SPEAKER BIOGRAPHIES

DAY ONE: Wednesday, April 10, 2024

Brenda Stodart, PharmD, BCGP, RAC-US

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

Iilun Murphy, MD

Director, Office of Generic Drugs (OGD)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Iilun Murphy, M.D., serves as the Director of the Office of Generic Drugs (OGD) in the Center for Drug Evaluation and Research (CDER). This office is responsible for the review and approval of abbreviated new drug applications. OGD's mission is to ensure, through a scientific and regulatory process, that generic drugs are safe and effective for the American public.

Dr. Murphy began her FDA career in 2007 as a medical officer in CDER's Office of New Drugs, Division of Gastroenterology Products. In 2011 she joined the Center for Tobacco Products where she helped to expand the Office of Science. Dr. Murphy rejoined CDER in January 2020 as OGD's Deputy Director for Clinical and Regulatory Affairs. She oversaw the implementation of the Generic Drug User Fee Amendments' goals and reviewed management activities. She was instrumental in leading OGD's 2021-2022 reorganization and served as acting director for OGD's new Office of Safety and Clinical Evaluation. Dr. Murphy was integral in the creation of the first Generic Drug Global Cluster, a collaborative forum for the world's leading regulatory agencies. In June 2023, she became the Director for the Office of Generic Drugs.

Dr. Murphy is a board-certified pediatrician and an assistant clinical professor of pediatrics at The George Washington University School of Medicine. She earned her bachelor's degree from Cornell University and her medical degree from Stanford University.

Susan Rosencrance, PhD
Deputy Director of Science, Acting Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Susan Rosencrance, Ph.D., serves as the Acting Deputy Director for Science in CDER's Office of Pharmaceutical Quality (OPQ). She is performing this role in addition to serving as the Director for the Office of Product Quality I, also within OPQ. She has spent more than 20 years at the FDA serving in a variety of senior roles including 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. Before joining the FDA, Susan worked in research and development at Merck. She holds a Ph.D. in Chemistry from American University and completed her dissertation research at the NIH Laboratory for Biophysical Chemistry.

Sau (Larry) Lee, PhD
Deputy Director of Science, Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Dr. Sau (Larry) Lee is the Deputy Super Office Director of Science in the Office of Pharmaceutical Quality. He directs the activities of staff members in OPQ sub-offices responsible for the quality assessment of regulatory submissions (Office of Biotechnology Products (OBP), Office of Lifecycle Products (OLDP), Office of New Drug Products (ONDP), and Office of Pharmaceutical Manufacturing Assessment (OPMA)). He represents OPQ in programs and activities that impact quality assessments by coordinating with OPQ, CDER, and ORA. He also serves as the point person for the pharmaceutical industry and scientific/academic groups in developing programs to support science- and risk-based application assessment and approval.

Dr. Lee has been with the FDA since 2005, serving as a regulatory scientist, team lead, Associate Director for Science, Deputy Office Director, and Office Director. He has provided exemplary leadership in developing OPQ science, research and testing programs to support quality assessment, inspection, surveillance and policy. He developed and implemented CDER's Emerging Technology Program to facilitate the adoption of novel technologies for pharmaceutical development and manufacturing. In 2016, Dr. Lee was appointed to the Senior Biomedical Research Service (SBRS) because of his extensive regulatory and scientific contributions to manufacturing science, complex drug substances and products, and emerging pharmaceutical technologies. Prior to joining the FDA, Dr. Lee received a B.S. degree in Chemical Engineering from the University of Virginia with a minor in Materials Science and a Ph.D. in Chemical Engineering from Princeton University.

CAPT Jouhayna Saliba, PharmD
Team Leader
Drug Shortage Staff (DSS)
Office of the Center Director
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

CAPT Jouhayna Saliba, PharmD, is a Team Leader in CDER's Drug Shortage Staff at FDA. She joined the FDA in 2000 as a Regulatory Project Manager for the Division of Special Pathogen and Immunologic Drug Products in the Center for Drug Evaluation and Research. She has been in her current position since 2003. Prior to joining the FDA, she held a position as a clinical pharmacist in the Pediatric Critical Care Unit at Walter Reed Army Medical Center. She received her Bachelor of Science degree from Massachusetts College of Pharmacy and Allied Health Sciences in 1992 and later completed the non- traditional pharmacy program at the University of Arkansas and received her PharmD in 2001.

Tina Kiang
Director, Division of Regulatory and Guidance (DRGS) | Office of Policy for Pharmaceutical Quality (OPPQ)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Tina Kiang, Ph.D. serves as the Director of the Division of Regulation and Guidance in OPQ/OPPQ. She came to the FDA in 2005 as a chemistry and engineering reviewer in the Division of Ophthalmic and Ear, Nose and Throat Devices (DOED) in CDRH. In 2009, she became branch chief of the Intraocular, Cornea, and Neuromaterials Branch (ICNB), which reorganized in 2012 into the Intraocular and Corneal Implants Branch (ICIB). In 2015, Tina became the Deputy Director of the Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices (DAGRID,) and became Acting Director in 2016, prior to the CDRH reorganization. In 2018, when the Office of Product Evaluation and Quality (OPEQ) was established, Tina became the Director of the Division of Drug Delivery and General Hospital Devices and Human Factors (DHT3C) in the Office of Health Technology 3 (OHT3). She received her Bachelor of Engineering in chemical engineering from The Cooper Union in New York and her Ph.D. in Biomedical Engineering from The Johns Hopkins University School of Medicine.

Martha Nguyen
Director, Division of Policy Development (DPD) | Office of Generic Drug Policy (OGDP) | Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Since 2014, Martha Nguyen has served as the Director of the Division of Policy Development in FDA CDER OGD's Office of Generic Drug Policy, where she provides strategic leadership and direction on broad generic drug regulatory policy issues. She oversees the development and clearance of regulations, guidance documents, and statements of policy affecting regulation of generic drug products, including reauthorization and implementation of the Generic Drug User Fee Amendments (GDUFA).
Ms. Nguyen has nearly three decades of strategic health policy experience, honed at several nonprofit think tanks and law firms in Washington, DC, and in CDER's Office of Regulatory Policy prior to joining OGD. She earned a JD from the Georgetown University Law Center and a BA in Sociology of Health and Medicine from the University of Pennsylvania.

Rosanne Pagaduan
Supervisory General Health Scientist, Division of Filing Review (DFR) | Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Rosanne (Rosie) Pagaduan, Pharm.D., is a Supervisory General Health Scientist in the Division of Filing Review (DFR) within the Office of Regulatory Operations (ORO). Rosie graduated from the University of Florida with a Bachelor of Science in Microbiology and Cell Science and a Doctorate of Pharmacy. Post-graduation, Rosie worked in a retail pharmacy for three years before joining the FDA in 2014. Prior to becoming a Supervisor, Rosie worked as a primary Filing Reviewer as well as a Team Leader in the DFR.

Arlene Figueroa
Regulatory Counsel, Division of Legal and Regulatory Support (DLRS) | Office of Generic Drug Policy (OGDP)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Arlene Brens Figueroa joined the FDA in 2020 and serves as a Regulatory Counsel in the Office of Generic Drugs/Office of Generic Drug Policy within CDER. Arlene provides policy consultation on the generic drug regulatory review process within FDA, such as the implementation of the Hatch-Waxman Amendments to the FD&C Act, pertinent regulations, and FDA guidance documents. She previously worked for the Social Security Administration as an Attorney Advisor for 11 years. Arlene received her J.D. from Indiana University — Maurer School of Law in 2005 and her B.A. from Syracuse University in 2002.

Joe Kotsybar, PharmD
Regulatory Health Project Manager, Office of Research and Standards (ORS) | Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Joseph (Joe) Kotsybar 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. Joe 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 Associate and a Production Chemist for Biomerieux and MilliporeSigma, respectively. Joe continued his postgraduate education and graduated from St. Louis College of Pharmacy with a Doctor of Pharmacy degree, while also working 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 and was later hired as a Regulatory Health Project Manager. Joe's work focuses on coordination of the PSG program to align with ORS's commitments under GDUFA, as well as facilitating the program's communication and transparency with all stakeholders.

Reynolds (Rey) Cantave, PharmD
Senior Regulatory Health Project Manager, Enterprise Project Management (EPM) Staff
Office of Quality Assurance (OQA) | Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Dr. Rey Cantave currently serves as the Senior Regulatory Health Project Manager at FDA. He began his journey with the FDA in 2013 as an Advanced Special Project Liaison with the FDA's Office of the Commissioner during his tenure as a pharmacy student. From 2015, he delivered quality assessment project management support for pre-and-post approval applications and subsequently served as a Project Management Team Lead to a staff supporting post-approval applications. Dr. Cantave currently holds the role of OPQ Drug Shortage Coordinator and serves as lead project manager for the OPQ Nitrosamine Working Group, coordinating efforts in support of OPQ's response to the Nitrosamine Incident. In October 2021, he was honored with an "FDA Leveraging and Collaboration Award" by the CDER Director for exceptional contributions to the CDER Small Business & Industry Assistance Group. Dr. Cantave earned a Doctor of Pharmacy degree from Hampton University School of Pharmacy and a Bachelor of Science in Health Science from the University of Florida.

Marcia Fields
Lieutenant Commander (LCDR), United States Public Health Service (USPHS) | *Regulatory Officer,* Office of Regulatory Operations (ORO) | Immediate Office (IO) | Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

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 in 2012. Prior to joining CDER, she was in FDA's Office of Regulatory Affairs, Office of Medical Products and Tobacco Operations, Office of Pharmaceutical Quality Operations as a Pharma Investigator. Before joining the 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)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Dr. Zhen Zhang is a Master Pharmacologist at FDA's Office of Generic Drugs (OGD), Office of Bioequivalence. His expertise encompasses a broad range of areas including data analysis, modeling and simulation, dissolution studies, and topical product evaluations. He co-leads the OGD's Oral PBPK Expert Committee and spearheads the efforts to modernize SAS programs, thereby enhancing the efficiency of the bioequivalence review process. With a rich background in addressing complex bioequivalence challenges, Dr. Zhang has contributed to the development of multiple FDA guidances and the Manual of Policies and Procedures (MAPP). Prior to joining the FDA in 2014, he obtained his Ph.D. in Pharmacology from the University of Wisconsin-Madison and completed his postdoctoral training at the National Institutes of Health.

Jenn Anim
Pharmacologist, Policy Development & Evaluation Branch 1 (PDEB1) | Division of Internal Policies & Programs (DIPP) | Office of Policy for Pharmaceutical Quality (OPPQ) | Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Dr. Jennifer Anim joined the agency in 2014 as a generic drug Filing Reviewer/Pharmacist and transitioned to the Office of Pharmaceutical Quality's policy office as a Policy Lead/Controlled Correspondence Coordinator. She performs independent analysis on Controlled Correspondence and provides industry with appropriate responses and answers to their queries within the scope of the OPQ ensuring that responses are in line with FDA policies. Dr. Anim graduated from Howard University in 2001.

Maria Monroy-Osorio
Regulatory Health Project Manager, Office of Research and Standards (ORS) | Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (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 and streamline staff workload management. 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. Maria is currently obtaining her master's in professional studies in Emergency & Disaster Management from Georgetown University and received her Bachelor of Science in Biomedical Engineering from the University of Virginia.

Hiren Patel, PhD
Senior Staff Fellow, Division of Bioequivalence II (DB II) | Office of Bioequivalence (OB) | Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Dr. Hiren Patel is a bioequivalence assessor in the Division of Bioequivalence II within the Office of Generic Drugs (OGD). Prior to joining the FDA, he earned his M.S. and Ph.D. with specialization in Pharmacokinetics at Long Island University, Brooklyn, New York. At the FDA, he is responsible for assessing the bioequivalence of the various dosage forms of generic drugs. He is the lead for the topical and transdermal drug products and the advanced techniques for demonstrating bioequivalence of such complex drug products within the Office of Bioequivalence.

He is the co-chair for Bio-Equivalence Standards for Topicals (BEST) Expert Committee within OGD. He has also actively served as a consultant in the research initiatives which are the collaborative efforts of FDA and global research institutions pertaining to the topical and transdermal drug products funded through FDA. Dr. Patel is also actively involved in the review panel for the Product Specific Guidance for generic topical drug products.

Karen Bengtson
Supervisory Regulatory Health Project Manager | Office of Research and Standards
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Karen Bengtson is a Supervisory Regulatory Health Project Manager in the Office of Research and Standards (ORS), Office of Generic Drugs (OGD), CDER, FDA. She joined ORS in 2018 and is involved in process development and implementation of the pre-ANDA Program under GDUFA. Prior to joining ORS, Karen worked as a regulatory project manager in the Office of New Drugs and the Office of Surveillance and Epidemiology of CDER. She was in private industry for 14 years and worked for several small biotech companies during that time, before joining the FDA. She received her Bachelor of Arts degree in biological sciences from the University of Baltimore, Baltimore County.

Edward (Ted) Sherwood
Director, Office of Regulatory Operations (ORO) | Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

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. Ted received his bachelor's degree from the University of Maryland in 1992.

Andrew Kim
Commander (CDR), United States Public Health Service (USPHS) | *Supervisory Project Manager*, Division of Project Management (DPM) | Office of Regulatory Operations (ORO) | Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)
CDR Andrew Kim has been 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.

Andrei Perlloni
Supervisory Consumer Safety Officer, Imports Compliance Branch (ICB) | Division of Global Drug Distribution & Policy (DGDDP) | Office of Drug Security, Integrity, and Response (ODSIR) | Office of Compliance (OC)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Andrei Perlloni is responsible for overseeing the FDA's human drugs Imports Compliance Branch at the Center for Drug Evaluation and Research. The Branch serves as FDA's focal point for all policy and operational compliance issues related to imported human drugs that are regulated by FDA and develops policies and compliance strategies for protecting the public health by assuring drug product quality and supply chain integrity.
Andrei has over 22 years of experience as a scientist and consumer safety officer at FDA, and this prior experience includes serving as the Director of the Office of Emergency Operation within the Office of Crisis Management in the FDA's Office of the Commissioner. Andrei holds a degree in Bachelor of Science in Chemistry from the University of Puerto Rico- Mayaguez.

Tom Ching
Regulatory Project Manager, Division of Project Management (DPM) | Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Tom Ching is a Regulatory Project Manager in the Division of Project Management (DPM), Office of Regulatory Operations (ORO) within the Office of Generic Drugs (OGD). Prior to joining the FDA, Tom was a community pharmacist from 2013 to 2021. He received his Pharm.D. from Notre Dame of Maryland University School of Pharmacy.

Steven Yang
Lieutenant Commander (LCDR), US Public Health Service (USPHS) | *Regulatory Business Process Manager,* Regulatory & Business Process Management Branch 4 (RBPMB4) | Division of Regulatory & Business Process Management II (DRBPMII) | Office of Program and Regulatory Operations (OPRO) | Office of Pharmaceutical Quality (OPQ) | Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)Steven Yang is a Regulatory Business Process Manager in the Office of Program and Regulatory Operations within the Office of Pharmaceutical Quality (OPQ). Steven joined OPQ in 2014 and is a graduate of the University of Maryland School of Pharmacy.

Yang Lu, PhD
Senior Staff Fellow, Division of Bioequivalence III (DB III) | Office of Bioequivalence (OB) | Office of Generic Drugs (OGD) Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Dr. Yang Lu is currently a Senior Staff Fellow/Senior Bioequivalence Reviewer in Division of Bioequivalence III (DB III)/Office of Bioequivalence (OB)/Office of Generic Drugs (OGD). At this position, Dr. Lu's work focuses on assessment of the bioequivalence parts in generic drug applications (e.g., ANDAs, correspondence controls, etc.). Dr. Lu is the technical lead of Risk-Based Excipient Evaluation in Pediatric Population project within the OGD and a co-developer of an internal pediatric excipient assessment flowchart. Dr. Lu also serves as a person of contact (POC) within OB for addressing complex pediatric excipient evaluation found in ANDAs. Dr. Lu received his Ph.D. in Chemistry and Chemical Biology from the University of New York at Stony Brook.

Tao Bai, PhD
Senior Advisor, Office of Bioequivalence Immediate Office (OBIO) | Office of Generic Drugs (OGD) Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Dr. Tao Bai is Senior Advisor in the Office of Bioequivalence (OB) in the Office of Generic Drugs (OGD). In her current role, she provides expert advice and guidance on strategic planning, regulatory policy development, and office operations for OB. She also serves as an expert advisor on ANDA bioequivalence review program, bioequivalence review practice and policy, processes, procedures, and other complex areas that impact OB's functions and activities. Prior to joining FDA in 2010, Dr. Bai was a postdoctoral Research Fellow at University of Maryland School of Pharmacy studying Nasal and Inhalation Drug Products. She received her Ph.D. in Pharmaceutical Sciences from the University of Maryland.

Andrea Dugas, MD, PhD
Physician, Division of Clinical Safety and Surveillance (DCSS) | Office of Safety and Clinical Evaluation (OSCE)
Office of Generic Drugs (OGD) | Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Dr. Andrea Dugas has been with the FDA since 2020 and currently serves as clinical reviewer in the Division of Clinical Safety and Surveillance in the Office of Safety and Clinical Evaluation in the Office of Generic Drugs. In this role, Dr. Dugas leads the evaluation of clinical data and clinical issues required to support the safety and surveillance of generic drug products. Dr. Dugas is a board-certified emergency medicine physician. She earned her bachelor's degree from Yale University, her medical degree from Vanderbilt University School of Medicine, and her PhD from the Johns Hopkins Bloomberg School of Public Health.

Shabnam Foroughi, MD
Physician, Division of Clinical Review (DCR) | Office of Safety and Clinical Evaluation (OSCE)
Office of Generic Drugs (OGD) | Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Dr. Shabnam Foroughi is a clinical reviewer in the Division of Clinical Review within the Office of Safety and Clinical Evaluation. Dr. Foroughi joined the FDA in 2021 where she provides clinical input related to the development of generic drug products. This work includes assessment of Abbreviated New Drug Applications, development of Product-Specific Guidance documents, response to controlled correspondences from generic product developers, and collaboration with various FDA divisions on clinical issues encountered in the review of generic drug applications.

Prior to joining the FDA, Dr. Foroughi practiced for over 15 years at the Walter Reed National Military Medical Center Allergy, Immunology, and Immunizations clinic and at her solo outpatient practice. She is board-certified in Pediatrics and in Allergy and Immunology. Dr. Foroughi obtained her Bachelor of Science in Biochemistry from the University of Maryland and her medical degree from the George Washington University School of Medicine. She completed her residency in Pediatrics at Children's National Medical Center and her fellowship in Allergy and Immunology at the National Institutes of Health.

Jimena Dancy, PhD
Pharmacologist, Division of Pharmacology/Toxicology Review (DPTR) | Office of Safety and Clinical Evaluation (OSCE)
Office of Generic Drugs (OGD) | Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)
Jimena Dancy, PhD, is a Pharmacologist in the Division of Pharmacology/Toxicology Review (DPTR) within the Office of Safety and Clinical Evaluation (OSCE). Jimena's role focuses on assessing the safety of excipients, impurities, and extractables and leachables in generic drug submissions. Jimena joined FDA in 2018 as an ORISE fellow with focused research on clinical pharmacology of biologics. She received her undergraduate degree in Public Health from Johns Hopkins University and PhD in Cancer Biology from University of Maryland School of Medicine.

Govindaraj Kumaran, PhD
Chemist, Life Cycle Branch 1 (LCB1) | Division of Life Cycle API (DLCAPI) | Office of New Drug Products (ONDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Dr. Kumaran currently works as a chemist in the Office of Pharmaceutical Quality Assessment III (OPQA III), Office of Pharmaceutical Quality (OPQ), Center for Drug Evaluation and Research (CDER). Prior to joining the FDA, he worked in the pharma industry for over 11 years. He received Ph.D. in organic chemistry from the University of Pune, India. During the last 10 years, Dr. Kumaran has been working at the FDA assessing Chemistry Manufacturing and Controls (CMC) aspects in generic drug master files (DMF), assessing toxicity of drug impurities using computational (Q)SAR models and surrogate analysis of nitrosamine impurities.

David Awotwe-Otoo, PhD
Senior Pharmaceutical Quality Assessor (SPQA), Division of Product Quality Assessment III
Office of Product Quality Assessment I | Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) |Food and Drug Administration (FDA)

Dr. David Awotwe-Otoo, PhD, started working at the FDA in 2011 as a graduate student intern. After graduating with a PhD in Pharmaceutical Sciences from Howard University, he worked as an ORISE Fellow with the Division of Product Quality Research (DPQR) for six months before being hired permanently in 2012 as a Senior staff Fellow. As a Senior Staff Fellow with DPQR, he worked on complex regulatory research products including pre-formulation and formulation characterization of complex drug products, which formed the basis for CDER Research on bioprocess improvements for biosimilar drug products. He is currently a SPQA with the Office of Product Quality Assessment, involved with performing secondary reviews on post-approval CMC changes to generic drugs.

Asif Rasheed, PhD
Senior Review Chemist, Office of Pharmaceutical Quality Assessment II (OPQA II)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Dr. Asif Rasheed is currently a chemist/quality assessor in the Office of Pharmaceutical Quality Assessment II (OPQA II) in the Office of Pharmaceutical Quality (OPQ). In OPQ, he has been involved in assessment of a variety of dosage forms for oral, topical, parenteral, and ophthalmic routes and serves as application technical lead (ATL) for several applications. He received Ph.D. in Chemistry from the University of Tennessee, Knoxville and pursued postdoctoral fellowship at Georgia Institute of Technology, Atlanta. Dr. Rasheed joined the FDA in 2008. Prior to joining the FDA, he held a teaching position at the University of Wisconsin.

Kshitij Patkar, PhD
Senior Pharmaceutical Quality Assessor, Pharmaceutical Manufacturing Branch 10 (PMB10) | Division of Pharmaceutical Manufacturing Assessment IV (DPMAIV) | Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Kshitij Patkar is a Senior Pharmaceutical Quality Assessor in the Office Pharmaceutical Manufacturing Assessment (OMPA). He oversees the review activities of drug product manufacturing processes and facilities for both generic and new drug applications. At FDA, Kshitij has almost 10 years of experience in the assessment of liquid dosage form drug product applications. Before joining the FDA, Kshitij worked as a principal investigator and administrator of bioanalytical operations at Torrey Pines Institute for Molecular Studies, Florida. He received his PhD in Pharmaceutical Sciences from University of Maryland, Baltimore in 2002 with principal focus on peptide synthesis and analysis.

Jin Xu, PhD
Senior Pharmaceutical Quality Assessor, Office of Pharmaceutical Quality Assessment II (OPQA II)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) |Food and Drug Administration (FDA)

Jin Xu started his FDA career in 2014 as a pharmaceutical quality assessor. He currently serves as an application technical lead of an aligned team, overseeing the quality assessment of various parenteral, topical, and oral dosage forms. Prior to joining the FDA, he was Principal Scientist at Merck responsible for formulation, process development and commercialization. He received his PhD in Polymer Science from the University of Massachusetts at Lowell.

Derek Smith, PhD
Deputy Director, Division of Pharmaceutical Manufacturing Assessment IV (DPMA IV)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Derek Smith joined FDA in 2010 and has served as compliance officer, CMC assessor, Quality assessment lead, Branch Chief, and Division Director prior to his current role. Derek is the Associate Director of Regulatory Affairs (Acting) for the Office of Pharmaceutical Manufacturing Assessment within OPQ. He provides leadership and oversight for the assessment of the manufacturing process and facilities for biologics and small molecule drug applications with a focus on the integration of application assessment and inspection findings and data reliability assessments. He also serves as the co-chair for the New Inspection Protocol Project (NIPP) initiative for pre-approval inspections and is a member of the Knowledge-aided Assessment and Structured Application (KASA) initiative steering committee. He holds a PhD in Chemical and Biochemical Engineering from University of Maryland, Baltimore County.

Rakhi Shah, PhD
Associate Director, Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Dr. Rakhi Shah has been with the FDA since 2004, serving as a research scientist, senior reviewer, team lead, branch chief, associate director for regulatory affairs prior to her current role as associate director for science and communication in OPMA. She provides staff leadership and direction in assessment of manufacturing and facilities for A/NDAs and BLAs, and supplements including inspections to support applications action.
She is a recognized subject matter expert in pharmaceutical manufacturing and has served on multiple internal and external committees and working groups, notably, ICHM4Q(R2), KASA, NIPP, etc. She has a Ph.D. in pharmaceutical sciences, M.S. in Bioprocess technology and B.S. in Pharmaceutical Sciences.

Elisa Nickum, PhD, PMP
Senior Regulatory Health Project Manager, Office of Program and Regulatory Operations (OPRO)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Elisa Nickum, PhD, PMP, is a Senior Regulatory Business Process Manager in the Office of Program and Regulatory Operations within the Office of Pharmaceutical Quality in the Center for Drug Evaluation and Research in the U.S. FDA. Her office focuses on cross-functional project management for various regulatory programs and business process initiatives, and she serves as a project manager in support of the Emerging Technology Program, PDUFA VII Commitments, the 2022 Omnibus Appropriations Bill, and work related to Nitrosamine Impurities in Drug Products. Prior to her current role, Elisa served as a Chemistry Reviewer in the OPQ Office of Lifecycle Drug Products. Elisa joined the FDA in 2002 as an analytical chemist at the Forensic Chemistry Center in the Office of Regulatory Affairs. She earned her PhD in analytical chemistry at the University of Cincinnati and a BS in forensic chemistry at Ohio University.

John Arigo, PhD
Division Director, Division of Pharmaceutical Manufacturing Assessment 2 (DPMA2)
Office of Pharmaceutical Manufacturing Assessment (OPMA) | Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Dr. John Arigo is the Director of the Division of Pharmaceutical Manufacturing Assessment 2 in the Office of Pharmaceutical Manufacturing Assessment at the FDA. His experience is with sterility assurance and manufacturing submissions to support ANDA, NDA, and INDs. He began his career with the Office of Generic Drugs Microbiology team in 2008 and has been involved in multiple reorganizations to the current state. Prior to working at the FDA, Dr. Arigo obtained his Ph.D. from The Johns Hopkins University School of Medicine.

Erika Pfeiler, PhD
Unit Supervisor, Office of Pharmaceutical Manufacturing Assessment (OPMA) | Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Dr. Erika Pfeiler is a microbiologist and Unit Supervisor in the FDA/CDER Office of Pharmaceutical Quality/Office of Process and Manufacturing Assessment where she has extensive experience in the quality microbiology assessment of ANDAs, NDAs, INDs, and BLAs. She joined CDER in 2012. Her areas of particular interest in pharmaceutical microbiology include rapid microbiological testing methods, pharmacy compounding, and the microbiological aspects of nonsterile products. Dr. Pfeiler has an educational background in food microbiology and received a B.S. from the University of Tennessee and a Ph.D. from North Carolina State University.

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Sunny Pyon, Pharm.D., is a Labeling Project Manager in the Division of Labeling Review (DLR) within the Office of Regulatory Operations (ORO). She received her undergraduate degree in Public Health from The Johns Hopkins University and PharmD from University of Maryland, School of Pharmacy. Sunny joined FDA in 2015 as a Labeling Project Manager and has been with DLR since then.

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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 patient and exclusivity matters for brand and generic drugs.

Vincent Sansone, PharmD
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CAPT Vincent Sansone is currently the Division Director in the Office of Generic Drugs (OGD), Office of Regulatory Operations (ORO), Division of Project Management (DPM). He joined the FDA in 2012 as a Chemistry Project Manager in OGD and has held various positions in ORO such as: Team Leader, Supervisory Regulatory Project Manager, and Deputy Office Director.

Prior to working at the FDA, he served as a clinical pharmacist at the National Institute of Health/National Institute of Drug Abuse and staff pharmacist in the Federal Bureau of Prisons. He received his undergraduate degree from Towson University and Pharm D from the University of Maryland.

Rinku Patel PharmD, BCPS, RAC
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CDR Rinku Patel is currently the Associate Director of the Division of Legal and Regulatory Support within CDER OGD's Office of Generic Drug Policy. In this capacity, she provides strategic counsel and expert-level support on technical and regulatory policy matters, with a particular focus on issues pertaining to patents and exclusivity, linkage between patent litigation status and eligibility for approval. She also assists in determining eligibility for patent challenge and competitive generic therapy 180-day exclusivity. CDR Patel joined the FDA in 2012 and has held various positions within OGD.

Prior to her tenure at the FDA, she worked as a clinical pharmacist at the Indian Health Service. She earned a Doctorate of Pharmacy from Midwestern University and a Bachelors of Arts in Marketing, Transportation and Logistics from The Ohio State University.

Tawni Schwemer, CCMP
Senior Advisor, Immediate Office (IO), Office of Generic Drugs (OGD)
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Tawni Schwemer serves as the Senior Advisor for the OGD Immediate Office (OGD IO). In this role, she works closely with OGD senior management to develop and implement complex strategic initiatives consistent with strategic problem-solving. Tawni served as an integral member of OGD and CDER leadership through GDUFA II and III negotiations and implementation. She served as OGD's Lead on GDUFA III implementation. Her holistic approach to working through challenges in a collaborative, team-based manner brings innovative approaches to difficult problems.
Tawni began working in the OGD IO in 2019. Prior to coming to the IO, Tawni spent five years in the Office of Generic Drug Policy (OGDP), including three years as the OGDP Associate Director for Regulatory Affairs. As a member of OGD since 2014, Tawni has spent her entire career with CDER, beginning her work as a college student and progressing into valuable experiences in the Office of Compliance, the Office of Regulatory Policy, and the Office of Management. Tawni earned a bachelor's in psychology from West Virginia University, a Project Management (PM) Master's Certification from George Washington University, and most recently a Change Management Practitioner Certification in 2021.