SPEAKER BIOGRAPHIES

DAY ONE: Wednesday, September 13, 2023 - Welcome & Keynote

Robert M. Califf, MD

Commissioner of Food and Drugs
Food and Drug Administration (FDA)

Robert M. Califf, MD, is Commissioner of Food and Drugs. President Joe Biden nominated Dr. Califf to head the U.S. Food and Drug Administration and Dr. Califf was sworn in on February 17, 2022. Previously, Dr. Califf served as Commissioner of Food and Drugs from February 2016 to January 2017. As the top official of the FDA, Dr. Califf is committed to strengthening programs and policies that enable the agency to carry out its mission to protect and promote public health. Dr. Califf served as the FDA's Deputy Commissioner for Medical Products and Tobacco from February 2015 until his first appointment as Commissioner in February 2016.

Prior to rejoining the FDA, Dr. Califf was head of medical strategy and Senior Advisor at Alphabet Inc., contributing to strategy and policy for its health subsidiaries Verily Life Sciences and Google Health. He joined Alphabet in 2019, after serving as a professor of medicine and vice chancellor for clinical and translational research at Duke University. He also served as director of the Duke Translational Medicine Institute and founding director of the Duke Clinical Research Institute. A nationally and internationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research, Dr. Califf has led many landmark clinical trials and is one of the most frequently cited authors in biomedical science, with more than 1,300 publications in the peer-reviewed literature.

Dr. Califf became a Member of the National Academy of Medicine (formerly known as the Institute of Medicine (IOM)) in 2016, one of the highest honors in the fields of health and medicine. Dr. Califf has served on numerous IOM committees, and he has served as a member of the FDA Cardiorenal Advisory Panel and the FDA Science Board's Subcommittee on Science and Technology. Dr. Califf has also served on the Board of Scientific Counselors for the National Library of Medicine, as well as on advisory committees for the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Environmental Health Sciences, and the Council of the National Institute on Aging. While at Duke, Dr. Califf led major initiatives aimed at improving methods and infrastructure for clinical research, including the Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by the FDA and Duke. He also served as the principal investigator for Duke's Clinical and Translational Science Award and the NIH Health Care Systems Research Collaboratory Coordinating Center.

Dr. Califf is a graduate of Duke University School of Medicine. He completed a residency in internal medicine at the University of California, San Francisco, and a fellowship in cardiology at Duke.

Brenda Stodart, PharmD, BCGP, RAC-US

Captain, United States Public Health Service | *Director*, Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM) | CDER |Food and Drug Administration (FDA)

CAPT Brenda Stodart is currently the Director for the Center for Drug Evaluation and Research's (CDER's) Small Business and Industry Assistance (SBIA) Program. Prior to her current position, CAPT Stodart was a Senior Regulatory Management Officer in the Office of Regulatory Policy (ORP). Before ORP, CAPT Stodart served as a Senior Health Promotion Officer in the Division of Drug Information for nine years. CAPT Stodart received her MS in Regulatory Science from University of Maryland, PharmD from the University of Arkansas Medical Sciences and BS in Pharmacy from Howard University. She is also a Board-Certified Geriatric Pharmacist (BCGP). CAPT Stodart has had experience in hospital and retail pharmacy before joining the FDA.

DAY ONE: Wednesday, September 13, 2023 - Session 1

Session Leads:

Darby Kozak, PhD| Deputy Director | Division of Therapeutic Performance I (DTP I) | Office of Research and Standards (ORS) | Office of Generic Drugs (OGD) | Center for Drug Evaluation and Research (CDER)

Dr. Darby Kozak is the Deputy Division Director for the Division of Therapeutic Performance I in the FDA's Office of Generic Drugs. Dr. Kozak leads a group of interdisciplinary scientists on the development of new analytical methods and equivalence evaluation methodologies for complex drug substances and parenteral, ophthalmic, and otic formulations. Prior to joining the FDA, Dr. Kozak was Chief Scientist for Izon Science and Research Fellow at the Australian Institute for Bioengineering and Nanotechnology. Dr. Kozak has a B.Sc. in Chemical Engineering from the University of Washington (Seattle, WA) and Ph.D. in Chemistry from the University of Bristol (United Kingdom).

Ahmed Zidan, PhD | Senior Staff Fellow | Division of Product Quality Research (DPQR) | Office of Testing and Research (OTR) | Office of Pharmaceutical Quality (OPQ) | Center for Drug Evaluation and Research (CDER)

Dr. Ahmed Zidan is a senior pharmacologist staff in the Division of Product Quality Research of Office of Testing and Research of CDER. Ahmed leads the topical and transdermal drug products laboratories of DPQR and provides hands-on trainings to reviewers on various topics including transdermal delivery systems, in vitro release, and permeation testing of pharmaceuticals, and preformulation consideration for development of topical and oral drug products. In his current role, Dr. Zidan leads the regulatory science research related to topical and transdermal drug products of OPQ. Ahmed leads the research projects of CDER related to the development of in vitro characterization methods for demonstration of bioequivalence of topical products. Dr. Zidan also leads OTR research efforts supporting the development of general and product-specific guidance documents, review strategies for pre-ANDAs and ANDAs and citizen petitions for topical drug products. Ahmed is also an FDA-USP liaison of complex excipients Expert Committee. Ahmed coordinated various workshops and symposia in various national and international events on the regulatory aspects of various dosage forms. His research activities and collaborations produced over 90 publications and 3 book chapters. Prior to joining the FDA, Dr. Zidan was a professor of Pharmaceutics at Zagazig University and King Abdulaziz University. Ahmed completed his bachelor's degree in pharmacy and master's degree in Zagazig University, and his doctoral degree in Drug Delivery in Zagazig University through a joint supervision program with Howard University, Washington D.C.

Priyanka Ghosh, PhD |Lead Pharmacologist | DTP I | ORS | OGD | CDER

Dr. Priyanka Ghosh is a senior pharmacologist within the Division of Therapeutic Performance. Her areas of expertise include products in the topical and transdermal drug delivery area. In her current role, Dr. Ghosh leads regulatory science research initiatives related to topical and transdermal drug products, including projects related to development of noninvasive imaging techniques for evaluation of cutaneous pharmacokinetics, under the GDUFA regulatory science program. Dr. Ghosh also leads the development of general and product-specific guidances, review strategies for pre-ANDA meeting requests and citizen petitions 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.

Hiren Patel, PhD | Senior Staff Fellow | Division of Bioequivalence II (DB II) | Office of Bioequivalence (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.

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

Megan Kelchen, Ph.D., is a pharmacologist in the Division of Therapeutic Performance I. Her specialization is drug products for topical, transdermal, and mucosal 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. Prior to joining FDA, Dr. Kelchen received her B.A. degree from Wartburg College in Biology and her Ph.D. in Clinical Pharmaceutical Sciences from the University of Iowa. She joined the FDA as an ORISE (Oak Ridge Institute for Science and Education) post-doctoral fellow in 2018 before moving into her current role.

Ke Ren, PhD | Deputy Division Director | Division of Bioequivalence III (DB III) | OB | OGD | CDER

Dr. Ke Ren is the currently an acting Deputy Director in the Division of Bioequivalence III (DBIII) in the Office of Bioequivalence of Office of Generic Drugs, CDER, FDA. In this role, she leads a team of scientists responsible for the assessment of the bioequivalence section of Abbreviated New Drug Applications. During her time in DBIII, Dr. Ke Ren has developed extensive expertise in generic drug development in various therapeutic areas, including orally inhaled and nasal drug products. She has participated in the drafting of numerous Agency guidances pertaining to bioequivalence. Dr. Ren received her Ph.D. in Pharmaceutical Science from the University of Florida in 2005 and then undertook post-doctoral training at the University of Florida before joining OGD in 2008.

Kairui (Kevin) Feng, PhD | Senior Chemical Engineer | Division of Quantitative Methods and Modeling (DQMM) | ORS | OGD | CDER

Dr. Kairui (Kevin) Feng joined the Quantitative Clinical Pharmacology team in DQMM/ORS/OGD/CDER/FDA in April 2019. Prior to joining FDA, he worked in Certara, with 13+ years' experience in quantitative clinical pharmacology in Pharsight (a Certara company in Cary, NC, USA) and in translational drug development in Simcyp (a Certara company in Sheffield, UK). He has extensive knowledge/experience in application of preclinical drug development and clinical drug development, including but not limited to drug submission, drug submission review, managing grant/contract applications and acting as grant/contract officer for communicating with internal and external stakeholders. Prior to joining Certara, he worked two years in finance modeling on a portfolio optimization project with Smith Institute in Oxford, UK. Dr. Kevin Feng received a Ph.D. in 2004 in Automatic Control and System Engineering at the University of Sheffield, UK.

Session 1 - Q&A Panel:
Priyanka Ghosh, PhD | Lead Pharmacologist | DTP I | ORS | OGD| CDER – Speaker & Panelist - *(see biography above)*
Hiren Patel, PhD | Senior Staff Fellow | DB II | OB | OGD | CDER – Speaker & Panelist - *(see biography above)*
Megan Kelchen, PhD | Senior Pharmacologist | DTP I | ORS | OGD | CDER – Speaker & Panelist - *(see biography above)*
Ahmed Zidan, PhD | Senior Staff Fellow | DPQR | OTR | OPQ | CDER – Speaker & Panelist - *(see biography above)*
Ke Ren, PhD | Deputy Division Director | DB III | OB | OGD | CDER – Speaker & Panelist - *(see biography above)*
Kairui (Kevin) Feng, PhD | Senior Chemical Engineer | DQMM | ORS | OGD | CDER – Speaker & Panelist - *(see biography above)*

Markham C. Luke, MD, PhD | Division Director | DTP I | ORS | OGD | CDER – Panel Only

Markham C. Luke, M.D., Ph.D. serves as FDA Supervisory Physician (Dermatology) and Director of the Division of Therapeutic Performance 1 (DTP1) in the Office of Research and Standards at OGD. DTP1 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. Markham has been at FDA since 1998 serving various roles, including as the Lead Medical Officer for dermatology drugs in the Office of New Drugs at CDER, Chief Medical Officer and Deputy Director for the Office of Device Evaluation in CDRH, and as Acting Director for Cosmetics in CFSAN. Markham has an M.D. degree and a Ph.D. in Pharmacology from Johns Hopkins University, internal medicine training at Johns Hopkins Bayview Medical Center, and dermatology residency and fellowship at Washington University, St. Louis, MO and at NCI/NIH, Bethesda, MD. Markham is an Associate Professor in Dermatology at the Uniformed Services University of the Health Sciences, Bethesda, MD. Markham has research interests in dermato-pharmacology, clinical pharmacology, product innovation and design – especially for combination drug-device products, clinical study design and endpoints assessment (including patient-reported outcomes) for medical, surgical, and aesthetic products and serves as consultant dermatologist to various parts of FDA

Sam Raney, PhD | Associate Director for Science | ORS | OGD | CDER – Panel Only

Dr. Sam Raney is a thought leader in topical and transdermal drug products, with over 30 years of experience in skin research, producing numerous research manuscripts, review articles, book chapters and patents in pharmaceutical product development. Dr. Raney has been a researcher and adjunct professor within academia, a principal or sub investigator on over 400 pharmaceutical product studies, has held senior management roles in industry, and serves on multiple expert committees and panels for the U.S. Pharmacopeia. He is the Associate Director for Science in the FDA's Office of Research and Standards and serves as the Chief Scientific Advisor for topical product bioequivalence issues in FDA's Office of Generic Drugs. 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.

Pahala Simamora, PhD | Division Director | Division of Liquid-Based Products II (DLBP II) | Office of Lifecycle Drug Products (OLDP) | OPQ | CDER - Panel Only

Dr. Pahala Simamora is a Division Director in OLDP/OPQ/CDER at the FDA. His division is responsible for collaborative assessment of Abbreviated New Drug Applications of drugs of various dosage forms and making risk-informed recommendations on their approvability. He has been involved in several key FDA initiatives including the current ANDA Integrated Quality Assessment process, the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) to evaluate future approaches for regulating mobile manufacturing technologies as well as the Knowledge Aided and Structured Assessment (KASA) initiative for structured drug product assessment of liquid-based products. Prior to joining the FDA in 2010, Pahala spent 14 years in pharmaceutical industry with experience in formulation development, process development and scale-up.

Rong Wang, PharmD, PhD | Associate Director | Division of Bioequivalence I (DB I) | OB | OGD | CDER – Panel Only

Dr. Rong Wang is currently the acting associate director in the Division of Bioequivalence I (DBI), Office of Bioequivalence (OB), Office of Generic Drugs (OGD). Dr. Wang has worked as a pharmacologist in OB for over ten years and accrued extensive knowledge and experiences in generic drug bioequivalence evaluation. She supervises DBI scientists in conducting bioequivalence assessment of abbreviated new drug applications (ANDAs) and addressing inquiries submitted by applicants through control correspondences and meetings such as post complete response meetings and mid-cycle meetings. Dr. Wang also actively participates in various working groups within the Agency where she has contributed her expertise and experiences in revising or developing general guidance for ANDA submission and establishing work process for ANDA assessment. Dr. Wang received her undergraduate degree in pharmacy from Shanghai Medical University and her Ph.D. in Microbial and Biochemical Pharmaceutical Science from Institute of Medicinal Biotechnology, Chinese Academy of Medical Science & Peking Union Medical College in China. Dr. Wang also earned her Pharm.D. from University of Florida. Prior to joining FDA, she had worked as a clinical pharmacist at University of California San Francisco Medical Center.

DAY ONE: Wednesday, September 13, 2023 - Session 2

Session Leads:
Darby Kozak, PhD | Deputy Director | DTP I | ORS | OGD | CDER - *(see biography above)*
Ahmed Zidan, PhD | Senior Staff Fellow | DPQR | OTR | OPQ | CDER - *(see biography above)*
Susan Boc, PhD | Scientific Researcher | DTP I | ORS | OGD | CDER

Dr. Susan Boc is a Pharmacokineticist working in the Division of Therapeutic Performance 1 and specializes in oral inhalation and nasal drug products. She is responsible for the development of product-specific guidances for generic drug development, reviewing and responding to controlled correspondences, pre-ANDA meeting requests, and internal consults. Prior to joining the FDA, she spent over 8 years in the pharmaceutical industry working in the development of drug products for oral inhalation. She received her B.S. in Biochemistry from University of California, Los Angeles, and her Ph.D. in Pharmaceutical Sciences from Virginia Commonwealth University.

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

Dr. Ross Walenga joined the FDA in 2015 as an Oak Ridge Institute for Science and Education Fellow. He is currently a Chemical Engineer at the Division of Quantitative Methods and Modeling at the Office of Research and Standards. 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 7 months as a postdoctoral fellow prior to joining FDA. His research interests include computational fluid dynamics modeling of orally inhaled, nasal, ophthalmic, and dermal drug products to answer questions pertaining to bioequivalence.

Nathan Reed, PhD | Chemist | Division of Complex Drug Analysis (DCDA) Branch 2 | OTR | OPQ | CDER

Nathan Reed, Ph.D. is a Chemist working at the Division of Complex Drug Analysis (DCDA), Office of Testing and Research (OTR), Office of Pharmaceutical Quality (OPQ), Center of Drug Evaluation and Research (CDER) at the FDA since July 2021. He was an ORISE Fellow at in the FDA within DCDA from September 2019 to July 2021. His expertise is primarily in the physiochemical characterization, aerosol dynamics, and dissolution of orally inhaled and nasal drug products (OINDPs). Nathan completed his B.S. in Integrative Biology from the University of Illinois-Urbana Champaign in 2009 and Ph.D. in Chemical Engineering from Washington University in St. Louis in 2019.

Elizabeth Bielski, PhD | Senior Pharmacologist | DTP I | ORS | OGD | CDER

Elizabeth Bielski, M.S., Ph.D. is a Senior Pharmacologist working at Division of Therapeutic Performance-I (DTP-I), Office of Research and Standards (ORS), Office of Generic Drugs (OGD), Center of Drug Evaluation and Research (CDER) at the FDA. Prior to her role as a Senior Pharmacologist, she served as a Pharmacologist (2020-2022), a Chemist (2020), and ORISE Fellow (2018-2020) within DTP. Her areas of expertise involve orally inhaled and nasal drug products (OINDPs) and drug-device combination products (DDCPs). She is actively involved in regulatory guidance development and research initiatives to promote generic drug development of OINDPs and DDCPs. Elizabeth completed her Ph.D. in Chemical Engineering from Wayne State University (Detroit, MI, USA) in 2018. She also received her Master of Science in Biomedical Engineering in 2012 and her Bachelor of Science in Biomedical Physics Honors with University Honors in 2011 from Wayne State University.

Session 2, Q&A Panel:
Susan Boc, PhD | Pharmacokineticist | DTP I | ORS | OGD | CDER – Speaker & Panelist - *(see biography above)*
Ahmed Zidan, PhD | Senior Staff Fellow | DPQR | OTR | OPQ | CDER – Panel Only - *(see biography above)*
Ross Walenga, PhD | Senior Chemical Engineer | DQMM | ORS | OGD | CDER – *(see biography above)*
Nathan Reed, PhD | Chemist | DCDA | OTR | OPQ | CDER – Speaker & Panelist - *(see biography above)*
Elizabeth Bielski, PhD | Senior Pharmacologist | DTP I | ORS | OGD | CDER – *(see biography above)*

Vipra Kundoor, PhD | Pharmacologist| DB I | OB | OGD | CDER – Panel Only

Dr. Vipra Kundoor is a Pharmacologist in the Division of Bioequivalence I within Office of Generic Drugs. She is responsible for assessing the bioequivalence of the various dosage forms of generic drugs. She is also involved in addressing controlled correspondences and pre-ANDA meeting packages. She is the focal point expert for nasal and inhalation drug products within the division and conducts secondary reviews for these complex dosage forms. She is also actively involved in the review panel for the Product-Specific Guidances for nasal and inhalation drug products. Prior to joining FDA in 2010, Dr. Kundoor earned her Ph.D. with specialization in Pharmaceutics at University of Maryland and M.S. with specialization in Pharmacology at South Dakota State University.

Mai Tu, PhD | Chemist, DLBP II | OLDP | OPQ | CDER – Panel Only

Dr. Mai Tu is a Chemist for the Division of Liquid-Based Drug Products II in OPQ's Office of Lifecycle Drug Products. In this role, she has experience working with both solid and liquid dosage forms for different route of administrations, including peptides, inhalation products, complex injectables, ophthalmics, otic products, and topicals. Dr. Tu is an active member of a CDER-wide working group tasked with developing solutions to challenges involved with Maximum Daily Dose. Prior to joining FDA, she worked in the pharmaceutical industry as a formulation scientist in research and development for biological products. She received her Ph.D. in Pharmaceutical Sciences from the University of Iowa and her B.Sc. in Pharmaceutical Sciences from Drake University.

DAY ONE: Wednesday, September 13, 2023 - Session 3

Session Leads: **Cameron Smith, PhD** | Branch Chief | DLBP I | OLDP | OPQ | CDER

Cameron is a Branch Chief in the Office of Lifecycle Drug Products/Office of Pharmaceutical Quality in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration in Silver Spring, MD. Prior to his Agency tenure, he spent 15 years in the pharmaceutical industry as a medicinal chemist, primarily at Merck Research Laboratories in Rahway, NJ and before that at OSI Pharmaceuticals in Durham, NC. Cameron completed his Ph.D. studies in chemistry at the University of Cambridge in Cambridge, UK and followed this up with postdoctoral studies at the University of Utah in Salt Lake City, UT. He obtained his undergraduate degree at Monash University in Melbourne, Australia.

Yan Wang, PhD | Lead Pharmacologist | DTP I | ORS | OGD | CDER

Dr. Yan Wang is the team lead for Complex Drug Substances & Formulation Team in the Division of Therapeutic Performance, Office of Research and Standards. In her current role, Dr. Wang works with a group of interdisciplinary scientists developing product-specific guidances, addressing controlled correspondences, pre-ANDA meeting requests, citizen petitions, and internal consults in the areas of complex drug substances and complex formulations for various routes of administration and dosage forms. She also manages research projects on 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.

Qiangnan Zhang, PhD | Staff Fellow | DTP I | ORS | OGD | CDER

Dr. Qiangnan Zhang is currently a staff fellow in the Division of Therapeutic Performance I, in OGD's Office of Research and Standards. In her current role, Dr. Zhang is responsible for the development of product-specific guidance for generic drug development, reviewing and responding to controlled correspondences, pre-ANDA meeting requests and internal consults. Dr. Zhang also supports research projects on developing new analytical methods and equivalence evaluation methodologies for complex parenteral products. Dr. Zhang completed her Ph.D. in Pharmaceutical Sciences from Temple University and received her B.S. in Pharmaceutical Sciences from China Pharmaceutical University.

Eric Pang, PhD | Senior Chemist | DTP I | ORS | OGD | CDER

Dr. Eric Pang serves as a senior chemist in the Office of Generic Drugs. He specializes is in the analysis of peptide and large molecule drugs. Currently, he serves as the SME for peptide drug products, develops of product-specific guidances of complex drug products, responds to controlled correspondences, pre-ANDA meeting requests, citizen petitions, and consultations. He is also managing several regulatory science projects related to generic peptide products and topics related to immunogenicity. Dr. Pang has over 10 years of experience in the Agency as a research chemist, a CMC reviewer, and a policy lead. Dr. Pang received his Ph.D. in Biochemistry from UCLA, and undergraduate degrees in Molecular Cell Biology and Legal Studies from UC Berkeley.

Session 3, Q&A Panel:
Qiangnan Zhang, PharmD | Staff Fellow | DTP I | ORS | OGD | CDER – Speaker & Panelist - *(see biography above)*
Eric Pang, PhD | Senior Chemist | DTP I | ORS | OGD | CDER – Speaker & Panelist - *(see biography above)*
Dapeng Cui, PhD | Lead Pharmacologist | DB I | OB | OGD | CDER – Panel Only

Dr. Dapeng Cui obtained his B.S. in Microbiology from ShanDong University (Jinan, China) and his Ph.D. in Pharmacology from Chinese Academy of Medical Sciences (Beijing, China). He also has a Master's degree in Pharmacokinetics and Pharmacodynamics from State University of New York at Buffalo, School of Pharmacy and Pharmaceutical Sciences. Dapeng has 5 years of postdoc training in Pharmacology at Georgia State University Department of Biology and Emory University School of Medicine. Before joining the FDA in 2015, Dapeng has 5 years of pharmaceutical industry experience at ICON, a global CRO focusing on clinical pharmacology support for new drug development. Dapeng is currently an Acting Team Lead in FDA/OGD/OB.

Cameron Smith, PhD | Branch Chief | DLBP I | OLDP | OPQ | CDER – Panel Only - *(see biography above)*

DAY ONE: Wednesday, September 13, 2023 - Session 4

Session Leads: **Brock Roughton, PhD** | Branch Chief | DLBP II | OLDP | OPQ | CDER

Dr. Brock Roughton is a Branch Chief in Office of Lifecycle Drug Products (OLDP) Division of Liquid-Based Products II. In this role, he supports his staff in assessment of a variety of liquid-based dosage forms including drug-device combination products and peptide drug products. He is also a member of the OLDP User Acceptance Testing Group for Knowledge-Aided Assessment and Structured Application (KASA) initiative and provides technical support to OLDP staff using KASA for assessment of solid-oral dosage forms. His assessment experience covers a variety of dosage forms, including drug-device combination products and transdermal systems.

Ke Ren, PhD | Deputy Division Director | DB III | OB | OGD | CDER - *(see biography above)*
Qiuxi Fan, PhD | Pharmaceutical Scientist | DLBP II | OLDP | OPQ | CDER

Dr. Qiuxi Fan obtained his PhD degree from the Interdisciplinary Program of Material Science & Engineering from New Jersey Institute of Technology with the research focusing on innovative topical / transdermal drug delivery device/system (formulation, characterizations, IVRT & IVPT). After graduation, he has worked at both brand and generic pharmaceutical companies as well as CROs for more than ten years. Since March 2018, he became the primary CMC assessor in OLDP.

Yoriko Harigaya, PharmD | Senior Staff Fellow | DB II | OB | OGD | CDER

Dr. Yoriko Harigaya is a pharmacologist and staff fellow at the Division of Bioequivalence II, Office of Bioequivalence within the Office of Generic Drugs, CDER/FDA. Prior to joining the Office of Generic Drugs, she served as a clinical pharmacologist and staff fellow of Office of Clinical Pharmacology, Office of Translational Sciences, FDA. In the Office of Generic Drugs, she assesses a wide array of generic drug products. One area of focus for Dr. Harigaya is the assessment of complex ophthalmic drug products and topical dermatological drug products, especially with the recent developments in the characterization-based in-vitro approaches.

Bin Qin, PhD | Senior Chemist | DTP I | ORS | OGD | CDER

Dr. Bin Qin is currently staff fellow in the Division of Therapeutic Performance I, in OGD's Office of Research and Standards. In his current role, Dr. Qin is responsible for the development of product-specific guidance for generic drug development, reviewing and responding to controlled correspondences, pre-ANDA meeting requests and internal consults. Dr. Qin is also the project officer on multiple regulatory science research initiatives related to complex drug products, under the GUDFA regulatory science research program. Dr. Qin completed his Ph.D. in Pharmaceutical Sciences from University of Missouri-Kansas City, and pursued a postdoctoral training in University of Pittsburgh Medical Center. Dr. Qin received his B.S. in Pharmacy and M.S. in Pharmaceutics from China Pharmaceutical University.

William Smith, PhD | Research Scientist | DPQR | OTR | OPQ | CDER

William C. Smith (Billy) is currently an ORISE Fellow with Dr. Xiaoming Xu in the Division of Product Quality Research working on complex drug formulations from emulsions to implantable polymeric devices. His research focuses on the physicochemical characterization of nano- and micro-scale materials, including the development of analytical and in vitro release test methodologies to support assessment and review, equivalence determination, and evaluation of drug product quality. Billy received his Ph.D. in 2019 from the Colorado School of Mines under Dr. Kim R. Williams, in analytical chemistry. His Ph.D. focused on the development of thermal field-flow fractionation for the characterization of hybrid colloidal nanomaterials and polymers with complex architectures.

Session 4, Q&A Panel:
Qiuxi Fan, PhD | Pharmaceutical Scientist | DLBP II | OLDP | OPQ | CDER –Speaker & Panelist - *(see biography above)*
Yoriko Harigaya, PharmD | Senior Staff Fellow | DB II | OB | OGD | CDER – Speaker & Panelist - *(see biography above)*
Bin Qin, PhD | Senior Chemist | DTP I | ORS | OGD | CDER – Speaker & Panelist - *(see biography above)*
William Smith, PhD | Research Scientist | DPQR | OTR | OPQ | CDER – Speaker & Panelist - *(see biography above)*
John Jiang, PhD | Chemist | DLBP II | OLDP | OPQ | CDER – Panel Only

John is a chemist in the Office of Lifecycle Drug Products/Office of Pharmaceutical Quality in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration in Silver Spring, MD. Prior to his Agency tenure, he spent 9 years in US pharmaceutical industry as a formulation principal scientist at Fresenius Kabi USA (previously known as APP Pharmaceuticals) in Skokie, IL. Before his career in pharmaceutical industry, he worked in an NCI contract lab at University of Kentucky College of Pharmacy in Lexington, Kentucky. John completed his MSc and Ph.D. studies in pharmaceutical sciences at Fudan University Shanghai Medical College (previously known as Shanghai Medical University) in Shanghai, China and followed this up with 8 years teaching and research in School of Pharmacy there until coming to the United States in March 2003. He worked as a pharmacist in a hospital pharmacy in Suzhou, China after he received his first degree from China Pharmaceutical University (previously known as Nanjing College of Pharmacy) in Nanjing, China.

Hee Chung, PhD | Lead Pharmacologist | DB I | OB | OGD | CDER – Panel Only

Hee Sun Chung is a Lead Pharmacologist in the Division of Bioequivalence I in the Office of Bioequivalence. She has more than 12 years of experience conducting bioequivalence assessment of generic drug related submissions, including, but not limited to, ANDA and ANDA supplements, pre-ANDA submission meeting requests, pre-ANDA product development meeting requests, controlled correspondences, protocols, as well as product specific guidance (PSG) development requests. She has been involved in various multidisciplinary working groups addressing complex scientific and regulatory issues. More recently, she participated in working groups related to new meetings in GDUFA III, including PSG meetings. Hee Sun received B.S. in Chemistry and M.S. in Inorganic Chemistry from the University of Oklahoma, and Ph.D. in Pharmaceutical Sciences from the University of Michigan.

Khondoker Alam, PhD | Senior Pharmacologist | DQMM | ORS | OGD | CDER – Panel Only

Dr. Khondoker Alam obtained his Ph.D. in Pharmaceutical Sciences at the University of Oklahoma Health Sciences Center in 2017 and completed a one-year Fellowship in the Office of Clinical Pharmacology. Dr. Alam is currently working as a Sr. Staff Fellow at the Division of Quantitative Methods and Modeling at the Office of Research and Standards. His role in the division is to utilize translational tools such as physiologically based pharmacokinetic (PBPK) modeling to address specific questions pertinent to drug development process and/or regulatory decision making. 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 interaction.

Xiaoming Xu, PhD | Division Director | DPQR | OTR | OPQ | CDER – Panel Only

Dr. Xiaoming Xu is the Director of Division of Product Quality Research in Office of Testing and Research in FDA, where he leads multiple regulatory research areas such as complex formulations, nanomaterials and advanced manufacturing. Xiaoming is a member of FDA Nanotechnology Task Force and is responsible for developing international collaborative programs and standards in areas related to nanotechnology. Xiaoming is also an editorial board member of the International Journal of Pharmaceutics. He received his B.S. and M.S. degrees in Pharmaceutics from China Pharmaceutical University and Ph.D. degree in Pharmaceutical Sciences from University of Connecticut.

Closing Remarks:

Lei Zhang, PhD | Deputy Director | ORS | OGD | CDER

Dr. Lei Zhang is the Deputy Director in the Office of Research and Standards (ORS), OGD, CDER, U.S. FDA. ORS implements the Generic Drug User Fee Amendments (GDUFA) science and research commitments to ensure the therapeutic equivalence of generic drug products. Dr. Zhang is an accomplished professional with more than 24 years of combined experiences in the areas of drug research, development and regulatory review and approval. She has contributed to numerous guidance development and research projects focused on the science-based regulatory decision-making. Before joining FDA in 2002, she worked at Bristol-Meyers Squibb Company as a Research Investigator and Preclinical Candidate Optimization Team Leader. Dr. Zhang is an Adjunct Professor in the Department of Bioengineering and Therapeutic Sciences, University of California at San Francisco, Schools of Pharmacy and Medicine. Dr. Zhang received her Ph.D. in Biopharmaceutical Sciences from UCSF. She was a member of the ICH Generic Drug Discussion Group (GDG), serving as the U.S. FDA Topic Leader. Additionally, she is the Rapporteur for ICH M13 Informal Working Group that is developing M13 guideline to harmonize bioequivalence (BE) study design for immediate-release oral dosage form drugs. Dr. Zhang was named American Association of Pharmaceutical Scientists (AAPS) Fellow in 2013.

DAY TWO: Thursday, September 14, 2023 - Session 5

Session Leads: **Lanyan (Lucy) Fang, PhD** | Deputy Division Director | DQMM | ORS | OGD | CDER

Dr. Lanyan (Lucy) Fang currently serves as Deputy Director of the Division of Quantitative Methods and Modeling (DQMM) in OGD's Office of Research and Standards. Prior to that, she served as Associate Director and Team Lead of the Quantitative Clinical Pharmacology team 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 current position, Dr. Fang worked as the senior clinical pharmacology reviewer in the FDA's Office of Clinical Pharmacology (2009 – 2014) and senior pharmacokinetist in Merck (2007 – 2009). Dr. Fang obtained her Ph.D. in Pharmaceutical Sciences from Ohio State University and is a graduate of the Excellence in Government Fellows program (2014-2015).

Michael Spagnola, MD | Lead Physician | Division of Clinical Safety and Surveillance (DCSS) | Office of Safety and Clinical Evaluation (OSCE) | OGD

Dr. Michael Spagnola is an internal medicine and hospital medicine physician. He currently serves as a lead physician in the Division of Clinical Safety and Surveillance in the Office of Safety and Clinical Evaluation in the Office of Generic Drugs. Dr. Spagnola's focus includes the clinical review of orally inhaled generic products, evaluation of the user interface of complex drug-device generic combination products, and retention of reserve samples for bioequivalence studies. Dr. Spagnola received his M.D. from the George Washington University School of Medicine and Health Sciences.

Steven Chopski, PhD | Staff Fellow | DQMM | ORS | OGD | CDER

Dr. Steven Chopski is a chemical engineer in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards, Office of Generic Drugs, Center of Drug Evaluation and Research at the U.S. Food and Drug Administration (U.S. FDA). His research interests include physiologically-based pharmacokinetic (PBPK) modeling and computational fluid dynamics (CFD) modeling of both nasal and orally-inhaled drug products. He has 10+ years of experience in experimental imaging techniques including particle image velocimetry (PIV). He is engaged in regulatory science research initiatives related to generic drug-device combination products.
Dr. Chopski received his PhD in Mechanical Engineering and a B.S. degree in Biomedical Engineering from Virginia Commonwealth University in Richmond, Virginia. Prior to working at FDA, Steven completed a postdoctoral fellowship in the School of Biomedical Engineering, Science and Health Systems at Drexel University which was funded by the American Heart Association.

Zhen Xu, PhD | Staff Fellow | DB III | OB | OGD | CDER

Dr. Zhen Zhang is a Master Pharmacologist in the Division of Bioequivalence I at the Office of Generic Drugs (OGD). With a multifaceted skill set, he serves as a subject matter expert in areas such as data analysis, dissolution, and topical products. He co-leads OGD's Oral PBPK Expert Committee and spearheads the Office of Bioequivalence's efforts to modernize SAS programs to streamline the bioequivalence review process. Dr. Zhang has extensive review experience in complex bioequivalence issues and has contributed to the development of multiple FDA guidance and MAPP. Prior to joining the FDA in 2014, he obtained his Ph.D. in Pharmacology from the University of Wisconsin-Madison and completed his postdoctoral training at the National Institutes of Health.

Fang Yuan, PhD | Senior Chemist | Immediate Office (IO) | OLDP | OPQ | CDER

Dr. Fang Yuan received her PhD degree in Pharmaceutical Science from University of Nebraska Medical Center. She leads the pre-ANDA triage efforts and co-leads the OPQ pre-ANDA Steering Committee by providing periodic updates on pre-ANDA program in quarterly meetings. She is the main Point of Contact for OPQ, focusing on coordinating the communications amongst OPQ stakeholders and facilitating the collaboration with OGD counterparts for the pre-ANDA program. She has been a Chemistry Reviewer in Office of Lifecycle Drug Product since 2016, specialized in quality assessment of pre-market ANDA submissions and pre-ANDA submissions of complex generics including orally inhaled and nasal drug products, and long-acting injectable drug products. She serves as a government liaison in the USP Expert Committee – Aerosol Subcommittee and is a member of several FDA/CDER Working Groups (WGs) including Essential Drug Delivery Outputs (EDDOs) Guidance WG, Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) MDI / DPI products – Quality Considerations Guidance WG, and Long-acting Drug Products WG.

Andrew Clerman, MD, PhD | Senior Physician | Division of Therapeutic Performance I (DTP I) | ORS | OGD | CDER

Dr. Andrew Clerman is a Senior Physician in the Division of Therapeutic Performance I within OGD. Dr. Clerman provides clinical expertise for the division across a variety of regulatory areas and research programs, with a specific interest in the development of generic inhalation products. He serves as OGD's Human Subject Protection Liaison to the FDA's Office of the Chief Scientist, facilitating FDA's generic drug research program. Prior to joining OGD, Dr. Clerman was a Clinical Reviewer in the Office of New Drugs Division of Pulmonology, Allergy and Critical Care. Dr. Clerman has a PhD in Molecular Microbiology and Immunology from the University of Maryland, Baltimore and maintains clinical board certifications in Internal Medicine, Pulmonary Disease, and Critical Care Medicine.

Session 5, Q&A Panel:
Steven Chopski, PhD | Staff Fellow | DQMM | ORS | OGD | CDER – Speaker & Panelist - *(see biography above)*
Zhen Xu, PhD | Staff Fellow | DB III | OB | OGD | CDER – Speaker & Panelist - *(see biography above)*
Fang Yuan, PhD | Chemist | DIMRP III | OLDP | OPQ | CDER – Speaker & Panelist - *(see biography above)*
Andrew Clerman, MD, PhD | Senior Physician | DTP I | ORS | OGD | CDER – Speaker & Panelist - *(see biography above)*
Elizabeth Bielski, PhD | Senior Pharmacologist | DTP I | ORS | OGD | CDER – Panel Only - *(see biography above)*
Srinivas Behara, PhD | Chemist | DIMRP III | OLDP | OPQ | CDER – Panelist Only

Srinivas Behara is serving as a Quality Assessor in Office of Life Cycle Drug Products within the Office of Pharmaceutical Quality. He received M.S (by research) from the University of Sydney, Australia, and Ph.D. from Monash University, Australia, both in the field of orally inhaled drug products. Srinivas Behara has experience reviewing CMC aspects of pre-ANDA, Bio-IND and complex ANDA submissions including nasal sprays and inhalation products.

Tian Ma, PhD | Senior Staff Fellow | DB I | OB | OGD | CDER – Panel Only

Dr. Tian Ma is a bioequivalence reviewer within the Division of Bioequivalence I (DBI), Office of Bioequivalence (OB), Office of Generic Drugs (OGD). In her current role, Dr. Ma is responsible for the bioequivalence review of ANDA applications, including complex ANDAs for nasal and orally inhaled drug products. Prior to joining the FDA, Dr. Ma was a postdoctoral fellow in Dartmouth College. She obtained her B.Sc. in Pharmacology from the University of Toronto, Canada, and her Ph.D. in Pharmacology from Dartmouth College.

DAY TWO: Thursday, September 14, 2023 - Session 6

Session Leads:
Brock Roughton, PhD | Branch Chief | DLBP II | OLDP | OPQ | CDER - *(see biography above)*
Ke Ren, PhD | Deputy Division Director | DB III | OB | OGD | CDER - *(see biography above)*
Wei-Jhe Sun, PhD | Senior Staff Fellow, DTP II, ORS, OGD, CDER

Dr. Wei-Jhe Sun joined the FDA in 2018 and is currently a visiting associate in Office of Research and Standards at the Office of Generic Drugs. He has been working and collaborating on several projects to provide new standards for FDA to evaluate generic drug equivalence. Prior to joining FDA, he worked in the pharmaceutical industry as a formulator. Dr. Sun received his Ph.D. in Pharmaceutics from the University of Minnesota. He has a variety of research interests, including the formulation design, drug delivery, manufacturing sciences and solid-state pharmaceutics. Throughout his time working in the field, he has published 13 peer-reviewed journal articles.

Manar Al-Ghabeish, PhD | Staff Fellow | DTP II | ORS | OGD | CDER

Manar Al-Ghabeish received her B.S. in Pharmacy and M.S. in Pharmaceutical Sciences from the University of Jordan, and she earned her Ph.D. in Pharmaceutics from the University of Iowa. In 2015, Manar joined the Office of Testing and Research (OTR) at the U.S. Food and Drug Administration (FDA). She worked as regulatory research scientist and product quality assessor. The area of research she has been involved in includes abuse deterrent formulations (ADFs), nasal drug delivery, and gastrointestinal local acting drugs. In 2021, Manar moved to the Office of Research and Standards in the Office of Generic Drugs where she continues to be involved in regulatory science related to the therapeutic performance of oral dosage forms.

Suman Dandamudi, PhD | Acting Lead Pharmacologist | DB III | OB | OGD | CDER

Suman Dandamudi is Pharmacologist in the Division of Bioequivalence III, Office of Bioequivalence at FDA. She joined Office of Generic Drugs in 2008. In her current role, Dr. Dandamudi is responsible for the bioequivalence assessment of ANDAs and other regulatory submissions. She has extensive experience in reviewing a wide variety of complex products like liposomal drugs, topical products. She is also involved in addressing control correspondences and pre-ANDA meeting packages Dr. Dandamudi is an active member of several scientific and regulatory working groups with efforts ranging from development of the product specific guidances to global efforts in harmonization of bioequivalence standards. Dr. Dandamudi received her Ph.D. in Pharmaceutical Sciences from Northeastern University, Boston.

Session 6, Q&A Panel:
Manar Al-Ghabeish, PhD | Staff Fellow | DTP II | ORS | OGD | CDER – Speaker & Panelist - *(see biography above)*
Suman Dandamudi, PhD | Lead Pharmacologist | DB III | OB | OGD | CDER – Speaker & Panelist - *(see biography above)*
Alicia Hoover, PhD | Supervisory Chemist | Division of Pharmaceutical Analysis (DPA) | OTR | OPQ | CDER – Panel Only

Alicia Hoover is a chemist in the Office of Testing and Research. She earned her Ph.D. in analytical chemistry from Saint Louis University in 2014. Her research has included evaluating complex drug delivery systems such as transdermal products, drug products for enteral feeding tube delivery, and abuse deterrent opioid formulations.

Fang Wu, PhD | Senior Pharmacologist | DQMM | ORS | OGD | CDER – Panel Only

Dr. Fang Wu is a senior pharmacologist reviewer and scientific lead for oral Physiologically based Pharmacokinetic modeling in Division of Quantitative Methods and Modeling. Dr. Wu has been with FDA for more than 10 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 biopharmaceutics 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.

Hongfei Zhou, PhD | Senior Pharmacologist | DB III | OB | OGD | CDER – Panel Only

Dr. Zhou is a Senior Pharmacologist in the Division of Bioequivalence III (DBIII), Office of Bioequivalence (OB), Office of Generic Drugs (OGD), Center for Drugs Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). Dr. Zhou received his Ph.D. in Toxicology from University of Colorado and has a diversified educational background in Computer Science and Microbiology. He joined the OGD in 2014 as a bioequivalence assessor and has been actively involved in multiple scientific and regulatory working groups either as a group lead or a team member. He is experienced in assessing the in vivo and in vitro bioequivalence of various dosage forms of complex generic drug products. Prior to joining OGD, he has conducted laboratory and computational research to investigate drug induced adverse event mechanisms and provide professional support in scientific data evaluation.

DAY TWO: Thursday, September 14, 2023 - Session 7

Session Leads:
Lanyan (Lucy) Fang, PhD | Deputy Division Director | DQMM | ORS | OGD | CDER - *(see biography above)*
Michael Spagnola, MD | Lead Physician | DCSS | OSCE | OGD | CDER - *(see biography above)*
Sam Raney, PhD | Associate Director for Science | ORS | OGD | CDER - *(see biography above)*
Xiaoming Xu, PhD | Division Director | DPQR | OTR | OPQ | CDER - *(see biography above)*
Liang Zhao, PhD | Division Director | DQMM | ORS | OGD | CDER

Dr. Liang Zhao has been serving as the Director of Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards, Office of Generic Drugs, CDER/FDA since 2015. Dr. Zhao has a broad spectrum of scientific and management experience from industry and the regulatory agency. Through his 16-year professional career, he has established his leadership in industrial R&D, quantitative methods and modeling, and model based strategic decision makings in regulatory and industrial settings for generic and new drugs. He initially joined the FDA as a clinical pharmacology reviewer in the Office of Clinical Pharmacology in 2009 and worked as a team leader in the Division of Pharmacometrics in 2013-2015. Prior to joining FDA, he worked at Medimmune for biotech products, BMS for small molecule drug development, and Pharsight as an associate consultant for new drug R&D. Dr. Zhao has a diversified educational background in Pharmaceutical Sciences, Applied Statistics, and Business Administration.

Session 7, Q&A Panel:
Sam Raney, PhD | Associate Director for Science | ORS | OGD | CDER – Speaker & Panelist - *(see biography above)*
Xiaoming Xu, PhD | Division Director | DPQR | OTR | OPQ | CDER – Speaker & Panelist - *(see biography above)*
Liang Zhao, PhD | Division Director | DQMM | ORS | OGD | CDER – Speaker & Panelist - *(see biography above)*
Darby Kozak, PhD | Deputy Division Director | DTP I | ORS | OGD | CDER – Panel Only - *(see biography above)*
Zhen Zhang, PhD | Master Pharmacologist | DB I | OB | OGD | CDER – Panel Only - *(see biography above)*
Robert Lionberger, PhD | Director | ORS | OGD | CDER – Panel Only

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 18 years ago, he was an Assistant Professor of Chemical Engineering at the University of Michigan.

DAY TWO: Thursday, September 14, 2023 - Session 8

Session Leads:
Lei Zhang, PhD | Deputy Director | ORS | OGD | CDER - *(see biography above)*
Heather Boyce, PhD | Lead Pharmacokineticist | DTP II | ORS | OGD | CDER

Dr. Heather Boyce works for the Office of Research and Standards, Office of Generic Drugs, Center for Drug Evaluation and Research at the Food and Drug Administration in White Oak, MD. Heather has over 10 years of experience in the pharmaceutical industry including expertise in good manufacturing processes (GMP), pharmaceutical product development, bioequivalence trial design and analysis, and generic drug regulation. Heather currently leads the development of product specific guidance development for modified release oral drug products. Heather's current topics of interest and research are focused on clinical study design, clinical pharmacology, and modified release oral drug products. Heather received her PhD in Pharmaceutical Sciences at the University of Maryland, Baltimore, School of Pharmacy where her research focused on excipient properties and formulation design of abuse deterrent formulations. She received her Bachelor of Science degree in chemistry with a minor in mathematics from Temple University of Philadelphia, PA. Heather can be reached at heather.boyce@fda.hhs.gov.

Diana Vivian, PhD | Associate Director | DB II | OB | OGD | CDER

Dr. Diana Vivian joined the Division of Bioequivalence II (DBII) as a primary assessor in 2014 and has served as the Associate Director of DBII since 2019. Dr. Vivian has bioequivalence interests in diverse areas such as complex topical dosage forms, nasal and inhalation products, and the Biopharmaceutics Classification System (BCS). She is currently the co-chair of the CDER-wide BCS Committee. She received her Bachelor of Science degree in Chemical Engineering from the University of Maryland, College Park and her Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore.

Nilufer Tampal, PhD | Associate Director for Scientific Quality | OB | OGD | CDER

Dr. Nilufer Tampal is the Acting Associate Director of Scientific Quality in OGD's Office of Bioequivalence. In this role, Dr. Tampal develops strategies and oversees implementation of data quality and the scientific integrity of bioequivalence data submitted in Abbreviated New Drug Applications (ANDAs). She provides expertise in utilization of advanced analytic data tools supporting ANDA reviews. Dr. Tampal also engages actively in multiple global efforts to support generic drug program. She serves as the Rapporteur for ICH Generic Drug Discussion Group, FDA's Topic Lead on ICH M13 Expert Working Group and on the committee for Global Bioequivalence Harmonization Initiative. She started her career at the FDA in 2002, as an investigator in the Office of Study Integrity and Surveillance (OSIS; pka OSI) and has held various leadership positions in the Office of Bioequivalence in the last 14 years.

Sarah Ibrahim, PhD | Associate Director for Global Affairs | OGD | CDER

Sarah Ibrahim is the Associate Director for OGD's Generic Drug Global Affairs. In this role, Dr. Ibrahim develops strategies to address identified and emerging regulatory challenges in relation to the international nature of the generic drug industry. In collaboration with other CDER and FDA offices, she supports stakeholder engagement concerning issues related to globalization of the generic pharmaceutical supply and harmonization of regulatory approaches for generic drugs. Dr. Ibrahim received her PhD in Biopharmaceutics/Pharmaceutics from the School of Pharmacy, University of Cincinnati and a B.S. in Pharmacy and Pharmaceutical Sciences from Cairo University, Egypt. Dr. Ibrahim started her career at the FDA in 2014 as a scientific reviewer in the Office of Pharmaceutical Quality. Prior to her FDA career, she has years of experience in the US pharmaceutical industry in pharmaceutical development. She is also a coinventor in several patent applications. As an assistant professor, along with the founding faculty, Dr. Ibrahim established the pharmaceutical sciences department for the second school of pharmacy in the state of New Jersey.

Brian Folian, JD, MS | Deputy Director | Office of Study Integrity and Surveillance (OSIS) | Office of Translational Sciences (OTS) | CDER

Brian Folian is the Deputy Office Director in the Office of Study Integrity and Surveillance (OSIS), in FDA CDER's Office of Translational Sciences. His work in OSIS focuses on ensuring the reliability of bioavailability and bioequivalence and good laboratory practice studies to support FDA decision-making on human drug and biologic product applications.

Mr. Folian previously served as Regulatory Counsel in CDER's Office of Compliance (OC) in the Office of Scientific Investigations (OSI). In that role, he was responsible for supporting administrative, advisory, and enforcement actions taken by OSI, which includes ensuring preclinical and clinical studies are conducted in compliance with FDA's regulations.

Prior to joining FDA, Brian Folian worked in academic research at the University of California San Diego, Scripps Research, and the University of Colorado Boulder where his efforts at those institutions focused on diabetes, immunology and cardiovascular aging research, respectively. He holds a Masters of Science (Integrative Physiology) and Juris Doctorate with an emphasis on administrative law.

Session 8, Q&A Panel:
Nilufer Tampal, PhD |Associate Director for Scientific Quality|OB |OGD |CDER – Speaker & Panelist - *(see biography above)*
Lei Zhang, PhD | Deputy Director | ORS | OGD | CDER – Speaker & Panelist - *(see biography above)*
Sarah Ibrahim, PhD | Associate Director for Global Affairs | OGD | CDER – Speaker & Panelist - *(see biography above)*
Brian Folian, JD, MS | Deputy Director | OSIS | OTS | CDER – Speaker & Panelist - *(see biography above)*
Wenlei Jiang, PhD | Senior Advisor for Innovation and Strategic Outreach | ORS | OGD | CDER – Panel Only

Dr. Wenlei Jiang currently serves as Senior Science Advisor at the Office of Research and Standards (ORS)/Office of Generic Drugs (OGD)/Center for Drug Evaluation and Research (CDER)/U.S. FDA. She is leading complex drug product classification and research, promoting global harmonization of bioequivalence criteria, developing opportunities for scientific outreach, and coordinating post-market generic drug safety investigation. She is current Co-chair of International Pharmaceutical Regulator Program (IPRP) Nanomedicine Working Group, Chair at Product Quality Research Institute (PQRI) Steering Committee and serves at National Cancer Institute (NCI) Nanotechnology Characterization Laboratory (NCL) Scientific Oversight Committee. Prior to joining FDA, she was at Novartis Pharmaceutical Corporation where her responsibilities included formulation development of conventional liquid and solid dosage forms, as well as advanced parenteral drug delivery systems. She received her PhD in Pharmaceutics and Pharmaceutical Chemistry from Ohio State University.

Xiaojian Jiang, PhD | Deputy Division Director | DB II | OB | OGD | CDER – Panel Only

Dr. Xiaojian Jiang is currently the Deputy Director for the Division of Bioequivalence II, Office of Bioequivalence. The Division of Bioequivalence is responsible for the review of bioequivalence studies (with pharmacokinetic endpoint) submitted to support approved of ANDAs.

Dr. Xiaojian Jiang received her Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore. She joined the Division of Bioequivalence in 2003 as a pharmacologist reviewer. During her tenure in the FDA, Dr. Jiang made significant contributions to the approval and regulation of many complex generic products. She is an active member on multiple FDA committees and working groups. She has presented and published on a range of complex regulatory, scientific issues including, but not limited to BE approaches for locally acting drug products, in vitro alternative approach for NG tube administration, Uses of Adaptive Design Approach for Generic Bioequivalence Studies, BE assessments for NTI drug products.

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

Dr. Myong-Jin (MJ) Kim currently serves as the director of the Division of Therapeutic Performance II within the Office of Research and Standards. Since joining the Office of Generic Drugs in 2016, Dr. Kim has been leading the efforts to develop product-specific guidances for solid oral dosage forms. In addition to her efforts in product-specific guidance development, she serves as the FDA deputy topic lead for the ICH Expert Working Group on M13: Bioequivalence for Immediate Release Solid Oral Dosage Forms. Dr. Kim graduated from Georgia Institute of Technology in Atlanta, GA, with a Bachelor of Science in chemistry. Subsequently, she received a Doctor of Pharmacy from the Temple University School of Pharmacy in Philadelphia, PA and completed her postdoctoral training in Clinical Pharmacology at Bassett Healthcare (a major teaching affiliate of Columbia University of Physicians & Surgeons) in Cooperstown, NY. Dr. Kim was named a Fellow of American College of Clinical Pharmacology in 2017 and serves on the Editorial Boards of Journal of Clinical Pharmacology and Clinical Pharmacology and Therapeutics.

Closing Remarks

Robert Lionberger, PhD | Director | ORS | OGD | CDER - *(See biography on above page)*

End of Speaker Biographies Document