SPEAKER BIOGRAPHIES

DAY ONE: Wednesday, April 22, 2026

Brenda Stodart, PharmD, BCGP, RAC-US
Captain, United States Public Health Service (USPHS)
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI)
Center for Drug Evaluation and Research (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) and holds a RAC-US certificate. CAPT Stodart has had experience in hospital and retail pharmacy before joining the FDA

Kori Adair, PharmD
Pharmacist
SBIA | DDI | CDER | FDA

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

Darby Kozak, PhD
Deputy Director
Office of Generic Drugs (OGD)
CDER | FDA

Dr. Darby Kozak is the Deputy Director for the Office of Generic Drugs 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 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).

Susan Rosencrance, PhD
Deputy Director for Science
Office of Pharmaceutical Quality (OPQ)
CDER | FDA

Dr. Susan M. Rosencrance is an executive leader at the FDA's Center for Drug Evaluation and Research (CDER) with over 20 years of expertise in pharmaceutical regulatory assessment. Currently serving as Deputy Director for Science in the Office of Pharmaceutical Quality (OPQ), she provides executive leadership for five sub-offices focused on the CMC portion of application review. Throughout her career, Dr. Rosencrance has served in a variety of senior roles including the Director for OPQ's Office of Lifecyle Drug Products from 2015-2024, the Acting Director for CDER's Office of Generic Drugs in 2022-2023, as well as the Deputy Director for Generic Drug Chemistry in CDER's former Office of Pharmaceutical Science from 2013-2015. Before joining the FDA, Dr. Rosencrance worked in pharmaceutical research and development at Merck & Co. She holds a Ph.D. in Chemistry and completed her dissertation research at the NIH Laboratory for Biophysical Chemistry.

Marcia Fields, PharmD
Lieutenant Commander
United States Public Health Service (USPHS)
Regulatory Officer
Office of Regulatory Operations (ORO)
OGD | CDER | FDA

Lieutenant Commander Marcia Fields is a Controlled Correspondence Coordinator for the Office of Regulatory Operations in the Immediate Office in the FDA's Center for Drug Evaluation and Research (CDER). She received her Doctorate in Pharmacy from the Medical College of Virginia/Virginia Commonwealth University School of Pharmacy. Thereafter, she completed a Specialty Residency in Drug Information with West Virginia University. Prior to joining CDER, she was in FDA's Office of Inspections and Investigations as a Pharma Investigator. Before joining FDA, she gained experience in ambulatory care pharmacy and in the pharmaceutical industry.

Zhen Zhang, PhD
Master Pharmacologist
Division of Bioequivalence I (DB I)
Office of Bioequivalence (OB)
OGD | CDER | FDA

Dr. Zhen Zhang is a Master Pharmacologist in the Division of Bioequivalence I, Office of Bioequivalence, within the FDA's Office of Generic Drugs (OGD). His extensive expertise includes data analysis, modeling and simulation, dissolution studies, and topical product evaluations. Dr. Zhang leads efforts to modernize data analysis tools within the Office of Bioequivalence, significantly enhancing the efficiency of bioequivalence reviews. He also co-leads OGD's Oral PBPK Expert Committee. Over the course of his career, Dr. Zhang has addressed numerous complex bioequivalence challenges and played a key role in the development of several FDA general guidances. Dr. Zhang earned his Ph.D. in Pharmacology from the University of Wisconsin-Madison.

Truong-Vinh "Vinh" Phung, PharmD
Commander, United States Public Health Service (USPHS)
Regulatory Officer, Division of Filing Review (DFR)
ORO | OGD | CDER | FDA

Commander Vinh Phung is a supervisor in the Division of Filing Review (DFR). He joined the FDA in 2014 as a reviewer and has progressed through various positions including Project Manager and Team Leader. Prior to joining FDA, he served as a commissioned officer in the U.S. Air Force, where he held a spectrum of clinical, administrative, and leadership roles. Vinh received his Doctor of Pharmacy from Massachusetts College of Pharmacy and Health Sciences and brings over 15 years of combined military and regulatory experience to his leadership role.

Eric Twum, PhD
Regulatory Specialist
Division of Quality Intelligence II
Office of Quality Surveillance (OQS)
OPQ | CDER | FDA

Eric Twum is a Regulatory Specialist in the Office of Pharmaceutical Quality in the FDA's Center for Drug Evaluation and Research. Eric has experience supporting the evaluation of pharmaceutical quality systems, analyzing post-market surveillance data, and helping advance FDA's Quality Management Maturity (QMM) program.

Julia Lee, PharmD
Deputy Division Director
DFR | ORO | OGD | CDER | FDA

Dr. Julia Lee is the Deputy Director in the Division of Filing Review. She joined the Office of Generic Drugs in 2012 as a regulatory filing reviewer. Prior to working at the Agency, she was a retail pharmacist at Walgreens. She has also worked in the Chesapeake-Atlantic node of the Pediatric Emergency Care Applied Research Network as a clinical research assistant. She received her Doctor of Pharmacy at the University of Maryland, Baltimore, School of Pharmacy and her Bachelor of Science in Chemistry at The George Washington University.

Christina Marshall, MS
Project Manager
ORO | OGD | CDER | FDA

Christina Marshall is a Project Manager who works on controlled correspondences, she joined the Controls Team in 2018 in the Immediation of Office in the Office of Generic Drugs, where she supports the development and review of generic drug products within the Center for Drug Evaluation and Research. With a background in pharmaceutical sciences and over a decade of experience in regulatory operations, she specializes in stakeholder communication, regulatory policy, and drug development processes.

She has held roles across oncology, antimicrobial products, and biotechnology, contributing to postmarketing safety, regulatory submissions, and cross-agency coordination. Christina is passionate about advancing public health through science, communication, and regulatory excellence.

Diana Solana-Sodeinde, PharmD, MPH
Commander, United States Public Health Service (USPHS)
Lead Program Coordinator for FDA's Inactive Ingredient Database
Immediate Office (IO)
OB | OGD | CDER | FDA

CDR Diana Solana-Sodeinde is currently serving as the Lead Program Coordinator for the FDA Inactive Ingredient Database (IID) program, operated by the Immediate Office of the Office of Bioequivalence within the Office of Generic Drugs (OGD) at the Food and Drug Administration (FDA).
CDR Solana-Sodeinde received a doctorate degree in Pharmacy (Pharm.D.) from Howard University, Washington DC in 2007; a master's certificate in Project Management from the George Washington University, Washington DC in 2015; and a master's degree in Public Health- Global Health concentration (MPH-GH) from the Liberty University, Lynchburg, VA in 2021.

Upon graduation from pharmacy school, CDR Solana-Sodeinde worked as a Pharmacist at the Johns Hopkins Hospital, Baltimore, Maryland prior to joining the United States Public Health Service as a Pharmacy Officer in 2008. Since 2008, CDR Solana-Sodeinde worked at FDA in OGD's Office of Bioequivalence and served in different roles as Regulatory Health Project Manager from 2008 to 2013; Supervisory Project Manager from 2013 to 2016; Associate Director of Regulatory Affairs from 2016 to 2023; and then, transitioned in 2023 to lead the FDA IID program that was transferred from the Office of Pharmaceutical Quality to OGD on June 1, 2024.

Melanie Mueller, PharmD, PhD
Master Toxicologist
Division of Pharmacology/Toxicology Review (DPTR)
Office of Safety and Clinical Evaluation (OSCE)
OGD | CDER | FDA

Melanie Mueller is a Master Toxicologist in the Division of Pharmacology/Toxicology Review in the Office of Generic Drugs at FDA's Center for Drug Evaluation and Research. She earned her PharmD (2005) and PhD in Pharmaceutical Sciences (2009) from the University of Saarland, Germany.

Dr. Mueller has extensive expertise in safety assessment of generic drugs across multiple therapeutic areas. She represented OGD on several policy and guidance working groups, including the development of guidance for industry on using FDA's Inactive Ingredient Database, and has supported multiple ICH efforts. Dr. Mueller has also led initiatives to develop policies and procedures that ensure consistent review approaches throughout a drug product's lifecycle.

Likan Liang, PhD
Supervisory Pharmaceutical Scientist
Division of Product Quality Assessment X
Office of Product Quality Assessment II (OPQA II)
OPQ | CDER | FDA

Dr. Likan Liang is a unit supervisor in the Office of Product Quality Assessment II, OPQ, CDER, FDA. Dr. Liang served as the OPQ chair in reviews of many oligonucleotide pre-ANDAs and contributed to the development of many published product specific guidance for generic oligonucleotides. Dr. Liang had been a quality assessor in the previous immediate release drug product and modified release drug product review divisions, and a branch chief in the liquid-based drug product review division. Prior to joining the FDA in 2013, Dr. Liang has worked in the pharmaceutical industry for about 16 years, in areas including API synthesis, formulation development of various dosage forms and complex products, as well as process development, scale up, and commercial scale manufacturing of drug products. Dr. Liang has a Ph.D. degree in organic chemistry.

Karen Rothschild, JD
Regulatory Counsel
Division of Legal and Regulatory Support (DLRS)
Office of Generic Drug Policy (OGDP)
OGD | CDER | FDA

Karen Rothschild is a Regulatory Counsel in the Office of Generic Drug Policy, Division of Legal and Regulatory Support, and advises the Office of Generic Drugs on application-specific legal, regulatory, and policy issues, as well as serves as an expert on Hatch-Waxman and other generic drug regulatory issues. Karen earned her BA in Government from Oberlin College, a Certificate in International Human Rights Law from Oxford University (UK), her Juris Doctor (JD) from the Benjamin N. Cardozo School of Law, and a Certificate of Public Health from Georgetown University.

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

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

Bayli Larson, PharmD
Pharmacist
DLRS | OGDP | OGD | CDER | FDA

Bayli Larson joined FDA in 2023 in the Office of Generic Drug Policy as a pharmacist with the Patent and Exclusivity Team. Bayli advises OGD on generic drug application-specific legal, regulatory, and policy issues and patent and exclusivity matters for brand and generic drugs.

Andrew Kim, PharmD
Commander, United States Public Health Service
Supervisory Project Manager
Division of Project Management (DPM)
ORO | OGD | CDER | FDA

CDR Andrew Kim is a Supervisory Project Manager in the Division of Project Management (DPM), Office of Regulatory Operations (ORO) within the Office of Generic Drugs (OGD) since 2016. He began his career at the FDA as a Chemistry Project Manager in 2010 and served as a Regulatory Project Manager and a Team Leader in DPM. He received his Pharm.D. from the University of Maryland School of Pharmacy.

Heather Strandberg, PharmD
Pharmacist
Patent and Exclusivity Team (PET)
DLRS | OGDP | OGD | CDER | FDA

Heather Strandberg has been with the Patent and Exclusivity Team (PET) in the Division of Legal and Regulatory Support (DLRS) for 10 years. Prior to joining PET, Heather served in roles as a Regulatory Project Manager (RPM) and Team Leader in the Office of Generic Drugs (OGD) and Office of Pharmaceutical Quality (OPQ). Heather earned her Doctor of Pharmacy degree at the University of California, San Diego, and completed a post-doctoral fellowship focusing on drug safety surveillance and signal detection at Janssen Research and Development, LLC.

Truong Quach, PharmD
Team Lead Pharmacist
Division of Orange Book Publication and Regulatory Assessment (DOBPRA)
OGDP | OGD | CDER | FDA

Truong Quach is a Team Lead pharmacist working in the Office of Generic Drugs, Division of Orange Book Publication and Regulatory Assessment and has been with the DOBPRA since 2018. As an Orange Book Pharmacist, he helps the Orange Book publication by identifying drug products approved on the basis of safety and effectiveness by the FDA and related patent and exclusivity information.

Rosanne (Rosie) Pagaduan, PharmD
Supervisory General Health Scientist
DFR | ORO | OGD | CDER | FDA

Dr. Rosie Pagaduan serves as a supervisor in the Division of Filing Review (DFR). She holds a Bachelor of Science in Microbiology and Cell Science and a Doctor of Pharmacy (Pharm.D.) from the University of Florida. Before joining the FDA, she worked in retail pharmacy for three years in southern Maryland and the Washington, D.C. area. Since joining the FDA in 2014, Dr. Pagaduan has advanced through progressively responsible positions, including Filing Reviewer and Team Leader, before assuming her current supervisory role. Her expertise focuses on the regulatory and process oversight of the filing review of abbreviate new drug applications and the clinical and regulatory assessment of suitability petitions.

Joseph Kotsybar, PharmD
Regulatory Health Project Manager
Office of Research and Standards (ORS)
OGD | CDER | FDA

Dr. Joseph Kotsybar is the Program Lead for the Product-Specific Guidance (PSG) program, overseeing the development and management of guidance documents that provide recommendations to industry on demonstrating bioequivalence for generic drug products. He joined the FDA in 2020 as a Research Fellow, where he conducted research on tracking Product-Specific Guidance (PSG) Generic Drug User Fee Amendments (GDUFA) commitment measurables and supported the development of International Council for Harmonisation (ICH) M13 guidelines.

Dr. Kotsybar holds a Doctor of Pharmacy degree from St. Louis College of Pharmacy and dual Bachelor of Science degrees in Chemistry and Biological Sciences from Southern Illinois University, Edwardsville. His diverse scientific background combines practical knowledge in pharmaceutical sciences, chemistry, and biological research with regulatory expertise.

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

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

Myong-Jin (MJ) Kim, PharmD
Division Director
Division of Therapeutic Performance II (DTP II)
ORS | OGD | CDER | FDA

Dr. Myong Jin Kim serves as Director of the Division of Therapeutic Performance II within the Office of Research and Standards, Office of Generic Drugs at CDER/FDA. Since joining the FDA in 2001, she has held several key positions, including Deputy Director of the Division of Quantitative Methods and Modeling and Team Leader in the Office of Clinical Pharmacology.

Dr. Kim earned her Bachelor of Science degree in Chemistry from the Georgia Institute of Technology. She went on to receive her Doctor of Pharmacy degree from Temple University School of Pharmacy and completed a two-year postdoctoral fellowship in clinical pharmacology at Bassett Healthcare, a major teaching affiliate of Columbia University College of Physicians and Surgeons, in New York.

Sheela Rajesh, PhD
Senior Pharmaceutical Quality Assessor
OPQA II | OPQ | CDER | FDA

Dr. Sheela Rajesh is a Senior Pharmaceutical Quality Assessor (SPQA) in the Division of Product Quality Assessment IX (DPQA IX), within Office of Product Quality Assessment II (OPQA II) in OPQ/CDER at FDA. In this role, Dr. Rajesh performs secondary drug product quality assessments for ANDAs and serves as an Application Technical Lead (ATL) within her aligned team. Since 2014, she has worked on a variety of dosage forms, including parenteral, complex peptides, ophthalmic, topical, oral solutions, and solid oral drug products. She is also experienced in the assessment of INDs, controlled correspondence, and post approval supplements. Prior to joining FDA as a quality assessor, Dr. Rajesh was a Senior Medicinal Chemist for eight years in a Biotechnology company. She earned her PhD in Synthetic Organic Chemistry from CSIR- National Institute for Interdisciplinary Science and Technology (NIIST) in India. In addition, she completed two post-doctoral studies in Europe and one in USA.

Erin Skoda, PhD
Supervisory Pharmaceutical Scientist
Office of Product Quality Assessment III (OPQA III)
Office of Pharmaceutical Quality (OPQ)
CDER | FDA

Erin Skoda is currently a Supervisory Pharmaceutical Scientist in the Office of Product Quality Assessment III in the Office of Pharmaceutical Quality (OPQ). She has worked on CMC quality assessment, office initiatives and policies, and collaborations with several divisions and offices within the Agency. She holds a Ph.D. in organic chemistry from the University of Pennsylvania. Prior to joining the FDA in 2014, Erin worked as a medicinal chemist.

Deborah Johnson, PhD
Supervisory Pharmaceutical Scientist
OPQA III | OPQ | CDER | FDA

Deborah Johnson has a Ph.D. in Organic Chemistry from Brigham Young University. She worked as a pre-formulation chemist for Wyeth Pharmaceuticals for 4 years and then joined the US FDA in Aug 2010 as an CMC assessor for Abbreviated New Drug Applications (ANDAs). In 2012 she joined the newly formed Drug Masterfile Review team. After the Office of Pharmaceutical reorganization this group became known as the Division of Lifecycle API (DLAPI) and is now located in the Office of New Drug Products. In 2014 Deborah became a branch chief and is still serving in that position.

Madhusudhan Gowravaram, PhD
Senior Pharmaceutical Quality Assessor
OPQA III | OPQ | CDER | FDA

Madhusudhan Gowravaram is a Senior Pharmaceutical Quality Assessor and Team Leader in Division XVII/OPQA III/OPQ/CDER/FDA. He has been at the FDA since 2014. During his career at the FDA, he has been involved in the quality assessment of Active Pharmaceutical Ingredients (APIs) in support of ANDA and NDA applications. Prior to joining the FDA, he worked as a Medicinal Chemist in Pharmaceutical R&D for 20 years, where he contributed to several R&D programs in the infectious disease, cancer, and inflammatory disease areas. His educational background is in synthetic chemistry, with a Ph.D. in Organic Chemistry and an M.Sc. in Chemistry.

Sherry Bai, PhD
Chemist
Office of Product Quality Assessment I (OPQA I)
OPQ | CDER | FDA

Dr. Sherry Bai is a CMC (Chemistry, Manufacturing, and Controls) assessor at the FDA, where she has focused on drug product quality since 2017. Her role involves reviewing INDs and pre- and post-market ANDA submissions. She works on complex drug products, such as peptides and colloidal iron products. She also contributes to USP chapter reviews and the drafting of product-specific guidances (PSGs). Prior to joining the FDA, Dr. Bai gained seven years of industrial R&D experience in nanocomposite materials, covering synthesis, formulation, application development, and process scale-up. She holds a Ph.D. in Chemistry from the University of Maryland College Park.

Arlene Chen, PhD
Pharmaceutical Scientist
Division of Pharmaceutical Manufacturing Assessment III (DPMA III)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Generic Drugs (OGD)
CDER | FDA

Arlene Chen is a Pharmaceutical Scientist in the Office of Pharmaceutical Manufacturing Assessment in the FDA's Center for Drug Evaluation and Research. She received her B.S. in Microbiology and Ph.D. in Environmental Molecular Biology and Biotechnology from the University of Maryland. Arlene has experience in microbiological quality assessment of both sterile and non-sterile drug products in support of ANDA, NDA, and IND submissions.

Amit Kokate, PhD
Senior Biologist
DPMA III | OPMA | OGD | CDER | FDA

Amit Kokate, Ph.D., is a Senior Biologist in the Office of Pharmaceutical Manufacturing Assessment (OPMA), Office of Pharmaceutical Quality (OPQ), Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. His work focuses on the integrated quality assessment of the manufacturing process, facilities and microbiology for INDs, NDAs and ANDAs for a wide range of dosage forms, with specialization in drug-device combination products including transdermal and topical delivery systems (TDS). Prior to joining FDA in 2018, Amit worked in the pharmaceutical industry for 11 years with expertise in the areas of formulation & process development, scale-up, technology transfer and process validation. Amit received his M.S. and Ph.D. degrees in Pharmaceutical Sciences from University of the Pacific, California.

Vicky He, MS
Senior Chemist
DPMA III | OPMA | OGD | CDER | FDA

Vicky He is a Senior Chemist in Pharmaceutical Manufacturing Assessment within the Office of Pharmaceutical Quality at the FDA's Center for Drug Evaluation and Research. In this role, Vicky is responsible for reviewing the Chemistry, Manufacturing, and Control data for ANDAs and NDAs, covering a wide range of dosage forms, including oral inhalers. Prior to joining the FDA in 2019, Vicky spent over 15 years in the pharmaceutical industry focused on small-molecule drug product development. Vicky received her BS in Chemical Engineering from Rensselaer Polytechnic Institute, and MS in Chemical Engineering from Stevens Institute of Technology.

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

Dr. Ke Ren is the Deputy Division Director for 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.

Xin Fu, PhD, DABT
Senior Pharmacologist
Division of Pharmacology Toxicology Review (DPTR)
Office of Safety and Clinical Evaluation (OSCE)
OGD | CDER | FDA

Dr. Xin Fu serves as a Senior Pharmacologist Reviewer in the Division of Pharmacology/Toxicology Review in the Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research. She earned her Ph.D. in Pharmacology and Toxicology from the University of Louisville, Kentucky, and has been a Diplomate of the American Board of Toxicology (DABT) since 2005. Throughout her career at the FDA, she has developed extensive expertise in the scientific regulatory review and safety assessment of generic drugs and medical devices. Her work spans a broad range of therapeutic areas and toxicological specialties. She has been actively engaged in scientific research projects that directly support FDA regulatory reviews. In recent years, she has focused particularly on nitrosamine toxicological risk assessment, contributing to the FDA's ongoing efforts to address nitrosamine impurity-related safety concerns in pharmaceutical products.

Min Guo, PhD
Pharmacokineticist
Division of Bioequivalence I (DB I)
OB | OGD | CDER | FDA

Dr. Min Guo is a Pharmacokineticist in the Division of Bioequivalence I, Office of Bioequivalence, Office of Generic Drugs at the FDA's Center for Drug Evaluation and Research, a position he has held since April 2024. Previously, Dr. Guo served as a bioequivalence reviewer in the Division of Generic Animal Drugs at the FDA's Center for Veterinary Medicine from 2019 to 2024.

Prior to joining the FDA, Dr. Guo conducted postdoctoral research at the National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health (2015-2019), where he specialized in development and GMP production of C-11 and F-18 based PET imaging radiopharmaceuticals for studying substance abuse effects on the brain in clinical neuroimaging studies.

Dr. Guo earned his Ph.D. in Organic Chemistry and Biochemistry from the University of Maryland, College Park, and holds an M.S. and B.S. in Chemistry from Nanjing University, China.

Paramjeet Kaur, PHD
Lead Pharmacokineticist
Division of Bioequivalence II (DB II)
OB | OGD | CDER | FDA

Dr. Paramjeet Kaur is a Lead Pharmacokineticist in the Division of Bioequivalence II. In this role, she leads a team of scientists assessing the bioequivalence of the various dosage forms of generic drugs. She is also involved in addressing controlled correspondences and pre-ANDA meeting packages, as well as the development and revision of both product-specific and general guidances. Dr. Kaur received her Bachelor of Pharmacy from the Banaras Hindu University, India, and Doctorate in Industrial Pharmacy from St. John's University, NY.

Yuanling (Lynn) Liang, PhD
Senior Chemist
OPQA III | OPQ | CDER | FDA

Dr. Lynn Liang served as a primary assessor in the Division of Product Quality Assessment III within the Office of Pharmaceutical Quality (OPQ). As an active member of OPQ Nitrosamine Working Group since 2018, she has contributed to the development and implementation of FDA guidance on nitrosamine risk assessment and control in drug products. She has evaluated the majority of nitrosamine-related ANDA submissions received by the FDA since 2018.
Dr. Liang earned her Ph.D. in Analytical Chemistry from the University of Arizona and jointed the FDA in 2015.

Diaa Shakyela, PhD
Senior Research Scientist
Office of Pharmaceutical Quality Research (OPQR)
OPQ | CDER | FDA

Dr. Diaa Shakleya is a Senior Research Scientist within the Division of Product Quality Research. His areas of expertise include drug products quality, opioids, and regulated bioanalysis and pharmaceutical analysis. In his current role, Dr. Shakleya leads regulatory science research work related to nitrosamine impurities, including projects related to Mitigation strategies to reduce the risk of the NDSRI impurities in pharmaceutical drug products and effect of excipients on the formation of nitrosamines. Dr. Shakleya also leads the Opioids research project on the risk associated with opioids and opioids antagonists and creating an in vitro surrogate model platform to assess in vivo permeation and risk associated with the vaping opioids.

Diaa has been with the Food and Drug Administration (FDA) for over 11 years. Prior to joining FDA, Dr. Shakleya served as an associate director with biotech company where he led a group of scientists in preclinical evaluation of small drug molecules under drug discovery program. Diaa received his Ph.D. degree in Pharmaceutical Sciences from Mumbai University, India and Postdoctoral Fellowship from West Virginia University. Dr. Shakleya has over 65 peer-reviewed publications and more than 150 scientific podium and poster presentations

Jin Xu, PhD
Senior Pharmaceutical Quality
Division of Product Quality Assessment IX (DPQA IX)
Office of Product Quality Assessment II (OPQA II)
OPQ | CDER | FDA

Jin Xu serves as Senior Pharmaceutical Quality Assessor and Application Technical Lead, responsible for the review of ANDA, NDA, IND and post-approval supplements. Prior to joining FDA in 2014, Jin worked in pharmaceutical industry as a Principal Scientist responsible for formulation and manufacturing process development.

Vincent Crowley, PhD
Senior Pharmacologist
DPTR | OSCE | OGD | CDER | FDA

Dr. Vince Crowley is a Senior Pharmacology/Toxicology reviewer within the Office of Safety and Clinical Evaluation (OSCE) in the Office of Generic Drugs (OGD). His primary role is to conduct safety review of generic drug products and drug substances related to impurities, excipients, and extractables/leachables assessments. Additionally, he has served as the OGD resource for surrogate assessment in extractable/leachable safety reviews. Prior to joining DPTR in 2021, Dr. Crowley was a postdoctoral fellow at the Scripps Research Institute and received his PhD in medicinal chemistry from the School of Pharmacy at the University of Kansas.

Andre Raw, PhD
Associate Director for Science and Communication
Office of Pharmaceutical Quality Assessment I (OPQA I)
OPQ | CDER | FDA

Andre Raw received his B.S. degree from the Massachusetts Institute of Technology and his Ph.D. in chemistry from the University of California at Berkeley. Within his tenure at FDA, he has been promoted to FDA Agency Expert and to Chemistry Division Director. Currently, he is Associate Director for Science and Communication in the Office of Pharmaceutical Quality Assessment I (OPQA I) in the Office of Pharmaceutical Quality (OPQ).

Dr. Raw was involved in the development of several important FDA initiatives, including Guidances on Pharmaceutical Solid Polymorphism and Co-crystals, Regulations on Listing of Polymorph Patents, and on matters related to Nitrosamine Impurities. He was instrumental in FDA's approval of generic versions of complex active ingredients, including Lovenox (enoxaparin sodium) and Copaxone (glatiramer acetate). Currently, he is involved in Risk and Quality Informatics Initiatives and is a principal architect of Knowledge-Aided Assessment and Structured Application (KASA). More recently, he has been involved in informatics related to artificial intelligence.

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

Dr. Suman Dandamudi is a Lead Pharmacologist in the Division of Bioequivalence III at the FDA, where she leads a team of scientists responsible for assessing bioequivalence (BE) studies in Abbreviated New Drug Applications (ANDAs). Dr. Dandamudi has extensive experience evaluating complex scientific and regulatory issues across a range of generic drug submissions, including ANDAs and pre-ANDA meetings. She actively contributes to several scientific and regulatory working groups, with efforts spanning from the development of product specific guidances to global efforts in harmonization of bioequivalence standards. Dr. Dandamudi received her Ph.D. in Pharmaceutical Sciences from Northeastern University, Boston.

Yang Lu, PhD
Senior Staff Fellow
DB III | OB | OGD | CDER | FDA

Dr. Yang Lu is a Senior Staff Fellow in the Division of Bioequivalence III at the FDA. Dr. Lu's work focuses on assessment of bioequivalence (BE) studies in Abbreviated New Drug Applications (ANDAs). Dr. Lu's role also includes providing scientific and regulatory comments in response to applicant's request in controlled correspondences, pre-ANDA meetings, and post-CR scientific meetings. Dr. Lu leads several projects and working groups at the Office of Bioequivalence including complex bioanalytical review and endogenous drug bioanalysis. Dr. Lu also serves as the POC for challenging analytical review issues. Dr. Lu received his Ph.D. from the State University of New York at Stony Brook. Dr. Lu had extensive research and supervisory experience in GLP bioanalytical industry before joining the FDA.

Steve Rhieu, PhD
Commander, United States Public Health Service (USPHS)
Supervisor
OPMA | OPQ | CDER | FDA

CDR Steve Rhieu is a Supervisor in the Office of Pharmaceutical Manufacturing Assessment within the FDA's Center for Drug Evaluation and Research. In this capacity, he oversees the scientific review and quality evaluation of the pharmaceutical manufacturing data, including process development and facility assessments, for various types of regulatory submissions. Prior to joining the Agency in 2015, CDR Rhieu served as a National Research Council postdoctoral fellow at the National Institute of Standards and Technology. He holds a B.S. in Bioengineering from the University of California, Berkeley, and a Ph.D. in Biomedical Engineering from Brown University.

Allison A. Aldridge, PhD
Consumer Safety Officer
Division of Pharmaceutical Manufacturing Assessment V (DPMA V)
OPMA | OPQ | CDER | FDA

Dr. Allison A. Aldridge is a primary assessor in the Office of Pharmaceutical Manufacturing. She joined FDA as a chemist in the Office of Compliance and later transferred to the Office of Pharmaceutical Quality. Dr. Aldridge has experience with quality assessment of solid as well as sterile and nonsterile liquid dosage forms for NDAs, ANDAs and INDs. Prior to joining FDA, she worked in the pharmaceutical and personal care industries. She holds a B.S. in Biology from the University of Illinois, Champaign-Urbana and a Ph.D. in Chemistry from Loyola University, Chicago.

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Captain Kendra Stewart is the Director of the Office of Regulatory Operations for the Office of Generic Drugs (OGD) whereby she oversees the scientific and regulatory operations. Captain Stewart received her Doctor of Pharmacy degree from the School of Pharmacy at Florida A&M University and completed her clinical pharmacy residency at the James A. Haley Veterans Affairs (VA) hospital in Tampa, FL. She's a lifelong public servant and has devoted her career of over 23 years to various scientific and managerial roles in the federal government specializing in the areas of health informatics, drug policy and regulatory operation.