SPEAKER BIOGRAPHIES

DAY ONE: Wednesday, April 9, 2025

Brenda Stodart, PharmD, BCGP, RAC-US
Captain, USPHS
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM)
CDER | 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 | OCOMM
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) within the Office of Communications (OCOMM) 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)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (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. 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).

Geoffrey Wu, PhD, PHP, CPH
Commander, United States Public Health Service (USPHS)
Acting Director, Office of Product Quality Assessment I (OPQA I)
Office of Pharmaceutical Quality (OPQ)
CDER | FDA

Commander Geoffrey Wu joined the FDA's Office of Testing and Research (OTR) in 2010, has served in multiple capacities, including research scientist, science staff, chemistry reviewer, staff supervisor, Associate Director of Sciences and Communication (ADSC), acting Division Director, acting Office Director, and Deputy Office Director. He is a scientist officer in the United States Public Health Service. Throughout his FDA tenure, he has been deeply involved, leading or co-leading regulatory review and research for PDUFA and GDUFA programs. Between 2013 and 2017, he served as a founding member on the OPQ Emerging Technology Team (ETT). In the recent years, he has been a core and/or leading member in multiple policy and/or scientific development efforts, such as emerging technology, continuous manufacturing, comparability protocols, knowledge-aided assessment and standard submissions (KASA), pharmaceutical quality chemistry manufacturing and controls (PQ/CMC, aka Structured Pharmaceutical Quality Submissions (SPQA)), novel complex generic drugs, and advanced analytics. He has training and education in pharmacy, pharmaceutical science, protein chemistry, polymer chemistry, process analytical technology, and data science.

Edward (Ted) Sherwood
Director
Office of Regulatory Operations (ORO)
OGD | CDER | FDA

Edward (Ted) Sherwood has been the Director of the Office of Regulatory Operations (ORO) within the Office of Generic Drugs (OGD) since 2014. ORO consists of three divisions: Division of Project Management, Division of Filing Review, and Division of Labeling Review. Previously, he served as the Associate Director of Immediate Office Operations, Office of Pharmaceutical Science [now the Office of Pharmaceutical Quality (OPQ)]. Prior to joining OPQ in 1999, he spent a dozen years in OGD. He held various positions including, reviewing new submissions for determination of fileability, conducting program analyses, and coordinating congressional activities. Edward received his bachelor's degree from the University of Maryland in 1992.

Scott Vehovic
Commander, USPHS
Supervisory Project Manager, Division of Project Management (DPM)
ORO | OGD | CDER | FDA

Scott Vehovic is a Supervisory Project Manager, supervising a team responsible for the regulatory management of Abbreviated New Drug Application (ANDA) generic drug approvals in the Office of Generic Drugs, USFDA. An officer with the United States Public Health Service (USPHS) for over 15 years, I'm a strong advocate of the mission and vision of the USPHS and the Food and Drug Administration, including the pharmacy profession, by supporting the availability of safe and effective generic drugs to the American public.

Joe Shin, PharmD
Lead Regulatory Health Project Manager, DPM
ORO | OGD | CDER | FDA

Dr. Joe Shin has been with the FDA since 2014, serving as a Regulatory Project Manager prior to his current position as Lead Regulatory Health Project Manager in the Division of Project Management (DPM), Office of Regulatory Operations (ORO) within the Office of Generic Drugs (OGD). He leads a team of RPMs providing guidance and support as they manage the regulatory review process of Abbreviated New Drug Applications. He also serves as DPM's subject matter expert on Requests for Reconsideration providing expertise and training to numerous offices in OGD. He received his Doctor of Pharmacy degree from Howard University in 2008.

Yi Zhang, PhD
Associate Director, Division of Bioequivalence III (DBIII)
Office of Bioequivalence (OB)
OGD | CDER | FDA

Dr. Yi Zhang is the Associate Director for Division of Bioequivalence III in the Office of Bioequivalence, Office of Generic Drug. Dr. Zhang joined Office of Bioequivalence in 2014, and throughout his tenure, Dr. Zhang has served as a primary, secondary, and tertiary assessor to conduct critical evaluation of bioequivalence studies in abbreviated new drug applications (ANDAs), Control Correspondences (CCs), Protocols, and various other regulatory submissions for generic drug products, where he works collaboratively to address complex issues identified during bioequivalence assessments. Dr. Zhang is currently involved in several working groups and research projects at divisional and office levels to support scientific and regulatory-based decisions making for the review of generic products.

Churg (Stella) Chan, PharmD, BCPS
Pharmacist, Division of Labeling Review (DLR)
ORO | OGD | CDER | FDA

Dr. Churg "Stella" Chan serves as a primary assessor for the Division of Labeling Review (DLR) within the Office of Regulatory Operations (ORO), Office of Generic Drugs (OGD) since 2021. As a primary assessor, Stella reviews labeling for generic drug products, such as Prescribing Information, container and outer packaging, Medication Guides, and other patient labeling to ensure its accuracy and safety when compared with the reference listed drug (RLD). She also works with other Divisions and Offices within the agency, if necessary, to ensure that the labeling is accurate and is in accordance with the RLD, guidances, and regulations.

Previously, she served as a primary biopharmaceutics assessor within the Office of Pharmaceutical Quality (OPQ). Prior to joining the FDA in 2019, Stella was an internal medicine pharmacist at MedStar Union Memorial Hospital in Baltimore, MD. She received her Doctor of Pharmacy from the University of Maryland, Baltimore in 2015.

Nuri Tawwab, PharmD, MPH
Lieutenant Commander, USPHS
Stakeholder Engagement Team, Division of Prevention Communication and Public Engagement (DPCPE)
Center for Substance Abuse Prevention (CSAP)
Substance Abuse and Mental Health Services Administration (SAMSHA)

LCDR Nuri Tawwab is a Senior Regulatory Business Process Manager at the U.S. Food and Drug Administration (FDA) with extensive expertise in drug regulation, generic drug approval processes, and the implementation of the Generic Drug User Fee Amendments (GDUFA). With a career spanning over a decade in pharmaceutical quality and regulatory affairs, LCDR Tawwab plays a pivotal role in ensuring the timely approval of generic drugs while maintaining compliance with congressionally mandated guidelines.

In their current role within the Office of Pharmaceutical Quality at the FDA's Center for Drug Evaluation and Research (CDER), LCDR Tawwab manages the lifecycle of over 100 generic medications and oversees teams of chemistry and biology drug reviewers to facilitate the approval of Abbreviated New Drug Applications (ANDAs). Their leadership in GDUFA III implementation and process optimization has contributed to enhanced efficiency, improved stakeholder engagement, and substantial cost savings for both the agency and the public.
Recognized for their contributions to regulatory excellence, LCDR Tawwab has successfully expedited high-priority drug approvals, coordinated international industry meetings to streamline regulatory processes, and provided strategic oversight to enhance review timelines. Their expertise in regulatory affairs, stakeholder communication, and program management uniquely positions them to deliver a comprehensive and insightful presentation on GDUFA III and its impact on drug regulation at the FDA.

This session will provide attendees with a deeper understanding of the evolving regulatory landscape, best practices in generic drug review, and the critical role of GDUFA III in advancing public health.

Thu (Suzanne) Phan, PharmD
Pharmacist, Division of Legal & Regulatory Support (DLRS)
Office of Generic Drug Policy (OGDP)
OGD | CDER | FDA

Suzanne Phan is a Pharmacist with the Patent and Exclusivity Team. Prior to joining the FDA, Suzanne worked as a Pharmacy Research Coordinator at Inova Schar Cancer Institute. She earned her PharmD from Virginia Commonwealth University and undergraduate degree in Biology from George Mason University.

Heather Strandberg, PharmD
Pharmacist, 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 9 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.

Zakia R. Williams-Greene, PhD
Senior Pharmacologist, Division of Bioequivalence I (DBI)
OB | OGD | CDER | FDA

Dr. Zakia Williams-Greene serves as a Senior Pharmacologist in the Division of Bioequivalence I, within the Office of Bioequivalence, Office of Generic Drugs. In this role she assesses bioequivalence studies for various generic drug products, and currently serves as the lead Secondary Assessor for DBI Inactive Ingredient controlled correspondence (CC) reviews. She has been active in numerous Office and Division level committees and working groups and involved in the development and revision of product specific and general guidances.

Dr. Williams-Greene earned her PhD in Pharmacology from Florida A & M University and her BA in Chemistry with a minor in Spanish from Lincoln University, Pa. She completed post-doctoral training at the National Institutes of Health National Institute on Drug Abuse (NIDA) where she studied stimulant therapy.

Pamela Dorsey, MS, PhD
Senior Pharmacologist, DBIII
OB | OGD | CDER | FDA

Pamela Dorsey serves as a Senior Pharmacologist for the Division of Bioequivalence III, within the Office of Bioequivalence, Office of Generic Drugs. Dr. Dorsey has experience in assessing bioequivalence for various generic drug products, and currently addresses bioequivalence related controlled correspondences. She has been with the FDA in the Office of Bioequivalence since 2014. She earned a Bachelor of Science and Master of Science in Chemical Engineering from North Carolina Agricultural and Technical State University. In addition, she received her Ph.D. in Pharmaceutical Science from The University of Georgia College of Pharmacy. Before joining the FDA, she was a Ruth Kirschstein Post-doctoral fellow within the Whitaker Cardiovascular Institute at Boston University Medical Center.

Qing Liu, PhD
Deputy Director, DBI
OB | OGD | CDER | FDA

Dr. Qing Liu is the Deputy Division Director in the Division of Bioequivalence I, Office of Generic Drugs within the FDA's Office of Generic Drugs. She has over 10 years of experience in the assessment of bioequivalence for abbreviated new drug applications, controlled correspondences, citizen petitions, product-specific guidance and protocols submitted to the Agency. In her current role, Dr. Liu works with a group of scientists on complex generic drug products, such as nasal/orally-inhaled drug products, long-acting injectables, topicals and ophthalmic suspensions.

Julia Yang, PhD
Pharmacologist, Division of Pharmacology/Toxicology Review (DPTR)
Office of Safety & Clinical Evaluation (OSCE)
OGD | CDER | FDA

Dr. Yang serves as a Pharmacologist in the Division of Pharmacology/Toxicology Review, within the Office of Safety and Clinical Evaluation, Office of Generic Drugs. In this role she evaluates toxicology justification to support the safety of excipient in the formulation and impurities in the product specification in generic drug products.

Prior to her service in OGD, Yang served as a research reviewer in Office of Vaccine Research and Review in CBER and reviewed the clinical and cellular immunogenicity studies in support of quality and efficacy in the vaccine products. She received her M.S. in Biomedical Science from Texas A&M university and Ph.D. in Pharmacology from Temple University.

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

Joseph (Joe) Kotsybar graduated from Southern Illinois University, Edwardsville, with two Bachelors of Science in Chemistry and Biological Sciences. After graduation, he spent several years as a Production Chemist. Joe continued his post-graduate education and graduated from St. Louis College of Pharmacy with a Doctor of Pharmacy (Pharm.D.) degree. While completing his Pharmacy Degree, he worked as a Visiting Student Researcher at Washington University School of Medicine's Radiation Oncology Lab.

Joe began with the FDA in 2020 as an ORISE fellow with research focusing on tracking of PSG Generic Drug User Fee Amendments (GDUFA) commitment measurables and ICH M13A implementation. In his current role, Joe serves as the current acting-lead for the Product-Specific Guidance (PSG) program.

Caliope Sarago, MHSA
Team Lead, Regulatory Health Project Manager, ORS
OGD | CDER | FDA

Caliope Sarago is a Team Lead Regulatory Health Project Manager for the Immediate Office of OGD's Office of Research and Standards (ORS). In this role, Caliope facilitates teams of interdisciplinary scientists and project managers responding to controlled correspondence submissions, pre-ANDA meetings, scientific working groups and furthering research science for the development of generic drugs. Caliope began her FDA career in 2013, at the Center of Tobacco Products and joined the OGD in 2018.

Prior to joining the FDA, Caliope held supervisory positions at American Type Culture Collection, in the Quality Control for Microbiology, Protistology and Mycology laboratories, and at the George Washington University Hospital (GWH), in the Transfusion (Blood Bank) Service and Ancillary Testing Program. While at GW, she also worked as a molecular biologist to develop clinical testing by PCR and immunohistochemistry for CMV, HIV and breast cancer receptors. Caliope has a B.Sc. in Applied Science and Medical Technology from Youngstown State University (Youngstown, Ohio) and a Masters in Healthcare Service Administration, with a focus in policy, from George Washington University (Washington, DC). She completed her Masters Certificate in Project Management from Duke University.

Arun Agrawal, PhD
Pharmacologist, DBI
OB | OGD | CDER | FDA

Dr. Arun Agrawal is currently a Pharmacologist (bioequivalence assessor) in DBI, OB, OGD, and is responsible for the assessment of bioequivalence parts of various dosage forms of generic drugs (e.g., ANDAs, Controlled Correspondences, etc.). Prior to joining OGD in 2014, he worked for 5 years as a Pharmacologist in the Office of Clinical Pharmacology, FDA, assessing new drug applications (NDAs). Prior to joining the FDA in 2009, he worked in the pharmaceutical industry for over 11 years, and before that in academic institutions doing teaching and research for over 14 years. Dr. Agrawal received his Ph.D. in Biochemistry at the Central Drug Research Institute, Lucknow, India.

Onyekachukwu (Onyeka) Ihezie, PharmD
Regulatory Business Process Manager, Division of Regulatory and Business Process Management I (DRBPMI)
OPRO | OPQ | CDER | FDA

Dr. Onyeka Ihezie is a Regulatory Business Process Manager within the Division of Regulatory and Business Process Management I (DRBPMI) in the Office of Program and Regulatory Operations (OPRO), Office of Pharmaceutical Quality (OPQ) at the U.S. Food and Drug Administration (FDA). Since joining the agency in September 2022, she has played a key role in optimizing regulatory review processes, ensuring efficiency, and facilitating timely decision-making within the ANDA and NDA programs.

In her current role, Onyeka collaborates with multidisciplinary teams to streamline regulatory workflows, enhance operational efficiencies, and support compliance with FDA policies and timelines. She provides strategic oversight and process improvements that help maintain the integrity and effectiveness of the pharmaceutical quality review process. By leveraging her expertise in regulatory affairs and pharmaceutical sciences, she ensures that critical deadlines are met and that the regulatory review process remains transparent and consistent.

Prior to joining the FDA, Onyeka served as an Ambulatory care pharmacist at Kaiser Permanente in Largo, MD, where she provided direct patient care, medication management, and clinical support to optimize therapeutic outcomes. She earned her Doctor of Pharmacy degree from Hampton University School of Pharmacy in 2012.

Thaoly Nguyen, PharmD
Regulatory Business Process Manager, DRBPMIII
OPRO | OPQ | CDER | FDA

Thaoly Nguyen serves as a regulatory business process manager (RBPM) within the Office of Pharmaceutical Quality (OPQ). As a RBPM, she oversees the regulatory processes associated with the quality assessment of Abbreviated New Drug Applications. Her efforts in OPQ include implementing improvements to enhance the efficiency of regulatory processes for quality assessment activities. Prior to joining the FDA in 2022, Thaoly served as a vaccination and hormonal contraception prescribing pharmacist in Annapolis, MD, for 14 years. She received her Doctor of Pharmacy from the University of Maryland, Baltimore, in 2008 and recently completed her project management professional training with Duke University in 2024.

Haitao Li, PhD
Supervisor, Division of Pharmaceutical Manufacturing Assessment V (DPMAV)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER | FDA

Dr. Haitao Li is the supervisor of Unit 2, Division of Pharmaceutical Manufacturing Assessment V. Dr. Li oversees quality assessment of manufacturing processes and facilities submitted in various types of regulatory submissions to the FDA. She received her Ph.D. in organic chemistry from the University of California at San Diego.

DAY TWO: Thursday, April 10, 2025

Ravikanth Kona, PhD
Pharmaceutical Scientist, Division of Product Quality Assessment I (DPQA I)
Office of Product Quality Assessment I (OPQA I)
Office of Pharmaceutical Quality (OPQ) | CDER | FDA

Dr. Ravikanth Kona is a Pharmaceutical Scientist in Division of Product Quality Assessment I, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research. Dr. Kona is an experienced Drug Product Reviewer with over 8 years of regulatory experience within the U.S Food and Drug Administration in reviewing, evaluating, assessing scientific and regulatory information of complex generic drug products in CMC submissions.

Prior to joining agency, Dr. Kona worked as Pharmaceutical Technology Specialist, Principal in Pharmaceutical industry overseeing commercial process development and process optimization of oral dosage forms. Dr. Kona holds a Ph.D. in Pharmaceutical Sciences from University of Maryland, Baltimore, an M.S. in Chemistry from Missouri State University, and B.S. in Pharmacy from Osmania University.

Reynolds (Rey) Cantave, PharmD
Senior Regulatory Health Project Manage, Enterprise Project Management Staff
Office of Quality Assurance (OQA) | OPQ | CDER | FDA

Dr. Rey 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.

Paramjeet Kaur, PhD
Team Leader, Division of Bioequivalence II (DB II)
Office of Bioequivalence (OB)
Office of Generic Drugs (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.

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

Truong Quach is a team lead pharmacist working in the Office of Generic Drugs Policy, Division of Orange Book Publication and Regulatory Assessment (DOBPRA) since 2018 and has been with the FDA since 2014. As an Orange Book TL 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. As a subject matter expert in DOBPRA, Truong is also responsible for reviewing approved labeling and the content of clinical data in new drug original and efficacy supplement approvals to make Hatch-Waxman exclusivity determinations.

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 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.

Juhyun Kim, PhD
Senior Pharmacologist, DBIII
OB | OGD | CDER | FDA

Dr. Juhyun Kim serves as a bioequivalence assessor in DBIII, OB, OGD. She reviews bioequivalence studies of various dosage forms of generic drugs (e.g., ANDAs, Controlled Correspondences, protocol etc.). Currently, she serves as a subject matter expert lead for pharmacokinetics in DBIII and topical subject matter expert. Prior to joining OGD in 2014, she worked in the pharmaceutical industry as drug metabolism and pharmacokinetic specialist for 7 years and also taught graduate student as an adjunct professor. She received her PhD in pharmaceutics from The Ohio State University.

Ying Fan, PhD
Team Lead, Division of Clinical Review (DCR)
Office of Safety and Clinical Evaluation (OSCE)
OGD | CDER | FDA

Dr. Ying Fan is the Lead Pharmacologist in Division of Clinical Review, Office of Safety and Clinical Evaluation, Office of Generic Drugs. She received her Ph.D. in major of Pharmaceutical Sciences and minor of Statistics from Oregon State University. During her more than 16 years tenure in the FDA, she made significant contributions to the approval and regulation of local acting drug products and complex generic drug products. She is a subject matter expert in comparative clinical endpoint study review and a valuable mentor in training new reviewers. She has been an active member on various committees and working groups within FDA. She initiates, leads or participates in multiple research projects, general guidances and product specific guidances development or revision.

Jayani Perera, PhD
Senior Chemist, Division of Product Quality Assessment XIX (DPQAXIX)
Office of Product Quality Assessment III (OPQAIII)
OPQ | CDER | FDA

Jayani Perera is a senior chemist in the Office of Product Quality Assessment III (OPQAIII) in the Office of Pharmaceutical Quality (OPQ) in the FDA's Center for Drug Evaluation and Research. She has assisted in the design, optimization, and management of the GDUFA Completeness Assessment process and the Timely Consult and Early Information Request (TCIR) Process for Drug Master Files. Jayani has also served in the GDUFA III DMF implementation working group and assisted in drafting the Review of Drug Master Files in Advance of Certain ANDA Submissions Under GDUFA draft guidance. Jayani holds a Ph.D. degree in Inorganic/Organometallic Chemistry from Wayne State University in Detroit, Michigan.

David Green, MS
Senior Pharmaceutical Quality Assessor, DPQAXVII
OPQAIII | OPQ | OGD | CDER | FDA

Mr. David Green is a chemist and Senior Pharmaceutical Quality Assessor in the Division of Product Quality Assessment XVII, Office of Product Quality Assessment III, Office of Pharmaceutical Quality at the FDA Center for Drug Evaluation and Research. Mr. Green has been with the Agency for almost 17 years and came to the Agency with over ten years of pharmaceutical and biotechnology experience. Mr. Green received his M.S. (with Thesis) in Chemistry from Syracuse University, and a B.S. in Chemistry from the University of Maryland, College Park.

Mr. Green joined the FDA in 2008, as a generic drug chemistry reviewer in the Center for Drug Evaluation and Research. In his current position as Senior Pharmaceutical Quality Assessor with the FDA's Office of Pharmaceutical Quality, he focuses on the chemistry, manufacturing and controls (CMC) of generic active pharmaceutical ingredients. He is also a drug substance subject matter expert for several regulatory initiative within the Agency.

Fang Yuan, PhD
Senior Pharmaceutical Scientist, Immediate Office (IO)
OPQAI | OPQ | CDER | FDA

Dr. Fang Yuan is a Senior Pharmaceutical Scientist in the Office of Product Quality Assessment I (OPQAI) within the Office of Pharmaceutical Quality (OPQ). As a senior drug product quality assessor for over 9 years at FDA, she currently conducts assessment of lifecycle applications, pharmaceutical equivalence, and policy inquiries such as citizen petitions. Her efforts in OPQAI also include managing ORISE fellowship program, coordinating overarching science communication and research activities, and serving as the point of contact for issues related to compendial standards and pharmacological toxicology consult requests for generic drug applications. Fang received her Ph.D. in Pharmaceutical Science from University of Nebraska Medical Center in 2014.

Andrew Idzior
Chemist, Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER | FDA

Andrew Idzior currently performs manufacturing process and facility assessment of CMC sections for drug applications. As a prior FDA investigator, Andrew Idzior led cGMP and pre-approval inspections of drug manufacturing facilities. Additionally, Andrew Idzior performed and developed analytical chemistry test methods for drug samples as an FDA regulatory chemist.

Tahseen Mirza, PhD
Associate Office Director for Regulatory Affairs (ADRA)
Office of Study Integrity and Surveillance (OSIS)
Office of Translational Sciences (OTS) | CDER | FDA

Dr. Tahseen Mirza is an accomplished scientist and leader with over thirty years of industrial and regulatory experience in the areas of generic and branded pharmaceutical, and device development. He holds a Ph.D. in Pharmaceutical Sciences from University of Cincinnati.

In his current job, Dr. Mirza is Associate Director for Regulatory Affairs in FDA/CDER Office of Study Integrity and Surveillance. Prior to joining the FDA, he worked in various pharmaceutical companies (Novartis and Sanofi) and The United States Pharmacopeia where he led groups of chemists and scientists in various R&D and QC/QA departments.

He has moderated national and international conferences/workshops on variety of topics such as GMP, drug release, dissolution, QbD and PAT. He has published in peer-reviewed journals and co-authored book chapters.
Dr. Mirza is a member of American Association of Pharmaceutical Scientists (AAPS) and is the current and founding Chairman of the AAPS community, In Vitro Release Testing and Dissolution.

Xiaojian Jiang, PhD
Deputy Division Director, DBII
OB | OGD | CDER | FDA

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

Fang Lu, PhD
Team Leader, DBI
OB | OGD | CDER | FDA

Fang Lu has a Ph.D. in Toxicology from the University of Nebraska Medical Center. He joined the U. S. Food and Drug Administration in 2009 and is Team Leader of the Division of Bioequivalence I (DBI), Office of Bioequivalence (OB) in the Office of Generic Drugs (OGD). Dr. Lu has solid knowledge of the fields of pharmacology, toxicology, chemistry, and statistics with 16 years of experience in reviewing in vivo and in vitro bioequivalence study data. He is interested in the regulatory scientific research landscape and actively takes on leadership roles for projects and initiatives, including, but not limited to: Assessment of Global Submission Quality and Data Integrity on Bioequivalence Study in Generic Drug Applications, Comprehensive Assessment on Alcohol-Induced Dose Dumping in Generic Drug Products, PK Abuse Deterrence Studies, Impacts of Bio-batch Adequacy on Bioequivalence Evaluations, and Evaluating the Safety of Excipients Used in Generic Drug Formulations with Pediatric Indications.

Kendra S. Stewart, RPh, PharmD
Captain, United States Public Health Service
Deputy Director for Operations, OGD
CDER | FDA

Captain Kendra Stewart is the Deputy Director of 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.