# SPEAKER BIOGRAPHIES

**DAY ONE: Tuesday, October 31, 2023**

## 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) | 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). CAPT Stodart has had experience in hospital and retail pharmacy before joining the FDA.

## DAY ONE: Tuesday, October 31, 2023

**Michael Kopcha, PhD, RPh**
*Director*
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Michael Kopcha, PhD, R.Ph. is the Director of the FDA's Office of Pharmaceutical Quality (OPQ). This office has over 1,300 staff responsible for assuring the availability of quality medicines for the American public through assessment, inspection, surveillance, research, and policy. OPQ contributes to the assessment of nearly every type of human drug marketing application including New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologics License Applications (BLAs), including 351(k) applications (i.e., biosimilars). OPQ also performs the quality assessment of Investigational New Drug Applications (INDs) and establishes quality standards for over-the-counter drug products and facilities.

Prior to joining the FDA, Dr. Kopcha amassed more than 25 years of experience in major and mid-sized innovator, generic, drug/device, and over-the counter (OTC) pharmaceutical and consumer health companies. He developed expertise in areas including formulation and process development, product scale-up, process validation, technology transfer, project management, change management, and off-shoring/outsourcing. Dr. Kopcha most recently served as Vice President, and global research and development franchise head, for cough, cold, and respiratory products at Novartis Consumer Health, Inc.

Dr. Kopcha earned his doctorate and master's degrees in pharmaceutical science, and a bachelor's degree in pharmacy from Rutgers University. He also served as an adjunct assistant professor in the Department of Pharmaceutics at Ernest Mario School of Pharmacy at Rutgers.

**Neil Stiber, PhD**
*Associate Director for Science and Communication*
Office of Quality Surveillance (OQS)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Neil Stiber is the Associate Director for Science and Communication in CDER/OPQ/Office of Quality Surveillance. During ten years in CDER, he has innovated risk-based approaches, provided collaborative program leadership, and engaged business partners and stakeholders to advance pharmaceutical quality. Previously, he was the director of ORA's Risk Management Staff and for eight years was an environmental scientist at the U.S. EPA. Neil received a PhD in Engineering and Public Policy from Carnegie Mellon University.

**Sau "Larry" Lee, PhD**
*Deputy Director of Science*
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. 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. 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. He developed and established the Emerging Technology Program in CDER. He has been serving as a rapporteur for ICH Q13 on Continuous Manufacturing of Drug Substances and Drug Products. Dr. Lee received a B.S. degree in Chemical Engineering from the University of Virginia with a minor in Materials Science and a PhD in Chemical Engineering from Princeton University.

**Susan Kirshner, PhD, MSc**
*Director*
Division of Biotechnology Review and Research III (DBRRIII)
Office of Biotechnology Products (OBP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Dr. Susan Kirshner received an M.Sc. from University of North Carolina School of Public Health in the field of environmental toxicology. She received a PhD in Immunology from the Weizmann Institute of Science, where she worked on the development of an immunomodulatory peptide for the treatment of Myasthenia gravis. Dr. Kirshner's post-doctoral training was at the National Cancer Institute in the area of transcriptional regulation of MHC class I genes. Dr. Kirshner worked as a Program Officer in the Clinical Immunology Division of the Extramural Administrative Program at NIAID and in industry before joining OBP in 2002, where she is currently the Director of the Division of Biotechnology Review and Research 3.

**Hong Cai, PhD**
*Division Director*
Division of New Drug Product II (DNDPII)
Office of New Drug Products (ONDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)

Dr. Hong Cai is a division director in the Office of New Drug Products within the Office of Pharmaceutical Quality in the FDA's Center for Drug Evaluation and Research. Her division performs new drug product quality assessments supporting applications in disease areas including Immunology and Inflammation, Rare Diseases, Urologic, Reproductive and Neuroscience. During her tenure at FDA, Dr. Cai served as a quality reviewer, a CMC Lead, and a Branch Chief before assuming her current role. Additionally, she serves as the FDA liaison to the USP Expert Committees on Simple Excipients and Complex Excipients (2020-2025).

Prior to joining the FDA in 2015, Dr. Cai spent more than 17 years in the pharmaceutical industry. Her working experience expands from early drug discovery to late-stage development at Johnson and Johnson, Bristol Meyer Squibb, and Glaxo Smith Kline.

**Yue "Helen" Teng, PhD**
*Division Director*
Division of Immediate and Modified Release Products III (DIMRPIII)
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)

Helen Teng is a Division Director in OPQ's Office of Lifecycle Drug Products. She received a PhD in Chemistry from the University of Texas in 2000. Helen has over 20 years of industry and regulatory working experience. She has extensive experience with both immediate release and modified release solid oral dosage forms, and has represented OLDP on several policy and guidance working groups, such as Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations guidance working group, Risk Based Quality Assessment Working Group, Team-Based Integrated Quality Assessment Team working group, etc.

**Alonza Cruse, BS**
*Director*
Office of Pharmaceutical Quality Operations (OPQO)
Office of Medical Products & Tobacco Operations (OMPTO)
Office of Regulatory Affairs (ORA)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)

Alonza Cruse is director of the Office of Pharmaceutical Quality Operations within the Office of Regulatory Affairs (ORA) in the Food and Drug Administration (FDA). His office is responsible for all pharmaceutical quality inspections and investigations, working in conjunction with FDA's Center for Drug Evaluation & Research and the Center for Veterinary Medicine. Additionally, Mr. Cruse led ORA's pharmaceutical collaboration efforts under our Program Alignment initiative.

From 2013 – 2015, Mr. Cruse served as the acting director of the Office of Medical Products & Tobacco Operations within ORA, overseeing activities such as implementation of the Generic Drug User Fee Amendments within ORA, of pharmacy compounding, and of the development of a new inspection protocols program.

Prior to that, Mr. Cruse was the director of the Los Angeles District Office, where his responsibilities included providing executive leadership to implement, manage and evaluate FDA's regulatory operations. Mr. Cruse first joined ORA in 1983 as a microbiologist. He received his Bachelor of Science degree in medical technology from York College (City University of New York).

**Christopher Downey, PhD**
*Director*
Division of Biotechnology Manufacturing
Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Christopher (Chris) Downey is the Director of the Division of Biotechnology Manufacturing Assessment in FDA/CDER's Office of Pharmaceutical Manufacturing Assessment (OPMA), serving in this role since May 2022. His division is responsible for assessing CMC information related to microbiology and to manufacturing and testing facilities, including conducting pre-license inspections (PLI) for CDER-regulated biologics, both for original applications and biosimilars. Prior to joining OPMA, he served in FDA/CDER's Office of Biotechnology Products from 2012 – 2022, where he led application review teams and managed technical staff in the assessment CMC information related to product quality for CDER-regulated biologics. Dr. Downey holds a PhD in Biochemistry from the University of Colorado at Boulder and was postdoctoral fellow at the University of Colorado and Georgetown University Medical Center.

**Leila Wieser, BA, Master's Cert (Publications)**
*Director*
Editorial and Project Management Staff
Office of Policy for Pharmaceutical Quality (OPPQ)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
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Leila Wieser is Director of the Editorial and Project Management Staff (EPMS) in the Office of Policy for Pharmaceutical Quality (OPPQ) in the Office of Pharmaceutical Quality (OPQ). Leila joined FDA in 2008 as a Senior Writer/Editor in OPS/IO. She later served as Team Leader for the Writer/Editor staff until the OPQ reorganization. Prior to working at FDA, Leila worked as a Senior Writer/Editor in the Office of Investigations, Office of the Inspector General, Department of Transportation. She also spent several years as a Writer/Editor (both as a federal employee and as a contractor) for the Department of Justice, where she worked on criminal justice-related publications for federal, state, and local law enforcement and on publications in support of juvenile justice. Leila received her Publications Specialist master's certification from The George Washington University and her bachelor's degree from the University of Illinois Urbana-Champaign.

**Theresa Mullin, PhD**
*Associate Director for Strategic Initiatives*
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Theresa Mullin is the CDER Associate Center Director for Strategic Initiatives. She oversees areas of strategic interest, leading a variety of CDER efforts including Patient-Focused Drug Development (PFDD). She leads CDER's International Program, representing FDA at the International Council on Harmonization (ICH) where she serves as Chair of the ICH Management Committee. She also serves as FDA CDER representative to the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and the International Pharmaceutical Regulators Programme (IPRP). Within the International Coalition of Medicines Regulatory Authorities (ICMRA) she co-chairs the Pharmaceutical Quality Knowledge Management (PQKM) Working Group advancing work on a global regulatory capability to enhance the availability of quality medicines to patients.

Dr. Mullin previously served as director of CDER's Office of Strategic Program which she established and led for almost a decade. She led FDA negotiations with industry to support the 2017 reauthorization of the Prescription Drug User Fee Act (PDUFA) and Biosimilar User Fee Act and led the previous 3 cycles of negotiation for the 2002, 2007 and 2012 reauthorizations of PDUFA, now providing $1B in annual funding. Before joining CDER in 2007, Dr. Mullin was the FDA Assistant Commissioner for Planning.

Since joining FDA Dr. Mullin has received numerous awards including the 2023 DIA Global Inspire Award for Global Connector, 2019 Reagan-Udall Foundation Leadership Award for Innovations in Regulatory Science, US Food and Drug Law Institute 2017 Distinguished Service and Leadership Award, US Presidential Rank Awards including for Distinguished Service in 2011 and for Meritorious Service in 2006. Theresa received her bachelor's degree, magna cum laude, in economics from Boston College, and doctorate in public policy analysis from Carnegie-Mellon University.

**Mahesh Ramanadham, PhD**
*Commander (CDR)*, United States Public Health Service (USPHS)
*Deputy Director*
Office of Policy for Pharmaceutical Quality (OPPQ)
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Commander (CDR) Mahesh Ramanadham is the Deputy Director for the Office of Policy for Pharmaceutical Quality, within FDA's Center for Drug Evaluation and Research, Office of Pharmaceutical Quality (OPQ). He joined the FDA in November 2009 after graduating with his Doctor of Pharmacy degree from the University of Maryland and his M.B.A. from the University of Baltimore. Within FDA, he has served in leadership roles in the Office of Compliance and the Office of Pharmaceutical Manufacturing Assessment within OPQ. Prior to joining FDA, CDR Ramanadham had experience in solid oral dosage manufacturing ranging from OTC products to schedule II narcotics. Outside of FDA, CDR Ramanadham continues to practice pharmacy in the community setting to maintain perspective on the clinical relevancy and impact of FDA's efforts in pharmaceutical quality.

**Dongmei Lu, PhD**
*Policy Lead*
Office of Policy for Pharmaceutical Quality (OPPQ)
Office of Pharmaceutical Quality (OPQ)
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Dr. Dongmei Lu obtained her PhD degree in Pharmaceutical Sciences from the University of North Carolina at Chapel Hill. She has pre-formulation and formulation working experience in GlaxoSmithKline, Wyeth, and Pfizer. Before joining Office of Policy for Pharmaceutical Quality, she was a team leader in Office of Bioequivalence in Office of Generic Drugs. In OPPQ, Dongmei has been working on the policies of nitrosamine-impacted products. She was the primary author of the FDA guidance for industry "Control of Nitrosamine Impurities in Human Drugs". Dongmei also engaged in leading a couple of FDA sponsored research projects on nitrosamine mitigations. Dongmei serves as a member of PQRI Biopharmaceutics Technical Steering Committee.

**Pallavi Nithyanandan, PhD**
*Director*
Office of Policy for Pharmaceutical Quality (OPPQ)
Office of Pharmaceutical Quality (OPQ)
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Dr. Pallavi Nithyanandan is the Director for the Compendial Operations and Standards Staff, Office of Policy for Pharmaceutical Quality, Center for Drug Evaluation and Research (CDER). She has been with US FDA since 2010. She received her PhD in Pharmaceutical Sciences from the University of Maryland Baltimore in 2005, and, Bachelors in Pharmaceutical Sciences from Mumbai University in 2000. Her dissertation research was in the area of Pharmaceutics and Inhalation Drug Delivery. Prior to joining FDA, she worked as a research scientist at the United States Pharmacopeial Convention from 2005-2010.

In her current role, she leads the group that manages CDER's interactions with compendial and voluntary consensus standard development organizations. She serves as one of CDER's experts on Compendial issues and is the CDER Delegate to the United States Pharmacopeial Convention. She is also involved in policy development activities relevant to standards and pharmaceutical quality.

**Xiaoming Xu, PhD**
*Director*
Division of Product Quality Research
Office of Testing and Research (OTR)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Xiaoming Xu is the Director of Division of Product Quality Research in Office of Testing and Research in FDA, 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 of better integrating research in complex PSG development. He is also a member of 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 PhD degree in Pharmaceutical Sciences from University of Connecticut.

**R. Angelo de Claro, MD**
*Associate Director for Global Clinical Sciences (Acting)*
FDA Oncology Center of Excellence (OCE)
Division Director
Division of Hematologic Malignancies I (DHMI)
Office of Oncologic Diseases (OOD)
Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Dr. de Claro is currently the Associate Director (Acting) for Global Clinical Sciences with US FDA Oncology Center of Excellence (OCE). In this role, he leads OCE efforts to advance global cancer drug development and regulatory science, including direction of Project Orbis, an international collaborative review program started in 2019. Dr. de Claro is also the Division Director for the Division of Hematologic Malignancies I with Office of Oncologic Diseases. He provides leadership and scientific direction to staff engaged in the review and evaluation of applications for investigational new drugs and drug approvals. He is board certified in Internal Medicine, Hematology, and Medical Oncology.

**Matthew Dionne, PharmD, MBA**
*Captain (CAPT*), United States Public Health Service (USPHS)
*Compliance Officer*
Division of Drug Quality II (DDQ II)
Global Compliance Branch 6
Office of Manufacturing Quality (OMQ)
Office of Compliance (OC)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Matt Dionne is a pharmacist serving in the United States Public Health Service and Compliance Officer in the Office of Manufacturing Quality (OMQ) in the FDA's Center for Drug Evaluation and Research (CDER). He received a Pharm.D. from the University of Rhode Island in 2001 and Master of Business Administration from Colorado State University in 2012. He joined FDA in 2006 and has experience in regulatory oversight and enforcement for a wide range of drug products from complex sterile injectables to topical over-the-counter products. He also led many of the CDER OMQ excipient initiatives related to the 2022-2023 international diethylene glycol and ethylene glycol poisoning.

**Timothy Pohlhaus, PhD**
*Consumer Safety Officer*
Office of Manufacturing Quality (OMQ)
Office of Compliance (OC)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Dr. Timothy Pohlhaus is a Senior Policy Advisor in CDER/OC/OMQ at the FDA. In his 14 years in CDER's Office of Compliance, he has played significant roles enhancing establishment surveillance programs, assessing facilities for pre-approval/pre-license purposes, advising on CGMP compliance actions, and developing CGMP guidance and policy. He has focused on biotechnology, positron emission tomography, and other sterile drug manufacture. Prior to joining FDA, Timothy worked manufacturing and quality roles in the craft brewing industry. He has a PhD in Biochemistry from Duke University and a BS in Biochemistry from The University of Maryland Baltimore County.

**Nandini Rakala, PhD, MS, BS**
*Visiting Associate & Data Scientist*
Division of Quality Intelligence II (DQIII)
Office of Quality Surveillance (OQS)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Dr. Nandini Rakala is a Mathematician and Data Scientist, currently working as a Visiting Associate within the Center for Drug Evaluation and Research at the U.S. FDA. Dr. Rakala earned her PhD in Operations Research in May 2020, from the Department of Mathematical Sciences at Florida Tech, with her primary research work in Optimization and Machine Learning. She also holds a master's degree in applied mathematics and computing and a bachelor's degree in Mathematics Honors from India. During her past four and a half years with the agency, Dr. Rakala has worked on multidisciplinary regulatory research projects, employing her expertise in operations research, machine learning, natural language processing, programming skills, and knowledge of efficient quality management practices regarding pharmaceutical manufacturing. She is currently serving as an Analytics Team Lead, Developer, and Subject Matter Expert on critical OPQ programs such as the Quality Management Maturity, Quality Metrics, Predictive Modeling of Pharmaceutical Quality System Effectiveness, Prioritization of Field Alert Reports, Quality Signal Detection, Topic Modeling of Post-Market Surveillance Data, and Research BAAs; thereby helping innovate FDA's regulatory processes to drive greater efficiencies. Dr. Rakala has presented as an invited speaker, served as a session chair, and led workshops at various global industry conferences and academic seminars, and is a recipient of several awards.

**Stephen Cahill, MS, MBA, BA**
*Operations Research Analyst*
Division of Quality Intelligence (DQI)
Office of Quality Surveillance (OQS)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Stephen Cahill is an Operations Research Analyst for the Division of Quality Intelligence (DQI) in the Office of Quality Surveillance/OPQ/CDER/FDA and member of the OQS Drug Sampling and Testing (DQST) program. The objective of the DQST program is to assess drug product quality through a risk-based sampling and testing assignments to aid the detection of drug substances and drug products that may pose quality and safety risks to the U.S patients and consumers. Mr. Cahill supports the DQST program by conducting risk-based selection of drug products for sampling and testing, analytical testing selection, and by tracking and executing the sampling and testing assignments with ORA and ORS offices.

Mr. Cahill is a chemist with 10 years of specialized experience in the consumer goods and pharmaceutical industry including 3 years at the Food and Drug Administration. He received his BA in Chemistry from California State University-Fullerton and MBA from Western Michigan University. He is currently a MS Regulatory Science Candidate at University of Maryland School of Pharmacy. He has held roles including research fellow, analytical chemist, and technical project manager.

**John Wan**
*Supervisory Operations Research Analyst*
Division of Quality Data Science
Office of Quality Surveillance (OQS)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

John Wan is a supervisor in CDER OPQ OQS, where he leads an interdisciplinary team of experts in support of the mission for Office of Quality Surveillance. He leads the CDER ORA Site Selection Model (SSM) program that prioritize sites for risk-based surveillance inspection and supervise the maintenance of catalog of CDER regulated manufacturing sites.

Prior to joining the FDA, he served in several leadership roles at Social Security Administration (SSA) in Enterprise Program Management Operations; Analytics Center of Excellence; and performance management office. As a computer scientist, he also contributed to various SSA's effort in expanding internet services to the public.
He is an adjunct faculty in the Data Science Program at University of Maryland, Baltimore County. He is also Six Sigma Black Belt certified. He graduated from Georgia Institute of Technology with an MBA in IT Management and Operations and a bachelor's degree in computer engineering.

**Thomas O'Connor, PhD**
*Deputy Office Director*
Office of Testing and Research (OTR)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Dr. O'Connor is the deputy director of the Office of Testing and Research in the Office of Pharmaceutical Quality and is the vice-chair of CDER's Emerging Technology Team (ETT). His responsibilities include managing research and testing projects that answer and anticipate pharmaceutical quality-related regulatory challenges through scientific approaches. The impact of OTR research and testing is utilized to support regulatory assessment and policy development in areas such advanced manufacturing, drug quality standards, characterization of complex drug substances and drug products, and post-market product quality and public health issues. Tom is a co-author of several papers on emerging pharmaceutical technology (such as continuous manufacturing, 3D printing, and the utilization of modeling and simulation for quality assurance). Through the ETT he has contributed to the review of several regulatory applications utilizing novel technologies. He is the co-chair of the OPQ Manufacturing Science and Innovation Center of Excellence and is a member of the advanced manufacturing working groups within the FDA.
Tom originally joined the FDA as chemistry reviewer in the Office Generic Drugs. Prior to joining the FDA, Tom worked at ExxonMobil Research and Engineering, where he held job functions in both process analytical technology and process control. Dr. O'Connor earned a B.S. in chemical engineering from the Cooper Union and a PhD in chemical engineering from Princeton University.

**Adam Fisher, PhD**
*Director of Science Staff*
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Adam Fisher, PhD, is the Director of Science Staff in the Office of Pharmaceutical Quality in the Center for Drug Evaluation and Research at the U.S. FDA. He focuses on engaging FDA stakeholders and supporting advanced pharmaceutical manufacturing technologies. At the FDA, he has served as a primary and secondary reviewer of Abbreviated New Drug Applications (generics) and Drug Master Files, team lead, subject matter expert on complex drug substances and advanced biomanufacturing, and liaison to the United States Pharmacopeia BIO1 Expert Committee. He joined the FDA in 2014 as a chemical engineer with expertise in the synthesis of biomolecules. Prior to the FDA, he was co-founder and chief science officer of a biotechnology startup company. He earned his BS in chemical engineering at the University of Maryland College Park and his PhD in chemical and biomolecular engineering at Cornell University.

**Rapti D. Madurawe, PhD**
*Division Director*
Office of Process and Facilities (OPF)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Dr. Rapti Madurawe is a Division Director in the Office of Process and Facilities, Office of Pharmaceutical Quality at FDA. She has broad regulatory experience in the CMC review of investigational, new, and generic drug applications as well as emergency user, breakthrough, and bioterrorism applications. Dr. Madurawe has worked extensively on developing the regulatory framework for continuous manufacturing of pharmaceuticals. She is the FDA topic lead for the ICH Q13 guidance on continuous manufacturing. Dr. Madurawe is a member of CDER's Emerging Technology Team. She holds a PhD and bachelor's degree in chemical engineering and a Master of Science degree in Biochemistry. Prior to joining the FDA, Dr. Madurawe worked in biotech and biopharmaceutical industries as a process development engineer.

**Geng "Michael" Tian, PhD**
*Lieutenant Commander (LCDR*), United States Public Health Service (USPHS)
Branch Chief
Division of Product Quality Research, Branch III
Office of Testing and Research (OTR)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Lieutenant Commander Tian is the Lab Chief in the Division of Product Quality Research Branch III, Office of Testing and Research, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. He received a PhD in Mechanical Engineering from the Virginia Commonwealth University in 2011. Geng leads various research projects aimed at enhancing regulatory quality assessment of drug applications utilizing emerging manufacturing technologies and has consistently represents the office through participating in workgroups, delivering presentations, and publishing peer-reviewed journal articles.

**Jayanti Das, PhD**
*Research Scientist*
Division of Product Quality and Research III (DPQR III)
Office of Testing and Research (OTR)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Jayanti Das is the Research Scientist in the Office of Testing and Research in the FDA's Center for Drug Evaluation and Research. She received her PhD in Mechanical Engineering from the University of California, Davis in 2017. Her work is directly related to scientific investigation and research on advanced manufacturing for pharmaceutical product quality assessment and control, product image characterization, data analysis, and data visualization.

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