Physiologically Based Biopharmaceutics Modeling, PBBM Best Scientific Practices to Drive Drug Product Quality: Latest Regulatory and Industry Perspectives

University of Maryland Center of Excellence in Regulatory Science and Innovation
Food and Drug Administration

Public In-Person Workshop
August 29-31, 2023 | 8:30 AM – 5:30 PM Eastern Time

Biographies

Amin Rostami-Hodjegan, PhD, FCP, FAAPS, FJSSX, FBPS
Professor of Systems Pharmacology and Director of Centre for Applied Pharmacokinetic Research (CAPKR), University of Manchester, UK & SVP of R&D Chief Scientific Officer (CSO), Certara, Princeton, USA

Dr. Amin Rostami-Jodjegan was listed by The Institute of Scientific Information (ISI, Clativate) as one of the world's most highly cited researchers (under 'Pharmacology & Toxicology') in 2017. Amin is also at 0.05% top rank of the Highly Cited Researchers List by Elsevier for pharmacology (2021). He has published over 300 peer reviewed highly influential scientific articles (>22,000 citations, h-index = 80). The work of Professor Rostami covers wide areas of drug development over the last 30 years, ranging from pharmaceutics (e.g., bioavailability and bioequivalence) to clinical pharmacology (e.g. mixture pharmacology of drug/metabolites), translational and systems pharmacology (e.g. quantitative proteomics of enzymes and transporter for *in vitro to in vivo* (IVIVE) scaling).

Amin was co-founder of two spin-off companies from the University of Sheffield (Simcyp Limited and Diurnal PLC). As a leader in the field of physiologically-based pharmacokinetics (PBPK) and quantitative systems pharmacology (QSP), he is internationally recognized for his expertise in *IVIVE* to predict the behavior of drugs in human body and understanding the associated inter-individual variabilities. He was one of the founding editors of *Pharmacometrics and System Pharmacology*, and serves on the Editorial Boards of several other journals.

As the Senior Vice President of Research & Development (SVP) and Chief Scientific Officer at Certara, he facilitates the incorporation and integration of the latest advances in translational modelling to biosimulation platforms offered by Certara to its clients, with the aim of accelerating the development and regulatory approval of safer drug products and bringing them to the patients.

Jennifer Dressman, PhD
Group Leader
Pharmaceutical Technology
Fraunhofer Institute of Translational Pharmacology and Medicine

Dr. Jennifer Dressman, who retired as Professor of Pharmaceutical Technology at the Goethe University in 2021, now leads a formulation group at the Fraunhofer Institute of Translation Medicine and Pharmacology in Frankfurt am Main, Germany.

Prof. Dressman's research interests focus principally on predicting the in vivo performance of drugs and dosage forms after oral administration. She is best known for pioneering the use of Biorelevant dissolution testing and her contributions to combining dissolution testing with physiologically based pharmacokinetic modelling, in order to achieve quantitative predictions of oral drug absorption.

In recognition of her research excellence, she has been made a Fellow of the AAPS, the CRS, AJPST, and the FIP. In 2008, she was awarded the Distinguished Scientist Award of the FIP and in 2017 was named the International Woman Pharmaceutical Scientist of the Year by the APSTJ. In 2022, a special issue of the *Journal of Pharmaceutical Sciences* was dedicated to her contributions to the Pharmaceutical Sciences.

Haritha Mandula, PhD
Senior Pharmaceutical Quality Assessor
BB3 | DB | ONDP | OPQ | CDER | FDA

Dr. Haritha Mandula is a Senior Pharmaceutical Quality Assessor in the Division of Biopharmaceutics, ONDP, OPQ in the FDA's Center for Drug Evaluation and Research. She received a PhD in Pharmaceutical Sciences from Texas Tech University, Health Sciences Center in 2005. Haritha has experience supporting review of the biopharmaceutical aspects of new and generic drug product review submissions across a wide range of therapeutic areas. Haritha also serves on several review committees at the FDA including the Biopharmaceutical Classification System (BCS) committee, In Vitro In Vivo Correlations (IVIVC) committee, and Physiologic Based Biopharmaceutics Modeling Committee (PBBM). She has been the recipient of several awards at FDA including CDER Regulatory Science Excellence Awards, CDER Special Recognition Awards, and FDA Commissioner's Special Citation Awards.

Kevin Wei, PhD
Pharmacologist, Division of Biopharmaceutics
ONDP | OPQ | CDER | FDA

Dr. Kevin Wei is a Biopharmaceutics reviewer at the Division of Biopharmaceutics, Office of New Drug Products, Office of Pharmaceutical Quality (OPQ), Center of Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). Dr. Wei has been conducting Biopharmaceutics assessment for a wide variety of drug products submitted under Investigational New Drugs (INDs), New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and supplements. Dr. Wei started his career at Novartis. Prior to joining FDA in 2017, he had over 10 years of experience in the pharmaceutical industry working on drug development programs from proof of concept to regulatory approval. Dr. Wei received his PhD in Pharmaceutical Sciences from the University of North Carolina at Chapel Hill.

Kimberly Raines, PhD
Branch Chief, Division of Biopharmaceutics
ONDP | OPQ | CDER | FDA

Dr. Kimberly Raines is a Supervisory Pharmacologist at the FDA. Dr. Raines and her team lead efforts in establishing in vitro dissolution/release specifications and assessing biopharmaceutics topics (e.g., biowaiver, bridging, IVIVC, etc.) in regulatory submissions. Additionally, Dr. Raines develops CDER biopharmaceutic guidances, leads research projects within her division, and provides subject matter expertise to FDA policy initiatives. She has co-authored original research articles and presented on bioequivalence, biowaivers, in vitro dissolution, and physiologically based model informed quality risk assessment. Her tenure at the Agency began in the Office of Generic Drugs 15 years ago as a bioequivalence reviewer and controlled correspondence team lead. Prior to joining the FDA, Dr. Raines received post-doctoral training at the University of North Carolina Lineberger Comprehensive Cancer Center where she was an UNCF-Merck Fellow. In 2006 she received her PhD in Pharmaceutical Sciences from the University of Maryland School of Pharmacy and a BS in Chemistry with a concentration in pharmacology from Duke University.

Bhagwant Rege, PhD
Division Director, Division of Biopharmaceutics
ONDP | OPQ | CDER | FDA

Dr. Bhagwant Rege is the Division Director for the Division of Biopharmaceutics in CDER/OPQ/Office of New Drug Products at the FDA. His division at FDA is responsible for assessment of clinically relevant in vitro release specifications for drug products, in vitro-in vivo correlations (IVIVC), physiologically-based biopharmaceutics models (PBBM), scientific bridging strategies, biowaivers, and BCS classification requests. Most recently he served as a division director for CDER/OPQ/OLDP/ Division of Immediate and Modified Release Products III. Prior to joining FDA in 2010, he worked in industry for many years in oral biopharmaceutics and formulation development groups. Bhagwant has served as a team leader and review chemist in the Office of Generic Drugs where he was part of the team that developed the QbD examples for the generic industry. He is a member of the FDA Emerging Technology Team (ETT) and ICH Q12 Expert/Implementation Working Group. He served as FDA liaison on the USP expert committee on dosage forms general chapter (2015-2020). Bhagwant received his BS and MS in Pharmacy from the University of Mumbai, India and a PhD in Pharmaceutical Sciences from the University of Maryland, Baltimore.

Parnali Chatterjee, PhD, RPh
Pharmacologist
DB | ONDP | OPQ | CDER | FDA

Dr. Parnali Chatterjee is a Biopharmaceutics assessor within the Division of Biopharmaceutics at the FDA who is involved in the evaluation of in vitro, in vivo, and in silico absorption, metabolism, distribution, and elimination (ADME) data in support of dissolution methods, clinically relevant dissolution specifications, biowaivers, animal and clinical studies, in vitro-in vivo relation/correlation (IVIVR/IVIVC) to support regulatory approvals.

Dr. Chatterjee received her doctoral degree in Pharmaceutical Sciences from the University of Louisiana, LA, following which she pursued a post-doctoral training in Pharmacology/Toxicology at the University of Utah, UT. Dr. Chatterjee has worked in the pharmaceutical industry supporting drug discovery and development activities. She held a faculty position at St. John's University, NY. Her research interests include formulation development, cell culture, animal and clinical studies, and analytical/bioanalytical chemistry to support in vitro, in vivo, and in silico ADME.

Anitha Govada, PhD
Biopharmaceutics Team Lead, Senior Pharmaceutical Quality Assessor
DB | ONDP | CDER | FDA

Dr. Anitha Govada is a Biopharmaceutics Team Lead serving as a Senior Pharmaceutical Quality Assessor (SPQA) in the Division of Biopharmaceutics/Office of New Drug Products at CDER/FDA. In this position, she provides leadership and oversight for the biopharmaceutics assessments of investigational, new, and generic drug product submissions in Oncology and Hematologic Malignancy therapeutic areas. She serves as an Application Technical Lead (ATL) for NDAs including priority Breakthrough Therapy Fast Track submissions supporting the Oncology Center of Excellence's initiatives such as Project Orbis, Real-Time Oncology Review (RTOR) program. She began her FDA career in 2007, joining CDER's Office of Generic Drugs as a Bioequivalence Reviewer and later transitioned to Office of Pharmaceutical Quality (OPQ) as a CMC, biopharmaceutics reviewer, and manufacturing facility investigator. In her 16 years of multidisciplinary experience spanning the entire product lifecycle from pre-IND to NDA, pre-ANDA to ANDA and post marketing supplements, she was involved in aspects related to research, review, and guidance development. She led multiple internal and external committees, working groups and cross-center collaborations as a subject matter expert (SME) for complex drug products. She received several awards and honors at the FDA including CDER Regulatory Science Excellence Awards and CDER Center Director's Special Recognition Award. Prior to joining the FDA, Anitha worked in the pharmaceutical industry as a senior formulation scientist and as a pharmacist. She received her Bachelor of Pharmacy from Kakatiya University and a PhD in Pharmaceutical Sciences from Texas Tech University School of Biomedical Sciences.

Rajesh Savkur, PhD
Biopharmaceutics Reviewer
DB | ONDP | OPQ | CDER | FDA

Dr. Rajesh Savkur is a Biopharmaceutics Reviewer in the Division of Biopharmaceutics (DB) in the Office of New Drug Products/Office of Pharmaceutical Quality at the U.S. Food and Drug Administration (FDA). Dr. Savkur received a Bachelor and Master of Science in Chemistry and Biochemistry, respectively from the University of Mumbai, India, and a PhD in Biochemistry/Pharmacology from the University of Mississippi Medical Center, Jackson, Mississippi. During his PhD, he designed novel anti-cancer chemotherapeutic drugs (Daunorubicin derivatives) that exhibited increased specificity to the target DNA. During his stint in the pharmaceutical industry, he identified novel targets for the development of NME drugs for the treatment of cardio-endocrine-metabolic diseases, including atherosclerosis, dyslipidemia, type 2 diabetes, and heart failure. He has extensive experience in pharmacogenomics, proteomics, biomarker validation, and pharmacokinetic/pharmacodynamic (PK/PD) modeling approaches for pre-clinical and clinical studies. Dr. Savkur has authored and co-authored several peer-reviewed journal articles, invited review articles and book chapters, and serves as an editorial consultant for several journals including *Biochemical Pharmacology*, *PPAR Research*, *Endocrinology*, and *Expert Opinion in Therapeutic Targets*. In his current role in the DB at the FDA, he evaluates the pharmacological and biopharmaceutical studies associated with drug and drug-device-combination applications that are submitted to the Agency.

Hansong Chen, PharmD, PhD
Senior Interdisciplinary Scientist
DB | ONDP | OPQ | CDER | FDA

Dr. Hansong Chen is a senior interdisciplinary scientist, the Division of Biopharmaceutics/ONDP/OPQ/CDER. He initially joined the Office of Study Integrity and Surveillance in 2013, where he conducted two years of BA/BE inspection. In 2015, he joined the Division of Biopharmaceutics. Before joining the FDA, he worked at a biopharmaceutics company as a chemist.

Fang Wu, PhD
Senior Pharmacologist
DQMM | ORS | OGD | CDER | FDA

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 four 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.

Anders Lindahl, MSc, PhD
Quality Assessor
Swedish Medical Products Agency; Uppsala, Sweden

Dr. Anders Lindahl has over 12 years of regulatory experience, both as Pharmacokinetics Assessor and Quality Assessor at the Swedish Medical Products Agency (MPA). In addition, he has more than 12 years of experience from pharmaceutical development in drug industry (AstraZeneca and Catalent Pharma Solutions). Dr. Lindahl is a Pharmacist (MSc) and received his PhD in Pharmaceutical Sciences from Uppsala university, Sweden in 1999. He is an Associate Professor in Industrial Biopharmaceutics, University of Helsinki, Finland, since 2022.

Christer Tannergren, PhD
Principal Scientist in Biopharmaceutics at Oral Product Development, Pharmaceutical Technology & Development
AstraZeneca; Gothenburg, Sweden

Dr. Christer Tannergren received his PhD in Biopharmaceutics at the Department of Pharmacy, Uppsala University, Sweden in 2004. He has held various Biopharmaceutics expert positions and Product Development Lead roles since joining AstraZeneca in 2003. His main areas of research interest include physiologically based biopharmaceutics modeling and regional intestinal absorption/bioavailability as well as development of low solubility and Modified Release drug products. He has co-supervised four PhD students and has published 36 peer-reviewed papers as well as inventing one formulation patent. Christer.Tannergren@AstraZeneca.com
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Elizabeth Gray, PhD
Biopharmaceutics Reviewer
DB | OPQ | CDER | FDA

Dr. Elizabeth Gray is a Biopharmaceutics Reviewer in the Division of Biopharmaceutics within the Office of Pharmaceutical Quality at the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). Elizabeth received a Bachelor of Science and Master of Science from St. John's University in Queens, NY. Subsequently, she worked as a science instructor and adjunct professor before returning to school for her doctorate. In 2022, she obtained her Doctor of Philosophy in Pharmacology from the University of Houston College of Pharmacy.

Miyoung Yoon, PhD
Senior Pharmacokineticist
DP | OCP | OTS | CDER | FDA

Dr. Miyoung Yoon is Senior Pharmacokineticist in the Physiologically-Based PharmacoKinetic (PBPK) team in the Division of Pharmacometrics in the Office of Clinical Pharmacology, FDA. Prior to the current position, she served as Team Leader in the Division of Quantitative Methods and Modeling in the Office of Research and Standards in the Office of Generic Drugs where she focused on regulatory and research activities for bioequivalence and generic drug assessment. Prior to joining FDA in 2019, she worked in consulting and research industry focused on human health assessment in particular for women and children based on new in vitro methods and computational modeling such as PBPK modeling. She has been actively communicating her research in national and international conferences as well as publishing numerous scientific publications.

Poonam R. Delvadia, PhD
Clinical Pharmacology Assessor
OCP | OTS | CDER | FDA

Dr. Poonam Delvadia is currently a clinical pharmacology assessor in the Office of Clinical Pharmacology (OCP, FDA) since December 2021, specifically working in neuropsychiatric pharmacology. Prior to joining OCP, Dr. Delvadia was a biopharmaceutics lead in the Division of Biopharmaceutics in the Office of New Drug Products (DB\ONDP\OPQ\FDA) where she performed the primary and secondary assessment of the biopharmaceutics aspects of the new and generic drug product submissions and involved in biopharmaceutics related research activities. Dr. Delvadia completed her PhD in Pharmaceutical Sciences at Virginia Commonwealth University (VCU, Richmond, Virginia) where her research focused on the development of a novel biorelevant in vitro system to predict the in vivo performance of oral transmucosal dosage forms. Prior to joining the PhD program, she worked as a research assistant in formulation development in Sun Pharmaceutical Advanced Research Company (India, 2006-2008). She received Bachelor's in Pharmacy and Masters in Pharmaceutics (2000-2006) from L.M. College of Pharmacy, Gujarat University, India.

Amitava Mitra, PhD, FAAPS
Senior Director, Clinical Pharmacology
Kura Oncology

Dr. Amitava Mitra is Senior Director of Clinical Pharmacology at Kura Oncology, where he supports global drug development programs. He has 16 years of experience in the pharmaceutical industry supporting various therapeutic areas and has previously worked at Merck, Novartis, and J&J. Amitava has a PhD in Pharmaceutical Sciences from University of Maryland, Baltimore. Amitava's main research interests include clinical pharmacology, modeling & simulation, pharmacokinetics, and biopharmaceutics. He has interacted with several regulatory agencies like FDA, EMA, and PMDA on these topics. Amitava has published more than 50 research and review articles and has more than 30 podium presentations in national & international conferences. He has won several awards including the Novartis VIVA Leading Science award in 2019 for his modeling efforts, an award that celebrates exceptional contribution by scientists across the company's R&D organization worldwide. Amitava actively volunteers in AAPS and ASCPT, and has participated in consortia such as IQ and IMI. He teaches a course on Clinical Pharmacology at the University of Maryland School of Pharmacy.

Mark McAllister, PhD
Senior Director and Head of Global Biopharmaceutics, Drug Product Design group
Pfizer; Sandwich, Kent

Dr. Mark McAllister is a Senior Director and Head of Global Biopharmaceutics, part of the Drug Product Design group at Pfizer in Sandwich, Kent. He is a Pharmacy graduate from Queen's University Belfast and has a pharmaceutics PhD from Aston University. Mark has over 25 years industrial development experience and has specialised in oral delivery systems and biopharmaceutics. He is a former chair of the Academy of Pharmaceutical Sciences and is currently a visiting senior lecturer at King's College London. Mark co-led the IMI 'OrBiTo' biopharmaceutics project, an academic/industrial collaboration, focused on the development of the next generation of models to predict oral absorption and he currently participates in a number of pre-competitive research programmes including COLOTAN, AGePOP, and InPharma Marie Skłodowska-Curie innovative training networks. Mark is a Fellow of the Royal Pharmaceutical Society and the Academy of Pharmaceutical Sciences.

Konstantinos Stamatopoulos, PhD
Investigator and GSK Fellow, Biopharmaceutics, DPD, MDS
GlaxoSmithKline; Ware, UK
Honorary Research Fellow
School of Chemical Engineering, University of Birmingham, UK

Dr. Konstantinos (Kostas) Stamatopoulos received his PhD at the University of Birmingham (2017) on the development of in vitro and in silicon tools for designing colon specific drug delivery systems and he pioneered the in vitro Dynamic Colon Model (DCM). In 2017, he joined Certara (Simcyp division) and worked within the absorption team focusing on the development and implementation of absorption models in ADAM model, leading the development of the dynamic bile salt model. In 2020, he joined the biopharmaceutics team in GSK (Ware, UK) as Investigator in biopharmaceutics within the product development division using PBPK/PBBM simulations to support drug product development. He has 30 peer reviewed research articles and several posters, book chapters, and presentations in international conferences. He is a co-supervisor in four PhD projects focusing on digital twins of human organs, food effect on oral absorption, in vivo tablet disintegration using MRI imaging, and on other areas of biopharmaceutics. He is a member of the IQ consortium (Food effect focused group) and member of the industrial advisory board in COLOTAN.

Philip Bransford, PhD
Senior Fellow, Data and Computational Sciences
Vertex Pharmaceuticals, Inc.

Dr. Philip Bransford is a Scientific Fellow in Data and Computational Sciences at Vertex Pharmaceuticals. He provides biopharmaceutics modeling support for preclinical and clinical small molecule drug candidates, focusing on solid form selection, formulation development, and food-drug interactions. Philip collaborated with industry peers on biowaiver harmonization and food effect prediction by physiology-based modeling. He has a PhD in Biological Engineering from the Massachusetts Institute of Technology and a Bachelor of Biomedical Engineering from the University of Minnesota.

Eleftheria Tsakalozou, PhD
Senior Pharmacologist
DQMM | ORS | OGD | CDER | FDA

Dr. Eleftheria Tsakalozou joined the FDA in 2015 as an Oak Ridge Institute for Science and Education (ORISE) Fellow. She is currently a Senior Pharmacologist at the Division of Quantitative Methods and Modeling at the Office of Research and Standards with expertise on physiologically-based pharmacokinetic modeling and simulation approaches for topical and transdermal drug products. Dr. Tsakalozou obtained her PhD in Pharmaceutical Sciences at the University of Kentucky in 2013 and completed a two-year Fellowship in Clinical Pharmacokinetics and Pharmacodynamics at the University of North Carolina at Chapel Hill. Her research interests also include the development of quantitative modeling and simulation tools to support bioequivalence assessments and the interactions between inactive ingredients and molecular targets including gut transporters.

Deanna Mudie, PhD
Senior Principal Engineer, Global Research & Development
Lonza Small Molecules

Dr. Deanna Mudie is a Senior Principal Engineer in Research and Development at Lonza's site in Bend, Oregon, USA. She earned her BSE in Chemical Engineering and her PhD in Pharmaceutical Sciences from the University of Michigan. Since joining Lonza in 2016, Deanna has focused on enabling bioavailability-enhancing amorphous solid dispersion (ASD) formulations by developing dosage form platforms and in vitro/in silico strategies for predicting ASD bioperformance. During her doctoral and post-doctoral work, Deanna developed mechanistic in vitro and in vivo drug transport models to predict oral dosage form dissolution and intestinal absorption. Deanna began her career in the pharmaceutical field as an engineer at Pfizer and Merck characterizing, developing, and manufacturing oral dosage forms from preclinical to commercial scales.

Sumit Arora, PhD
Senior Scientist, Biopharmaceutics group
The Janssen Pharmaceutical Companies of Johnson & Johnson

Dr. Sumit Arora is a Senior Scientist in Biopharmaceutics group at The Janssen Pharmaceutical Companies of Johnson & Johnson. His primary responsibility involves leading cross-functional teams to implement biopharmaceutical development strategies across preclinical development, clinical development, and CMC development. He is an experienced PBPK/PBBM modeler focusing on efficient formulation development, assessment of impact of CMC variables on drug pharmacokinetics and outlining phase appropriate bridging strategies during the drug development process. Before joining Janssen, he worked as senior research scientist in the field of virtual bioequivalence in the modeling and simulation (M&S) group at Certara UK, Simcyp Division. At Certara, he led the FDA awarded grant investigating the integration of formulation drug product quality attributes in dermal physiologically based pharmacokinetic models for topical/transdermal drug products and involved in the development of oral absorption module in the Simcyp simulator. His research interests include all aspects of biopharmaceutics with a focus on the application of M&S approaches. He received his PhD from National Institute of Pharmaceutics Education and Research (NIPER), SAS Nagar, India and was recipient of Endeavor Research Fellowship at University of Sydney and DAAD Scholar at Max Planck Institute of Polymer Research, Germany. He has published over 20 peer-reviewed manuscripts, more than 15 abstracts and two book chapters.

Hans Lennernäs, PhD
Professor, Biopharmaceutics
Uppsala University, Sweden

Dr. Hans Lennernäs is a professor of Biopharmaceutics at Uppsala University, Sweden since July 1, 2000, and he has been an adjunct professor of Biopharmaceutics at Copenhagen University, Denmark 2000-2012. His research objectives have been and are to develop novel strategies of tissue drug targeting and delivery that is expected to improve the clinical use and efficacy of drugs in various diseases, such as metabolic, endocrinological, and cancer diseases. He has been the Principal Investigator in an extensive collaboration with U.S. Food Drug & Administration, University of Michigan, USA, and Medical Product Agency, Sweden during 1992-2000 to develop the novel FDA regulatory guideline named the Biopharmaceutics Classification System.

He has established an extensive human pharmacokinetic database with jejunal permeability values for 45 drug compounds that today is widely used in academia and pharmaceutical industry. Dr. Lennernäs has been the chairman for numerous international conferences. He serves as reviewer for several scientific journals in clinical pharmacology and pharmaceutical science with a focus on drug delivery and pharmacokinetics. His work had led to more 245 peer-reviewed publications, 350 invited lectures, and more than 350 submitted presentations at scientific meetings. He is a well-cited author with more than 17,250 citations and a H-index of 64 (web of science). He has supervised 29 doctorial theses and acted as co-supervisor for two neurologists. He has obtained several national and international research grants such as Swedish Research Council, Swedish Cancer Society, and Innovative Medicine Initiative (EU). His research is currently supported by the Swedish Research Council (Sweden's largest governmental research organization) and Swedish Cancer Society (one of the largest financiers of cancer research in Sweden). Dr. Lennernäs has received Glaxo Wellcome Achievement Award 1997 and Annual Award from the Industrial Pharmacy Section 1998, Fédération Internationale Pharmaceutique (FIP), and an Honourable Mentions at EURAND AWARD 2000, been elected the AAPS Fellow 2004 and received the AAPS Meritorious Manuscript Award 2004, New Safe Medicine Faster Award 2008 and Hjärnäpplet (Innovation Award at Uppsala University) 2017. He received Lilly och Sven Thuréus Awards at Swedish Royal Society of Sciences at Uppsala in 2019 and Academy of Pharmaceutical Sciences (UK) Award (sponsored by AstraZeneca) in 2020 and Humboldt Research Award 2022. He has been the managing entity for an EU-grant from IMI (Innovative Medicine Initiative) of 24.5 MEuro during 2012-2018. He received the highest research rank after an external international evaluation at UU during 2011 (Quality and Renewal 2011).

Based on pharmacokinetic and pharmacodynamics principles, his research group has, during more than 25 years, been active in developing a local drug delivery strategy for treatment of localized prostate and urology cancer and primary liver cancer. Prototypes emerging from this research are currently evaluated in phase II clinical trials. He is the inventor of more than 22 drug delivery patents/patent applications. He is one of the innovators and developers of a novel sublingual drug delivery system currently used for the treatment of various acute pain conditions (Rapinyl®). He has also, together with co-inventors, initiated five other start-up companies. One company has developed a novel oral replacement therapy (Plenadren®) for Addison disease (approved by EMA 2011) and the second public company is developing a local drug product of localised prostate cancer, which is to enter phase III-trials. Another innovation was the basis for Empros Pharma in the therapeutic area of obesity and metabolic disease and a phase IIa study has been successfully completed. He has been on the board on several companies such as Aquilion AB, LIDDS AB, Recipharm Pharmaceutical AB, Nanologica AB, Empros Pharma AB, Canthera AB, Endoriz AB Sweden. His research is today focused on new treatment approaches for hepatocellular cancer, endocrinology, and various local gastrointestinal diseases. His research has a strong translational focus with innovation and development of novel drug combinations in innovative drug delivery systems.

André Dallmann, PhD
Scientist Systems Pharmacology & Bayer Science Fellow,
Pharmacometrics/Modeling & Simulation
Bayer AG, Germany

Dr. André Dallmann is a Scientist for Systems Pharmacology in the department of Pharmacometrics/Modeling & Simulation at Bayer, Germany. He completed his PhD with a focus on PBPK modeling in special populations at the University of Münster, Germany, in 2017. Thereafter, he joined the Pediatric Pharmacology & Pharmacometrics Research Center at the University Children's Hospital Basel, Switzerland, as a postdoctoral researcher before joining Bayer in 2018.

In his role as Scientist for Systems Pharmacology at Bayer, André develops and applies mechanistic models throughout the clinical development phase to quantitatively characterize drug candidates, e.g., with respect to their biopharmaceutical behavior and drug-drug-interaction risk.

André is principal investigator or "in kind" contributor in five grant programs in the European Union and the U.S. Together with various scientists across academia, industry, and regulatory agencies, he has co-authored more than 40 peer-reviewed articles and book chapters. Building on his scientific outreach and leadership, he has been elected as a Bayer Science Fellow in 2022.

Rodrigo Cristofoletti, PhD
Assistant Professor, Center for Pharmacometrics & Systems Pharmacology,
Department of Pharmaceutics
University of Florida

Dr. Rodrigo Cristofoletti is an Assistant Professor at the University of Florida (UF), Department of Pharmaceutics and the Associate Director of the Center for Pharmacometrics and Systems Pharmacology at the UF. Before joining the Gator Nation, he served as a Reviewer/Inspector in the Biopharmaceutics & Clinical Pharmacology Office of the Brazilian Health Regulatory Agency (Anvisa) for 15 years. He received his BS in Pharmaceutical Sciences from the University of Sao Paulo, Brazil in 2004. Dr. Cristofoletti received his PhD *summa cum laude* from the Johann Wolfgang Goethe University, Frankfurt am Main, Germany, under the supervision of Prof. Dr. Jennifer Dressman in 2017. He has also been a member of the Biopharmaceutics Classification System (BCS) and Biowaivers Focus Group which is part of the Special Interest Group on Regulatory Sciences of the International Pharmaceutical Federation (FIP). Dr. Cristofoletti's lab focuses on translational PK and molecular pharmaceutics. His research interests are developing organotypic models and microphysiological systems to model ADME in special populations (e.g., Down Syndrome, Cystic Fibrosis, Allan-Herndon-Dudley syndrome patients and others) and to investigate disease mechanisms affecting the gastrointestinal system (i.e., inflammatory and genetic diseases) and integrity of the biological barriers (i.e., leaky BBB and inflammatory diseases affecting the lung epithelium). His lab is also interested in applying PBPK and QSP modeling to inform drug development. Dr. Cristofoletti has published more than 65 peer-reviewed articles in highly respected journals in the pharmaceutical sciences arenas and he is co-editing a novel PBPK book to be released in Q1/24.

Raimar Löbenberg, PhD
Founder and Director, Drug Development and Innovation Centre
University of Alberta

Dr. Raimar Löbenberg holds a BS in Pharmacy from the Johannes Gutenberg-University in Mainz, Germany. He received his PhD in Pharmaceutics from the Johann Wolfgang Goethe-University in Frankfurt for his work in drug delivery using nanoparticles. He joined the University of Alberta in 2000.

His research interests are in Biopharmaceutics to predict the oral performance of drugs and botanicals and inhalable nanoparticles to treat lung diseases like lung cancer, tuberculosis. or leishmaniasis.

He is founder and director of the Drug Development and Innovation Centre at the University of Alberta. The center holds a Natural Health Product Site License and a Drug Establishment License. Dr. Löbenberg is the Head of the Quality Assurance department and the senior person in charge for cannabis, precursor and controlled substance licenses.

He was president of the Canadian Society for Pharmaceutical Sciences 2014-2015. He is a member and vice chair of the United States Pharmacopeia Dietary Supplement Expert Committee. He is vice chair of the Specialty Committee of Traditional Chinese Medicine in Pharmaceutics of the World Foundation of Chinese Medicine Science. He is a member of the Health Canada Scientific Advisory Committee on Pharmaceutical Sciences and Clinical Pharmacology. He is a member of the Health Canada Scientific Advisory Committee on Opiate Abuse.

Sivacharan Kollipara, MPharm
Team Lead, Biopharmaceutics
Dr. Reddy's Laboratories Ltd.

Dr. Sivacharan Kollipara is currently working as Team Lead, Biopharmaceutics in the Global Clinical Management group, IPDO, at Dr. Reddy's Laboratories Limited (DRL), Hyderabad. He is responsible for biopharmaceutics evaluation, bioequivalence risk assessment, and bioequivalence prediction for conventional as well as complex generic products at DRL. He is also involved in PK modeling and simulations activities supporting generic drug development of various immediate release, modified release, and complex products at DRL and involved in utilizing novel PBPK and PBBM modeling approaches for regulatory justifications for various markets. Prior to joining DRL, he was Principal Scientist (Global Pharmaceutical Development) at Novartis Healthcare Pvt Ltd., Hyderabad. Previously he also has been associated with Ranbaxy Research Laboratories, Gurgaon (Metabolism and Pharmacokinetics). Dr. Kollipara obtained his Masters in Pharmaceutical Sciences from BITS, Pilani, Rajasthan and is currently pursuing a PhD. Overall, he has 16 years of experience in the field of drug discovery, development and generic product development, bioanalytical method development and validation, PK data modelling and simulations. He has authored/co-authored ~ 20 peer-reviewed publications. His research interests include PBPK/PBBM modeling, virtual bioequivalence simulations, IVIVC/R, drug-drug interactions, dissolution/bioequivalence safe space, bio-predictive dissolution methodologies, biowaivers, and food effect evaluations.

David C. Sperry, PhD
Executive Director, Synthetic Molecule Design & Development
Eli Lilly and Company, Indianapolis, IN USA

Dr. David Sperry obtained a BS degree in Chemistry from Indiana University, Bloomington, IN and a PhD degree in Chemistry from the University of Rochester, Rochester, NY. After receiving his degree, he took a postdoctoral research scientist position at Pharmacia & Upjohn where he developed an Artificial Stomach Duodenum model and studied its utility in drug development. Shortly thereafter, he accepted a research scientist position at Pharmacia (later Pfizer), working in the area of in vitro methods and biopharmaceutics. He then moved to Bausch and Lomb where he developed commercial ophthalmic formulations for late-stage molecules. In 2007, Dr. Sperry joined Lilly Research Laboratories, where he created a group focusing on in vitro drug product performance techniques and predictions of in vivo performance. Computational modeling capability was later added to the group, to support the full range of predictive biopharmaceutics tools. He now supports product development by using existing and creating new experimental techniques and models to predict product performance and oral absorption of small molecule drug formulations.

Jean-Flaubert Nguefack, PhD
Head of Biopharmacy Section, Synthetics Platform, Global CMC Development
Sanofi R&D

Dr. Jean-Flaubert Nguefack received his PhD in Chemistry from the Université de Lyon-France and completed a post-doctoral position in the Buchwald Research Group at MIT around Titanium-catalyzed imines reduction. After spending ten years in the Sanofi Research area where held various leadership positions in medicinal chemistry, he joined the CMC department in 2013. As Biopharmacy scientist, he was responsible of the transfer, to Sanofi's Biopharmacy teams, of the various dissolution tools developed as part of the OrBiTo consortium and was involved in the early drug product development for four years. These last years, as Senior Biopharmacy Scientist, he was involved in the late-stage development of various drug products including Amcenestrant and Tolebrutinib.

Luiza Novaes Borges, PharmD
Health Surveillance and Regulation Specialist, Therapeutic Equivalence Department - CETER/GGMED
Brazilian Health Regulatory Agency (ANVISA)

Dr. Luiza Novaes Borges is a pharmacist (2011) with a specialization degree in clinical research from Harvard T.H. Chan School of Public Health (2016). Working with Regulatory Affairs since her graduation, she has been at Brazilian Health Regulatory Agency (ANVISA) since 2014. In the General Board of Medicines (GGMED), she has worked as reviewer of clinical and pre-clinical studies for NME (2014-18), and presently acts as reviewer of bioequivalence and DDI studies and as inspector of CROs.

She has participated in global regulatory harmonization initiatives, representing ANVISA in the International Council for Harmonisation (ICH) as expert in M12: Drug Interaction Studies and M4E(R2): Benefit-Risk Information working groups and in Center for Innovation and Regulatory Science (CIRS) initiatives on benefit-risk assessment and reliance pathways. Currently, she leads the initiatives in ANVISA regarding biopharmaceutical applications of physiologically based pharmacokinetic models (PBBM).

Min Li, PhD
Clinical Pharmacology Assessor, Division of Neuropsychiatric Pharmacology
OCP | OTS | CDER | FDA

Dr. Min Li is a clinical pharmacology reviewer in the Division of Neuropsychiatric Pharmacology, Office of Clinical Pharmacology, at FDA. She has been taking on this role since 2021, as a primary assessor supporting review neurology-related products submitted in investigational new drugs (INDs), new drug applications (NDAs), and biologic license applications (BLAs). Previously, she has served as a biopharmaceutics team leader at FDA for five years. Her experience covers both clinical pharmacology and biopharmaceutics, including pharmacokinetics/pharmacodynamics and exposure-response analyses, physiologically based pharmacokinetics (PBPK) modeling, and in vitro in vivo correlation (IVIVC). Dr. Li received her PhD in Pharmaceutical Science in 2013 from Virginia Commonwealth University. She also holds a Bachelor's degree in Pharmacy and Master's degree in Medicinal Chemistry.

Duxin Sun, PhD
Associate Dean for Research, College of Pharmacy
Charles Walgreen Jr. Professor of Pharmacy
Professor of Pharmaceutical Sciences
The University of Michigan

Dr. Duxin Sun is the Associate Dean for Research in the College of Pharmacy at the University of Michigan. He is the Charles Walgreen Jr. Professor of Pharmacy and Professor of Pharmaceutical Sciences and serves as the Director of the Pharmacokinetics (PK) Core. Dr. Sun also has a joint appointment in the Chemical Biology program, the Interdisciplinary Medicinal Chemistry program, and University of Michigan's Comprehensive Cancer Center.

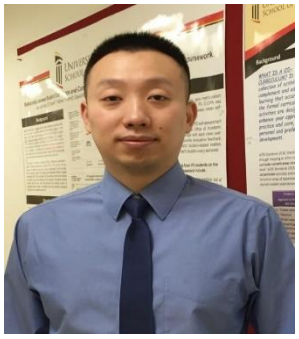
His research interests focus on drug development, nanomedicine, and pharmacokinetics. Dr. Sun developed the STAR system (Structure-Tissue/Cell Selectivity-Activity-Relationship) to address the 90% failure rate in drug development and enhance its success. He also proposed a drug/nanocarrier-specific anticancer nanomedicine design strategy to enhance clinical efficacy and improve clinical success rates. Dr. Sun earned his BS in Pharmacy, MS in Pharmacology, and PhD in Pharmaceutical Sciences, and has also received training in Molecular Biology as a visiting scientist. With research experience in both academia and the pharmaceutical industry, Dr. Sun has published over 260 papers and has mentored 37 PhD students and 70 postdoctoral fellows/visiting scientists.

Dr. Sun is an elected Fellow of both the American Association for the Advancement of Science (AAAS) and the American Association of Pharmaceutical Scientists (AAPS). He has served on the FDA Pharmaceutical Science and Clinical Pharmacology Advisory Committee and participated in study sections for the NIH and FDA.

Sherin Thomas, PhD
Pharmacologist, Division of Quantitative Methods and Modeling
OGD | CDER | FDA

Dr. Sherin Thomas earned her MS in Pharmacology from New York Medical College and PhD in Pharmaceutical Sciences from University of Maryland Baltimore where her research work focused on transdermal pharmacokinetics and in vitro-in vivo correlations. She joined the Division of Quantitative Methods and Modeling at FDA in 2020 where she contributes to regulatory and research projects involving population pharmacokinetic modeling and physiologically based pharmacokinetic modeling focused on bioequivalence and in vitro-in vivo correlations.

Yunming Xu, PharmD
ORISE Postdoc Fellow, Division of Biopharmaceutics
ONDP | OPQ | CDER | FDA



Dr. Yunming Xu is an ORISE Research Fellow in the Division of Biopharmaceutics in the Office of New Drug Products (ONDP) within the Office of Pharmaceutical Quality (OPQ) at the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). His work primarily revolves around Physiologically-Based Biopharmaceutics Modeling (PBBM) for BCS Class II drugs, a critical field in the development of safe and effective medications. Since 2022, he has provided his expertise to the PBPK committee in the Division of Biopharmaceutics, addressing challenges in modeling dissolution and absorption. Yunming earned his PharmD and a Master's degree in Pharmacometrics from the University of Maryland School of Pharmacy.

Andrew Babiskin, PhD
Lead Chemist, Division of Quantitative Methods and Modeling (DQMM)
ORS | OGD | CDER | FDA

Dr. Andrew Babiskin is a Lead Chemist in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs, CDER. He previously managed the Locally-acting Physiologically Based Pharmacokinetic Modeling Team in DQMM for five years and now manages the Quantitative Clinical Pharmacology Team in DQMM. His expertise lies in modernization of bioequivalence evaluation practices through model-integrated evidence. Dr. Babiskin received his BS degree from the University of Maryland (College Park) in Chemical Engineering and his MS and PhD degrees from the California Institute of Technology in Chemical Engineering. He joined the FDA in 2012 as an ORISE postdoctoral fellow in the OGD Science Staff (now ORS) and became an employee within DQMM in 2014.

Christian Wagner, PhD
Scientific Director
Global Healthcare Operations, Global CMC Development
Merck Healthcare KGaA, Darmstadt, Germany

Dr. Christian Wagner joined Merck Healthcare KGaA, Darmstadt, Germany, as preformulation lab head/Principal Scientist in 2015. In 2017, he was promoted and heads the CoE Translational Biopharmaceutics since then. Within this position, Christian and his team are accountable for the biopharmaceutical evaluation of Merck's NCE pipeline in Drug Discovery and Development. The focus is guiding form and formulation selection (Discovery), and prediction of drug absorption, (re-)formulation effects, as well as food and PPI effects (Discovery).

Christian received his license to practice as a pharmacist from the State of Hesse (Germany) in 2009. In 2013, he received a PhD from the Goethe University in Frankfurt/Main (Germany) (Jennifer Dressman's lab).

Upon completion of his PhD, Christian joined FDA's Office of Clinical Pharmacology in Silver Spring, MD (USA) as a postdoctoral researcher in 2013. As part of his research, he applied PBPK modeling to predict the impact of intrinsic (hepatic impairment) and extrinsic (CYP3A-based drug-drug interactions) factors on the pharmacokinetics of antiretroviral drugs.

Christian published over 25 peer-reviewed publications and book chapters and is active in various IQ working groups.

Øyvind Holte, PharmD
Scientific Officer
Norwegian Medicines Agency

Dr. Øyvind Holte has been a Quality assessor at the Norwegian Medicines Agency for more than 15 years. He has been involved in the assessment of numerous applications for marketing authorisation, post-approval variations, clinical trials, and scientific advice procedures for chemicals (small molecules) covering a range of formulations. In addition, he is an assessor of bioequivalence, and was involved in the assessment of several applications for generic and biosimilar drug products. In the Quality area, he has specialised in Process analytical technology (PAT) and Quality by Design, and is currently chair of the EDQM PAT working party.

D. Claire Mackie, PhD
Scientific Director, Biopharmaceutics group
Janssen Pharmaceutical Companies of Johnson & Johnson

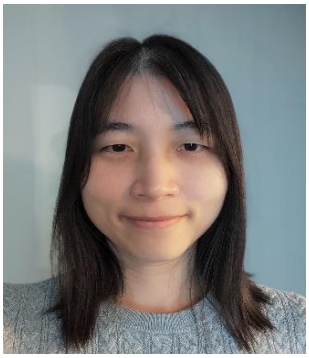
Dr. D. Claire Mackie is a scientific director within the Biopharmaceutics group at The Janssen Pharmaceutical Companies of Johnson & Johnson. Her key responsibilities include co-leading the Biopharmaceutics team, providing end to end biopharmaceutics project input and strategic direction, and leading the Biopharmaceutics Expert Team, a cross functional team including API, dissolution sciences, CMC Regulatory Affairs and Clinical Pharmacology, providing biopharmaceutics input and strategic governance across all synthetics projects from late Discovery through Life Cycle management. She has more than 30 years' experience in the Pharmaceutical industry from five different companies, Discovery through to Launch, with a focus on DMPK and CMC. Her research interests include human PK predictions using M&S approaches, pediatric, and geriatric/elderly population biopharmaceutics.

She received her PhD from Kings College London and has published more than 40 peer reviewed papers, > 30 abstracts and one book chapter.

Mary Malamatari, PhD
Clinical Pharmacology Assessor
Innovative Medicines, MHRA

Dr. Mary Malamatari is a Clinical Pharmacology Assessor at the MHRA. She obtained her undergraduate degree from the Aristotle University of Thessaloniki (MPharm, 2012). From 2012 to 2016, she carried out her PhD in the Centre for Doctoral Training in Targeted Therapeutics and Formulation Sciences at UCL. From 2016 to 2017, she worked as a research associate in pharmaceutical co-crystallisation processes at the University of Greenwich. Prior to becoming a Clinical Pharmacology Assessor, between 2018 and 2022, she worked as a Pharmaceutical Assessor at the MHRA focusing on quality of drug substances and drug products.

Yi-Hsien Cheng, PhD
Pharmaceutical Scientist (Contractor
DQMM |ORS | OGD | CDER | FDA



Dr. Yi-Hsien Cheng is currently working as a pharmaceutical scientist (contractor) at the Division of Quantitative Methods and Modeling (DQMM) within the Office of Research and Standards (ORS), Office of Generic Drugs (OGD) at FDA. She received her PhD degree in Bioenvironmental Systems Engineering from National Taiwan University, Taiwan in 2013, where she completed her first postdoctoral fellowship. Before joining FDA in 2021, she completed her second postdoctoral fellowship in the Institute of Computational Comparative Medicine (ICCM) at Kansas State University. Dr. Cheng is currently working on applying physiologically based pharmacokinetic (PBPK) modeling and simulation approaches to evaluate bioequivalence (BE) for different oral drug products at Oral PBPK Team in DQMM. Her research interests include implementing PBPK modeling and virtual BE simulations to evaluate the sensitivity of using parent vs. metabolite as analytes on BE assessment, food-formulation impact on fed BE studies, alcohol dose dumping effect on BE results, as well as single-sex impact on BE evaluation.

Sandra Suarez-Sharp, PhD
Vice President of Regulatory Affairs
Simulations Plus

Dr. Sandra Suarez-Sharp completed her undergraduate studies in Industrial Pharmaceutical Chemistry at the National Polytechnic Institute of Mexico City. Following her graduation, she gained practical experience working at Johnson and Johnson in Mexico. In 1997, she obtained her PhD in Pharmaceutical Sciences from the University of Florida and later conducted postdoctoral research on Pulmonary Drug Delivery and Pharmacokinetics at Chapel Hill University in North Carolina.

In 1999, Dr. Suarez-Sharp began her tenure at the U.S. Food and Drug Administration (FDA), specifically within the Office of Clinical Pharmacology (OCP). For a decade, she served as a primary and secondary reviewer, providing support to multiple therapeutics divisions. She also worked as a reviewer in the Office of Generic Products, Division of Bioequivalence. Over time, she transitioned into the roles of Master Reviewer and Scientific Advisor within the Division of Biopharmaceutics, Office of Product Quality. Her expertise spanned several areas, including in vitro-in vivo correlation, biowaivers, real-time release testing (RTRT) dissolution models, and physiologically based biopharmaceutics modeling (PBBM). During her tenure at the FDA, Dr. Suarez-Sharp actively contributed to the development of various industry guidance documents, with notable contributions to "The Use of Physiologically Based Pharmacokinetic Analyses — Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls (PBBM)" published in October 2020. She also represented the FDA at national and international scientific events.

In March 2020, Dr. Suarez-Sharp joined Simulations Plus as the Vice President of Regulatory Affairs. In this capacity, she leads a team of experienced professionals who have been extensively involved in drug development within regulatory, large pharmaceutical, biotech, and contract research organization (CRO) settings. The team leverages cutting-edge modeling and simulation techniques to enhance strategic planning, expedite decision-making processes, and implement meticulous risk mitigation strategies.

Dr. Suarez-Sharp has made substantial contributions to the field and has an extensive publication record in areas such as dissolution, in vitro-in vivo correlations, the establishment of drug product specifications with clinical relevance, and physiologically-based biopharmaceutics modeling (PBBM). Her work has advanced the fields of pharmaceutical sciences and regulatory practices.

Greg Rullo, MS
Executive Director, CMC Regulatory Innovation
AstraZeneca

Greg Rullo is an Executive Director of CMC Regulatory Innovation at AstraZeneca and has a wide range of experience in the strategic and tactical aspects of pharmaceutical drug development and global regulatory CMC requirements. His duties include leadership in the use of modeling such as Physiological Based Biopharmaceutical Models, Machine Learning, and AI. He is also leading a document to data transition within CMC RA including delivery of future data centric submissions such as PQ/CMC. He has extensive regulatory knowledge/experience of global CMC requirements with a detailed understanding of submission requirements in Brazil. He has direct experience with Health Authorities meetings throughout the world including FDA, EU health authorities, ANVISA, Health Canada, and Chinese authorities.

Shinichi Kijima, MSc
Associate Senior Scientist for Clinical Pharmacology and Pharmacokinetics
Office of New Drug V/Office of New Drug IV
Pharmaceuticals and Medical Devices Agency (PMDA)

Shinichi Kijima is Associate Senior Scientist for Clinical Pharmacology and Pharmacokinetics in PMDA, Japan. After graduating from Meiji Pharmaceutical University, since 2009, he has reviewed the pharmacokinetics, clinical pharmacology and pharmacometrics of new drugs. From 2016 to 2017, he worked as an ORISE Fellow for Division of Pharmacometrics, OCP/OTS/CDER/FDA. In PMDA, he is lead pharmacometrician of Modeling and Simulation project team. He contributed to development of Japanese pharmacometrics related guideline including PBPK guideline, Exposure-Response guideline and Population approach guideline published by the Ministry of Health, Labour and Welfare (MHLW), Japan. He was the leader on developing of the Japanese PBPK guideline in PMDA.

Cordula Stillhart, PhD
Senior Principal Scientist, Biopharmaceutics
F. Hoffmann-La Roche Ltd

Dr. Cordula Stillhart is a Senior Principal Scientist in Biopharmaceutics at F. Hoffmann-La Roche Ltd. She is currently leading the biopharmaceutics squad in formulation R&D and co-chairing the global biopharmaceutics working group at Roche. Cordula joined Roche as a biopharmaceutical scientist in 2013. In this role she is responsible for the biopharmaceutical characterization of oral drug formulations to guide formulation strategy selection, defining formulation bridging strategies, and supporting the definition of clinically-relevant drug product specifications. She has broad experience in the development and application of biopharmaceutics in vitro tools and physiologically-based biopharmaceutics modelling. She is currently involved in two Marie Skłodowska Curie funded European Consortia (InPharma and AGePOP) and is co-supervising four PhD students and two Postdocs. Cordula studied pharmacy at the University of Basel (Switzerland) and was a research scientist at the University of Applied Sciences and Arts Northwestern Switzerland before obtaining her PhD from the University of Basel.

Nikoletta Fotaki, Pharmacist, MSc, PhD, FAAPS
Professor of Biopharmaceutics
Centre of Therapeutic Innovation (CTI), Department of Life Sciences
University of Bath, UK

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 90 peer reviewed publications, one book, ten book chapters, 87 published conference contributions, and two 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.

Shereeni Veerasingham, MBBS, PhD
Acting Manager, Pharmaceutical Drugs Directorate/Health Products and Food Branch
Health Canada, Government of Canada

Dr. Shereeni Veerasingham is the Acting Manager, Division of Biopharmaceutics Evaluation 3 (DBE3) at the Bureau of Pharmaceutical Sciences, Health Canada. DBE3 is a pilot team that focuses on complex and evolving areas of biopharmaceutics, including physiologically based biopharmaceutics modelling (PBBM). Shereeni's expertise includes pharmacokinetics, comparative bioavailability, and biowaivers. Over the past 18 years, she has been involved in the development of many Health Canada policies related to biopharmaceutics and has served as Health Canada's Topic Leader on the ICH Biopharmaceutics Classification System-based biowaivers (M9) Expert Working Group. Shereeni obtained her Doctorate degree (PhD) with specialization in Pharmacology from the University of Ottawa, Ontario (2001), and her Degree in Medicine (MBBS) from the University of Ibadan, Nigeria (1990).

Tycho Heimbach, PhD, FAAPS
Senior Principal Scientist
Merck Research Laboratories

Dr. Tycho Heimbach is a Senior Principal Scientist at Merck in the Biologics Development and Biopharmaceutics Group which is part of the Sterile and Specialty Products Group. There he serves as a biopharmaceutics and PBBM/PBPK expert in oral and long-acting injectables drug development, which includes establishing the bioequivalence safe space of new drug candidates. Prior to that, Tycho was Director in DMPK at Novartis where he led a global PBPK modeling group and served as PBPK and biopharmaceutics expert and implemented PBPK/PBBM for oncology drugs.

Tycho served as cochair on working groups for the PBPK Modeling and the PBPK renal and hepatic impairment WG and the PBBM WG for the Innovation and Quality in Pharmaceutical Development (IQ) consortium. He is currently serving as the Merck representative on the PBBM Innovation & Quality (IQ) Consortium Working Group.

Dr. Heimbach has been a speaker at 50 national and international conferences. He has authored/coauthored ~65 peer-reviewed publications in ADME, PBPK, and formulation sciences and was recognized as an AAPS Fellow in 2021.

Xavier Pepin, PharmD, PhD
Associate VP Regulatory Affairs
SimulationsPlus

Dr. Xavier Pepin is a pharmacist (University Paris XI). He has a PhD 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 preformulation, 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 SimulationsPlus in May 2022 and supports 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.

Hiroyuki Tsuji, MS
Principal Reviewer, Office of New Drug
Pharmaceuticals and Medical Devices Agency (PMDA)

Hiroyuki Tsuji is a principal reviewer in the Office of New Drug at the Pharmaceuticals and Medical Devices Agency (PMDA). After several years of working in pharmaceutical companies, focusing on formulation development and analytical research, he moved to the PMDA in 2014. Since joining at PMDA, he has been reviewing the CMC part of new drugs about four years, and he has been participating in an advisory capacity on a Modeling and Simulation project team about two years.

Lanyan (Lucy) Fang, PhD
Deputy Director
DQMM | ORS | OGD | CDER | FDA

Dr. Lanyan (Lucy) Fang serves as Deputy Director of the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs (OGD), CDER/FDA. Since joining OGD in 2014, Lucy has held roles of increased responsibilities, Team Lead of the Quantitative Clinical Pharmacology team, Associate Director, and Deputy Director within DQMM. She has established herself as the FDA expert in the use of quantitative clinical pharmacology approaches in the review and regulation of generic drugs. She co-leads CDER work group tasked with the use of partial area under the curve for the bioequivalence assessment. Prior to her OGD career, Lucy worked as senior clinical pharmacology reviewer in the FDA's Office of Clinical Pharmacology and senior pharmacokineticist in Merck. Lucy obtained her PhD in Pharmaceutical Sciences from The Ohio State University and is a graduate of the Excellence in Government Fellows program (2014-2015).

Maitri Sanghavi, MS
Research Scientist
SIMCYP, Certara

With the strong academic background, Maitri Sanghavi holds an MS degree in Pharmaceutical Sciences from the National Institute of Pharmaceutical Education and Research (NIPER), Mohali, Punjab, India. With an overall experience of ~10 years in the pharma sector which included stints in organizations such as Dr Reddy's and Zydus Lifesciences, Maitri has proven expertise in Biopharmaceutics, Modelling & Simulation and Clinical development. Her work in pharmaceutical industries solidified her interest in Physiologically Based Biopharmaceutic (PBBM) Modelling. Maitri Sanghavi has recently joined Certara UK Limited (Simcyp Division) as a Research Scientist, to further pursue her interest in Mechanistic Modelling. Her expertise includes evaluation of predictive in vitro methodologies, formulation optimization, bioequivalence studies, IVIVC/IVIVR, virtual bioequivalence, and assessment of food effects. She also contributes to PBPK modeling in regulatory submissions. She has published research in this domain. Her extensive experience in this field has facilitated multiple PBPK/PBBM applications by guiding pharmaceutical scientists to improve the decision-making process during various stages of drug development. She also has experience of clinical execution of BABE studies, responding to regulatory queries, suggesting alternative BE approaches, biowaiver, animal healthcare product development, and 505b2 projects.

Grace Chen, PhD
Senior Scientific Director, Quantitative Clinical Pharmacology
Takeda Pharmaceuticals

Dr. Grace Chen has over 23 years of pharmaceutical research, development and health economic outcome research (HEOR) experiences in pharmacokinetics (PK), pharmacodynamics (PD), modeling and simulation (M&S), budget impact analysis, and value base contract analysis, spanning from lead identification, preclinical and clinical development, regulatory submissions, life-cycle management, and real world evidence generation and analysis across a variety of therapeutic areas (CNS, GI, immunology, CVM, ant-infectives and rare disease). As a Clinical Pharmacology lead, Dr. Chen has played a key role in the clinical development, regulatory submissions and approvals of multiple small molecules and biologics. She has published >40 peer-reviewed manuscripts and abstracts. Dr. Chen received her PhD in Pharmaceutical Sciences from The Ohio State University.

Michael H. Wang, MS
Associate Principal Scientist
Merck Research Laboratories. Merck & Co., Inc.

Michael Wang works in Biopharmaceutics group of Merck Research Laboratories. His work focus is on support of drug development using in vitro biorelevant dissolution models, in vivo preclinical models as well as simulation based on Physiologically Based Biopharmaceutics Model (PBBM). He obtained his MS degree from University of Minnesota and has been working at Merck with more than a couple of decades of pharmaceutical industrial experience in drug development.

Tzuchi "Rob" Ju, PhD
Director Drug Release and Product Performance group
AbbVie Inc.

Dr. Tzuchi Ju is recognized for his in-depth knowledge and experiences in both formulation and dissolution method development, as his teams were directly responsible for the formulation development of seven NDAs and dissolution method development of six NDAs. He is a Director at AbbVie where he established and leads the Drug Release and Product Performance group with focuses on in silico modelling, biopharmaceutics tools, and cross-functional alignment. Dr. Ju has extensive interactions with global regulators on the evolving and somewhat divergent reequipments of dissolution related to discrimination, biowaiver, safe space, IVIVC (two approved IVIVCs), and PBPK/PBBM modelling (two approved PBPK models). He has expertise in biopharmaceutics, in silico modelling, various modified release formulations, pediatric formulations, amorphous solid dispersion, and FDC technologies for challenging molecules. Patents filings and litigation. He has experience with eye care products (implants and eye drops) and high-concentration biologics. Broad-based understanding of drug product development including knowledge management, clinical supplies, risk assessment, compliance, and regulatory functions. Dr. Ju founded the Pediatric Working Group and chaired the Drug Product Leadership Group of IQ Consortium. He was inducted to the prestigious Vowiler Society within AbbVie, sat on the Scientific and Education Board of NIPTE, and an Adjunct Professor of Roosevelt University. In leisure, Rob enjoys coaching sport teams, working out in the gym, and reading.

Manuela L. T. Grimstein, PhD, MSc
Scientific Lead, PBPK Team, Division of Pharmacometrics
OCP | CDER | FDA

Dr. Manuela Grimstein currently serves as the Scientific Lead for the Physiologically-based Pharmacokinetics (PBPK) Team in the Division of Pharmacometrics (DPM), Office of Clinical Pharmacology (OCP) at U.S. Food and Drug Administration (FDA). She has over 10 years of regulatory experience, as a Post-doctoral Fellow, Clinical Pharmacology Reviewer and Pharmacometrics/PBPK Reviewer, supporting drug review across a wide range of therapeutic areas. She has published over 20 peer-reviewed scientific articles and represented OCP/DPM on several guidance working groups and research programs. Her research interest focuses on application of PBPK modeling to advance drug development for pediatrics and pregnant women. Dr. Grimstein received her PhD degree in Pharmaceutical Sciences from the University of Florida in 2011.

Flora Musuamba, PhD
Pharmacometrics and Pharmacovigilance Internal Expert
Belgian Federal Medicines Agency (FAMHP)

Dr. Flora Musuamba holds a PhD in Pharmacy and Biomedical Sciences from Université Catholique de Louvain, in Belgium. She is a Pharmacometrics and Pharmacovigilance internal expert at the Belgian Federal Medicines Agency (FAMHP). She is currently a member of the EMA scientific advice working party (SAWP) and the newly established methodology working party (MWP) at the European Medicines Agency (EMA). She is also Associate Professor of Clinical Pharmacology at University of Namur and University of Lubumbashi.

Megerle Scherholz, PhD
Principal Scientist, Drug Delivery Product Integration
Drug Product Development
Bristol Myers Squibb

Dr. Meg Scherholz started her career at BMS in Drug Product Development where she first supported late-stage formulation for oral solid dosage forms before earning her PhD at Rutgers University in Chemical Engineering through the BMS Doctoral Fellowship. Her graduate research focused on personalized medicine through systems biology and QSP modeling. Upon returning to BMS in 2019, she began supporting biopharmaceutics for early and late stage OSD development and currently leads a cross-functional team supporting biopharmaceutics for cardiovascular, neuroscience, and fibrosis assets. She also holds a MS from Penn State University and BS from Rowan University both in Chemical Engineering.

Tessa Carducci, PhD
Principal Scientist, Analytical Commercialization Technology (ACT)
Merck & Co.

Dr. Tessa Carducci is a Principal Scientist at Merck & Co. based in Rahway, NJ working in the Analytical Commercialization Technology department. She graduated with a BS in Chemistry and minor in Psychology from Duke University and a PhD in Analytical Chemistry from UNC-Chapel Hill. At Merck, Tessa has supported PBBM efforts, worked on real time release strategy development, and pioneered predictive dissolution modeling for release for a new drug product. She also enjoys pursuing novel analytical techniques for commercialization of drug products as well as innovative regulatory filing strategies. Outside of work Tessa enjoys city life with her husband, taking care of her dog, skiing and snowboarding, traveling, and trying new foods.

Paul Seo, PhD
Policy Lead
OCP | CDER | FDA

Dr. Paul Seo received his BS in Biochemistry from the University of Maryland at College Park in 1999. Shortly thereafter, he received his PhD in Pharmaceutical Sciences in 2004, from the University of Maryland, Baltimore. Paul has worked for the FDA for over 19 years. Upon joining the Agency, he spent five years in the Office of Generic Drugs, where he served as bioequivalence team leader and dissolution specialist. After his time at OGD, he also served as the lead for the Compendial Operations and Standards and Technology Team in CDER in the Office of Pharmaceutical Science. In this capacity, he was responsible for overseeing all activities as they related to the United States Pharmacopeial Convention as well as other standards setting organizations. In 2014, Paul joined the Office of New Drug Quality Assessment as lead of the Biopharmaceutics Staff. With the reorganization to the Office of Pharmaceutical Quality, he helped stand up the Division of Biopharmaceutics serving as the Division Director. In this capacity, he helped provide leadership in standing up the CDER Biopharmaceutics Council, publication of FDA's PBBM Guidance, and ICH M9: Biowaivers Based on the Biopharmaceutics Classification System. Currently, he serves as a Policy Lead in the Office of Clinical Pharmacology. Additionally, his professional experience included time at the National Institute of Standards and Technology, Shire Labs, Inc., and the Walter Reed Army Institute of Research.

Viera Lukacova, PhD
Chief Scientist
Simulations Plus, Inc.

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.

Erik Sjögren, PhD, Assoc. Prof.
Principal Consultant and PBPK-QSP Platform Scientific Lead
Pharmetheus, Uppsala, Sweden

Associate Professor in Biopharmaceutics at the Department of Pharmaceutical Biosciences
Uppsala University, Sweden

Dr. Erik Sjögren is a principal consultant and the PBPK-QSP platform scientific lead at Pharmetheus, focused on model informed drug development and strategies for application of physiologically based pharmacokinetics (PBPK), quantitative system pharmacology (QSP), and biopharmaceutics modelling. As Associate Professor at the Department of Pharmaceutical Biosciences, Uppsala University, his research involves PBPK and QSP as well as drug absorption, pharmaceutical formulations, and drug delivery. He has published over 50 articles in peer-reviewed journals. In addition, he tutors courses, supervises students, and contributes to scientific networks and meetings. He acts as Pharmetheus' and Uppsala University's representative in the Management Team of the Open System Pharmacology (OSP).

Evangelos Ch. Kotzagiorgis, MSc
Pharmaceutical Quality Senior Specialist, Pharmaceutical Quality Office,
Quality and Safety of Medicines Department
European Medicines Agency (EMA)

Evangelos is a Qualified Pharmacist and has got a MSc on Pharmaceutical Analysis and Quality Control from the University of Athens, Greece.

He joined the European Medicines Agency (EMA) in 2005. Currently he works as Quality Senior Specialist in the Quality of Medicines Office providing scientific support in the evaluation of new products, and in Scientific Advice requests. Evangelos is also involved in the work of the EMA Quality Working Party and Biologics Working Party and in the development of scientific guidelines.

He has been involved in the implementation of several regulatory initiatives e.g., ICMRA collaborative assessment, revision of the Variation Regulation, cooperation with WHO and African regulators.

He previously worked in the industry as Head Officer of Patent Information and Clinical Studies and in the R&D department of Pharmathen Pharmaceuticals SA and gained experience in pharmaceutical development, manufacturing, and quality control.

David Turner, PhD
Senior Principal Scientist
Simcyp Division, Certara

Dr. David B. Turner is a Senior Principal Scientist at Certara (Simcyp Division) having joined Simcyp in 2004. He is author or co-author on more than 40 peer-reviewed papers. His work at Simcyp has mainly focussed upon oral absorption modelling, for which he is the lead scientist, but also on physico-chemical aspects of PBPK modelling including tissue distribution and a variety of QSAR models. David was the PI for a recently completed FDA grant to develop modelling tools for handling supersaturating drug products and is currently co-PI on a second FDA grant focussed on BE of locally acting oral drugs. He has a Biochemistry BSc, a Computer Science MSc, and a PhD in Chemoinformatics and QSAR modelling all obtained at Sheffield University, UK. Prior to joining Simcyp, he worked in a Computational Chemistry Group (Synt:em SA, Nîmes, France) focussed on high throughput in silico discovery and virtual screening projects.

Ivy Song, PhD
Senior Director, Quantitative Clinical Pharmacology
Takeda Pharmaceuticals

Dr. Ivy Song has over 20 years of experience in Clinical Pharmacology and Drug Development. Currently she is a Senior Director leading a group of seasoned scientists supporting the Marketed Product Development portfolio at Takeda. Prior to Takeda, she worked at Shire, GlaxoSmithKline, and Quintiles (now IQVIA). She has extensive regulatory submission experience across multiple therapeutics areas, different modalities, and various regions. She has a strong interest in applying quantitative solutions in drug development, especially in pediatrics. Dr. Song completed her PhD in Pharmacokinetics at the University of Minnesota Twin Cities and her BS in Pharmaceutical Chemistry at Beijing Medical University.

Rebecca Moody, PhD
Biopharmaceutics Reviewer
DB | ONDP | OPQ | CDER | FDA

Dr. Rebecca Moody is a Biopharmaceutics Reviewer in the Division of Biopharmaceutics (DB), Office of New Drug Products (ONDP), Office of Pharmaceutical Quality (OPQ) at the FDA. Dr. Moody received a Bachelor of Science in Biology and Chemistry from Emory University, and a PhD in Chemical Biology from the University of Michigan. She evaluates biopharmaceutics and quality information (e.g., in vivo biowaivers, in vitro dissolution method development, etc.) in New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Investigational New Drug Applications (INDs). In addition, Dr. Moody serves as a scientific lead for physiologically based biopharmaceutics modeling (PBBM) in the DB Modeling and Simulation Committee.

Xiaojun Ren, MPH
Associate Director, Clinical PBPK Modeling
Novartis Pharmaceutical Company

Xiaojun Ren is an Associate Director of the Clinical PBPK Modeling group at Novartis Pharmaceutical Company. He has more than 25 years of experience in the pharmaceutical industry in the areas of DMPK and PBPK modeling. In his current role at Novartis, he supports biopharmaceutical development, DDI, and special population studies. He is the co-chair of BPEG (Biopharmaceutical expert group) at Novartis, where project development, risk mitigation, and regulatory strategies are aligned across Line Functions of TRD (Technical & Research Development) and PKS (PK Sciences). Xiaojun has a background in Chemical Engineering and received a Master of Public Health, industrial toxicology track, at Columbia University. Xiaojun worked in the Department of Pharmacology at Columbia University for four years conducting research focusing on neuro-degenerate diseases.

Zhuojun Joan Zhao, PhD
Senior Pharmacologist
DB | ONDP | OPQ | CDER | FDA

Dr. Zhuojun Joan Zhao is a Senior Pharmacologist in the Division of Biopharmaceutics, ONDP, OPQ in CDER since 2015. Dr. Zhao supports biopharmaceutical reviews of CDER's IND, NDA, and ANDA submissions as well as biopharmaceutical consults for combination product submissions to CDRH. Prior to joining Division of Biopharmaceutics, Dr. Zhao was a senior bioequivalence reviewer in Office of Generic Drugs (OGD). In addition, she worked as a patent attorney in Shanghai Patent and Trademark Law Office. Dr. Zhao received her PhD in Pharmaceutical Sciences from the Ohio State University and BE in Biochemical Engineering from East China University of Science and Technology.

Mario Cano Vega, PhD
Process Development Senior Scientist, Oral & Enabling Delivery Systems
Amgen

Dr. Mario Cano Vega joined Amgen as a Process Development Sr Scientist in the Oral & Enabling Delivery Systems group where he supports formulation development for oral FIH studies and is an active collaborator in the development of physiologically based pharmacokinetic models.

Prior to joining Amgen in 2020, Mario received a Bachelor of Pharmacy with honors from the National University of Mexico, and a doctorate in Agricultural and Biological Engineering from Purdue University where his research focused on the development of novel polymer-based formulations for controlled release of drugs for the treatment of obesity and modular dosage forms for personalized medicine.

Nikunjkumar (Nikunj) Patel, PhD
Senior Director of PBPK Consultancy Services
Certara Inc.

Dr. Nikunjkumar Patel is a Senior Director of PBPK Consultancy Services in the Simcyp division of Certara. Dr. Patel partners with Pharma companies to employ advanced PBPK modeling approaches to expedite internal decision making, support biowaivers via virtual bioequivalence assessments, develop model-informed regulatory strategies for novel products, generic formulations, scale-up and post-approval changes (SUPAC), and set dissolution specifications. He has more than 15 years' experience in computer-aided drug design and PKPD modeling, including 12+ years' experience focusing on PBPK modeling.

Rajendra Singh, PhD
Head, Pharmacometrics at Quantitative Pharmacology and Biosimilars Department
Teva Pharmaceuticals

Dr. Rajendra Singh is currently working as Head, Pharmacometrics at Quantitative Pharmacology and Biosimilars Department of Teva Pharmaceuticals. He received his Bachelor and Masters in Pharmacy (Pharmaceutics) degree from India. Dr. Singh received his PhD from Central Drug Research Institute in India with specialization in Pharmacokinetics of Antimalarial drugs. Dr Singh also completed a three year post-doctoral training at University of Florida from 2008-2011 where he specialized in population pharmacokinetic/pharmacodynamic, exposure response and Physiological based Pharmacokinetic (PBPK) modeling. Before joining Teva, he worked as Director, Clinical Pharmacology Modeling and Simulation at GlaxoSmithKline.

At Teva, he primarily supports Neuroscience and Immuno inflammation-Oncology therapeutic area and applies clinical pharmacology and pharmacometric skills to help in decision making. In addition, he also worked in cross functional teams and supported Biosimilars and Generic portfolio. He supports clinical programs in both early and late phases of development and provides input for dose selection, drug-drug interactions, and study design using PK-PD and translational principles.

Siri Kalyan Chirumamilla, MS
Senior Research Scientist
Certara UK Limited (Simcyp Division)

Siri Kalyan Chirumamilla is a Senior Research Scientist at Certara UK Limited (Simcyp Division) with a focus on absorption modelling of oral drug products. He was the lead for Expansion of IVIVC project and Virtual Bioequivalence (VBE) projects. He is currently leading the Oral absorption project. Prior to joining Simcyp in 2018, he worked for about five years as a Formulation Scientist, responsible for developing Oral drug products for ANDA and 505b2 applications in Dr. Reddy's Laboratories. He received his Master's degree from National Institute of Pharmaceutical Education and Research (NIPER S.A.S Nagar), India.
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Martin Hingle, PhD
Associate Director, Early Phase Product Development
Novartis Pharmaceuticals AG

Dr. Martin Hingle is an Associate Director of the Early Phase Product Development group at Novartis Pharmaceuticals AG. In his current role, he leads the biopharmaceutics group supporting formulation development across all dosing routes and is responsible for guiding biopharmaceutics risk assessments and characterization, PBBM, bridging strategies, biowaivers and supporting clinically relevant drug product specifications. He has previously held various positions at Elan Biotechnology Research and GSK within physical properties, oral and inhaled formulation development, predictive technologies and Biopharmaceutics. Martin participates in consortia IQ and AgePOP and is co-supervising two PhD students and a Postdoc. Martin studied Pharmaceutical Science at the University of Greenwich and obtained his PhD from the University of Brighton in Pharmaceutics.

James Polli, PhD
Professor and Ralph F. Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics
University of Maryland School of Pharmacy

Dr. James Polli is Professor of Pharmaceutical Sciences and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics at University of Maryland. His research interest is oral drug absorption. His two main research interests are 1) maximizing oral bioavailability through formulation and chemical approaches and 2) developing public quality standards for oral dosage forms. He has served as advisor to 24 PhD graduates. He is co-Director of the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI; www.cersi.umd.edu) and the Center for Research on Complex Generics (CRCG; www.complexgenerics.org), each an FDA-funded collaborative agreement with the Agency. He is Director of the online M.S. in Regulatory Science program (www.pharmacy.umaryland.edu/regulatoryscience).

He is a fellow of the American Association for Pharmaceutical Scientists. 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. He developed an FDA Level A IVIVC, with predictability, for an extended-release antileptic, allowing regulatory waiver of a clinical trial. He has published on the dependence of model selection on IVIVC acceptability.