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.

Yuqing Gong, PhD
Lead Pharmacologist
DQMM | ORS | OGD | CDER | FDA

Yuqing Gong is currently the Team Lead at the Quantitative Clinical Pharmacology Team in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs (OGD), Center for Drug Evaluation and Research (CDER)/FDA. She has led critical research priorities utilizing quantitative clinical pharmacology approaches and model-integrated evidence (MIE) to develop innovative study designs and methods supporting bioequivalence (BE) demonstrations for generics with complex in vivo study considerations. Dr. Gong received her Ph.D. degree in Pharmaceutical Sciences at the University of Tennessee Health Science Center (Memphis, TN, US) in 2020. Her Ph.D. thesis work was to develop a nanoformulation for antiretroviral drugs to suppress the viral load in the central nervous system across the blood-brain barrier.

Mark Donnelly, PhD
Senior Pharmacologist
DQMM | ORS | OGD | CDER | FDA

Mark Donnelly joined FDA in 2017 and is currently a Senior Pharmacologist in the Quantitative Clinical Pharmacology (QCP) team in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs (OGD). In his current role, Mark uses quantitative clinical pharmacology tools, including modeling and simulation, to address specific questions related to generic drug development, support regulatory decisions, and provide regulatory guidance recommendations. In addition, Mark participates in internal/external research efforts supporting OGD initiatives and has authored several publications. Currently, Mark is serving as Co-Chair of the Narrow Therapeutic Index (NTI) Drug Working Group at FDA. Prior to joining FDA, Mark worked in various positions at Mylan Pharmaceuticals, Bayer Healthcare, and Bayer Corporation. Mark received Bachelor of Science (B.S.) degree in Chemical Engineering from the Pennsylvania State University in 1999 and a doctoral (Ph.D.) degree in Pharmaceutical Sciences, with a research focus in clinical pharmacology, from the University of Pittsburgh in 2014.

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

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.

Arindom Pal, PhD
Pharmacokineticist
DQMM | ORS | OGD | CDER | FDA

Dr. Arindom Pal is a Pharmacokineticist in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards, Office of Generic Drugs at the U.S. Food and Drug Administration (FDA). Dr. Pal earned his Ph.D. in Pharmaceutical Sciences from the University of Pacific, California in 2019. Following his doctoral studies, he completed a three-year postdoctoral fellowship at Johns Hopkins University School of Medicine, where he contributed to the DMPK group within the Johns Hopkins Drug Discovery Center. Dr. Pal joined the FDA in 2023 as an ORISE Fellow and transitioned to his current role as Staff Fellow in 2024. His research expertise encompasses physiologically-based pharmacokinetic (PBPK) modeling, drug metabolism and pharmacokinetics (DMPK), and targeted drug delivery systems. At the FDA, Dr. Pal focuses on oral PBPK modeling and simulations to support regulatory reviews and advance research initiatives within DQMM. His multidisciplinary training in biopharmaceutics, pharmaceutical chemistry, and pharmacology provides a strong foundation for his contributions to pharmaceutical science and regulatory science.

Ja Hye Myung, PhD
Pharmacologist
Division of Bioequivalence III (DB III)
Office of Bioequivalence (OB) | OGD | CDER | FDA

Dr. Ja Hye Myung is a pharmacologist in the Division of Bioequivalence III, Office of Bioequivalence (OB) within the Office of Generic Drugs, CDER/FDA. In her current role, she assesses in vivo bioequivalence studies submitted by pharmaceutical companies through Abbreviated New Drug Applications (ANDAs), as well as in vitro bioequivalence studies for a variety of complex dosage forms, including topical creams and gels, nasal sprays, and long-acting injectables. She currently serves as a member of the OB Specialty Focus Group (SFG) on Modeling and Simulation (M&S) and Complex Data Analysis at FDA. Prior to joining the FDA, Dr. Myung was Chief Scientist at Capio Biosciences and a Postdoctoral Research Fellow at the Oak Ridge Institute for Science and Education. Dr. Myung holds a B.Sc. in Pharmacy and an M.Sc. in Industrial Pharmaceutics from Chungnam National University in South Korea, as well as a Ph.D. in Biopharmaceutical Sciences from the University of Illinois at Chicago.

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

Dr. Lanyan (Lucy) Fang serves as Director of the Division of Quantitative Methods and Modeling (DQMM) within the Office of Research and Standards, Office of Generic Drugs (OGD), CDER/FDA. In this capacity, she oversees quantitative medicine and leads the development of artificial intelligence strategies for FDA's generic drug program.
Dr. Fang has established herself as a recognized FDA expert in applying modeling and simulation methodologies to the review and regulation of generic drugs. She serves on the executive board of CDER's Quantitative Medicine Center of Excellence, contributing to the advancement of quantitative approaches across the center's regulatory activities.
Prior to her current role at OGD, Dr. Fang worked as a senior clinical pharmacology reviewer in FDA's Office of Clinical Pharmacology and as a senior pharmacokinetist at Merck. She holds a PhD in Pharmaceutical Sciences from The Ohio State University and is a graduate of the Excellence in Government Fellows program (2014-2015).

Ross Walenga, PhD
Senior Chemical Engineer
DQMM | ORS | OGD | CDER | FDA

Dr. Ross Walenga joined the FDA in 2015 as an Oak Ridge Institute for Science and Education (ORISE) Fellow. He is currently a Senior Chemical Engineer and the Acting Team Lead for the Locally Acting PBPK Team in the Division of Quantitative Methods and Modeling within the Office of Generic Drugs. He began his career at Virginia Polytechnic Institute and State University (Virginia Tech), where he earned a Bachelor Science in Aerospace Engineering. He later earned his Ph.D. in Engineering (mechanical track) from Virginia Commonwealth University in 2014, where he also spent seven months as a postdoctoral fellow prior to joining the FDA. His research interests include computational fluid dynamics (CFD) and physiologically based pharmacokinetic (PBPK) modeling of orally inhaled, nasal, ophthalmic, topical, and long-acting injectable drug products to answer questions pertaining to bioequivalence.

Khondoker Alam, PhD
Senior Pharmacologist
DQMM | ORS | OGD | CDER | FDA

Dr. Khondoker Alam is currently working as a senior staff fellow in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs (OGD) in FDA. Dr. Alam is serving as scientific lead for complex injectables such as long-acting injectables, liposomal injections etc. His role in the division is to utilize physiologically-based pharmacokinetic (PBPK) modeling and other quantitative tools to address specific questions pertinent to drug development process and/or regulatory decision making. He is responsible for reviewing pre-abbreviated new drug applications (pre-ANDA) meeting packages, ANDA post complete response letter (post-CRL) scientific meeting packages, ANDA consults and controlled correspondences on complex injectables and topical dermatological drug products where model based alternative bioequivalence approach is proposed by ANDA applicant. He is serving as project lead and key technical member for multiple FDA research projects on complex injectables, topical dermatological drug products, buccal/sublingual drug products as well as projects related to mitigation strategy for N-nitrosamine impurities. His research interests include PBPK modeling, development of computational tools for virtual bioequivalence, studying the role of transporter proteins and metabolizing enzymes in drug disposition and drug-drug interactions.

Mingliang Tan, PhD
Senior Pharmacokineticist
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Dr. Ming-Liang Tan is a Senior Pharmacokineticist in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs (OGD). In this role, his responsibilities include managing research projects to support bioequivalence assessments, addressing controlled correspondences and citizen petitions, responding to pre-ANDA meeting requests and internal consults, and developing product-specific guidances. His primary research interests are in physiologically based pharmacokinetics (PBPK) modeling and simulation, with an emphasis on locally acting complex drug products and orally administered drug products.

Fang Wu, PhD
Senior Pharmacologist
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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 14 years. She is responsible for using modeling and simulations tools for reviewing pre-abbreviated new drug applications (pre-ANDA) meeting packages, ANDA consults and controlled correspondences. Prior to joining DQMM, Dr. Fang Wu was a biopharmaceutics reviewer for more than 4 years and responsible for NDA and ANDA reviews. She has been a principal and co-principal investigator for multiple FDA research projects and involved in several guidance working groups and grant review panels.

Colleen Kuemmel, PhD
Policy Analyst
Office of Clinical Pharmacology
Office of Translational Sciences | CDER | FDA

Dr. Kuemmel conducts policy research and development, communications, and outreach in FDA's Office of Clinical Pharmacology. Upon joining the Agency, she began working on a harmonized framework for assessment of computational models and is currently supporting ICH M15 guidance implementation and education among staff. She has contributed to a range of other activities to support and advance model-informed drug development, including engagement with FDA's Modeling & Simulation Working Group. Prior to FDA, she held positions at Novo Nordisk and Argonne National Laboratory. She holds a Ph.D. in Biochemistry from SUNY Upstate Medical University and completed postdoctoral training in Chemical Biology at Cornell University.

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

Yan Wang, PhD
Deputy Division Director
Division of Therapeutic Performance I (DTP I)
ORS | OGD | CDER | FDA

Dr. Yan Wang is the Deputy Director in the Division of Therapeutic Performance I (DTP-I), Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). DTP-I is responsible for facilitating pre-application development of generic drugs by conducting and promoting regulatory science research to establish standards to ensure therapeutic equivalence of new generic drug products. Yan has been at the U.S. Food and Drug Administration since 2013. Prior to her current role, Yan served in various roles, including as the subject matter expert in the area of complex long-acting drug products, and as the Team Lead for the Complex Drug Substance and Complex Formulation Team in ORS/DTP-1. Yan has research interests in developing new analytical methods, in vitro characterization, and drug release testing methodologies for complex drug products. She specializes in complex parenteral, ophthalmic, otic, intravaginal, and intrauterine formulations.

Jihong Shon, MD, PhD
Associate Director for Clinical Safety
Division of Therapeutic Performance II (DTP II)
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Robert Lionberger, PhD
Director
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