The Evolution of Biopharmaceutics: Risk Assessment and Clinical Relevance

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

Public In-Person Workshop
April 30-May 1, 2026 | 8:30 AM – 5:00 PM Eastern Time

Biographies

Carrie Coutant, PhD
Senior Director
Lilly Research Lab

Dr. Carrie Coutant, Senior Director, is an analytical chemist with over 25 years of experience in drug product development, spanning early clinical development to commercial launch. She specializes in product performance of oral dosage forms, with expertise in dissolution method development, analytical control strategy, BCS classification, biowaivers, and in silico modeling of in vitro dissolution. Dr. Coutant has contributed to the development and regulatory approval of seven commercial products. She is a member of the IQ Consortia Dissolution Working Group and served on the USP New Advancements in Product Performance Testing Expert Panel. She holds a doctorate in analytical chemistry from the University of Michigan and has received multiple company recognitions, including the Quality Advocate Award, Innovator Award, and Lilly Research Lab President's Award.

Dorota Danielak, PhD, dr hab
Senior R&D Specialist
Physiolution

Dr. Dorota Danielak is a Senior R&D Specialist at Physiolution, where she integrates biopredictive dissolution testing with mechanistic pharmacokinetic (PK) modeling. Her recent research is centered on the development of physiologically driven in vitro-in vivo extrapolations (IVIVE), utilizing the advanced PhysioCell apparatus to accurately simulate the complexities of gastric motility and inter-subject variability. By synergizing machine learning architectures with population PK simulations, Dr. Danielak develops robust, high-fidelity models designed to predict the in vivo performance of complex oral dosage forms, thereby streamlining the drug development process and enhancing the reliability of virtual bioequivalence studies.

A PhD graduate of the Poznan University of Medical Sciences, Dr. Danielak's academic foundation is rooted in the exploration of the genetic determinants of pharmacokinetic variability and in population PK modeling. Her career is marked by a strong commitment to international collaboration, including EU-funded research secondments at Zentiva in Prague and Physiolution in Greifswald. As an experienced academic educator, former associate professor, and guest lecturer within the CEEPUS network, she frequently shares her expertise at premier global forums, including AAPS PharmSci360, the Nordic PoP International Symposium, and APV.

Helena Engman, MSc, PhD
Senior Principal Scientist
Seda Pharmaceutical Development Services

Dr. Helena Engman is a Senior Principal Scientist in ADME Sciences at Seda, holding a Master of Science (MPharm) and a PhD in Biopharmaceutics from the University of Uppsala, Sweden. She is an experienced Biopharmaceutics Scientist with recognized expertise in Clinical Pharmacology and CMC regulatory science, gained over 21 years at AstraZeneca in roles spanning Early and Late-Stage Drug Product Development and Clinical Development.

At AstraZeneca, Helena and her team developed and implemented a new business strategy in which biopharmaceutics risk assessment serves as the critical component, published in 2025 (Engman et al., *Molecular Pharmaceutics* **2025** *22* (10), 6203-6214). She has also been a core member of the IQ working group which, together with the FDA, developed the framework for Biopharmaceutics Risk Assessment—work that now forms the foundation of the M-CERSI dissolution workshop taking place from 30 April to 1 May 2026. At Seda, Helena works as a senior advisor in Clinical Pharmacology, Biopharmaceutics, and Pharmacokinetics Modelling for clinical research and development, and regulatory submissions.

Emilija Fredro-Kumbaradzi, PhD
Director, Biopharmaceutics and Statistics, R&D
Apotex Inc

Dr. Emilija Fredro-Kumbaradzi is Director of Biopharmaceutics and Statistics at Apotex. She is responsible for Biopharmaceutics aspects in the development of generic drug products. Her work spans dissolution science, in vitro comparisons, in silico modeling, and biowaiver justifications, ensuring alignment with global regulatory standards. She also oversees clinical research activities related to bioequivalence studies and clinical study design, with a focus on regulatory strategy and scientific integrity. With over 20 years at Apotex, Dr. Fredro-Kumbaradzi brings extensive experience in the biopharmaceutic evaluation of solid oral dosage forms. She holds a PhD in Pharmaceutical Sciences from the University of Skopje, Macedonia, where she previously served as a Professor of Pharmaceutical Technology.

Robert Gaines, PharmD, MBA
Senior Director of Sciences and Regulatory Affairs
Association for Accessible Medicines (AAM)

Dr. Robert Gaines Jr. is Senior Director of Sciences and Regulatory Affairs at the Association for Accessible Medicines, supporting the development and oversight of AAM's Sciences and Regulatory Affairs initiatives. Prior to joining AAM, Robert spent 15 years working at the Food and Drug Administration, serving in various roles across offices in the Center for Drug Evaluation and Research. In his most recent FDA position, Deputy Director for the Office of Program and Regulatory Operations within the Office of Pharmaceutical Quality (OPQ), he led an office of more than 100 employees responsible for providing the project management function for OPQ's quality assessment of all drug application types. Robert also completed a distinguished 20-year career as a Commissioned Officer in the United States Public Health Service, retiring with the rank of Captain. Robert holds a PharmD from Howard University and an MBA from Trident University.

Anitha Palamakula Govada, PhD
Senior Pharmaceutical Quality Assessor
DPQA VI (Biopharmaceutics), OPQA I, OPQ, CDER, FDA

Dr. Anitha Palamakula Govada is a Senior Pharmaceutical Quality Assessor in the Office of Pharmaceutical Quality at the U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER). With over 18 years of regulatory experience, she provides leadership in biopharmaceutics assessments across the drug product lifecycle, from investigational drugs to post-marketing submissions. Dr. Govada is a key contributor to modernizing biopharmaceutics quality assessment at FDA and leads the Knowledge-Aided Assessment and Structured Application (KASA) initiative for biopharmaceutics assessment of ANDAs, INDs and NDAs. She has demonstrated exceptional expertise in priority NDA reviews under the ORBIS project for oncology drugs, including novel molecular entities, nano and liposomal products and radiopharmaceuticals, and serves as a subject matter expert for complex drug products. She has led multiple FDA committees and working groups, represented FDA as a panelist for the Generic Drug Cluster, and contributed to the ICH M4Q(R2) expert working group, fostering international regulatory harmonization. Dr. Govada has received numerous honors, including FDA Honor Awards, CDER Regulatory Science Excellence Awards, the Center Director's Special Recognition Award for her collaborative efforts and scientific contributions, the 2024 Service to the Citizen Award for KASA modernization effort and the Forum Innovation Award for delivering excellence in digital services.

Prior to joining FDA in 2007, Dr. Govada worked in the pharmaceutical industry as a senior formulation scientist and is a registered pharmacist. She holds a Bachelor of Pharmacy from Kakatiya University, India, and a PhD in Pharmaceutical Sciences from Texas Tech University.

Biljana Janković, PhD
Head of Pharmaceutical Research
Sandoz, Slovenia Development Centre

Dr. Biljana Janković is the Head of Pharmaceutical Research at Sandoz Development Centre Slovenia, where she leads IVIVC, Dissolution Studies and Data Science groups. She holds a PhD in Pharmaceutical Technology from the University of Ljubljana and has over 10 years of R&D experience spanning biorelevant method development, predictive modelling, advanced analytics, and preformulation science.

She leads multidisciplinary teams, drives scientific excellence initiatives, and collaborates closely with academic partners. Dr. Janković is also an Assistant Professor at the Faculty of Pharmacy in Ljubljana, where she teaches the course of Industrial Development of Pharmaceutics.

Her work has been recognized with numerous Sandoz and international awards in innovation, data science, and scientific leadership. She is the author of 27 SCI-indexed publications, an invited speaker, and mentor to undergraduate and doctoral researchers.

Tzuchi “Rob” Ju, PhD
Director
AbbVie Inc., North Chicago, IL

Dr. Tzuchi “Rob” Ju is recognized for his in-depth knowledge and technical experiences in both formulation and dissolution method development, as his teams were directly responsible for the formulation development of 7 NDAs, dissolution method development of 8 NDAs/Phase III projects, including oral biologics and implants. At AbbVie, he established the Drug Release and Product Performance group with focuses on in-silico modelling, images and functional excipient release, and cross-functional alignment. He advocates in vitro release method development based on formulation design and excipient release characteristics. Extensive interactions with global regulators on biowaiver, IVIVC, PBPK/PBBM modelling, and discrimination. Recognized expertise in biopharmaceutics, modified release formulations, pediatric formulations, amorphous solid dispersion, and FDC technologies for challenging molecules. Patents filings and litigation. Experiences with long acting injectables, oral peptides, and eye care products (implants and eye drops). Dr. Ju founded the Pediatric Working Group and chaired the Drug Product Leadership Group of IQ Consortium. He was inducted into the prestigious Vowiler Society within AbbVie, sat in the Scientific and Education Board of NIPTE, and was an Adjunct Professor of Roosevelt University. In leisure time, Rob enjoys coaching sport teams, working out in the gym, cycling, cooking and gardening.

Eva Karlsson, PhD
Associate Principal Biopharmaceutics
Global Product Development, AstraZeneca Gothenburg, Sweden

Dr. Eva Karlsson received her PhD in Biopharmaceutics at the Department of Pharmacy, Uppsala University, Sweden in 2006. Eva has 20 years of R&D experience as Biopharmaceutics expert and Product Development lead, working from lead generation up to launch. Her research interest evolves around in vivo relevant dissolution, focusing on understanding the mechanism for dissolution to inform formulation development and bridging strategy. She has also led several work tasks to improve PBBM models with the purpose of establishing a link between in vitro dissolution and in vivo exposure. She has taken part in and co-supervised PhD students in several research collaborations, such as OrBiTo, SweDeliver and InPharma. She has published 32 peer-reviewed papers and is co-author of a recent publication presenting an AstraZeneca developed biopharmaceutics risk assessment tool.

Filippos Kesisoglou, PhD, FAAPS
Distinguished Scientist, Pharmaceutical Sciences
Merck & Co., Inc., Rahway, NJ, USA

Dr. Filippos Kesisoglou is a Distinguished Scientist at Merck & Co., Inc., (Rahway, NJ, USA) where he is currently leading the Exploratory Biopharmaceutics efforts across modalities in the Pharmaceutical Sciences department. Filippos has 20 years of experience in the fields of biopharmaceutics and formulation development, pharmacokinetics, PBPK and IVIVC modeling as related to clinical, drug product development and CMC regulatory applications, including establishment of clinically relevant specifications, across modalities. He has been a key contributor to several new drug applications across therapeutic areas. He has authored/co-authored 95 manuscripts/book chapters and more than 100 conference abstracts/podium presentations/webinars in several national/international meetings in the fields of biopharmaceutics, PBPK modeling, formulation development and drug delivery. Filippos has been involved over the years in several cross-industry and academia consortia and since 2023 has joined the ICH M13 (Bioequivalence Guideline) Expert Working Group. He is currently serving as an Editor for Journal of Pharmaceutical Sciences and on the Editorial Advisory Boards for the AAPS Journal and Pharmaceutical Research. In 2017 he was elected a Fellow of the American Association of Pharmaceutical Scientists (AAPS).

Haritha Mandula, PhD
Acting Supervisor
DPQA VI, OPQA I, OPQ, CDER, FDA

Dr, Haritha Mandula is an Acting Supervisor in the Division of Biopharmaceutics (DPQA VI), Office of Product Quality Assessment (OPQA I), at the FDA's Center for Drug Evaluation and Research. She earned her PhD in Pharmaceutical Sciences from Texas Tech University Health Sciences Center in 2005 and brings over 18 years of regulatory expertise in reviewing biopharmaceutical aspects of new and generic drug product submissions spanning diverse therapeutic areas. She contributes to several FDA review committees, including the Biopharmaceutical Classification System (BCS) committee, the Modeling and Simulations (M&S) committee, and the Emerging Technologies Team (ETT). Her distinguished work has earned her multiple FDA honors, including CDER Regulatory Science Excellence Awards, CDER Special Recognition Awards, and FDA Commissioner's Special Citation Awards.

James Mann, MSci, PhD
Principal Scientist In Vitro Product Performance
AstraZeneca

Dr. James Mann is a principal scientist of in vitro product performance at AstraZeneca in the UK. An experienced analytical scientist with more than 20 years' experience in pharmaceutical industry specializing in all aspects of dissolution testing. Joining AstraZeneca in 2015, James has led the in vitro product performance expert working group and been involved in many successful product developments. Prior to joining AZ, James was with Merck in the UK where he jointly led the global in vitro predictive technologies team as well as supervising a small team of product development analysts. James received his first degree from University of Strathclyde, followed by a PhD from the University of East Anglia.

Johannes Moes, PharmD, PhD
Scientific Director Dissolution Sciences
J&J Innovative Medicine

Dr. Johannes Moes is the Scientific Director Dissolution Sciences at Johnson & Johnson Innovative Medicine. He leads global dissolution and in vitro performance strategies supporting drug product development and regulatory submissions across multiple modalities. His work focuses on using dissolution as a clinically and biopharmaceutically relevant performance test, enabling science-based specifications, robust method development, and opportunities for biowaivers. Johannes brings deep expertise at the interface of formulation, process, biopharmaceutics, and regulatory science.

Rebecca Moody, PhD
Pharmaceutical Scientist
OPQA II, OPQ, CDER, FDA

Dr. Rebecca Moody works in the Immediate Office (IO) of the Office of Drug Product Quality II (OPQA II) at the FDA. Previously, she was a Biopharmaceutics Reviewer in the Division of Biopharmaceutics (DB). 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 has experience evaluating 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.

Bassel Odeh, BSc, PGDip, MSc, PhD
Head of New Active Substances, innovative Medicines
Medicines and Healthcare Products Regulatory Agency (MHRA)

Dr. Bassel Odeh has a PhD in Clinical Pharmacy and MSC in Pharmaceutical Sciences from Kingston University and over 20 years of experience in the pharmaceutical industry. Dr Odeh is currently the Head of New Active Substances Team at the Medicines & Healthcare products Regulatory Agency and he is part of the Innovative Medicines senior leadership team. Dr Odeh is also a topic leader on ICH Expert Working Group for the revision of the Specifications Guidelines Q6(R1) and a member of the Agency Nitrosamines Working Group. Dr Odeh has also worked as a Leading Senior Pharmaceutical Assessor at the Agency where he conducted pharmaceutical assessments and provided regulatory and scientific advice to stakeholders. Prior to this role, he worked as a Senior Formulation Scientist where he conducted pre-formulation and formulation characterisation studies and supported drug product development, validation, and transferring into GMP manufacturing.

Hardikkumar Patel, PhD
Senior Biopharmaceutics Assessor
DPQA XII, OPQA II, OPQ, CDER, FDA

Dr. Hardikkumar Patel is currently a Senior Biopharmaceutics Assessor in DPQA XII, OPQA II, Office of Pharmaceutical Quality (OPQ), CDER, FDA. His responsibilities include risk-based biopharmaceutics assessment of NDAs, ANDAs, INDs, supplements, and pre-ANDA submissions. His areas of expertise include dissolution, IVRT, physicochemical characterization, and regulatory evaluation of drug product performance. Before joining his current role, Hardik was with the Office of Lifecycle Drug Products (OLDP), where he served as an ORISE fellow, a drug product assessor for oral drug products, and a drug product assessor for liquid-based drug products. He completed internships at GSK Consumer Healthcare as a bench scientist during the summers of 2012 and 2013. Hardik received his PhD in Pharmaceutical Sciences and MS in Industrial Pharmacy from Long Island University, New York. He earned his Bachelor of Pharmacy degree from Nirma University, India.

Sanjaykumar Patel, PhD
Senior Principal Scientist
Merck & Co., Inc.

Dr. Sanjaykumar Patel is Sr. Principal Scientist at Merck & Co., Inc. in Rahway, NJ. He has more than 20 years of experience in the pharmaceutical industry. His experience includes working on novel drug delivery formulations, including self-emulsifying drug delivery systems, amorphous solid dispersions, controlled-release and gastroretentive formulations, and parenteral formulations. His research interests are focused on developing predictive, biorelevant in vitro methodologies to understand the in vivo performance of oral and parenteral formulations. He has co-authored more than 20 scientific papers. He is an active member of AAPS and a past Chair of the IVRDT (In Vitro Release and Dissolution Testing) community. He is a board member of the Society of Pharmaceutical Dissolution Sciences-US Chapter in the area focusing on dissolution. He has been involved over the years in several industries and academia consortia, including the PQRI and IQ.

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

Dr. James Polli is 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 26 PhD graduates. He is co-Director of the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) and the Center for Research on Complex Generics (CRCG), each an FDA-funded collaborative agreement with the Agency. He is Director of the online MS 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 American Pharmacists Association Takeru Higuchi Research Prize. He was the recipient of the 2024 American Association of Colleges of Pharmacy 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).

Yihong Qiu, PhD
Chief Technical Director
QPD Solutions

Dr. Yihong Qiu currently serves as a technical advisor to pharmaceutical companies globally, providing a broad range of scientific expertise, technical know-how, and training across product and process development, regulatory filing, and commercial manufacturing. Prior to 2023, Dr. Qiu was a Senior Research Fellow in Formulation Sciences at AbbVie, where he spent over 30 years at Abbott and AbbVie. His expertise and experience covered the full drug product lifecycle, including preformulation, biopharmaceutics, pharmacokinetics, drug delivery research, product and process development, scale-up, technology transfer, manufacturing troubleshooting, regulatory filing, and intellectual property. His work has led to numerous successful products and processes, patented technologies, in vitro–in vivo correlations (IVIVC), and biowaivers. Dr. Qiu's research interests include modified-release drug delivery, dissolution, enhancement of oral bioavailability, IVIVC development, and science-based regulatory approaches. He is an elected Fellow of the American Association of Pharmaceutical Scientists (AAPS) and has authored more than 70 publications in journals and books, holds over 40 granted or pending patents, provides training lectures on various aspects of product development, and has delivered numerous invited presentations at conferences. He earned his BS in Pharmacy and MS in Pharmaceutics from China Pharmaceutical University, and his PhD in Pharmaceutics from the University of Iowa.

Kimberly Raines, PhD
Associate Director of Science
OPPQ, OPQ, CDER, FDA

Dr. Kimberly Raines serves as Associate Director of Science in the Office of Policy for Pharmaceutical Quality (OPPQ) within OPQ, where she contributes to the development and implementation of pharmaceutical quality policy. She joined FDA in 2008 as a Bioequivalence Reviewer in the Office of Generic Drugs, then moved to OPQ's Office of New Drug Products in 2015, serving as acting Biopharmaceutics Lead and later Branch Chief.

Dr. Raines completed postdoctoral training at UNC Lineberger Comprehensive Cancer Center as an UNCF-Merck Fellow. She holds a PhD in Pharmaceutical Sciences from the University of Maryland School of Pharmacy and a BS in Chemistry with a Pharmacology concentration from Duke University (Howard Hughes Scholar). Her work includes co-authoring research and presenting on drug product quality, bioequivalence, biowaivers, in vitro dissolution, and physiologically based model informed quality risk assessment, informing policy development in these areas.

Giuseppe Randazzo, MS
Senior Vice President, Sciences and Regulatory Affairs
Association for Accessible Medicines (AAM)

Mr. Giuseppe Randazzo is Senior Vice President of Sciences and Regulatory Affairs at the Association for Accessible Medicines (AAM) representing manufacturers of generic and biosimilar medicines**.** Prior to joining the association, Giuseppe worked on a global pharmaceutical company's policy and regulatory team, where he collaborated across multiple areas including drug and policy development, user fee agreement negotiations, and engagement with industry and trade organizations. Before that, Giuseppe spent nearly 15 years at the FDA, where he last served as an Office Director in Office of Pharmaceutical Quality within CDER. During his FDA tenure, he also held roles in new drug review, compliance, and played a key role in establishing a product quality office in coordination with the generic drugs program.

Giuseppe holds a BA in Chemistry and Physical Science Education from The Pennsylvania State University and an MS in Regulatory Science from The Johns Hopkins University.

Bhagwant Rege, PhD
Division Director for Biopharmaceutics
DPQA VI, OPQA I, OPQ, CDER, FDA

Dr. Bhagwant Rege is the Division Director for Biopharmaceutics in CDER/OPQ/OPQA I 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. Prior to his current position, he served as a Division Director for CDER/OPQ/OLDP/ Division of Immediate and Modified Release Products III. Before joining the 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.

Christos Reppas, PhD
Professor in Pharmaceutics, Department of Pharmacy,
National and Kapodistrian University of Athens (NKUA), Greece

Research interests focus to the effects of dosage form characteristics and of gastrointestinal physiology on intraluminal performance of xenobiotics and to the development of *in vitro* tests that are predictive of the intraluminal performance of orally administered xenobiotics. He has supervised 14 completed PhD Theses. He is coauthor of more than 170 peer reviewed papers and chapters in international journals and books, two books on Biopharmaceutics and Drug Disposition and one world patent. He is associate editor at The AAPS Journal, and member of the editorial board of European Journal of Pharmaceutical Sciences, Journal of Pharmacy and Pharmacology, and Journal of Drug Delivery Science and Technology. He has been principal investigator in several EU funded Training and Research programs (OrBiTo, PEARRL, COLOTAN, InPharma, AGePOP) and vice-chair of one COST action (UNGAP). He has served as Chair of the Department of Pharmacy at NKUA (2022-2024).

Rajesh Savkur, PhD
Senior Biologist
DPQA VI, OPQA I, OPQ, CDER, FDA

Dr. Rajesh Savkur is a senior assessor in the Division of Pharmaceutical Quality Assessment VI in the 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 DPQAVI at the FDA, he evaluates the pharmacological and biopharmaceutical studies associated with drug and drug-device-combination product applications that are submitted to the Agency.

Robert Schwabe, BS
Senior Scientist
Boehringer Ingelheim Pharmaceuticals, Inc.

Mr. Robert Schwabe is a Senior Scientist in the Biopharmaceutics group at Boehringer Ingelheim Pharmaceuticals, where he serves as the Global Lead for TIM Systems and represents the company in the Experts Working Group and the TIM Pharma Core User Group. Over the past six years, Robert's research has focused on biorelevant dissolution and the application of *in vitro* systems to improve *in vivo* predictability, culminating in six publications and broader cross-functional collaboration within development teams.

With more than two decades at Boehringer Ingelheim, Robert has supported initiatives spanning Drug Product development including lipid-based formulations, amorphous solid dispersions, and the integration of Drug Substance–Drug Product relationships to inform robust product design. His scientific contributions were recognized with the Boehringer President's Award in 2022. Robert earned his BS in Biochemistry from the University of Illinois at Urbana-Champaign in 2003.

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.

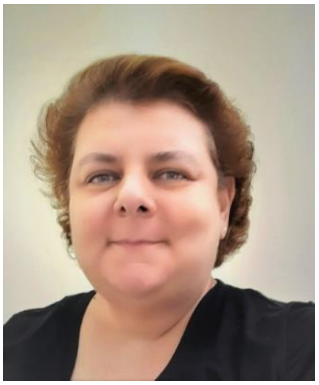
Duxin Sun, PhD
Associate Dean for Research, College of Pharmacy
Director of Institute of AI-driven Therapeutics Discovery
Charles Walgreen Jr. Professor of Pharmacy
Professor of Pharmaceutical Sciences
The University of Michigan

Dr. Duxin Sun is the Associate Dean for Research in the College of Pharmacy and Director of Institute of AI-driven Therapeutics Discovery (AI-Tx) 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.

Dr. Sun's research interests focus on direct measurement of drug dissolution in human GI tract, drug development, cancer nanomedicine, cancer vaccine, and pharmacokinetics. Dr. Sun established the STAR system (Structure-Tissue/Cell Selectivity-Activity-Relationship) to enhance drug development success by addressing the 90% failure rate. He designed albumin based nanomedicines to enhance clinical efficacy of immuno-oncology drugs by targeting immune cells in the lymphatic system and tumors. He also developed SARS-CoV-2 B epitope-guided neoantigen peptide or mRNA cancer vaccine to enhance their anticancer efficacy by activating CD4/CD8 T cell immunity through B cell-mediated antigen presentation.

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 300 papers, and has mentored 40 PhD students and 75 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.

Maria Verzoni, PhD
Professor, Pharmaceutical Technology and Biopharmaceutics,
Department of Pharmacy
National and Kapodistrian University of Athens, (NKUA) Greece

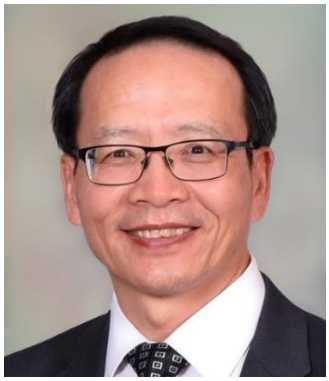


Dr. Maria Vertzoni is a Professor in Pharmaceutical Technology and Biopharmaceutics, Department of Pharmacy, National Kapodistrian University of Athens (NKUA), Greece. She received her Bachelor in Chemistry in 1994, her Master of Science in Analytical Chemistry in 1999 and her PhD in Pharmaceutical Sciences in 2004 from NKUA. In 2016, she received her Master of Science in Medical and Pharmaceutical Statistics from Athens University of Economics and Business. Her research interests focus to the physicochemical characterization of intraluminal environment and oral drug absorption with special interest in special populations. She is co-author of more than 140 peer reviewed papers and chapters in international journals and books (h-index 44). She is member of the editorial board of *Molecular Pharmaceutics*, *Journal of Pharmacy and Pharmacology*, *Pharmaceutics* and *Die Pharmazie*. She had supervised 3 PhD Theses and is currently supervising 5 PhD Theses. She has been involved in several EU funded training and research programs, i.e. AGePOP (coordinator), PEARRL, InPharma, OrBiTo and COLOTAN, and one COST action (UNGAP).

Commander Geoffrey Wu, PhD, PMP, CPH
Office Director
OPQA I, OPQ, CDER, FDA

Commander Geoffrey Wu joined the FDA's Office of Testing and Research (OTR) in 2010, has served in multiple capacities, including research scientist, science staff, chemistry reviewer, staff supervisor, Associate Director of Science and Communication (ADSC), acting Division Director, acting Office Director, and Deputy Office Director. He is a scientist officer in the United States Public Health Service. Throughout his FDA tenure, he has been deeply involved, leading or co-leading regulatory review and research for PDUFA and GDUFA programs. Between 2013 and 2017, he served as a founding member on the CDER Emerging Technology Team (ETT). In the recent years, he has been a core and/or leading member in multiple policy and/or scientific development efforts, such as emerging technology, continuous manufacturing, comparability protocols, knowledge-aided assessment and standard submissions (KASA), pharmaceutical quality chemistry manufacturing and controls (PQ/CMC), novel complex generic drugs, and advanced analytics. He has training and education in pharmacy, pharmaceutical science, protein chemistry, polymer chemistry, process analytical technology, and data science.

Lawrence X. Yu, PhD
Director
OPQA II, OPQ, CDER, FDA



Dr. Lawrence X. Yu is the Director of the Office of Product Quality Assessment II at the U.S. Food and Drug Administration (FDA) and serves as the Rapporteur for the ICH M4Q(R2) Expert Working Group. He is also an adjunct professor at the University of Michigan and an Associate Editor of *The AAPS Journal*. Dr. Yu has made transformative contributions to pharmaceutical science and regulation. He developed the Compartmental Absorption and Transit (CAT) model, which became the scientific foundation for commercial simulation platforms including GastroPlus™ and Simcyp®. As chair of FDA's Biopharmaceutics Classification System (BCS) Committee from 2000 to 2016, he advanced global acceptance of BCS and contributed to the 2019 ICH M9 guideline. He pioneered Pharmaceutical Quality by Design (QbD) as a regulatory paradigm, emphasizing design, understanding, control, and lifecycle management. Most recently, he originated the Knowledge-aided Assessment and Structured Applications (KASA) initiative to strengthen knowledge management and enable artificial intelligence in regulatory decision-making. Dr. Yu currently leads the ICH Expert Working Group revising the M4Q(R1) guideline to modernize pharmaceutical product registration and lifecycle management. He has authored over 178 scientific publications, delivered more than 400 invited presentations, and co-edited three influential books on biopharmaceutics and drug development.

Hailing Zhang, PhD
Division Director
DPQA XII, OPQA II, OPQ, CDER, FDA

Dr. Hailing Zhang serves as Division Director of the Division of Product Quality Assessment XII (DPQA XII) in the Office of Product Quality Assessment II (OPQA II), Office of Pharmaceutical Quality (OPQ). Dr. Zhang earned her PhD in Organic Chemistry and Physical Organic Chemistry from Emory University in Atlanta, Georgia. Prior to joining the FDA in 2014, she was an Associate Professor of Pharmaceutical Science in the College of Pharmacy at Mercer University in Atlanta, Georgia. In her current role as Division Director of DPQA XII, Dr. Zhang leads a team of accomplished pharmacokineticists who provide biopharmaceutic assessments and approvals for various submissions under the GDUFA and PDUFA programs.

Ahmed Zidan, PhD
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Dr. Ahmed Zidan is a Senior Research Pharmacologist in the Division of Pharmaceutical Quality Research (DPQR V), Office of Pharmaceutical Quality Research (OPQR), within the Office of Pharmaceutical Quality (OPQ) at the U.S. Food and Drug Administration (FDA). He received his Ph.D. in Pharmaceutics in Zagazig University through a scholarship at Howard University, where his training focused on drug delivery, biopharmaceutics, advanced manufacturing, and formulation science, providing a strong foundation for his work in oral drug product performance and regulatory science. His work focuses on the mechanistic understanding of oral drug product performance and the development of regulatory science frameworks integrating biopredictive dissolution, in vitro–in vivo correlation (IVIVC), and physiologically based pharmacokinetic (PBPK) modeling to support bioequivalence assessment.

Dr. Zidan has led and contributed to multiple FDA translational and research programs addressing complex generic drug development, including modified-release formulations and products where conventional bioequivalence approaches are challenged. He has authored numerous peer-reviewed publications and scientific reports and has delivered invited presentations at national and international scientific conferences on biopharmaceutics and other regulatory science. He has also received several FDA recognition awards for his contributions to advancing the additive manufacturing and regulatory sciences.