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.

Karen Li, PharmD
Staff Fellow
Division of Therapeutic Performance II (DTP II)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD) | CDER

Karen Li is a Pharmacologist on the Clinical Safety and Human Subject Research Team within the Division of Therapeutic Performance II, Office of Research and Standards. Her work primarily focuses on the protection of human subjects in bioequivalence studies by providing guidance and addressing safety inquiries related to product-specific guidance development and pre-application support. Dr. Li has served as the project lead on published work related to swallowability of solid oral dosage forms and pharmacogenetic approaches in generic drug development. She received her Doctor of Pharmacy degree from the University of Maryland School of Pharmacy.

Vilayat Sayeed, PhD
Division Director
Division of Product Quality Assessment II
Office of Product Quality Assessment I (OPQA I)
Office of Pharmaceutical Quality (OPQ) | CDER

Vilayat Sayeed, in his current position, is responsible for the drug product quality assessment of ANDAs and NDAs and related submissions in the division and provides regulatory and technical support to the division staff. He has a Ph.D. in Chemistry from University of Manitoba, Winnipeg, Canada. He is a member of the OGD post-marketing Surveillance team, OND Drug Safety Team and CDER representative in IPRP (International Pharmaceutical Regulators Programme) Quality Working Group.

Andrew Fine, PharmD, BCPS
Commander, United States Public Health Service
Associate Director for Regulatory Affairs
Office of Clinical Review
OGD | CDER

Commander Andrew Fine currently serves as the Associate Director for Regulatory Affairs (ADRA) in OGD's Office of Safety and Clinical Evaluation (OSCE). In his role, he provides clinical, regulatory, and process oversight for generic drug activities in the office. His expertise focuses on clinical and regulatory assessment of suitability petitions and drug-device combination products. Commander Fine joined OGD in 2014 and previously served as Senior Advisor and Team Leader in OGD/OSCE's Division of Clinical Review (DCR). He earned his PharmD from the University of Illinois College of Pharmacy and completed a pharmacy practice residency at Northwestern Memorial Hospital. Andrew is board certified in pharmacotherapy and earned a certificate in pharmacoepidemiology from the University of Pennsylvania.

Fang Wu, PhD
Senior Pharmacologist
Division of Quantitative Methods and Modeling
ORS | OGD | CDER

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.

Jihong Shon, MD, PhD
Associate Director for Clinical Safety
DTP II | ORS | OGD | CDER

Meirong Hao, MS
Lead Pharmacologist
Division of Bioequivalence III
Office of Bioequivalence (OB) | OGD | CDER

Dr. Meirong Hao is a Lead Pharmacologist in the Division of Bioequivalence III (DBIII) within the Office of Bioequivalence, Office of Generic Drugs, CDER, FDA. In her current role, she supports scientific divisional leadership by assessing, evaluating, and determining the acceptability of scientific and regulatory submissions and applications, while providing scientific guidance and technical expertise to team members. Dr. Hao has contributed to the development of FDA guidances and the Manual of Policies and Procedures (MAPP). She leads the pediatric excipient data evaluation working group and has participated in multiple working groups related to excipient evaluation for pediatric populations. Prior to joining the FDA in 2014, she worked as a Senior Pharmacokineticist at Pharmaceutical Product Development (PPD), Inc. Dr. Hao holds a Ph.D. in Medicinal Chemistry/Pharmacology from Peking University in Beijing, China, and a Master's Certificate in Clinical Investigation from Weill Cornell Graduate School of Medical Sciences.

Hye Lim Lim, PharmD
Visiting Associate
DTP II | ORS | OGD | CDER

Hyelim Lim is a Pharmacologist in the Immediate Release (IR) Team in DTP II as a Visiting Associate (Staff Fellow). She works on regulatory activities including product-specific guidance (PSG) development, controlled correspondence review, and pre-ANDA for IR oral drug products. Her research includes administration methods for chewable products in bioequivalence studies, and she is the first author of a published study on standardizing bioequivalence administration methods for chewable tablets. She also serves as Project Officer for research on predicting food-drug and drug-drug interaction risks for high-risk oral drugs. The DTP II is proactively developing PSGs for suitability petition-enabled generic products, including chewable tablet dosage forms. Hyelim presents her research at scientific meetings including the American College of Clinical Pharmacology and American Society for Clinical Pharmacology and Therapeutics. She received her PharmD from the University of Wisconsin – Madison.

Wen Cheng Yang, MD
Senior Staff Fellow
DTP II | ORS | OGD | CDER

Duyen Nguyen, PharmD
Staff Fellow
DTP II | ORS | OGD | CDER

Dr. Duyen Nguyen joined the FDA in 2021 and is currently a Staff Fellow (Pharmacologist) in ORS. She has experience in clinical safety assessments, contributing to the development of product-specific guidances and addressing public inquiries through controlled correspondences, pre-abbreviated new drug application meetings, and docket comments. Her regulatory research focuses on various aspects of subject safety in bioequivalence studies, including reproductive risks, Risk Evaluation and Mitigation Strategy requirements, and concomitant medications. Dr. Nguyen obtained her PharmD from the University of Maryland School of Pharmacy and practiced as a community pharmacist prior to joining the FDA.

Wei-Jhe Sun, PhD
Senior Staff Fellow
DTP II | ORS | OGD | CDER

Dr. Wei-Jhe Sun is a senior pharmacologist in Office of Research and Standards, Office of Generic Drugs, at the U.S. Food and Drug Administration. Dr. Sun contributes to the development of product-specific guidances and drives research projects to improve generic drug quality and establish new regulatory standards. Prior to joining the FDA, he worked in the pharmaceutical industry as a formulation scientist. Dr. Sun earned his Ph.D. in Pharmaceutics from the University of Minnesota. His diverse research interests include abuse-deterrent formulations, formulation design, drug delivery, manufacturing sciences, and solid-state pharmaceutics.

Heather Boyce, PhD
Lead Pharmacokineticist
DTP II | ORS | OGD | CDER

Heather Boyce, PhD, is a Team Lead and Research Scientist in the Office of Generic Drugs at the U.S. Food and Drug Administration (FDA), where she specializes in the regulatory science of complex oral drug products and patient-centric formulation development. Over her nearly ten years at FDA, Dr. Boyce has contributed to the advancement of bioequivalence policy, translational biopharmaceutics, and science-based regulatory strategies supporting generic drug development. Her work focuses on complex oral dosage forms, including modified release and patient-centric formulations, with particular emphasis on bioequivalence assessment, formulation performance, and regulatory pathway development. She has led and supported multidisciplinary initiatives involving FDA guidance development, external research collaborations, and regulatory policy efforts aimed at improving access to high-quality generic medicines.

Dr. Boyce earned her Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore and her B.S. in Chemistry from Temple University. She has presented extensively on topics related to oral drug delivery, complex generics, and pharmaceutical regulatory science. At the SBIA workshop “Advancing Generic Drug Development: Bioequivalence Challenges for Patient-Centric Oral Formulations,” Dr. Boyce will present on orally disintegrating tablets and the unique scientific and regulatory considerations associated with demonstrating bioequivalence for these patient-focused dosage forms.

Shamema Nasrin, PhD
Research Scientist
DTP II | ORS | OGD | CDER

Shamema Nasrin currently serves as a Research Scientist in the Division of Therapeutic Performance II within the Office of Research and Standards at FDA CDER's Office of Generic Drugs. As a member of the Immediate Release Team, her research focuses on ICH M13A implementation and refinement, metabolite analysis and strength waiver frameworks for bioequivalence studies guidance. Her work also encompasses developing and revising Product-Specific Guidances, reviewing controlled correspondence, and evaluating pre-ANDA meeting requests. Prior to joining FDA, she was a Research Scientist in DMPK at Gilead Sciences, where she conducted pharmacokinetic and toxicokinetic analyses, bioanalytical method development, and IND-enabling translational studies. Earlier in her career, she worked in generic pharmaceutical development and regulatory affairs. She holds a Ph.D. in Pharmaceutical Sciences and Molecular Medicine from Washington State University, Spokane, Washington.

Geng Tian, PhD
Research Officer
Division of Pharmaceutical Quality Research VI
Office of Pharmaceutical Quality Research
OPQ | CDER

Lieutenant Commander Geng (Michael) Tian, PhD, serves as a Supervisory Research Officer in the Office of Pharmaceutical Quality within the Center for Drug Evaluation and Research at FDA. Dr. Tian serves as a technical liaison, collaborating with industry, academia, and other government agencies on FDA extramural research programs to advance the development and implementation of innovative manufacturing technologies that ensure drug quality. He actively contributes to regulatory guidance development, supports IND, NDA, and ANDA consults, and participates in Agency workgroups, presentations, and peer-reviewed publications. He currently serves as Vice Chair of ASME V&V 80 and is a member of the FDA Emerging Technology Program (ETP), FDA AI Council, and FDA Advanced Manufacturing Council.

Xiaojian Jiang, PhD
Deputy Division Director
Division of Bioequivalence II
OB | OGD | CDER

Dr. Xiaojian Jiang received her Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore. As a Divisional management and tertiary reviewer of complex BE issues, Dr. Jiang has successfully addressed numerous key scientific/regulatory issues of complex topical dosage forms, locally acting GI products, long acting injectables as well as nasal and inhalation products. During her tenure in the FDA, Dr. Jiang made significant contributions to the approval and regulation of generic locally acting GI drug products, including vancomycin, mesalamine and orlistat. She was the key speakers at various FDA, national and international venues. She also led/participated in many working groups in development of a BE standard for methylphenidate modified-release formulations, NTI method development, NG tube study method and made leading effort to FDA general and individual guidance's covering these areas.

Myong-Jin Kim, PharmD
Division Director
DTP II | ORS | OGD | CDER

Dr. Myong Jin Kim serves as Director of the Division of Therapeutic Performance II within the Office of Research and Standards, Office of Generic Drugs at CDER/FDA. Since joining the FDA in 2001, she has held several key positions, including Deputy Director of the Division of Quantitative Methods and Modeling and Team Leader in the Office of Clinical Pharmacology. Dr. Kim earned her Bachelor of Science degree in Chemistry from the Georgia Institute of Technology. She went on to receive her Doctor of Pharmacy degree from Temple University School of Pharmacy and completed a two-year postdoctoral fellowship in clinical pharmacology at Bassett Healthcare, a major teaching affiliate of Columbia University College of Physicians and Surgeons, in New York.