Advancing Generic Drug Development: Translating Science to Approval Workshop

Speaker, Panelist, and Moderator Biographies

In order of appearance (see Agenda)

Day 1 Faculty

Welcome and Introduction

Maria Monroy-Osorio
Regulatory Health Project Manager
ORS | OGD | CDER | FDA

Maria Monroy-Osorio is a Regulatory Health Project Manager in the Office of Research and Standards (ORS), Office of Generic Drugs (OGD), Center for Drug Evaluation and Research (CDER) and the FDA. As a regulatory health project manager, Maria provides regulatory project management and coordination in alignment with ORS's commitments under the GDUFA program, along with project management and coordination for new, innovative technologies and efforts from ORS to increase industry interaction with FDA such as the Model-Integrated Evidence (MIE) pilot and the Type V Drug Master File (DMF)/Model Master File (MMF) programs. Maria also helps spearhead the development, planning, and execution of internal and external workshops held by ORS in conjunction with other FDA offices and organizations. Prior to her role at FDA, Maria served as a project manager in software development for precision medicine initiatives in cancer clinical trials supported by the National Cancer Institute. Maria also has experience in working with medical device manufacturers helping navigate their regulatory and quality affairs. Outside of her work at the FDA, Maria volunteers as an active member and Operations Captain with her local fire and rescue organization, providing EMS services to the community. Maria is currently obtaining her Master in Professional Studies in Emergency & Disaster Management from Georgetown University and received her Bachelor of Science in Biomedical Engineering from the University of Virginia.

Darby Kozak, PhD
Deputy Director
OGD | CDER | FDA

Dr. Darby Kozak is the Deputy Director for the Office of Generic Drugs (OGD) where he serves as a senior agency advisor in the development and implementation of FDA policies and long-range objectives for generic drug scientific programs and activities, including the development of a strategic plan for the Generic Drug Program. Dr. Kozak started his FDA career in April 2015 in OGD's Office and Research and Standards where he helped develop new analytical methods and equivalence evaluation methodologies for complex generic drug substances and parenteral, ophthalmic, otic, and inhalation formulations. Prior to joining the FDA, Dr. Kozak was Chief Scientist for Izon Science and Research Fellow at The University of Queensland's 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).

Session 1: Insights to Product-Specific Guidance for Complex Products: From Research to Standards

Wenlei Jiang, PhD
Senior Advisor for Innovation and Strategic Outreach
ORS | OGD | CDER | FDA

Dr. Wenlei Jiang is a Senior Biomedical Research and Biomedical Product Assessment Service (SBRBPAS) Expert and currently serves as Senior Advisor for Innovation and Strategic Outreach in the Office of Research and Standards/Office of Generic Drugs. She is leading complex product classification and research, promoting global harmonization of bioequivalence criteria, and developing opportunities for scientific outreach. She is co-chairing a cross-office Subject Matter Expert (SME) Triage Team of Office of Generic Drugs (OGD) and Office Pharmaceutical Quality (OPQ) to facilitate research to support product-specific guidance development for complex products. She also chairs International Pharmaceutical Regulator Programme (IPRP) Nanomedicine Working Group, and supports ICH M13, generic drug cluster, and other global regulatory affairs activities. She is current US Co-Chair for Global Bioequivalence Harmonization Initiative (GBHI) to facilitate science-driven regulations in the field of bioequivalence assessment. She serves at National Cancer Institute (NCI) Nanotechnology Characterization Laboratory (NCL) Scientific Oversight Committee and was the immediate past Chair for Product Quality Research Institute (PQRI) Steering 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 The Ohio State University.

Nahid Kamal, PhD
Pharmacologist
DPQRV | OPQR | OPQ | CDER | FDA

Dr. Nahid Kamal is a Research Pharmacologist and CMC Assessor at 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 cutting-edge research on transdermal, topical, microneedle, implant, and intravaginal drug products. Her research focuses on understanding drug substances, excipients, formulations, and process parameters while evaluating in vitro and in vivo performance through advanced analytical methods for complex generics. She develops comprehensive control strategies to ensure product quality and therapeutic performance. Dr. Kamal has made significant contributions to the FDA's regulatory science initiatives, particularly in evaluating complex drug products and drug-device combinations for women's health under the GDUFA regulatory science research program. Her research has been widely published in peer-reviewed journals and has earned her multiple intramural grants and FDA awards for scientific excellence, recognizing her impact on advancing pharmaceutical regulatory science.

Rangeeta Kumari
Project Manager
OPQR | OPQ | CDER | FDA

Rangeeta Kumari serves as a Project Manager in the Immediate Office of the Office of Pharmaceutical Quality Research (OPQR), where she oversees key programs and initiatives including managing product-specific guidance for complex drug products, overseeing research, testing, and consult portfolios, and leading process improvement efforts. She joined the FDA in November 2016 as a Health Science Policy Analyst in the Center for Devices and Radiological Health (CDRH), bringing prior healthcare experience from Walter Reed National Military Medical Center and Blanchfield Army Community Hospital, as well as private sector experience as a Food Technologist. Rangeeta holds a Master's degree in Healthcare Administration from Austin Peay State University, a Master's in Business Studies, and a Bachelor's in Food Technology, and is a certified Project Management Professional (PMP).

Liangfeng Han, MD, PhD
Clinical Analyst
DTPI | ORS | OGD | CDER | FDA

Liangfeng Han is a Clinical Analyst at Division of Therapeutic Performance, Office of Generic Drugs, FDA. He earned his MD degree at Shanghai Second Medical University and PhD degree at Johns Hopkins University School of Medicine. He has been working on reviewing Pre-ANDA (Abbreviated New Drug Application) meeting requests, Product-Specific Guidances (PSGs) and Controlled Correspondences submitted by pharmaceutical companies for the development program of the proposed generic products and provide recommendations on proposals related to in vitro and clinical study design, clinical efficacy bioequivalence (BE) and human subject safety.

Megan Kelchen, PhD
Senior Pharmacologist
DTPI | ORS | OGD | CDER | FDA

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.

Zhen Xu, PhD
Senior Staff Fellow
DBIII | OB | OGD | CDER | FDA

Dr. Xu reviews bioequivalence of various generic drug products based on the guidances promulgated in FDA. He serves as a focal point for the assessment of complex generic nasal and inhalation products in the Division of Bioequivalence III. He earned his Ph.D. in Pharmaceutical Sciences from Eshelman School of Pharmacy, University of North Carolina where his focus was on dry powder inhalers. Before joining FDA, he had experiences in both academic and industry on aerosol drug delivery. He also received his M.S. degree in carbohydrate chemistry at Michigan State University.

Xiaoming Xu, PhD
Division Director
DPQRV | OPQR | OPQ | CDER | FDA

Xiaoming Xu, Ph.D., serves as Division Director in the Office of Pharmaceutical Quality Research (OPQR) at the U.S. Food and Drug Administration (FDA). In this role, he oversees multiple regulatory science initiatives focused on complex formulations, nanomaterials, and advanced manufacturing. Dr. Xu plays a leading role in the implementation of the Generic Drug User Fee Amendments (GDUFA) III, serving as co-lead of the Complex Product-Specific Guidance (PSG) Working Group, where he promotes the integration of regulatory research into PSG development for complex drug products. He is an active member of the FDA Nanotechnology Task Force and leads international collaborations and standards development in the area of nanotechnology-enabled products. Dr. Xu is an editorial board member of the International Journal of Pharmaceutics and a Fellow of the Controlled Release Society (CRS) and American Association of Pharmaceutical Scientists (AAPS). He holds a B.S. and M.S. in Pharmaceutics from China Pharmaceutical University and earned his Ph.D. in Pharmaceutical Sciences from the University of Connecticut.

Session 2: Novel Bioequivalence Study Design Recommendations

Angelique Besold, PhD
Senior Pharmacologist
DBII | OB | OGD | CDER | FDA

Dr. Angelique Besold is a Senior Pharmacologist in the Division of Bioequivalence II in the Office of Bioequivalence within the Office of Generic Drugs at the FDA. Her primary responsibility is the assessment of bioequivalence studies submitted as part of Abbreviated New Drug Applications (ANDAs). Prior to joining the FDA, Dr. Besold received her PhD in Pharmaceutical Sciences from the University of Maryland School of Pharmacy in 2014. Subsequently, she completed postdoctoral research in the Department of Biochemistry and Molecular Biology at the Johns Hopkins School of Public Health before becoming a Research Associate in 2018. She joined the FDA in in 2021.

Andrew Babiskin, PhD
Lead Pharmacokineticist
ORS | OGD | CDER | FDA

Dr. Andrew Babiskin is a Lead Pharmacokineticist in 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.

CDR Yi Zhang, PhD
Senior Scientific Advisor
DTPII | ORS | OGD | CDER | FDA

CDR Yi Zhang is currently serving as the Senior Advisor for immediate-release oral drug products in Office of Research and Standards. She has a Ph.D. in Pharmacology, Master and Bachelor degrees in Pharmaceutical Sciences. During her detail as the Staff Director in Office of Generics (OGD), she had supervised and led multiple highly impactful projects to implement OGD's executive and strategic plans. CDR Zhang had collaborated with OGD executive leadership to understand office needs, resources, and data available and utilized knowledge management initiatives to enhance information exchange and support office mission. As a subject matter expert in developing and establishing optimal and rigorous bioequivalence (BE) standards and approaches for various drug dosage forms to promote generic drug development and approval, she has pioneered, established and supervised the first-ever developed Product Specific Guidance (PSG) program while she served as the BE Director in OB; led multiple teams in ORS, including PSG Development Team, Dermatological and Topical Product Team, and Immediate Release Oral Solid Dosage Forms Drug Team; expedited international harmonization on generic drugs guidance; collaborated with external stakeholders in leading the development of automatic assessment tools to improve efficiency and accuracy by applying novel artificial intelligence and machine learning; dynamically improved assessment process via implementing templates and tools. She has developed more than 20 educational training programs, mentored and trained more than 200 review staff and team leaders to rally assessment workforce. CDR Zhang also leads multiple research projects to address broad regulatory scientific issues encountered throughout generic drug approvals with more than a dozen publications, especially for Biopharmaceutics Classification System Class III Biowaiver, for a fundamental paradigm change from clinical trials to a novel in-vitro approach for the first time in history to develop generics for topical dermatological products etc. Through developing PSGs, responding to public inquires (including controlled correspondences and citizen petitions), managing pre-ANDA meetings, addressing internal consults, and leading research projects to establish novel BE approaches, CDR Zhang has led her groups to improve FDA's generic drug approval process, provided the transparency to the generic drug industry regarding to regulatory and scientific perspectives, and facilitated the generic industry develop generic

drug products more efficiently and effectively by submitting high quality applications to the FDA.

Usha Katragadda, PhD
Senior Pharmacologist
DBIII | OB | OGD | CDER | FDA

Usha Katragadda serves as a Bioequivalence Reviewer in the Office of Generic Drugs (OGD) located in the Center for Drug Evaluation and Research (CDER). She is responsible for assessing the bioequivalence of the various dosage forms of generic drugs. Usha Katragadda began her service with FDA in 2014. Prior to joining OGD, she conducted one year of post-doctoral training with specialization in transdermal delivery dosage forms at the Division of Product Quality Research/CDER/FDA. Dr. Katragadda has earned a Doctor of Philosophy degree in Pharmaceutical Sciences from Mercer University, Atlanta, GA and worked on nano formulation development. She had earned a Master of Science degree in Chemistry from University of Dayton, Dayton, OH.

Fang Wu, PhD
Senior Pharmacologist
DQMM | ORS | OGD | CDER | FDA

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 13 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.

Min Tzu Chung, PharmD
Pharmacokineticist
DBIII | OB | OGD | CDER | FDA

Min Tzu Chung (goes by Min) is a primary assessor in Division of Bioequivalence III, Office of Bioequivalence/Office of Generic Drugs. Since joining the division in June 2023, Min has been involved in the comprehensive evaluation of generic drug applications. She has been actively engaging in a working group dedicated to the safety evaluation of inactive ingredient for pediatric population. Her work in this area addresses critical knowledge gaps in pediatric drug safety and supports the development of age-appropriate generic formulations. Prior to joining the FDA, Min obtained her Pharm.D. degree from Midwestern University Chicago College of Pharmacy. Following graduation, she gained valuable real-world experience as a clinical pharmacist at United Healthcare, where she applied her clinical expertise to optimize medication therapy management and improve patient outcomes in a managed care setting.

Deniz Ozdin, PhD
Pharmacologist
DQMM | ORS | OGD | CDER | FDA

Deniz Ozdin, PharmB, MSc, PhD, is a pharmacologist in the Division of Quantitative Methods & Modeling (DQMM), Office of Research and Standards (ORS), in the Office of Generic Drugs (OGD) at the FDA. Dr. Ozdin is responsible for reviewing and responding to controlled correspondences, consults, and pre-ANDA meeting requests for generic drug-related submissions and develops product-specific guidances. Her work emphasizes resolving issues associated with alternative bioequivalence approaches and study designs. She utilizes population pharmacokinetics (PPK) modeling and simulations to address questions related to generic drug development and clinical pharmacology-related bioequivalence evaluations. Dr. Ozdin received her PhD in Clinical Pharmacology-Pharmacometrics from the University of Montreal, Canada. During her doctoral studies, she worked as a visiting researcher at the Cancer University Institute of Toulouse (Oncopole) in France, in collaboration with INSERM, focusing on PK modeling of chemotherapeutic agents. Prior to joining the FDA, Dr. Ozdin worked in industry as a pharmacometrician at Learn and Confirm Inc. and subsequently at Syneos Health.

Karen Li, PharmD
Pharmacologist
DTPII | ORS | OGD | CDER | FDA

Karen Li, PharmD is currently a Pharmacologist in the Clinical Safety and Human Subject Research Team within the Division of Therapeutic Performance II, Office of Research and Standards, Office of Generic Drugs. Her current 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 B.S. degree in Biochemistry from the University of Maryland College Park and her Doctor of Pharmacy degree from the University of Maryland School of Pharmacy.

Duyen Nguyen, PharmD
Pharmacologist
DTPII | ORS | OGD | CDER | FDA

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 antiemetic administration. Dr. Nguyen obtained her PharmD from the University of Maryland School of Pharmacy and practiced as a community pharmacist prior to joining the FDA.

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

Yuqing Gong is currently a Senior Pharmacologist 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. Her research focuses on utilizing quantitative tools such as population pharmacokinetics, modeling and simulations, to address specific questions relate to generic drug development process and/or regulatory decision making. Before joining the FDA, she received comprehensive trainings in pharmaceutical sciences with focuses on drug delivery, pharmacokinetics, and drug-drug interactions. 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.

Diana Vivian, PhD
Associate Division Director
DBII | OB | OGD | CDER | FDA

Dr. Diana Vivian joined the Division of Bioequivalence II (DBII) 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 CDERwide 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.

Wanjie Sun, PhD
Master Mathematical Statistician
DBVIII | OB | OTS | CDER | FDA

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 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, Co-Principal Investigator, and Lead Research Scientist. She received her PhD degree in Biostatistics from the George Washington University. Wanjie served as the President of the FDA Statistical Association in 2024. 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.

Closing Remarks Day 1

Yan Wang, PhD
Deputy Division Director
DTPI | 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.

Day 2 Faculty

Welcome and Introduction

Irfan Memon, PharmD
Regulatory Health Project Manager
ORS | OGD | CDER | FDA

Dr. Irfan Memon is a Regulatory Health Project Manager in the Office of Research and Standards (ORS), Office of Generic Drugs (OGD), Center for Drug Evaluation and Research (CDER) and the FDA. As a regulatory health project manager, Irfan provides regulatory project management support for controlled correspondence submissions and pre-ANDA meetings. Irfan Memon received his Doctor of Pharmacy degree from Howard University College of Pharmacy in 2018. Following graduation and licensure as a pharmacist, Irfan held a pharmacy manager position at a community pharmacy and Ambulatory Care Clinical Pharmacist position at the University of Maryland Medical Center.

Session 3: Common Deficiencies and Resolutions: Complex Drug Substances, Complex/Critical Excipients, and Complex Products

Yan Wang, PhD
Deputy Director
DTPI | ORS | OGD | CDER | FDA

See biography above.

Dominick Roselle, PhD
Supervisory Chemist
DPQAIV | OPAI | OPQ | CDER | FDA

Dr. Dominick Roselle is a Supervisory Pharmaceutical Scientist in the Office of Product Quality Assessment I, Office of Product Quality where he provides leadership, program direction, and general supervision for his work unit in the Division of Product Quality Assessment IV. Prior to joining FDA, Dr. Roselle worked as a postdoctoral researcher at the Naval Research Laboratory, Washington, DC, in the Optical Sciences Division after receiving his PhD in Chemistry at the University of Akron.

Bin Qin, PhD
Senior Staff Fellow
DTPI | ORS | OGD | CDER | FDA

Dr. Bin Qin is currently a senior 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 a project officer on multiple regulatory science research initiatives related to complex drug products, under the GDUFA regulatory science research program.

Sami Nazzal, PhD
Senior Pharmacologist
DTPII | ORS | OGD | CDER | FDA

Dr. Sami Nazzal is a Senior Pharmacologist in the Office of Research and Standards (ORS) within the Office of Generic Drugs (OGD) at the U.S. Food and Drug Administration, where he joined in 2024. His areas of expertise include pharmaceutical formulation development of oral immediate and modified release products, lipid-based delivery systems, manufacturing process optimization, analytical characterization techniques, and Quality by Design methodologies. Prior to joining the FDA, Dr. Nazzal served as Professor at Texas Tech University Health Sciences Center and previously at the University of Louisiana at Monroe, where he led an extensively funded research laboratory, developing innovative drug delivery technologies including novel dosage forms and advanced characterization methods. He also gained early industry experience at Cardinal Health, working on formulation development projects for lipid-based and soft gelatin capsule products. Dr. Nazzal is an accomplished researcher with over 90 peer-reviewed publications in leading pharmaceutical journals and holds several patents in drug delivery technologies. He received his Ph.D. in Pharmaceutical Sciences from Texas Tech University Health Sciences Center.

Jinhui Zhang, PhD
Senior Pharmaceutical Scientist
OPQR | OPQ | CDER | FDA

Dr. Jinhui Zhang is a Senior Pharmaceutical Scientist at the FDA/CDER/OPQ/OPQR. His research at FDA focuses on using advanced mass spectrometry and automation for clinical studies and characterization of biotherapeutics and complex drug products. Prior to joining FDA, he held a research faculty appointment at Texas Tech University. He has given over 60 invited podium presentations and 50 peer reviewed publications on regulatory science, drug products quality, proteomics, clinical and preclinical pharmacokinetics, bio-analytical methodologies, pharmacogenomics and omics-based pharmacodynamics biomarkers. Dr. Zhang is an editorial advisory board member of Bioanalysis, and organizing committee member of CASSS DC Discussion Group.

Maotang Zhou, PhD
Division Director
DPQAXVII | OPQAIII | OPQ | CDER | FDA

Dr. Maotang Zhou is currently a Division Director in the Office of Pharmaceutical Quality Assessment III (OPQAIII) within OPQ, CDER, FDA, where he leads a team of scientists in assessing drug substance information for INDs, NDAs, BLAs, and ANDAs. Since joining FDA in 2008 with the former Office of New Drug Quality Assessment (ONDQA), Dr. Zhou has developed extensive expertise in quality assessment and policy development across multiple OPQ suboffices, including OPMA, OPPQ, and OPQAIII. Throughout his tenure at the Agency, Dr. Zhou has made significant contributions to the development of guidances, policies, and Manuals for Policies and Procedures (MaPPs) through his service on various working groups and technical committees at CDER. Prior to his FDA career, he spent 12 years in the pharmaceutical industry, gaining comprehensive experience at both major pharmaceutical companies such as BMS and Pfizer/Wyeth, as well as specialty companies including Chiral

Quest and Cambrex. As an experienced pharmaceutical leader, Dr. Zhou remains committed to FDA's mission of ensuring the availability of safe and effective medicines for patients.

Keduo Qian, PhD
Chemist
DPQAXIX | OPQAIII | OPQ | CDER | FDA

Dr. Keduo Qian has received her Ph.D. in Pharmaceutical Sciences from the University of North Carolina at Chapel Hill. She has joined FDA since 2013 working as a drug substance reviewer. She has also detailed in OPMA in 2018 to 2019, focusing on the assessment of complex API and drug product manufacturing, as well as compliance of manufacturing facilities. Keduo has worked extensively in the assessment of complex APIs, such as low molecular weight heparins, iron colloid products, polysaccharides such as pentosan polysulfate sodium, polymers and peptides. She is a member in the Product Specific Guidance Working Group and serves as the subject matter expert in the area of oligonucleotides, polymers, botanical and complex mixtures.

Dahui Liu, PhD
Senior Pharmaceutical Quality Assessor
DPQAIV | OPQAI | OPQ | CDER | FDA

Dr. Dahui Liu serves as Senior Pharmaceutical Quality Assessor in Unit 1, OPQAI/DPQAIV. She is a member in several working groups on iron colloid products. She joined FDA in 2014, work on solid product first then on liquid-based product since 2017. She has worked on CMC reviews of a large variety of dosage forms, including complex products such as iron colloids, peptides, and liposomes, etc. Dr. Liu received her B.S. degree in Chemistry from Peking University, China and Ph.D. degree in Organic Chemistry from University of Kansas. She then did her postdoc work in Dr. Bill DeGrado’s group at University of Pennsylvania, working on protein design using non-natural building blocks. Before joined FDA, she was a drug discovery and development team leader at PolyMedix, where she invented and led development of two drug candidates that went to phase II clinical trials.

Session 4: Nitrosamines – Known Issues and Practical Advice

Reynolds (Rey) Cantave, PharmD
Senior Regulatory Health Project Manager
Enterprise Project Management Staff
OQA | OPQ | CDER | FDA

Dr. Reynolds Cantave, PharmD has served as a Project Manager enabling the Office of Pharmaceutical Quality's response to the Nitrosamine incident since November 2018. He facilitated Subject Matter Expert engagement in the development of Nitrosamine Guidance and serves as are resource to assessment teams on emerging nitrosamine-related issues, enabling the use and communication of best practices

Christopher Morgan, PhD
Pharmacologist
DPTR | OSCE | OGD | CDER | FDA

Dr. Christopher Morgan is a Pharmacologist in the Division of Pharmacology/Toxicology Review (DPTR), in the Office of Safety and Clinical Evaluation (OSCE), Office of Generic Drugs (OGD). In this role, Dr. Morgan conducts safety assessments on impurities, residual solvents, excipients, and extractables/leachables in generic drug products during pre-ANDA submission, post-ANDA submission, and post-approval stages. Prior to joining DPTR in 2022, Dr. Morgan worked as a researcher at the University of Maryland School of Medicine studying the impact of the parental experience on offspring neurodevelopment. Dr. Morgan received his Ph.D. in Pharmacology from the University of Pennsylvania.

Gang Zhao, PhD
Research Fellow
DTPII | ORS | OGD | CDER | FDA

Gang Zhao joined the Division of Therapeutic Performance (DTP) II within the Office of Research and Standards (ORS) as an ORISE fellow in November 2023. As a member of the Immediate Release (IR) Team, he conducts risk assessments for complex oral drug formulations and supports ICH M13A guidance implementation. His work includes developing and revising product-specific guidances (PSGs) for IR oral drug products, reviewing controlled correspondence on bioequivalence study design, and evaluating the impact of critical excipients and formulation strategies on drug absorption and bioequivalence. Prior to joining the FDA, Gang served as a senior scientist at Ensign Pharmaceutical, where he led preclinical pharmacology studies and specialized in polymeric prodrug delivery systems for poorly soluble drugs and long-acting therapeutics. He earned his B.S. in Biotechnology from Jilin University and Ph.D. in Pharmaceutical Sciences from the University of Nebraska Medical Center.

Matthew Vera, PhD
Supervisory Chemist
DPQAII | OPQAI | OPQ | CDER | FDA

Matthew Vera completed his B.S. in chemistry at Lebanon Valley College, and was a Fulbright Scholar in chemistry at the University of Munich. He subsequently returned to the U.S. and earned a Ph.D. in organic chemistry from the University of Pennsylvania. After completing his degree at Penn, Matt worked as a research scientist in the pharmaceutical industry in the areas of new drug discovery and medicinal chemistry. Matt joined the FDA Office of Generic Drugs in 2010 as a CMC review chemist, focusing on the quality assessment of drug master files (DMFs) and generic drug applications (ANDAs) for solid oral dosage forms. Matt has worked as a review team leader and currently serves as a supervisor in OPQ's Office of Product Quality Assessment I. His group focuses on the quality assessment of pre- and post-market submissions and GDUFA controlled correspondences. Matt currently serves as FDA topic lead in the ICH Q6(R1) expert working group for quality specifications. Additionally, he has extensive experience handling nitrosamine issues from

the quality assessment perspective. Matt also serves as an advisor in some internal nitrosamine research projects with OPQ's Office of Pharmaceutical Quality Research.

Xin Fu, PhD, DABT
Pharmacologist
DPTR | OSCE | OGD | CDER | FDA

Dr. Fu serves as a Pharmacology/Toxicology (Pharm/Tox) reviewer in OGD's Division of Pharmacology/Toxicology Review (DPTR) within the Office of Safety and Clinical Evaluation (OSCE). Her primary role is to conduct safety related Pharm/Tox reviews of generic drug products and drug substances. Before joining OGD in 2017, Dr. Fu was a research scientist, premarket reviewer of medical devices, and nonclinical reviewer of tobacco products at FDA. In her 20-year career across various FDA centers, while primarily serving as a regulatory scientific reviewer, Dr. Fu has led and participated in various toxicological research projects, including ongoing nitrosamine research in recent years. Dr. Fu holds a PhD in Pharmacology and Toxicology from the School of Medicine at the University of Louisville, Kentucky, and has been a Diplomate of the American Board of Toxicology (DABT) since 2005.

Rong Wang, PharmD, PhD
Associate Division Director
DBI | OB | OGD | CDER | FDA

Dr. Rong Wang is currently the Supervisory Associate Director in Division of Bioequivalence I (DBI), Office of Bioequivalence (OB), Office of Generic Drugs (OGD). Dr. Wang started her regulatory science career at Food and Drug Administration (FDA) in 2010 and has since gained approximately 15 years of extensive experience within OGD. Throughout her tenure, Dr. Wang has served as a primary, secondary and tertiary assessor of abbreviated new drug applications (ANDAs), Control Correspondences (CCs), Protocols and various other generic drug related regulatory submissions. Dr. Wang has played an active role in various working groups within the Agency where she has contributed her expertise and experience in revising or developing general guidance for ANDAs and establishing work process for ANDA assessment. Dr. Wang has actively engaged in cross-office and intra-office working groups focused on nitrosamine-related issues. Dr. Wang received her undergraduate degree in pharmacy from Shanghai Medical University and her Ph.D. in Microbial and Biochemical Pharmaceutical Science from the Institute of Medicinal Biotechnology, Chinese Academy of Medical Science & Peking Union Medical College. Dr. Wang also holds a Pharm.D. degree from the University of Florida.

Ee-Sunn (Joanne) Chia, PhD
Division Director
DPQAX | OPQAII | OPQ | CDER | FDA

Dr. Joanne Chia serves as Division Director of the Division of Product Quality Assessment X within the Office of Product Quality Assessment II at the U.S. Food and Drug Administration. In this role, she oversees a team of experienced drug product assessors who provide critical support for Generic Drug User Fee Act (GDUFA) activities and regulatory review processes. Dr. Chia leads several strategic nitrosamine-related initiatives within the product quality assessment office. Her extensive FDA experience includes leadership positions overseeing

units and divisions focused on active pharmaceutical ingredients (APIs), new drug products, and over-the-counter monograph products. Currently, Dr. Chia serves as the FDA Topic Lead on the International Council for Harmonisation (ICH) Q1 Expert Working Group, contributing to international pharmaceutical quality standards development. Dr. Chia holds a Ph.D. in Chemical Engineering from Princeton University and a Bachelor of Science in Chemical Engineering from the University of Virginia.

Closing Remarks for Day 2

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

Dr. Lei Zhang serves as the Deputy Director of Office of Research and Standards within Office of Generic Drugs at the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). She oversees the Generic Drug User Fee Amendments (GDUFA) science and research program to ensure the therapeutic equivalence of generic drug products. Dr. Zhang was previously Senior Advisor for Regulatory Programs and Policy in the Office of Clinical Pharmacology at CDER, FDA. Dr. Zhang is an accomplished professional with more than 26 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 science-based regulatory decision making. Before joining FDA in 2002, she worked at Bristol Meyers Squibb 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 (UCSF), Schools of Pharmacy and Medicine. Dr. Zhang received her Ph.D. in Biopharmaceutical Sciences from UCSF. She is currently the Rapporteur for the ICH M13 Expert Working Group that is developing harmonized guidelines on bioequivalence (BE) for immediate-release solid oral dosage form drugs including M13A, M13B and M13C. Dr. Zhang was inducted American Association of Pharmaceutical Scientists (AAPS) Fellow in 2013. She received the American Society for Clinical Pharmacology and Therapeutics (ASCPT) Malle Jurima-Romet Mid-Career Leadership Award in 2023. She is a member of ASCPT, ISSX, AAPS, and ACCP. She serves/has served various volunteer and leadership roles in these organizations. She has published more than 140 peer-reviewed papers and book chapters.

Thank you for joining us for this year's Advancing Generic Drug Development: Translating Science to Approval Workshop!

List of Acronyms Used in This Document

Center for Drug Evaluation and Research (CDER)
Division of Biometrics VIII (DBVIII)
Division of Bioequivalence I (DBI)
Division of Bioequivalence II (DBII)
Division of Bioequivalence III (DBIII)
Division of Pharmaceutical Quality Research V (DPQRV)
Division of Pharmacology/Toxicology Review (DPTR)
Division of Product Quality Assessment II (DPQAII)
Division of Product Quality Assessment IV (DPQAIV)
Division of Product Quality Assessment X (DPQAX)
Division of Product Quality Assessment XIX (DPQAXIX)
Division of Product Quality Assessment XVII (DPQAXVII)
Division of Quantitative Methods and Modeling (DQMM)
Division of Therapeutic Performance I (DTPI)
Division of Therapeutic Performance II (DTPII)
Food and Drug Administration (FDA)
Office of Bioequivalence (OB)
Office of Biostatistics (OB)
Office of Generic Drugs (OGD)
Office of Pharmaceutical Quality (OPQ)
Office of Pharmaceutical Quality Research (OPQR)
Office of Product Quality Assessment I (OPQAI)
Office of Product Quality Assessment II (OPQAII)
Office of Product Quality Assessment III (OPQAIII)
Office of Quality Assurance (OQA)
Office of Research and Standards (ORS)
Office of Safety & Clinical Evaluation (OSCE)
Office of Translational Sciences (OTS)