitment to diversity as the winner of the UCSF Martin Luther King Award at UCSF and by the UCSF United Filipinx Association. She is a world-renowned scientist as a leader in the field of membrane transporters on pharmacogenomics. She cloned and discovered the endogenous role of the human transporter, OCT1 (SLC22A1), and recently de-orphaned SLC22A10, SLC22A24 and SLC22A15, discovering physiologic and pharmacologic substrates of the transporters. Together with others, she co-founded the International Transporter Consortium and the Pharmacogenomics Global Research Network. She is the Co-Principal Investigator of the UCSF-Stanford Center of Excellence in Regulatory Sciences and Innovation, funded by the Food and Drug Administration. She has received numerous awards for her scientific accomplishments and is an elected member of the National Academy of Medicine.



Michelle Rohrer, PhD is Global Head of Product Development Regulatory for Genentech Roche. She received her PhD from the University of California, Davis. She began her career at Genentech Roche as a post-doctoral research fellow. Subsequently, she worked as a clinical scientist, project team leader, site head and regulatory strategist. In her current role, she leads a global organization of ~600 regulatory professionals responsible for the end-to-end development of products in Roche’s pharmaceutical pipeline. In 2013, Michelle was named by the SF Business Times as one of “The Most Influential Women in Bay Area Business.” In 2014, she was selected by PharmaVOICE as one of the 100 most inspiring leaders in healthcare. In 2015, she served as an industry representative to the FDA-industry Prescription Drug User Fee Act VI negotiation team. She currently serves on the Board for TransCelerate Biopharma Inc, is a founding member of Accumulus Synergy and is the PhRMA representative to the ICH Management Committee and Assembly. Michelle views policy work and molecule work as complementary. In her work and leadership roles, she strives to identify areas where policy can speed the development of innovative medicines for patients.

Session 2 - Clinical pharmacology considerations for specific patient subpopulations



Anuradha (Anu) Ramamoorthy, PhD, is a Master Scientist and Policy Lead in the Guidance and Policy Team (GPT) in the Office of Clinical Pharmacology (OCP), Center for Drug Evaluation and Research (CDER), US Food and Drug Administration (FDA). In her current role, Dr. Ramamoorthy contributes to regulatory policy development, stakeholder engagement, and research focused on clinical pharmacology. Prior to that she was a Reviewer in OCP contributing to the regulatory review of investigational new drug (IND), new drug application (NDA), and biologic licensing application (BLA) to effectively incorporate pharmacogenomic and clinical pharmacology strategies in drug development. She is co-investigator in a number of research projects that are focused on current and emerging regulatory topics that impact the development and regulatory assessment of new drugs. Dr. Ramamoorthy received her Ph.D. in Medical and Molecular Genetics from Indiana University and completed her post-doctoral fellowship at the National Institute on Aging (NIA, NIH) and at OCP, FDA. She is the Co-Chair of the FDA/MCERSI Workshop “Clinical Pharmacology Guidances Advancing Drug Development and Regulatory Assessment: Role and Opportunities.”



Elimika Pfuma Fletcher, PharmD, PhD, is a Policy Lead in the Office of Clinical Pharmacology (OCP) at the FDA. Her primary areas of focus are pediatric and maternal pharmacology. She previously served as a Senior Clinical Pharmacology Reviewer supporting Oncology drug products from 2009-2016. She holds a Doctor of Pharmacy (PharmD) degree and a PhD in Pharmaceutical Sciences from the University of Houston College of Pharmacy.



Aarti Sawant, PhD is a Clinical Pharmacologist at AstraZeneca supporting all programs in oncology and immunology from early development through approvals. She started her industry career at Pfizer, Groton labs. as a senior scientist supporting programs in neuroscience as drug metabolism and pharmacokinetics project lead and later on as Clinical Pharmacologist in early clinical development. Aarti has worked across different therapeutic areas including inflammation and immunology, oncology, and cardiometabolic diseases. Dr. Sawant has authored numerous publications in the area of drug metabolism and Clinical Pharmacology. She is currently the IQ Working Group co-chair on the Role of clinical Pharmacology in diversity in clinical trials. Aarti is also an adjunct Faculty at University of Arizona, R. K. Coit College of Pharmacy. She volunteers on committees for ACCP and ASCPT and also serves as an elected member on the Board of health in the town of Needham, Massachusetts. Aarti pursued a BSc. and MSc. From Mumbai University as well as Diploma in Food and Drug technology from V.J.T.I Engineering school. She holds a PhD from University of Illinois, College of Pharmacy.



Sara K. Quinney, PharmD, PhD, is a Professor in the Department of Obstetrics and Gynecology and Division of Clinical Pharmacology, Department of Medicine, at Indiana University School of Medicine. She received her Pharm.D. and Ph.D. in pharmacy practice from Purdue University and completed clinical pharmacology and bioinformatics fellowships at Indiana University. Dr. Quinney serves as the Director of the Indiana Clinical and Translational Sciences Institute (CTSI) Disease and Therapeutic Response Modeling program. Dr. Quinney utilizes in vitro, preclinical, clinical, and bioinformatics data to develop quantitative systems pharmacology models to improve understanding of drug disposition and response in special populations. She leads the Indiana University-Ohio State University MPRINT Data and Model Knowledge Research Coordination Center (IU-OSU MPRINT DMKRCC), with a goal of enhancing maternal and pediatric pharmacotherapy through integrating data using innovative pharmacometric modeling approaches. She also supports a number of preclinical drug development efforts in cancer and Alzheimer's disease. Dr. Quinney has served as a mentor to numerous students, residents, postdoctoral fellows, and junior faculty from a variety of disciplines. She is an active member of ASCPT and ISOP.



Michael Neely, MD is a Professor of Pediatrics and Clinical Scholar in the Department of Pediatrics at the Keck School of Medicine of the University of Southern California. He is a Board-certified pediatric infectious disease specialist physician with more than 20 years of experience in patient care, research, and mentoring of over 50 undergraduates, medical students, residents, fellows, PhD students, post-docs, and visiting scholars in clinical pharmacology and pharmacometrics. He serves as the Chief of Infectious Diseases at the Children's Hospital of Los Angeles (CHLA) and the director of the CHLA Laboratory of Applied Pharmacokinetics and Bioinformatics. Dr. Neely's lab created and maintains the Pmetrics population modeling and simulation package for R and the BestDose software to optimize individual patient dosing through applied pharmacometric and machine learning techniques. His lab is increasingly involved in the use of artificial intelligence to enhance the use of drug therapies. He has recently expanded his lab to include hollow fiber capabilities, focusing on optimizing treatment of serious infections in pediatric patients such as Mycobacterium abscessus, Staphylococcus aureus, and resistant Gram-Negative bacteria. His research has been continually funded by the NIH since 2000, with additional

funding from FDA and private foundations. He lectures and conducts pharmacometric workshops internationally and has published almost 200 peer-reviewed publications and ten book chapters.

Session 3 - Application of clinical pharmacology for rare disease drug development



Michael Pacanowski, PharmD, MPH is the Director of the Division of Translational and Precision Medicine in FDA's Office of Clinical Pharmacology. He oversees a multidisciplinary team of clinical scientists who lead the Office's regulatory review, research, and policy activities related to pharmacogenomics, biomarkers, targeted therapies, and drug development for rare diseases. Dr. Pacanowski received his Pharm.D. from the Philadelphia College of Pharmacy and his M.P.H. from the University of Florida. He completed a residency in clinical pharmacology at Bassett Healthcare in Cooperstown, NY, and a clinical research fellowship in cardiovascular pharmacogenomics at the University of Florida.



Robert Schuck, PharmD, PhD is the Deputy Director of the Division of Translational and Precision Medicine (DTPM) in the Office of Clinical Pharmacology (OCP) at the FDA. DTPM is a multidisciplinary team consisting of translational scientists with clinical pharmacology, human genomics, epidemiology, and molecular biology expertise. The division focuses on regulatory review, research, and policy development in the areas of pharmacogenomics, biomarker qualification, drugs for rare diseases and inborn errors of metabolism, and genetically targeted therapies.



Marshall L. Summar, MD is well-known for his pioneering work in caring for children diagnosed with rare diseases. He is now the Chief Executive Officer of Uncommon Cures, LLC, a rare disease clinical trials company. He founded and led the Rare Disease Institute at Children's National in Washington DC. He has developed new drugs for sickle cell anemia, congenital heart disease, and neonatal lung disease. He is the past-board chairman of the National Organization for Rare Disorders where he helped establish the Clinical Centers of Excellence Program and IAMRARE natural history program. He also developed the international rare disease clinical treatment protocols program, RareCap. He has organized and is a part of a number international work groups and has numerous board positions. In 2022, he was awarded NORD's Lifetime Achievement Award for his work in rare disease.



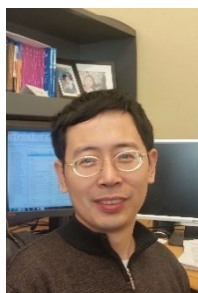
Steven W. Ryder MD, FACP currently serves as Chief Medical Officer, Rallybio. He previously served as Chief Development Officer, Alexion Pharmaceuticals (2013-2018) and President, Astellas Pharma Global Development (2008-2013). Prior to Astellas, he worked at Pfizer for 21 years where he held positions including Head of Worldwide Clinical Development and, prior to that, at Wyeth/Ayerst Pharmaceuticals. He is the past- President of ASCPT and has held leadership positions in the Health Section Governing Board, Regulatory Executive Committee, and Board of BIO, the Science and Regulatory Section of PhRMA, and the Clinical Pharmacology Advisory Committee of the of the PhRMA Foundation. He has served as the industry representative on the FDA's Metabolic/Endocrine Drugs Advisory Committee. He received an M.D. from the Icahn School of Medicine

at Mount Sinai, trained in Internal Medicine and Endocrinology, Metabolism, and Diabetes at SUNY Stonybrook, and was a Research Fellow at the Berson Laboratory, Bronx VAMC.

Session 4 – Global harmonization of clinical pharmacology considerations



Kellie Schoolar Reynolds, PharmD is Director of the Division of Infectious Disease Pharmacology in the Office of Clinical Pharmacology, CDER, FDA. She received her B.S. in Biochemistry from Virginia Tech, Pharm.D. from Virginia Commonwealth University, and completed a fellowship in Clinical Pharmacokinetics and Drug Development at University of North Carolina and Burroughs Wellcome Company. Her work involves application of clinical pharmacology to development of antiviral and anti-infective drugs and drugs developed under the animal rule. Her interests include dose selection for sub-populations, drug interactions, risk/benefit assessment, and communication. Her work at FDA began in 1994 during a pivotal phase of HIV drug development, allowing her to experience the essential contribution of clinical pharmacology to development of drugs for a life threatening disease. Dr. Reynolds has participated in FDA/CDER working groups related to drug interactions, renal impairment, drug interaction labeling, and regulatory review policy. She is the FDA topic lead for the International Council for Harmonization (ICH) Drug Interaction Working Group. Dr. Reynolds is a past president of the American Society for Clinical Pharmacology and Therapeutics, chaired the Strategic Planning Task Force and the Award Selection Task Force, and was an associate editor for Clinical Pharmacology and Therapeutics.



Xinning Yang, PhD is a Policy Lead in Guidance & Policy team (GPT) under the Office of Clinical Pharmacology (OCP), CDER of FDA. He was graduated from the Dept. Pharmaceutical Sciences of State University of New York at Buffalo (SUNY-Buffalo), mentored by Dr. Marilyn Morris. He is the Chair of Transporter Focus Group of International Society of Studying Xenobiotics (ISSX), a committee member of the Regulatory Affairs of ISSX, Chair of the Membrane Transporter (MT) community of the American Society of Clinical Pharmacology and Therapeutics (ASCPT), a committee member of the PBPK community of ASCPT, and a member of International Transporter Consortium (ITC) committee. He is participating in the International Council Harmonization (ICH) M12 DDI guidance global harmonization working group and serves as the Deputy Topic Lead from FDA.



Vikram Sinha, PhD is the Global Head of Therapeutic Areas of PK Sciences at Novartis. He is a senior leader with over twenty years' experience in drug research & development. In his role, Vikram leads a global team that is responsible for strategy and execution of all clinical pharmacology related aspects with an emphasis in integrating experimental and predictive approaches in informing dosing; probability of technical success for a trial and program; and assess the overall benefit/risk for various populations. He is passionate about developing new medicines by building great teams. Vikram has made notable contributions to the general scientific community through teaching, publications, and engagement with industry and government consortia dedicated to advancing innovation in drug discovery and development. He is a co-author of several ICH guidance documents, key contributor to workshops and consortiums, a leader in the IQ Consortium, and associate editor and

peer reviewer for several notable journals. He holds three patents and is a Fellow of the American College of Clinical Pharmacology. Vikram has a PhD from the University of Arizona.



Paulo Paixão, PhD is an Assistant Professor in Pharmacokinetics and Biopharmaceutics at the Pharmacy Faculty of Lisbon University since 2012. He is also a Clinical Pharmacology assessor at INFARMED (Portuguese Regulatory Agency) since 2003 and a member of the former Pharmacokinetics Working Party (PKWP) from EMA and a current member of the Methodological Working Party MWP, also from EMA. In his regulatory work, he has been involved in the assessment of bioequivalence and general clinical pharmacokinetics in Centralized, Decentralized, Mutual recognition and National Procedures. He has also been Involved in Scientific Advices Procedures

both at the National and European level. Regarding research, his main topics of interest has been related to pharmacokinetics and Therapeutic Drug Monitoring. In particular, he has been involved on creating and optimizing drug development tools, namely, on the use of QSAR and data integration procedures with PBPK models. Regarding PBPK models, he has been mainly focused in modelling and simulation on oral drug absorption with several papers with direct implication on bioavailability/bioequivalence regulatory sciences, namely on the establishment of pharmacokinetics metrics for bioequivalence of modified release formulations, and on the evaluation of similarity metrics for dissolution profiles. Latter research interests are related to the better understanding of the physiology of the GI tract and its consequences in clinical variability for oral drug products.



Jenny Chien, PhD is an associate VP and a scientific lead in the Global PK/PD and Pharmacometrics Department at Eli Lilly and Company. She received her Ph.D. degree in Pharmaceutical Sciences from the University of Washington, Seattle in 1997. She is recognized for her expertise in model-informed drug development (MIDD) strategy, applying drug-disease models in trial design optimization and dose-finding in Drug Discovery and Development. Dr. Chien has given lectures and published around 90 manuscripts, conference presentations and 3 book chapters on innovative approaches in clinical pharmacology that supported impactful MIDD

efforts in R&D and global regulatory submissions.



Akihiro Ishiguro, PhD is a Division Director of the Office of Review Management, Pharmaceuticals and Medical Devices Agency (PMDA). His professional experience includes new drug review and post marketing drug safety. He had the opportunity to join projects to develop regulatory guidelines in the field of Clinical Pharmacology such as the MHLW guidelines (e.g., Drug Interaction, Population Pharmacokinetics, Exposure Response Analysis) and the ICH guidelines (e.g., Qualification of Genomic Biomarkers, Genomic Sampling). Currently he is also working as a leader in the field of Pharmacokinetics in Offices of Drug Review, PMDA; a leader of Omics working group,

Project across multi-offices in PMDA; a regulatory chair of the ICH M12 (Drug Interaction Studies) expert working group.

Session 5 – Role of quantitative medicine in drug development and decision making



Rajanikanth (Raj) Madabushi, PhD has over 15 years of regulatory experience as a Pharmacometrics Reviewer and Clinical Pharmacology Team Lead in the Office of Clinical Pharmacology, OTS/CDER/FDA. He currently serves as the Associate Director, Guidance and Scientific Policy in the Immediate Office of Clinical Pharmacology. Dr. Madabushi plays an instrumental role in FDA’s PDUFA MIDD initiatives and is the CDER Point-of-Contact for the MIDD Paired Meeting Program. Dr. Madabushi is also involved in global harmonization activities as the Rapporteur for ICH M12 Expert Working Group – Drug Interaction Studies. Dr. Madabushi received his PhD. in Pharmaceutical Sciences from Birla Institute of Technology and Sciences (BITS), Pilani, India.



Hao Zhu, PhD, is the director of the Division of Pharmacometrics, Office of Clinical Pharmacology, Office of Translational Science, Center of Drug Evaluation and Research, U.S. Food and Drug Administration. Dr. Zhu received his Ph.D. in pharmaceutical sciences and Master in statistics from the University of Florida. He started his career in modeling and simulation teams in Johnson & Johnson and Bristol-Myers-Squibb. He joined FDA as a pharmacometrics reviewer more than 17 years ago. Dr. Zhu has been a clinical pharmacology team leader for more than 6 years and a QT-IRT scientific lead for 2 years. Then he became the deputy director at the Division of Pharmacometrics. His division reviews the pharmacometrics related submissions and supports pharmacometrics-related policy development.



Daniele Ouellet, PhD is Vice President, Global Head of Clinical Pharmacology & Pharmacometrics (CPP), at Johnson & Johnson where she leads the global team of clinical pharmacologists, pharmacometricians, and the Phase 1 Clinical Pharmacology Unit. Daniele has about 30 years of experience in the pharmaceutical industry and has been a champion of quantitative clinical pharmacology approaches throughout her career. In her role at Johnson & Johnson, she ensures that CPP provides end-to-end clinical pharmacology and model informed drug development expertise, starting at first-in-human study up to registration and beyond, covering clinical drug development projects for small & large molecules, and other novel modalities across the portfolio. Daniele has a Bachelor degree in Pharmacy from the University of Montreal and graduated with a MS and PhD degrees from the University of North Carolina at Chapel Hill. Daniele has served on the Board of Directors of the American Society of Clinical Pharmacology and Therapeutics (ASCPT; 2021-2024), the International Society of Pharmacometrics (2014-2017) and IQ Consortium (2021-2023). She is a fellow of the International Society of Pharmacometrics (FSOP), was awarded the ISoP Leadership Award in November 2020, and has received the ACCP Honorary Fellowship Award (2023). Daniele has published more than 80 original articles, multiple abstracts, and chaired annual scientific meetings and various symposiums.



Joga Gobburu, PhD, MBA is a Professor at the University of Maryland, Baltimore, MD, USA. With a rich background at the US FDA spanning from 1998 to 2011, he brings extensive expertise in regulatory affairs and drug approval processes. During his tenure, he oversaw the review of numerous Investigational New Drug Applications (INDs) and New Drug and Biological Licensing Applications, contributing significantly to FDA Guidances and policies on drug approval and labeling. His exceptional contributions were recognized with prestigious awards including the FDA's Outstanding Achievement Award and the Senior Biomedical Research Scientist appointment. Additionally, he has been honored with awards from leading organizations such as the American Conference on Pharmacometrics and the American College of Clinical Pharmacology. Dr. Gobburu's scholarly impact is evident through his extensive publication record, comprising over 120 papers and book chapters, and his editorial roles in several esteemed journals.



Karen Rowland Yeo, PhD is Senior Vice-President, Client & Regulatory Strategy at Certara UK Limited's Simcyp Division. Prior to this, she was the Head of PBPK Consultancy Services at Simcyp where she led projects relating to the application of physiologically based pharmacokinetic (PBPK) modeling in the drug development process. This involved putting a framework in place for developing PBPK models used for both internal decision-making and regulatory submissions. Her work ranged across most therapeutic areas and included the development of models used for dosing of special populations and assessment of drug-drug interactions. Prior to joining Simcyp Ltd in 2002, Karen held a 5-year lectureship in the Department of Clinical Pharmacology & Therapeutics at the University of Sheffield. She received her BSc Honours degree in Physics at the University of Natal in South Africa in 1989 and her PhD in Drug Metabolism from the University of Sheffield in 1995. Karen has been the author/co-author of more than 100 peer reviewed articles and is frequently called as an invited speaker and session organiser/moderator at international meetings in the field. Karen is currently serving as the Chair of the Scientific Program Committee for the 2024 ASCPT annual meeting and is Deputy-Editor-in-Chief of the CPT: Pharmacometrics & Systems Pharmacology journal.

Session 6 - Clinical pharmacology guidances supporting the lifecycle of a new therapeutic product



James Polli, PhD is the Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics at University of Maryland. His research interest is oral drug absorption, involving laboratory and clinical research. He has served as the advisor to 24 PhD graduates. He is co-Director of the University of Maryland Center of Excellence in Regulatory Science and Innovation and the Center for Research on Complex Generics, each an FDA-funded collaborative agreement with the Agency. He is Director of the online M.S. in Regulatory Science program. He is a fellow of the American Association for Pharmaceutical Scientists (AAPS) and served as an editor of Pharmaceutical Research for 12 years. He is the 14th recipient of the APhA Takeru Higuchi Research Prize. He was the recipient of the 2024 AACP Volwiler Research Achievement Award, the 2022 AAPS Global Leadership Award, and the 2021 TOPRA Education Award. He is a member of the University of

Maryland General Clinical Research Center Advisory Committee and the University of Maryland institutional review board (IRB). He is a member of the Scientific Advisory Board of Simulations Plus.



Ethan Stier, PhD is the Associate Director of Lifecycle Management in the Office of Clinical Pharmacology, OTS/FDA. Prior to that, he served as Division Director of Bioequivalence, Associate Director for Science, and Acting Deputy Office Director in the Office of Bioequivalence OGD/FDA. He is an expert in the design and interpretation of in vitro, in vivo, and in silico bioequivalence and comparative bioavailability studies used generic and new drug applications. He is a recognized leader in guidance and policy in the generic and new drug spaces having overseen the development of numerous FDA and ICH Guidances, as well as Product Specific Guidance Development. Currently he is the lead in the Office of Clinical Pharmacology for Citizen Petitions, bridging formulations, 505B2 policy development and knowledge management, ICH Guidance development on BE/BA topics and coordination of lifecycle activities with partners across CDER. He earned in PhD in Pharmaceutical Sciences from the University of Michigan and Bachelor in Pharmacy from the University of Connecticut.



Roger Nosal, MA is currently Principal Consultant with *Roger Nosal PharmaCMC Regulatory Consultants* and serves as Head of Regulatory Strategy for *NGT BioPharma Consultants*, a consortium of experienced experts and leaders in development of pharmaceutical products. For 12 years prior to September 2022, he was Vice President and Head of Global Chemistry, Manufacturing and Controls at Pfizer where he was accountable for all global regulatory CMC strategies and applications for innovative products and medical devices. Roger led development of the CMC regulatory strategy and was responsible for negotiating clinical and commercial requirements with global regulatory authorities for authorization/ approval of the first mRNA vaccines to effectively address the COVID-19 virus. From 2018 – 2023 Roger served as Rapporteur for the ICH Quality Discussion Group and has been a representative to several ICH Expert Working Groups since 1994 including ICH M9 – BCS Biowaivers. Roger was instrumental in development and implementation of *Quality by Design* and, in 2013, was awarded the *Pharmaceutical Discovery, Development and Manufacturing Forum Award* from AIChE for outstanding contributions to advancing QbD. Roger's 41 years of experience at G. D. Searle, Monsanto, Pharmacia and Pfizer includes 28 years in regulatory CMC and 13 years as a Medicinal and Process Chemist. He is co-author of 24 patents. He has publicly presented and published on a wide variety of regulatory and pharmaceutical policy initiatives and topics.



Xavier Pepin, PharmD, PhD is Associate VP of Regulatory Affairs at Simulations Plus. He is pharmacist (University Paris XI). He has a Ph.D. in granulation technology where he studied powder surface energy and liquid bridges during wet high-shear granulation. He has more than 25 years' experience in the pharmaceutical industry and has occupied several positions from pre-formulation, clinical and commercial formulation development, industrial transfer, regulatory CMC and biopharmaceutics. He's worked in biopharmaceutics for 15 years using in vitro, in silico, and in vivo tools to support evaluation of drugs along the development value chain and post marketing. He was the co-leader of WP4 in silico tools for the OrBiTo IMI project 2012-2018. He joined Simulations Plus in May 2022 in regulatory affairs focusing on PBBM to support product quality evaluation and

change management. He has 50+ publications in the field of powder surface energy, granulation technology and biopharmaceutics modeling and simulation.



Kimberly Raines, PhD currently serves as the Associate Director of Science in the Office of Policy for Pharmaceutical Quality (OPPQ) in the Office of Pharmaceutical Quality (OPQ) providing scientific and technical leadership on matters related to the advancement of policy related to pharmaceutical quality. Her tenure at the Agency began in the Office of Generic Drugs (OGD) in 2008 as a Bioequivalence Reviewer. In 2015, she joined the newly formed OPQ, Office of New Drug Products (ONDP), as an acting Biopharmaceutics Lead and later assumed a leadership role as supervisory Branch Chief. Prior to joining the FDA, she received post-doctoral training at the

University of North Carolina Lineberger Comprehensive Cancer Center where she was an UNCF-Merck Fellow. Kimberly received her Ph.D. in Pharmaceutical Sciences from the University of Maryland School of Pharmacy and a Howard Hughes B.S. in Chemistry with a concentration in Pharmacology from Duke University. In addition to her daily duties, Kimberly has co-authored original research articles and presented on drug product quality, bioequivalence, biowaivers, in vitro dissolution, and physiologically based model informed quality risk assessment.
