SPEAKER BIOGRAPHIES

Kori Adair, PharmD
Pharmacist
Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Kori Adair is a drug information pharmacist and team member of the Small Business and Industry Assistance (SBIA) program within the Division of Drug Information (DDI) in the Center for Drug Evaluation and Research (CDER) at FDA. As a drug information pharmacist, Kori responds to a wide variety of inquiries from consumers, healthcare professionals, and industry professionals, including small business, regarding CDER-regulated human drug products. Prior to joining the FDA, Kori earned her B.S. in Biochemistry from Baylor University and her Doctor of Pharmacy degree at the Texas Tech University Health Sciences Center School of Pharmacy. Kori then completed a post-doctoral fellowship in Drug Information with Purdue University, Janssen Pharmaceuticals, and the FDA.

Priyanka Ghosh, PhD
Master Pharmacologist
Division of Therapeutic Performance I (DTP I)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD) | CDER

Dr. Priyanka Ghosh is a master pharmacologist within the Division of Therapeutic Performance, ORS, OGD. Her areas of expertise include characterization of drug delivery from topically applied drug products. In her current role, Dr. Ghosh leads regulatory science research initiatives under the GDUFA regulatory science program, development of general and product-specific guidances, review strategies for industry meeting requests and is the co-chair of the Bioequivalence Standards for Topicals Committee within OGD. Prior to joining FDA, Dr. Ghosh completed her Bachelor's degree in Biotechnology from West Bengal University of Technology (India) and a Ph.D. in Pharmaceutics and Drug Design from the University of Kentucky.

Tannaz Ramezanli, PharmD, PhD
Senior Pharmacologist
DTP I | ORS | OGD | CDER

Dr. Tannaz Ramezanli is a senior pharmacologist within the Office of Research and Standard (ORS) at Office of Generic Drugs (OGD) at the U.S. FDA. She specializes in topical, transmucosal, and transdermal products. She is responsible for the development of product-specific bioequivalence guidances, reviewing and responding to controlled correspondences, citizen petitions, and industry meeting requests. She also leads multiple regulatory science research initiatives related to development of bioequivalence standards for complex topical drug products through FDA-funded collaborations with research institutions around the world. She received her Ph.D. in Pharmaceutical Sciences from Rutgers University and her Pharm.D. from Tehran University of Medical Sciences.

Allison Schafer, PhD
Senior Interdisciplinary Scientist
Division of Bioequivalence II (DBII) | Office of Bioequivalence (OB) | OGD | CDER

Dr. Allison Schafer is a Senior Interdisciplinary Scientist in the Office of Bioequivalence, Office of Generic Drugs, at the U.S. Food and Drug Administration. In this role, she reviews and evaluates the results of clinical and non-clinical pharmacological studies on various dosage forms submitted by generic drug sponsors in support of abbreviated new drug applications (ANDAs) to assess the relative pharmacology of the drug products. Prior to joining the FDA, Dr. Schafer received her B.Sc. in Biochemistry with a concentration in Medicinal Chemistry from Arizona State University and a Ph.D. in Pharmaceutical Sciences from the University of Michigan.

Eleftheria Tsakalozou, PhD
Lead Pharmacologist
Division of Quantitative Methods and Modeling (DQMM) | ORS | OGD | CDER

Eleftheria Tsakalozou obtained her Ph.D. 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 before joining the FDA in 2015 as an Oak Ridge Institute for Science and Education (ORISE) Fellow. She is currently a Lead Pharmacologist at the Division of Quantitative Methods and Modeling at the Office of Research and Standards with expertise in physiologically based pharmacokinetic modeling and simulation approaches for topical and transdermal drug products. She is focused on the development and regulatory application of mechanistic modeling and simulation tools to support virtual bioequivalence assessments for non-orally administered drug products.

Robert Lionberger, PhD
Director
ORS | OGD | CDER

Robert Lionberger, Ph.D. serves as Director of the Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). Dr. Lionberger leads OGD's implementation of the GDUFA science and research commitments including internal research activities and external research grants and collaborations to ensure the therapeutic equivalence of generic drug products. ORS also provides pre-submission advice on complex generics through pre-ANDA meetings, product specific guidance and correspondence responses.
He received his undergraduate degree from Stanford University in Chemical Engineering, and a PhD from Princeton University in Chemical Engineering. After his Ph.D., he conducted post-doctoral research in Australia in the Department of Mathematics and Statistics at the University of Melbourne. Prior to joining the FDA 20 years ago, he was an Assistant Professor of Chemical Engineering at the University of Michigan.

Partha Roy, PhD
Director
OB | OGD | CDER

Dr. Partha Roy is a regulatory expert with 24 years of drug development experience in new and generic drugs. Dr. Roy currently serves as the Director of the Office of Bioequivalence in the Office of Generic Drugs, an FDA/CDER Office that oversees assessment of all bioequivalence (BE) data required to support Abbreviated New Drug Application (ANDA) applications.
Prior to his current role, Partha was Vice President in PAREXEL's Regulatory and Access Consulting Global Business Unit, providing executive management, regulatory strategy and thought leadership focused on driving corporate growth and delivery. Following his PhD from the University of South Florida, Tampa, Florida, Partha completed his Postdoctoral Fellowship in Drug Metabolism and Pharmacokinetics (DMPK) from Boston University, Boston, MA.

William Chong, MD
Director
Office of Safety and Clinical Evaluation (OSCE) | OGD | CDER

Dr. William Chong is the Director of OGD's Office of Safety and Clinical Evaluation. He leads a multidisciplinary group of scientists that work to ensure that generic drug products have the same safety and efficacy profile as the reference listed drug. Dr. Chong joined FDA in 2012 in CDER's Office of New Drugs where he primarily evaluated new drug products for patients with diabetes mellitus. He subsequently joined OGD in 2019 as the Associate Director for Clinical Affairs before becoming the Director of OSCE in 2022. He is a board-certified internist and endocrinologist, and completed his Internal Medicine residency at Thomas Jefferson University Hospital in Philadelphia, PA and his Endocrinology and Metabolism fellowship at the National Institutes of Health in Bethesda, MD. Dr. Chong earned his undergraduate degree in Engineering Science at Penn State University, and his Medical Degree from Temple University School of Medicine.

Pahala Simamora, PhD
Director
Division of Product Quality Assessment IX (DPQA IX)
Office of Product Quality Assessment II (OPQA II)
Office of Pharmaceutical Quality (OPQ) | CDER

Dr. Pahala Simamora serves as the Director of the Division of Product Quality Assessment IX (DPQA IX), within the Office of Product Quality Assessment II (OPQA II), OPQ/CDER at the FDA. His division oversees the quality assessment of regulatory submissions under both the GDUFA and PDUFA programs, including those involving radiopharmaceutical drug products. Dr. Simamora has played an important role in several key FDA initiatives. These include the Abbreviated New Drug Application (ANDA) Integrated Quality Assessment process, which streamlines the review of generic drug submissions; the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME), which explores innovative regulatory approaches for mobile and advanced manufacturing technologies; and the Knowledge Aided and Structured Assessment (KASA) initiative, which advances structured quality assessments of generic drug applications. Before joining the FDA in 2010, Dr. Simamora brought with him 14 years of pharmaceutical industry experience, with deep expertise in formulation development, process development, and manufacturing scale-up - a foundation that continues to inform his regulatory and scientific leadership at the Agency.

Ahmed Zidan, PhD
Senior Research Pharmacologist
Division of Product Quality and Research V (DPQR V)
Office of Pharmaceutical Quality Research (OPQR)
OPQ | CDER

Dr. Ahmed Zidan is a Senior Research Pharmacologist in FDA's Center for Drug Evaluation and Research, where he leads regulatory science research focused on topical and transdermal drug products. His work emphasizes formulation and product characterization, microstructure, in vitro release testing (IVRT), in vitro permeation testing (IVPT), and understanding relationships between product quality attributes and performance. His research supports the development of scientific approaches for generic topical and transdermal products, including general and product-specific guidances, pre-ANDA interactions, and ANDA assessments. Dr. Zidan also provides scientific training to FDA reviewers on topical and transdermal drug delivery, IVRT, IVPT, and biopharmaceutic considerations for complex drug products. He serves as an FDA liaison to a USP Expert Committee and has contributed to peer-reviewed publications, book chapters, workshops, and professional training. He received his Ph.D. in Drug Delivery from Zagazig University in collaboration with Howard University.

Nahid Kamal, PhD
Pharmacologist
DPQR V | OPQR | OPQ | CDER

Dr. Nahid Kamal is a Research Pharmacologist and CMC Assessor in the Office of Pharmaceutical Quality (OPQ), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). She earned her Bachelor of Pharmacy from the University of Science and Technology Chittagong, Bangladesh, and her Ph.D. in Pharmaceutical Sciences from Long Island University, New York.
As a Principal Investigator and Subject Matter Expert in complex drug delivery systems, Dr. Kamal leads research on transdermal, topical, microneedle, implant, and intravaginal drug products. Her work focuses on understanding drug substances, excipients, formulation, and process variables, and their impact on product performance using advanced analytical tools, including AI-enhanced image analysis and characterization techniques.
Dr. Kamal has contributed significantly to FDA regulatory science initiatives, particularly in the evaluation of complex drug products and drug–device combinations for women's health under the GDUFA program. She actively participates in and co-chairs internal scientific workshops and collaborative initiatives to advance regulatory science. Her work has been widely published and recognized through multiple intramural grants and FDA awards for scientific excellence.

Hiren Patel, PhD
Senior Staff Fellow
DBII | OB | OGD | CDER

Dr. Hiren Patel is a bioequivalence assessor in the Division of Bioequivalence II within Office of Generic Drugs (OGD). Prior to joining FDA, he earned his M.S. and Ph.D. with specialization in Pharmacokinetics at Long Island University, Brooklyn, New York. At U.S. FDA, he is responsible for assessing the bioequivalence of the various dosage forms of generic drugs. He is the lead for the topical and transdermal drug products and the advanced techniques for demonstrating bioequivalence of such complex drug products within the Office of Bioequivalence. He is the co-chair for Bio-Equivalence Standards for Topicals (BEST) Expert Committee within OGD. He has also actively served as a consultant in the research initiatives which are the collaborative efforts of FDA and global research institutions pertaining to the topical and transdermal drug products funded through FDA. Dr. Patel is also actively involved in the review panel for the Product Specific Guidance for the generic topical drug products.

Sam Raney, PhD
Associate Director for Science and Chief Scientific Advisor
ORS | OGD | CDER

Dr. Sam Raney is the Associate Director for Science and Chief Scientific Advisor in the FDA's Office of Research and Standards and Office of Generic Drugs, where he oversees the research portfolio of FDA's generic drug research program. He has over 30 years of experience in pharmaceutical drug development, specializing in topical and transdermal products, and producing numerous research manuscripts, review articles, book chapters and patents. He has been a researcher and adjunct professor within academia, a principal or sub investigator on over 400 pharmaceutical product studies, held senior management roles in industry, served on multiple expert committees and panels for the U.S. Pharmacopeia, and is frequently invited to speak at scientific meetings around the world. Dr. Raney holds a Bachelor's Degree in Molecular Biophysics & Biochemistry from Yale University, and a Ph.D. in Biochemistry & Molecular Biology from the University of British Columbia in Canada.

Xiaoming Xu, PhD
Director
DPQR V | OPQR | OPQ | CDER

Xiaoming Xu, Ph.D., is a Division Director in the Office of Pharmaceutical Quality Research (OPQR) at the U.S. Food and Drug Administration (FDA), where he leads regulatory science initiatives supporting complex drug products, nanomaterials, and advanced pharmaceutical manufacturing. His work focuses on strengthening the scientific foundation for modern manufacturing approaches, including continuous manufacturing, advanced process control, and data-driven quality assessment. Dr. Xu plays a key leadership role in the implementation of the Generic Drug User Fee Amendments (GDUFA) III as co-lead of the Complex Product-Specific Guidance (PSG) Working Group, where he promotes the integration of regulatory research into guidance development for complex drug products. He is an active member of the FDA Nanotechnology Task Force and leads international collaborations and standards-development efforts related to nanotechnology-enabled pharmaceutical products. He serves on the editorial board of the International Journal of Pharmaceutics and is an elected Fellow of the Controlled Release Society (CRS) and the American Association of Pharmaceutical Scientists (AAPS). Dr. Xu received his B.S. and M.S. in Pharmaceutics from China Pharmaceutical University and earned his Ph.D. in Pharmaceutical Sciences from the University of Connecticut.

Andrew Babiskin, PhD
Deputy Director
DQMM | ORS | OGD | CDER

Dr. Andrew Babiskin is the Deputy Division Director of the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs, CDER. He previously led the Locally-acting Physiologically Based Pharmacokinetic Modeling Team and the Quantitative Clinical Pharmacology Team in DQMM. Dr. Babiskin's expertise lies in modernization of bioequivalence evaluation practices through model-integrated evidence. Dr. Babiskin received his B.S. degree from the University of Maryland (College Park) in Chemical Engineering and his M.S. and Ph.D. 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.

Ying Jiang, PhD
Chemist
DTP I | ORS | OGD | CDER

Dr. Ying Jiang is currently a Staff Fellow (Chemist) at the FDA's Office of Generic Drugs, Division of Therapeutic Performance I (DTP I), Office of Research and Standards (ORS), where her work relates to dermal, transdermal, and transmucosal drug products. Dr. Jiang responds to questions from industry and internal stakeholders and develops guidances related to therapeutic equivalence demonstration to support the development of generic products. She also engages in regulatory science research initiatives related to these products, especially transdermal products. Dr. Jiang obtained her Ph.D. in Pharmaceutical Sciences (topical and transdermal delivery) from Mercer University.

Megan Kelchen, PhD
Senior Pharmacologist
DTP I | ORS | OGD | CDER

Megan Kelchen, Ph.D., is a senior pharmacologist in the Division of Therapeutic Performance I (DTP I) in FDA's Office of Generic Drugs (OGD). Her specialization is drug products for topical, transdermal, and transmucosal drug delivery. Dr. Kelchen is responsible for the development of product-specific guidances for generic drug development, reviewing and responding to controlled correspondences, citizens petitions, and pre-ANDA meeting requests. Dr. Kelchen is also engaged in regulatory science research initiatives related to complex generics under the GDUFA regulatory science research program. Dr. Kelchen received her B.A. degree in Biology from Wartburg College and her Ph.D. in Clinical Pharmaceutical Sciences from the University of Iowa.

Markham C. Luke, MD, PhD
Director
DTP I | ORS | OGD | CDER

Dr. Markham C. Luke, MD, PhD, FAAD, is a supervisory physician and Director of the Division of Therapeutic Performance in the Office of Generic Drugs at the U.S. Food and Drug Administration. Earning his MD and PhD in Pharmacology from Johns Hopkins University, he has served at the FDA since 1998. Dr. Luke specializes in dermatopharmacology and regulatory science, ensuring the therapeutic equivalence of complex generic drug products.

Robert Berendt, PhD
Supervisory Pharmaceutical Scientist
Division of Product Quality Assessment V (DPQA V)
Office of Product Quality Assessment I (OPQA I) | OPQ | CDER

Dr. Robert (Bob) Berendt is a supervisory pharmaceutical scientist in the Office of Product Quality Assessment I (OPQA I) within the Office of Pharmaceutical Quality (OPQ). Dr. Berendt and members of his unit are subject matter experts in quality assessment of generic drug-device combination products formulated as solid polymeric systems, including intravaginal and intrauterine systems, implants, and transdermal and topical delivery systems (TDS). In his role, he oversees and contributes to the risk-based assessment of controlled correspondence, pre-ANDA meeting requests, pre- and post-market (A)NDA submissions, and Type IV DMFs. He and his work unit also participate in guidance development, regulatory science research, and working group activities associated with drug-device combination products. Prior to joining OPQ as a quality assessor, Dr. Berendt was a laboratory chemist in the FDA's Office of Testing and Research, supporting regulatory review and policy activities. He earned his doctorate in pharmaceutical chemistry from the University of Kansas, where he focused on solid-state characterization of pharmaceutically relevant systems using solid-state NMR spectroscopy.

Wanjie Sun, PhD
Master Mathematical Statistician
Division of Biometrics VIII (DB VIII) | Office of Biostatistics (OB)
Office of Translational Sciences (OTS) | CDER

Wanjie Sun is a Master Mathematical Statistician at the FDA/CDER/OTS/Office of Biostatistics/DB8, where she leads a team reviewing generic and biosimilar drug applications. Wanjie was the President of the FDA Statistical Association in 2024. She joined the FDA in 2013 after working in industry for a couple of years and spending twelve years at George Washington University as a Principal Investigator (PI), Co-PI, and Lead Research Scientist. She received her PhD degree in Biostatistics from the George Washington University.
Wanjie is actively engaged in regulatory research and has contributed to multiple ICH and FDA guidance. She has received numerous FDA awards recognizing her contributions to regulatory research, scientific communication, and leadership. She has authored/co-authored 60+ publications and serves as an Associate Editor for Pharmaceutical Statistics.

Ying Fan, PhD
Lead Pharmacologist
Division of Clinical Review (DCR)
OSCE | OGD | CDER

Dr. Ying Fan is the Lead Pharmacologist in Division of Clinical Review, Office of Safety and Clinical Evaluation, Office of Generic Drugs. She received her Ph.D. in major of Pharmaceutical Sciences and minor of Statistics from Oregon State University. During her more than 18 years tenure in the FDA, she made significant contributions to the approval and regulation of local acting drug products and complex generic drug products. She is a subject matter expert in comparative clinical endpoint study review and a valuable mentor in training new reviewers. She has been an active member on various committees and working groups within FDA. She initiates, leads or participates in multiple research projects, general guidances and product specific guidances development or revision.