SPEAKER BIOGRAPHIES

DAY ONE: Tuesday, September 24, 2024

Robert M. Califf, MD
Commissioner of Food and Drugs
Food and Drug Administration (FDA)

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

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

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

Brenda Stodart, PharmD, BCGP, RAC-US
Captain, United States Public Health Service
Director, Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM)
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

Nora Lim, PharmD, BCPS
LCDR | USPHS | *Pharmacist*
SBIA | DDI | OCOMM
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

LCDR Nora Lim is a pharmacist within the Center for Drug Evaluation and Research's (CDER's) Small Business and Industry Assistance (SBIA) Program. She has served as a Drug Information Specialist in the Division of Drug Information for six years. LCDR Lim received her PharmD from the University of Maryland Baltimore School of Pharmacy and BS in Biochemistry & Molecular Biology from the University of Maryland, Baltimore County. She is also a Board-Certified Pharmacotherapy Specialist (BCPS) and has had experience in hospital pharmacy practice prior to her current position.

Agm (Abu) Mostofa, PhD
Pharmacologist
Division of Bioequivalence I (DBI)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)

Dr. Agm Mostofa earned his Ph.D. in Pharmaceutical Sciences from Texas Tech University and is currently a Staff Fellow (Pharmacology Reviewer) in the Office of Bioequivalence (OB) in the Office of Generic Drugs (OGD). He conducts bioequivalence assessments for generic drug-related submissions, including ANDAs, ANDA supplements, pre-ANDA submissions, controlled correspondences, and post-Complete Response Letter (CRL) clarification and scientific meetings. Mostofa is developing expertise in complex drug products, particularly in situ depot-forming long-acting injectables. He also engages in regulatory science research and was previously involved in product-specific guidance development at the Office of Research and Standards (ORS).

Thilak Mudalige, PhD
Research Chemist
Arkansas Human & Animal Food Laboratory (ARLHAF)
Office of Human & Animal Food Laboratory Operations (OHAFLO)
Office of Regulator Science (ORS)
Office of Regulatory Affairs (ORA)

Thilak Mudalige is a Research Chemist at the NCTR-ORA nanotechnology core facility of the U. S. Food and Drug Administration. He is developing novel methods for the characterization of nanomedicine, which include analysis of lipid-based formulation for distribution of active pharmaceutical ingredients, drug release profiling, quantitation of excipients and excipient related impurities, and developing drug release profiling methods for protein and lipid-based formulations. Dr. Mudalige is a member of the FDA Nanotechnology Task Force and an editorial board member of AAPS PharmSciTech. His prior experiences include the synthesis, characterization, and application of nanomaterials and bio-nanomaterials composites. Dr. Mudalige is a recipient of multiple awards, including ORA Scientist of the Year in 2016, and his collaborative work with the Center for Drug Evaluation and Research (CDER) received the FDA Excellence in Analytical Science group award in 2019.

Dongkai Zhu, PhD
Visiting Associate
Division of Pharmaceutical Quality Research VI (DPQR VI)
Office of Pharmaceutical Quality Research (OPQR)
Office of Pharmaceutical Quality (OPQ)

Dr. Dongkai Zhu received his Ph.D. in Bioengineering at Clemson University and is currently a Staff Fellow (Research Scientist) in the Division of Product Quality Research VI (DPQR VI), Office of Pharmaceutical Quality Research (OPQR) in the Office of Pharmaceutical Quality (OPQ). Dr. Zhu joined the U. S. Food and Drug Administration in 2020 as an ORISE fellow working on developing an automated vitro release testing (IVRT) system, named adaptive perfusion, to measure in vitro release behavior of complex formulations. He has also worked with regulatory reviewers to support regulatory decision making, such as ANDA and pre-ANDA submission. Dr. Zhu is developing his expertise in the complex drug product field, especially in developing an IVRT method for complex formulations and advanced manufacturing of complex formulations.

Hee Sun Chung, PhD
Lead Pharmacologist
Division of Bioequivalence I (DBI)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)

Dr. Hee Sun Chung has almost 14 years of experience in bioequivalence assessment of generic drug related submissions including, but not limited to, ANDA and ANDA supplements, pre-ANDA submission meeting requests, pre-ANDA product development meeting requests, controlled correspondences, protocols, and requests for product-specific guidance development. She currently serves as a Team Leader in the Division of Bioequivalence I (DBI), Office of Bioequivalence (OB), in the Office of Generic Drugs (OGD). Dr. Chung received her B.S. in Chemistry and M.S. in Inorganic Chemistry from the University of Oklahoma and her Ph.D. in Pharmaceutical Sciences from the University of Michigan.

Xiaoming Xu, PhD
Director
Division of Pharmaceutical Quality Research V (DPQRV)
Office of Pharmaceutical Quality Research (OPQR)
Office of Pharmaceutical Quality (OPQ)

Dr. Xiaoming Xu serves as a Division Director in the Division of Pharmaceutical Quality Research V (DPQRV), Office of Pharmaceutical Quality Research (OPQR) in the Office of Pharmaceutical Quality (OPQ), where he leads multiple regulatory research areas such as complex formulations, nanomaterials, and advanced manufacturing. In support of GDUFA III implementation, Xiaoming co-leads the Complex PSG Working Group, with a focus on better integrating research in complex PSG development. He is also a member of the FDA Nanotechnology Task Force and is responsible for developing international collaborative programs and standards in areas related to nanotechnology.

Xiaoming is an editorial board member of the International Journal of Pharmaceutics. He received his B.S. and M.S. degrees in Pharmaceutics from China Pharmaceutical University and his Ph.D. degree in Pharmaceutical Sciences from the University of Connecticut.

Megan Kelchen, PhD
Senior Pharmacologist
Division of Therapeutic Performance I (DTP-I)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Megan Kelchen, PhD, is a Senior Pharmacologist in the Division of Therapeutic Performance I (DTP-I) in U. S. Food and Drug Administration's Office of Generic Drugs (OGD). Her specialization is drug products for topical, transdermal, and transmucosal drug delivery. Dr. Kelchen is responsible for the development of product-specific guidances for generic drug development, reviewing and responding to controlled correspondences, citizens petitions, and pre-ANDA meeting requests. Dr. Kelchen is also engaged in regulatory science research initiatives related to complex generics under the GDUFA regulatory science research program. Dr. Kelchen received her B.A. degree in Biology from Wartburg College and her Ph.D. in Clinical Pharmaceutical Sciences from the University of Iowa.

Eleftheria Tsakalozou, PhD
Lead Pharmacologist
Division of Quantitative Methods and Modeling (DQMM)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Eleftheria Tsakalozou joined the U.S. Food and Drug Administration in 2015 as an Oak Ridge Institute for Science and Education (ORISE) fellow. She is currently a Senior Pharmacologist at the Division of Quantitative Methods and Modeling (DQMM) in the Office of Research and Standards (ORS) and serves as the lead for the mechanistic modeling and simulation methodologies for non-orally administered (locally acting) drug products.

Dr. Tsakalozou obtained her Ph.D. in Pharmaceutical Sciences at the University of Kentucky in 2013 and completed a two-year Fellowship in Clinical Pharmacokinetics and Pharmacodynamics at the University of North Carolina at Chapel Hill. Her research interests include physiologically based pharmacokinetic modeling and simulation approaches for topical and transdermal drug products, the development of quantitative modeling and simulation tools to support bioequivalence assessments, and the study of interactions between inactive ingredients and molecular targets, including gut transporters.

Tannaz Ramezanli, PhD, PharmD
Senior Pharmacologist
Division of Therapeutic Performance I (DTP-I)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Dr. Tannaz Ramezanli is a Senior Pharmacologist within the Office of Research and Standard (ORS) in Office of Generic Drugs (OGD). She specializes in topical, transmucosal, and transdermal products. She is responsible for the development of product-specific bioequivalence guidances, reviewing and responding to controlled correspondences, citizen petitions, and industry meeting requests. She also leads multiple regulatory science research initiatives related to development of bioequivalence standards for complex topical drug products through FDA-funded collaborations with research institutions around the world. She received her Ph.D. in Pharmaceutical Sciences from Rutgers University and her PharmD from Tehran University of Medical Sciences.

Hiren H. Patel, PhD
Senior Staff Fellow
Division of Bioequivalence II (DB II)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)

Dr. Hiren Patel is a Bioequivalence Assessor in the Division of Bioequivalence II (DB II), Office of Bioequivalence (OB) in the Office of Generic Drugs (OGD). Prior to joining U.S. Food and Drug Administration, he earned his M.S. and Ph.D. with a 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 topical and transdermal drug products and the advanced techniques for demonstrating bioequivalence of such complex drug products within OB. He is the Co-Chair of the Bio-Equivalence Standards for Topicals (BEST) Expert Committee within OGD. He has also actively served as a consultant in collaborative research initiatives of the FDA and global research institutions pertaining to topical and transdermal drug products. Dr. Patel is also actively involved in the review panel for product-specific guidances for generic topical drug products.

Pahala Simamora, PhD
Division Director
Division of Product Quality Assessment IX (DPQA IX)
Office of Product Quality Assessment II (OPQA II)
Office of Pharmaceutical Quality (OPQ)

Dr. Pahala Simamora is Director of the Division of Product Quality Assessment IX (DPQA IX), Office of Product Quality Assessment II (OPQA II), in the Office of Pharmaceutical Quality (OPQ). His division is responsible for collaborative assessment of INDs, NDAs and ANDAs for various therapeutic drugs, including medical imaging and ophthalmic and non-prescription drug products, and making risk-informed recommendations on their approvability. He has been involved in several key FDA initiatives, including the current ANDA Integrated Quality Assessment process, the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) to evaluate future approaches for regulating mobile manufacturing technologies, as well as the Knowledge Aided and Structured Assessment (KASA) initiative for structured drug product assessment of liquid-based products. Prior to joining the FDA in 2010, Dr. Simamora spent 14 years in the pharmaceutical industry with experience in formulation development, process development, and scale-up.

Liangfeng Han, MD, PhD
Clinical Analyst
Division of Therapeutic Performance 1 (DTP-1)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Dr. Liangfeng Han is a Clinical Analyst in the nasal and inhalation drug product team in the Division of Therapeutic Performance 1 (DTP-1), Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). Dr. Han examines controlled correspondences, consults, and pre-ANDA meeting requests and also develops product-specific guidances. His work emphasizes resolving issues associated with alternative bioequivalence approaches in lieu of clinical studies and in vivo study designs. Additionally, he serves as a contracting officer's representative for regulatory science research, focusing on investigating product performance to advance both scientific understanding and regulatory standards for drug products. Dr. Han earned his M.D. from Shanghai Second Medical University and his Ph.D. in Human Genetics from Johns Hopkins University.

Ross Walenga, PhD
Senior Chemical Engineer
Division of Quantitative Methods and Modeling (DQMM)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Dr. Ross Walenga joined the U.S. Food and Drug Administration in 2015 as an Oak Ridge Institute for Science and Education (ORISE) Fellow. He is currently a Senior Chemical Engineer at the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), in the Office of Generic Drugs (OGD). He began his career at Virginia Polytechnic Institute and State University (Virginia Tech), where he earned a Bachelor of Science in Aerospace Engineering. He later earned his Ph.D. in Engineering (mechanical track) from Virginia Commonwealth University in 2014, where he also spent seven months as a postdoctoral fellow prior to joining the U.S. Food and Drug Administration. His research interests include computational fluid dynamics modeling of orally inhaled, nasal, ophthalmic, and dermal drug products to answer questions pertaining to bioequivalence.

Changning Guo, PhD
Supervisory Chemist
Division of Pharmaceutical Quality Research II (DPQR II)
Office of Pharmaceutical Quality Research (OPQR)
Office of Pharmaceutical Quality (OPQ)

Dr. Changning Guo is a Supervisory Chemist at the U. S. Food and Drug Administration. He currently serves as a Unit Supervisor in the Division of Pharmaceutical Quality Research II (DPQR II), Office of Pharmaceutical Quality Research (OPQR) in the Office of Pharmaceutical Quality (OPQ). His research at the FDA focus on inhalation drug characterization, particle sizing, X-ray powder diffraction (XRPD), and spectroscopy. He has been a PI/co-PI on multiple FDA research projects and served as a subject matter expert for FDA working groups, guidance teams, ANDA review teams, and FDA research grant review committees. He received a B.S. degree in Chemistry from Tsinghua University and a Ph.D. in Analytical Chemistry from Syracuse University.

Elizabeth Bielski, MS, PhD
Senior Pharmacologist
Division of Therapeutic Performance I (DTP-I)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Elizabeth Bielski, MS, PhD, is a Senior Pharmacologist working in the Division of Therapeutic Performance-I (DTP-I), Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). Prior to her role as a Senior Pharmacologist, she served as a Pharmacologist (2020-2022), a Chemist (2020), and ORISE Fellow (2018-2020) within DTP. Her areas of expertise involve orally inhaled and nasal drug products (OINDPs) and drug-device combination products (DDCPs). She is actively involved in regulatory guidance development and research initiatives to promote generic drug development of OINDPs and DDCPs.

Dr. Bielski completed her Ph.D. in Chemical Engineering from Wayne State University (Detroit) in 2018. She also received her Master of Science in Biomedical Engineering in 2012 and her Bachelor of Science in Biomedical Physics with University Honors in 2011 from Wayne State University.

Zhen Xu, PhD
Senior Staff Fellow
Division of Bioequivalence (DBIII)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)

Dr. Zhen Xu reviews bioequivalence of various generic drug products based on the guidances promulgated by the U.S. Food and Drug Administration. He serves as a focal point for the assessment of complex generic nasal and inhalation products in the Office of Bioequivalence (OB). He earned his M.S. degree in Carbohydrate Chemistry at Michigan State University and his Ph.D. in Pharmaceutical Sciences from Eshelman School of Pharmacy, University of North Carolina, where his focus was on dry powder inhalers. Before joining the FDA, he had experiences in both academia and industry in aerosol drug delivery.

Christina Streets, MD
Senior Physician
Division of Clinical Review (DCR)
Office of Safety and Clinical Evaluation (OSCE)
Office of Generic Drugs (OGD)

Dr. Christina Streets is a Senior Physician within the Division of Clinical Review (DCR), Office of Safety and Clinical Evaluation (OSCE) in the Office of Generic Drugs (OGD), where she began her career at the U. S. Food and Drug Administration in 2019. Dr. Streets has conducted numerous comparative analyses assessments, contributed to various working groups related to comparative analyses, and served as the DCR representative on the GDUFA Regulatory Science Research Proposal Committee for Grant Proposal RFA-FD-21-014, “Development of Methods to Evaluate the Impact of Design Differences to the User Interface of Generic Drug-Device Combination Products in Comparison to their Reference Listed Drugs.”

Prior to joining the FDA, Dr. Streets completed her pediatric residency at St. Christopher’s Hospital for Children in Philadelphia and her fellowship in Allergy/Immunology at Thomas Jefferson University in Philadelphia.

Betsy Ballard, MD
Medical Officer
Division of Therapeutic Performance (DTP-I)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Dr. Betsy Ballard joined the U. S. Food and Drug Administration in 2010, working in the Center for Devices and Radiological Health (CDRH) reviewing devices for the General Surgery Office. She transferred to the Office of New Drugs (OND) in the Center for Drug Evaluation and Research (CDER), where she reviewed new drug applications for combination products. She has worked in the Office of Generic Drugs (OGD) since 2020 and has conducted numerous comparative analyses assessments as a member of the Device Evaluation Team. She was a project officer for the human factors research grants.

Jing (Jenny) Wang, PhD
Staff Fellow
Division of Quantitative Methods and Modeling (DQMM)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Dr. Jing (Jenny) Wang is currently a Staff Fellow working at the Data Analytics Team of the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). Since joining ORS in 2020, she has been utilizing quantitative analytics approaches to support regulatory review efficiency and bioequivalence assessment. Her areas of expertise include data analytics methodologies, machine learning algorithms, Bayesian methods, and natural language processing techniques.

Before joining the U.S. Food and Drug Administration, Dr. Wang worked as a post-doctoral fellow in the Rehabilitation Engineering Research Center D.C. and the Department of Biomedical Engineering at The Catholic University of America. She received her Ph.D. in Rehabilitation Science from the University of Pittsburgh in 2015 and received both Bachelor's and Master's degrees in Biomedical Engineering from the Xi'an Jiaotong University, China, in 2009 and 2011.

Somesh Chattopadhyay, PhD
Lead Mathematical Statistician
Division of Biometrics VIII (DBVIII)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS)

Dr. Somesh Chattopadhyay received his Ph.D. in Statistics from the University of Virginia. He was a faculty member at Duke University and at Florida State University before joining the U.S. Food and Drug Administration as a Mathematical Statistician in the Office of Biostatistics (OB) within the Office of Translational Sciences (OTS), where he has supported review of oncologic products, generic drug products and biosimilar products. Currently, he is a team leader in the Division of Biometrics VIII (DBVIII) that supports the Office of Generic Drugs (OGD) and the Office of New Drugs (OND). From early 2019, he has been leading the team of statisticians that review comparative use human factors (CUHF) studies for generic drug-device combinations and interchangeable biologic-device combination products with a self-application delivery device component. He also leads in other generic and biosimilar product reviews, including complex generic products such as generic opioids with an abuse-deterrent formulation, and generic metered-dose inhalation products. He is involved in research in Bayesian statistics and statistical aspects of CUHF studies.

William Chong, MD
Director
Office of Safety and Clinical Evaluation (OSCE)
Office of Generic Drugs (OGD)

Dr. William (Bill) Chong is the Director of the Office of Safety and Clinical Evaluation (OSCE) in the Office of Generic Drugs (OGD). Dr. Chong started his U. S. Food and Drug Administration career in the Office of New Drugs (OND) reviewing applications for new drugs for diabetes mellitus prior to joining OGD in 2019 as the Associate Director for Clinical Affairs before assuming the role of Director for OSCE. In this role, Dr. Chong oversees the OGD divisions responsible for the analysis of pharmacologic/toxicologic data for excipients and impurities, comparative clinical data such as comparative clinical bioequivalence studies and comparative analyses and monitoring generic drug products in the post-marketing space in order to ensure that generic drug products are safe and therapeutically equivalent.

Prior to joining the FDA, Dr. Chong completed his training in Internal Medicine at Thomas Jefferson University in Philadelphia, PA and a fellowship in Endocrinology and Metabolism at the National Institutes of Health in Bethesda, MD.

Sau (Larry) Lee, PhD
Deputy Director of Operations
Office of Pharmaceutical Quality (OPQ)

Dr. Sau (Larry) Lee is currently Deputy Super Office Director for Operations and oversees research, quality surveillance, policy, quality assurance, and administrative operation functions in the Center for Drug Evaluation and Research's (CDER) Office of Pharmaceutical Quality (OPQ). Dr. Lee has been with the U. S. Food and Drug Administration since 2005, serving as a Regulatory Scientist, Team Lead, Associate Director for Science, Deputy Office Director, Office Director, and Deputy Super Office Director of Science. He has provided exemplary leadership in developing OPQ science, research and testing programs to support quality assessment, inspection, surveillance, and policy.

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 U.S. Food and Drug Administration, Dr. Lee received a B.S. degree in Chemical Engineering with a minor in Materials Science from the University of Virginia and a Ph.D. in Chemical Engineering from Princeton University.

Tina Jiao, MS
Chemist
Division of Product Quality Assessment IV (DPQA IV)
Office of Product Quality Assessment I (OPQA I)
Office of Pharmaceutical Quality (OPQ)

Tina Jiao is a Chemist in the Division of Product Quality Assessment IV (DPQA IV), Office of Product Quality Assessment I (OPQA I), in the Office of Pharmaceutical Quality (OPQ). Jiao has experience supporting generic drug product review across a wide range of therapeutic area and dosage forms. Prior to joining the U.S. Food and Drug Administration in 2017, Jiao spent 17 years in the pharmaceutical industry as an analytical lead to support the 505 (j)/505 (b)(2) regulatory submission.

Maria Flynn, PhD
Senior Pharmaceutical Quality Assessor
Application Technical Lead for Aligned Team 8 Unit II
Division of Product Quality Assessment VIII (DPQA VIII)
Office of Product Quality Assessment II (OPQA II)
Office of Pharmaceutical Quality (OPQ)

Dr. Maria Flynn joined U. S. Food and Drug Administration in 2008. She is a Senior Pharmaceutical Quality Assessor (SPQA) and Application Technical Lead in the Office of Product Quality Assessment II (OPQA II) in the Office of Pharmaceutical Quality (OPQ). For the past decade, she has been leading interdisciplinary pharmaceutical quality assessment teams in a multitude of therapeutic areas, including complex or combination drug products. Dr. Flynn has approved many first generic ANDAs. She is experienced with a variety of drug product dosage forms, such as solid oral modified release products, transdermal drug delivery systems (TDDS), topicals, sterile parenterals, solid oral immediate products, suppository products, oral solutions, otics, ophthalmics, oral liquids, and radiopharmaceuticals. She has assessed pre-ANDA, pre-marketing, and post-marketing ANDA submissions and has assessed USP monographs; much earlier in her career she assessed Type II Drug Master Files (DMFs). Dr Flynn has served as a subject matter expert on FDA prior approval inspections.

Currently, Dr. Flynn contributes to OPQ working groups and recently aided an external MAPP publication. She has trained over 290 new hires. She is most proud of her decade of efforts towards the Presidential Emergency Plan for Aids Relief (PEPFAR) program. She has a B.S. in Chemistry from the Massachusetts Institute of Technology (MIT), an M.S. and MPhil in Chemistry from Columbia University, a Ph.D. in Organic Chemistry from University at Buffalo-SUNY, and a postdoctoral fellowship at the National Institute of Health-National Cancer Institute, (NIH-NCI).

Nashwa El-Gendy, PhD
Senior Pharmaceutical Quality Assessor
Division of Product Quality Assessment V (DPQA V)
Office of Product Quality Assessment I (OPQA I)
Office of Pharmaceutical Quality (OPQ)

Dr. Nashwa El-Gendy has been a Senior Pharmaceutical Quality Assessor (SPQA) in the Division of Product Quality Assessment V (DPQA V), Office of Product Quality Assessment I (OPQA I) in the Office of Pharmaceutical Quality (OPQ) since 2023. Dr. El-Gendy received her B.S., M.S., and Ph.D. in Pharmaceutical Sciences from Cairo University, Egypt. Prior to joining the U.S. Food and Drug Administration, she held various positions with a multitude of responsibilities. She has worked as a Formulation Scientist/Senior Scientist at Banner Life Sciences and at Alcami Corporation. Prior to that, Dr. El-Gendy worked as a Postdoctoral Fellow/Scientist at the University of Kansas and served as Associate Professor at School of Pharmacy, Beni-Suef University, Egypt.

In 2017, Dr El-Gendy joined FDA as a Staff Fellow; she was promoted to Senior Chemist in 2022. She reviews and evaluates complex scientific submissions, including combination drug products such as drug powder inhalers (DPIs), metered-dose inhalers (MDIs), and nasal sprays. She has also applied her academic/industrial experience and subject matter expertise in medical devices and aerosolized therapeutics (U.S. patent and several publications) to make final science- and risk-based recommendations on the adequacy and acceptability of complex ANDA submissions, both from a scientific and regulatory perspective. In addition, has also worked on Bio-INDs, pre-ANDA assessments, controlled correspondences, and mentoring new assessors.

Dr. El-Gendy is currently serving as a member of multiple working groups (Draft CMC MDI/DPI Guidance Revision Working Group, Expert Group for Nasal and Inhalation Products, and FDA liaison on USP Joint Subcommittee on Lactose Grade for Inhalation and Injectables since 2021). She has also presented and given numerous talks on inhalation products at both internal and external forums. She has contributed to two review papers for the journal Advanced Drug Delivery Reviews, writing as first author on El-Gendy et al (October, 2023), Scientific and regulatory activities initiated by the U.S. Food and Drug Administration to foster approvals of generic dry powder inhalers: Quality perspective.

Yili Li, PhD
Senior Pharmaceutical Quality Assessor
Division of Product Quality Assessment XI (DPQA XI)
Office of Product Quality Assessment II (OPQA II)
Office of Pharmaceutical Quality (OPQ)

Dr. Yili Li is a Senior Pharmaceutical Quality Assessor (SPQA) in the Division of Product Quality Assessment XI (DPQA XI), Office of Product Quality Assessment II (OPQA II) in the Office of Pharmaceutical Quality (OPQ). She joined U. S. Food and Drug Administration in May 2016 as a Chemistry Reviewer and became an SPQA in August 2022. Dr. Li has extensive experiences in the review of complex peptide generic drug products and led the approval of several first generic peptide ANDAs.

Dr. Li received her B.S. and Ph.D. in Chemistry from Peking University, Beijing, China. She continued her career training as a Marie Curie Fellow of the European Commission in the Biochemistry Department, University of Cambridge, UK and as a Post-doctoral Fogarty Visiting Fellow in the National Cancer Institute, National Institutes of Health in Bethesda, MD. Before joining the FDA, Dr. Li was a Senior Scientist in the University of Maryland Institute for Bioscience and Biotechnology Research (IBBR) in Rockville, MD. She has two decades of research experience in the field of structural immunology and has published two dozen first author research papers in the world's most prestigious life science journals.

Bryan Newman, PhD
Lead Pharmacologist
Division of Therapeutic Performance 1 (DTP-1)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Bryan Newman, PhD, is a Lead Pharmacologist and team lead for nasal and inhalation drug products in the Division of Therapeutic Performance 1 (DTP-1), Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). Dr. Newman's work focuses on developing product-specific guidances, along with addressing controlled correspondences, citizen petitions, consults, and pre-ANDA meeting requests. He also serves as a project officer and contracting officer's representative for regulatory science research initiatives related to nasal and inhalation drug products. Dr. Newman received his B.S. degree from Louisiana State University in Biochemistry and his M.S. and Ph.D. degrees in Pharmaceutical Science from the University of Michigan.

Dr. Yang Lu
Senior Staff Fellow
Division of Bioequivalence III (DBIII)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)

Dr. Yang Lu is a Senior Staff Fellow in the Division of Bioequivalence III (DBIII), Office of Bioequivalence in the Office of Generic Drugs (OGD). Dr. Lu's work focuses on scientific and regulatory reviews of generic drug applications (e.g., ANDAs, controlled correspondence, pre- and post-ANDA meetings, etc.). Dr. Lu contributes to multiple collaborative projects at the OGD, including taking the lead role of the "complex bioanalysis" and "excipient safety evaluation in pediatric population" working groups. Dr. Lu also serves as the point of contact for complex ANDA review. Dr. Lu received his Ph.D. from the State University of New York at Stony Brook.

Fang Wu, PhD
Senior Pharmacologist
Division of Quantitative Methods and Modeling (DQMM)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Dr. Fang Wu is a Senior Pharmacologist reviewer and scientific lead for oral physiologically based pharmacokinetic modeling in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). Dr. Wu has been with U.S. Food and Drug Administration for more than 12 years. She is responsible for using modeling and simulations tools for reviewing pre-ANDA meeting packages, ANDA consults, and controlled correspondences. Prior to joining DQMM, Dr. Wu was a biopharmaceutics reviewer for more than four years and responsible for NDA and ANDA reviews. She has been a principal and co-principal investigator for multiple FDA research projects and involved in several guidance working groups and grant review panels.

Likan Liang, PhD
Supervisory Chemist
Division of Product Quality Assessment X (DPQA X)
Office of Product Quality Assessment II (OPQA II)
Office of Pharmaceutical Quality (OPQ)

Dr. Likan Liang is a unit supervisor in the Division of Product Quality Assessment X (DPQA X), Office of Product Quality Assessment II (OPQA II) in the Office of Pharmaceutical Quality (OPQ). Dr. Liang has served as the OPQ meeting chair in reviews of multiple complex drug pre-ANDA product development meetings, including all of the generic oligonucleotide pre-ANDAs thus far. Dr. Liang also contributed significantly to the development of product-specific guidances on generic oligonucleotides, many of which are now published. Before joining the U. S. Food and Drug Administration in 2013, Dr. Liang worked in the pharmaceutical industry for roughly 16 years in various capacities in areas including API synthesis, formulation development for multiple dosage forms and complex drugs, and drug product manufacturing process development and commercial scale manufacturing.

Yan Wang, PhD
Lead Pharmacologist / Acting Deputy Division Director
Division of Therapeutic Performance I (DTP-I)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Dr. Yan Wang is the Acting 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. Dr. Wang has been at the U.S. Food and Drug Administration since 2013, serving 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.

In her current role, Dr. Wang leads a group of interdisciplinary scientists in the development of new analytical methods and equivalence evaluation methodologies for complex drug substances and parenteral, ophthalmic, otic, intrauterine, and intravaginal formulations. Dr. Wang 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. Dr. Wang received her Ph.D. in Pharmaceutical Sciences from the University of Connecticut.

Hansong Chen, PharmD, PhD
Senior Interdisciplinary Scientist
Division of Product Quality Assessment XII (DPQA XII)
Office of Product Quality Assessment II (OPQA II)
Office of Pharmaceutical Quality (OPQ)

Dr. Hansong Chen initially joined Office of Study Integrity and Surveillance (OSIS) in 2013, where he conducted two years of BA/BE inspection. In 2015, he joined the Division of Biopharmaceutics in the Office of Nonprescription Drugs (ONDP). Currently, he works at Division of Product Quality (DPQA XII), Office of Product Quality Assessment II (OPQA II) within the Office of Pharmaceutical Quality (OPQ). Before joining FDA, he worked at a biopharmaceutics company as a chemist.

Greg Huang, PhD
Senior Chemist
Division of Product Quality Assessment IX (DPQA IX)
Office of Product Quality Assessment II (OPQA II)
Office of Pharmaceutical Quality (OPQ)

Dr. Greg Huang is a Senior Chemist in the Division of Product Quality Assessment IX (DPQA IX), Office of Product Quality Assessment II (OPQA II) in the Office of Pharmaceutical Quality (OPQ). He is responsible for CMC assessment for generic drug products such as liquid-based injections, long-acting injectables, semi-solids, and peptide products. He serves a subject matter expert for complex topical dermatological products and as a U.S. Food and Drug Administration liaison with the USP Excipient Expert Committee. Prior to joining the FDA in 2014, he spent 12 years in the pharmaceutical industry with experience in analytical and formulation development, process development, and technology transfer.

Fang Lu, PhD
Lead Pharmacologist
Division of Bioequivalence I (DBI)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)

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 15 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.

Priyanka Ghosh, PhD
Lead Pharmacologist
Division of Therapeutic Performance I (DTP-I)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Dr. Priyanka Ghosh is a Lead Pharmacologist within the Division of Therapeutic Performance I (DTP-I), Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). Her areas of expertise include products in the topical, transdermal, and transmucosal drug delivery areas. In her current role, Dr. Ghosh leads regulatory science research initiatives related to topical, transdermal, and transmucosal drug products under the GDUFA regulatory science program. Dr. Ghosh also leads the development of general and product-specific guidances, review strategies for industry meeting requests and citizen petitions, and is the co-chair of the Bioequivalence Standards for Topicals Committee within OGD. Prior to joining the U.S. Food and Drug Administration, Dr. Ghosh completed her Bachelor's degree in Biotechnology from West Bengal University of Technology (India) and received a Ph.D. in Pharmaceutics and Drug Design from the University of Kentucky.

Lei Zhang, PhD
Deputy Director
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Dr. Lei Zhang serves as the Deputy Director of the Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). Dr. Zhang oversees the implementation of the GDUFA science and research program to ensure the therapeutic equivalence of generic drug products. Dr. Zhang was previously Senior Advisor for Regulatory Programs and Policy in the Office of Clinical Pharmacology (OCP). Dr. Zhang is an accomplished professional with more than 25 years of combined experiences in the areas of drug research, development and regulatory review, and approval. She has contributed to numerous guidance development and research projects focused on science-based regulatory decision making.

Before joining the U.S. Food and Drug Administration in 2002, she worked at Bristol Meyers Squibb as a Research Investigator and Preclinical Candidate Optimization Team Leader. Dr. Zhang is an Adjunct Professor in the Department of Bioengineering and Therapeutic Sciences, University of California at San Francisco (UCSF), Schools of Pharmacy and Medicine. Dr. Zhang received her Ph.D. in Biopharmaceutical Sciences from UCSF. She is currently the Rapporteur for the ICH M13 Expert Working Group that is developing harmonized guidelines on bioequivalence for immediate-release solid oral dosage form drugs. She was a member of the ICH Generic Drug Discussion Group, serving as the U.S. FDA Topic Lead. Dr. Zhang was named an American Association of Pharmaceutical Scientists (AAPS) Fellow in 2013. She has published more than 130 peer-reviewed papers and book chapters.

Yuqing Gong, PhD
Senior Pharmacologist
Division of Quantitative Methods and Modeling (DQMM)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Yuqing Gong, PhD is currently a Senior Pharmacologist at the Quantitative Clinical Pharmacology Team in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). Her current role in the division is to utilize quantitative tools such as population pharmacokinetics, modeling, and simulations, to address specific questions related to the generic drug development process and regulatory decision making. Before joining the U.S. Food and Drug Administration, she received comprehensive trainings in pharmaceutical sciences with focuses on drug delivery, pharmacokinetics, and drug-drug interactions. Dr. Gong received her Ph.D. degree in Pharmaceutical Sciences at the University of Tennessee Health Science Center (Memphis) in 2020.

Nilufer Tampal, PhD
Associate Director of Scientific Quality
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)

Dr. Nilufer Tampal is the Associate Director for Scientific Quality in the Office of Bioequivalence (OB) within the Office of Generic Drugs (OGD). In this role, Dr. Tampal develops strategies and oversees implementation of data quality and the scientific integrity of bioequivalence data submitted in ANDAs. She is the subject matter expert in Bioanalytical Methods and Data Integrity in OGD, among other areas of generic drugs. Dr. Tampal received her Ph.D. in Toxicology from the University of Kentucky and an M.S. in Chemistry from Bombay University, India. She started her career at the U.S. Food and Drug Administration as an investigator in the Office of Study Integrity and Surveillance (OSIS) and has held various leadership positions in OB for the last 15 years.

Rachel Erdman, JD
Regulatory Counsel
Division of Policy Development (DPD)
Office of Generic Drug Policy (OGDP)
Office of Generic Drugs (OGD)

Rachel Erdman serves as regulatory counsel in the Division of Policy Development (DPD) in the Office of Generic Drug Policy (OGDP) within the Office of Generic Drugs (OGD).

Prior to the joining the U.S. Food and Drug Administration, she was an examiner for the United States Patent and Trademark Office, an associate attorney at Finnegan, Henderson, Farabow, Garrett & Dunner, and researcher in biochemistry crystallography at Emory University.

She received her J.D. from Emory University School of Law. She received a B.S. in biological sciences and B.A. in English from Florida State University.

Robert Lionberger, PhD
Director
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)

Robert Lionberger, PhD serves as Director of the Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). Dr. Lionberger leads OGD's implementation of the GDUFA science and research commitments, including internal research activities and external research grants and collaborations to ensure the therapeutic equivalence of generic drug products. ORS also provides pre-submission advice on complex generics through pre-ANDA meetings, product-specific guidances, and correspondence responses.

He received his undergraduate degree in Chemical Engineering from Stanford University and a Ph.D. in Chemical Engineering from Princeton University. After receiving his Ph.D., he conducted post-doctoral research in Australia in the Department of Mathematics and Statistics at the University of Melbourne. Prior to joining the U.S. Food and Drug Administration 18 years ago, he was an Assistant Professor of Chemical Engineering at the University of Michigan.