CDER Small Business and Industry Assistance (SBIA)

Regulatory Education for Industry (REdI) 2026

SPEAKER BIOGRAPHIES

Keynote & Plenary Speakers

Michael Davis, MD, PhD
Acting Director
Center for Drug Evaluation and Research (CDER)

Dr. Davis served as a Clinical Team Leader within CDER's Office of New Drugs, Division of Psychiatry from 2016-2022. During his prior FDA tenure, he received numerous honors and awards, including the Division of Psychiatry Annual Awards for Individual Supervisor and for Collaboration, and the FDA Outstanding Service Award for exemplary performance and leadership in advancing science in psychiatric drug development. Dr. Davis presented nationally and internationally on topics including regulatory issues in psychedelic drug development, estimands, and digital health technologies, and was dedicated to the advancement of novel treatments for patients with mental illness. After leaving the Agency, Dr. Davis served as Chief Medical Officer for Usona Institute, a nonprofit medical research organization developing psychedelics drugs for the treatment of major depressive disorder and PTSD.

Dr. Davis completed a Medical Scientist Training Program (MD, PhD in Pharmacology) at Case Western Reserve University, psychiatric residency training at the Semel Institute for Neuroscience and Human Behavior at UCLA, and a clinical research fellowship at the West Los Angeles VA Mental Illness Research, Education, and Clinical Center (MIRECC); his research interests focused on the development of novel therapeutics for schizophrenia. Following completion of his fellowship, he was a Staff Psychiatrist at the Michael E. DeBakey VA Medical Center in Houston, TX, and an Assistant Professor in the Baylor College of Medicine Department of Psychiatry and Behavioral Sciences. Dr. Davis is licensed to practice medicine and is board certified in Psychiatry.

Owen Faris, PhD
Deputy Director
Center for Devices and Radiological Health (CDRH)

Dr. Owen Faris is the Deputy Center Director for Regulatory Operations in the Center for Devices and Radiological Health at the FDA. In this capacity, Dr. Faris also oversees the Office of Product Evaluation and Quality (OPEQ) within CDRH. Dr. Faris received his B.S. in Mechanical Engineering from Rice University, and his Ph.D. in Biomedical Engineering from Johns Hopkins University. Dr. Faris joined the FDA in 2003. Dr. Faris helps oversee and guide CDRH's decisions and actions related to pre- and post-market activities across CDRH.

Katherine Szarama, PhD
Acting Director
Center for Biologics Evaluation and Research (CBER)

Dr. Katherine Szarama joined CBER as the Deputy Center Director from the Advanced Research Projects Agency for Health (ARPA-H) under the National Institutes of Health (NIH). In her current capacity, Dr. Szarama manages the development, execution, and stewardship of over 3000 BLAs from over 400 medical products, including drugs, devices, and biologics. Katherine received her B.A. in Neuroscience from Johns Hopkins University, and defended her Ph.D. thesis at Karolinska Institutet in Stockholm, Sweden as part of an international collaboration with NIH/NIDCD. As part of this

training, Dr. Szarama completed a fellowship in cell and molecular biology at St. Jude Children's Research Hospital in Memphis, Tennessee. She has previously served in the Centers for Medicare & Medicaid Services in the Center for Clinical Standards and Quality as well as on the Boards of Directors for the Clinical Trials Advisory Committee of NIH/NCI and the American Friends of Cancer Research.

CDER – Drugs Track (Last Name Alphabetical Order)

Brenda Stodart, PharmD, BCGP, RAC-US
Captain, USPHS
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI)
CDER | FDA

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

Kori Adair, PharmD
Pharmacist
SBIA | DDI
CDER | FDA

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

Cyrus Agarabi, PharmD, PhD, MBA, RPh
Captain | United States Public Health Service (USPHS)
Associate Director for Scientific Program Coordination Immediate Office
Office of Pharmaceutical Quality (OPQ) | CDER

CAPT Cyrus Agarabi is the Associate Director for Scientific Program Coordination within the Office of Pharmaceutical Quality (OPQ) in the Center for Drug Evaluation and Research (CDER). He has over 16 years of progressive FDA leadership experience spanning regulatory science, advanced manufacturing policy, and large-scale program development. In his current role, he serves as a technical lead for CDER to develop the FDA PreCheck program**,** an initiative designed to accelerate the establishment of domestic pharmaceutical manufacturing facilities.

Jessica Bonzo, PhD
Lead Pharmacologist Division of Pharmacology and Toxicology II (DPTII)
Office of Immunology and Inflammation (OII) |
Office of New Drugs (OND) | CDER

Dr. Jessica Bonzo is a Lead Pharmacologist in the Division of Pharmacology & Toxicology for Immunology and Inflammation (DPT-II) supporting the clinical Divisions of Pulmonology, Allergy, and Critical Care (DPACC) as well as Rheumatology and Transplant Medicine (DRTM) within OND. She joined CDER/OND in January 2018 as a primary pharmacology/toxicology. In addition to her secondary reviewer responsibilities, Jessica also serves as a subject matter expert for the ISTAND program and is involved in several internal initiatives evaluating NAMs for regulatory use.

Jessica earned her Ph.D. from the University of California San Diego studying the regulation of drug metabolism enzymes. She completed a Pharmacology Research Associate Training Program (PRAT) fellowship at the National Cancer Institute using metabolomics to investigate the roles of nuclear receptors in various metabolic pathways. Prior to joining the FDA, Jessica worked as a staff scientist at a leading biotechnology firm developing novel primary hepatocyte culture systems.

Meghana Chalasani, MHA
Associate Director for Clinical Trial Innovation
OND | CDER

Meghana Chalasani is the Associate Director for Clinical Trial Innovation in the Office of New Drugs (OND) in U.S. FDA's Center for Drug Evaluation and Research (CDER). She leads the CDER Center for Clinical Trial Innovation (C3TI) and is part of the FDA team for Prescription Drug User Fee Act (PDUFA) reauthorization negotiations for premarket activities. Previously, Meghana led OND's Advisory Committee Team and Science Strategies program and worked closely on CDER's Patient-Focused Drug Development program, Benefit-Risk Framework, and Rare Disease Cures Accelerator. Meghana holds a master's in health policy and management from Columbia University and a bachelor's in Medicine, Health and Society from Vanderbilt University.

Heather Crandall
IT Advisor
Office of Digital Transformation (ODT) | CDER

Heather Crandall has been with the FDA since 2012, working in CDER's Office of Business Informatics. She currently focuses on standards and processes around electronic submissions.

Oanh Dang, PharmD, BCPS
Senior Pharmacist
Regulatory Science and Applied Research Lead
CDER Emerging Drug Safety Technology Co-Lead
Regulatory Science Staff
Office of Surveillance and Epidemiology (OSE) | CDER

Oanh Dang is the Regulatory Science and Applied Research Lead in FDA's Office of Surveillance and Epidemiology at the Center for Drug Evaluation and Research. She has over a decade of experience leading multiple research and development initiatives that focus on user-centric designed applications of AI to enhance various drug safety post-market activities, including serving as the project lead for the Information Visualization Platform (InfoViP), an FDA AI-enabled decision support tool for adverse event analysis. She has over 20 years of combined clinical and pharmacovigilance (PV)

experience and has co-authored multiple peer-reviewed publications related to AI and PV. Oanh serves as FDA's Co-Lead for CDER's Emerging Drug Safety Technology Program and is the Co-Chair for CDER's AI Community of Practice.

Adam Fisher, PhD
Staff Director
Office of Quality Assurance
OPQ | CDER

Adam Fisher is the Director, Enterprise Project Staff in the Office of Pharmaceutical Quality (OPQ) in the Center for Drug Evaluation and Research (CDER) at the U.S. FDA, where he leads initiatives that advance pharmaceutical quality and manufacturing. Dr. Fisher chairs CDER's Emerging Technology Program which provides FDA engagements on technical and regulatory issues for novel technologies prior to filing regulatory submissions. He previously created and led CDER's Framework for Advanced Manufacturing Evaluation (FRAME) initiative which addresses the regulatory framework that supports the adoption of advanced manufacturing technologies.

At FDA, Dr. Fisher has served as a primary and secondary reviewer of Abbreviated New Drug Applications (generics) and Drug Master Files, a Team Lead, a subject matter expert on complex drug substances and advanced biomanufacturing, and a 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. He earned his B.S. degree from the University of Maryland College Park (Chemical Engineering) and his Ph.D. from Cornell University (Chemical & Biomolecular Engineering).

Emily Gebbia, JD
Associate Director of Regulatory Development
Office of Scientific Investigations (OSI)
Office of Compliance (OC) | CDER

Emily Gebbia is the Associate Director of Regulatory Development in the Office of Scientific Investigations (OSI) within the Office Compliance in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration. She provides strategic leadership and subject matter expertise supporting the development of regulations and guidance related to good clinical practice, human subject protection, postmarketing safety, and other bioresearch monitoring programs. She first joined FDA in CDER's Office of Regulatory Policy as a Regulatory Counsel.

Prior to joining FDA, Emily was an attorney at Hogan Lovells, advising a range of health sector clients, primarily on Medicare and Medicaid and other healthcare regulatory issues, and a law clerk for the Hon. Richard C. Tallman of the Ninth Circuit Court of Appeals in Seattle, WA. Emily holds a Juris Doctorate from Catholic University of America, Columbus School of Law.

Cheryl Grandinetti, PharmD
Associate Director for Clinical Policy
Division of Clinical Compliance Evaluation
OSI | OC | CDER

Dr. Cheryl Grandinetti is the Associate Director for Clinical Policy within the Office of Scientific Investigations' Division of Clinical Compliance Evaluation (DCCE) and provides leadership and subject matter expertise on policy issues related to good clinical practice, human subject protection, and clinical trial quality. She also serves as a subject matter expert in GCP inspections to evaluate data integrity, quality, and safety of human subjects in clinical trials.

Sean Y. Kassim, PhD
Director
Office of Study Integrity and Surveillance
Office of Translational Sciences | CDER

Dr. Sean Kassim is the director of the Office of Study Integrity and Surveillance (OSIS) in the Office of Translational Sciences (OTS) in FDA's Center for Drug Evaluation and Research (CDER). OSIS oversees bioequivalence and bioavailability studies and non-clinical laboratories in support of pharmaceutical development, as part of the Agency's Bioresearch Monitoring (BIMO) program. Previously, Sean was the director of the Office of Scientific Investigations (OSI), in CDER's Office of Compliance, overseeing compliance programs and enforcement for pharmaceutical BIMO (GCP, IRB) and post-market reporting (PADE, REMS, PMR) activities.

In OSI, he also served as Deputy Office Director; Associate Director for Policy and Communication; acting Associate Director for Risk Science, Intelligence, and Prioritization; and team leader for the Informatics and Infrastructure Team. He started at FDA as a reviewer for the bioequivalence and GLP compliance program in OSI's predecessor, the Division of Scientific Investigations. Before coming to FDA, Sean worked at the University of Washington in Seattle, using proteomic and genomic approaches to identify novel proteinase targets, identifying biomarkers for heart disease, and evaluating pulmonary anti-bacterial defenses. Sean received his doctorate from Washington University in St. Louis and his undergraduate degree from the University of Maryland Baltimore County.

Motiur Rahman, PhD, MS, MPharm
Senior Epidemiologist & Policy Advisor
Real-World Evidence Analytics
Office of Medical Policy (OMP) | CDER

Dr. Motiur Rahman is a Senior Epidemiologist and Policy Advisor in Real-World Evidence (RWE) Analytics within the Office of Medical Policy at CDER, FDA. He leads the consult service for reviewing RWD study submissions, leads international regulatory collaborations including ICH initiatives, and supports internal training and process development. He serves as FDA topic lead for the ICH E23 Working Group, contributes to FDA-funded demonstration projects, and is a core member of the RWE Subcommittee. Dr. Rahman joined FDA in 2022 after more than a decade of academic and industry experience conducting observational studies across diverse therapeutic areas. A pharmacist by training, he holds a PhD in Pharmacoepidemiology and a Master's in Statistics.

Jonathan Resnick, PMP
IT Advisor
ODT | CDER

Jonathan Resnick is a member of CDER's Division of Data Management Services and Solutions. His focus is on electronic submissions and has been with the FDA since 2011. Prior to joining FDA, Jonathan spent 18 years working in IT project management supporting federal and private sector clients.

Anindita (Annie) Saha, BSE
Associate Director for Data Science and AI Policy (Acting)
OMP | CDER

Anindita (Annie) Saha is Associate Director for Strategic Initiatives for the Digital Health Center of Excellence (DHCoE) in the Center for Devices and Radiological Health at FDA where she supports promoting innovation of digital health technologies, including those enabled by artificial intelligence. She is also serving as the acting Associate Director for Data Science and Artificial Intelligence Policy at the FDA Center for Drug Evaluation and Research to support the use of AI across the drug development lifecycle. Additionally, Annie helped incubate and continues to support to advance the science and adoption of patient input as evidence, including patient preference information (PPI), clinical outcome assessments (COAs). Previously, Annie was the Director of the Partnerships team in CDRH where she oversaw a broad program portfolio, supporting several strategic partnership and regulatory science programs.

Seyoum Senay, MS
Supervisory Operations Research
ODT | CDER

Seyoum Senay leads mission-critical informatics initiatives at the FDA's Center for Drug Evaluation and Research (CDER), where he directly supports the human drug regulatory review process through rigorous, customer-focused analysis and pragmatic, results-driven solutions. His work consistently advances CDER's public health mission by reducing operational complexity and delivering outcomes with measurable impact. Mr. Senay is currently spearheading the FDA enterprise transformation efforts and an AI Champion, fostering cross-organizational collaboration and enhancing operational efficiency in ways that meaningfully reduce regulatory burden for sponsors, research institutions, academic partners, and small businesses alike. Widely regarded as a trusted leader who delivers, Mr. Senay is a recipient of the U.S. Excellence in Government (EIG) Leadership Fellowship, a program dedicated to addressing national challenges through innovation, employee empowerment, and measurable results. Mr. Senay holds a Master of Science in Information Systems from Johns Hopkins University and currently pursuing a Doctor of Engineering in Artificial Intelligence at George Washington University.

Scott K. Winiecki, MD
Associate Director for Rare Disease (Acting) Rare Disease Team
Division of Rare Diseases and Medical Genetics
Office of Rare Diseases, Pediatrics, Urological, and Reproductive Medicine
OND | CDER

Dr. Scott K. Winiecki received his MD degree from the University of Maryland and completed his pediatric training at the Children's Hospital of Philadelphia. After 12 years in private pediatric practice, he joined the U.S. Food and Drug Administration in 2011. While working on the safety of blood products and vaccines, he received the FDA's "Outstanding New Reviewer" Award and a Public Health Achievement Award. After 5 ½ years working on biologics, he joined the Center for Drugs in 2016. He spent 6 years managing the Safe Use Initiative, a group whose goal is to reduce preventable harm from medications. In December 2022, he joined the Rare Disease Team where he works collaboratively with external and internal rare disease stakeholders to promote the development of treatments for rare disorders.

CDRH – Medical Devices Track (Last Name Alphabetical Order)

Aldo Badano
Director, Division of Imaging, Diagnostics, and Software Reliability
Office of Science and Engineering Labs
CDRH | FDA

Aldo Badano is Director of the Division of Imaging, Diagnostics and Software Reliability within the Office of Science and Engineering Laboratories at the FDA's Center for Devices and Radiological Health. In April of 2026, Aldo celebrated 25 years of service at the FDA dedicated to advancing innovative regulatory science including open-source computational pipelines and synthetic datasets in support of the evaluation of medical devices and enabling innovation in healthcare technology. Aldo earned his Ph.D. in Nuclear Engineering from the University of Michigan and among numerous awards and recognitions, he was appointed to the Senior Biomedical Researcher Service in 2017. Aldo is currently one of the most published scientists in the history of CDRH.

Ruth Bediakoh
Consumer Safety Officer
Postmarket Industry Education Teams
Division of Industry and Consumer Education
CDRH | FDA

Ruth Bediakoh is a Consumer Safety Officer in the Postmarket Industry Education Team, Division of Industry and Consumer Education (DICE), Center for Devices and Radiological Health (CDRH). She assists with DICE's efforts to educate and inform the medical device and radiological health industry on its FDA regulatory requirements for marketing medical devices and radiation-emitting products. Ruth has been with the FDA since 2015. Before joining DICE in 2019, she was an Export Certificate reviewer for medical devices and prior to that, she was a regulatory health project manager in the Center for Tobacco Products. Ruth has a Bachelor of Science degree from Pennsylvania State University.

Giselle Blanco, M.S.
Consumer Safety Officer
Premarket Industry Education Team
Division of Industry and Consumer Education
CDRH | FDA

Giselle Blanco is a Consumer Safety Officer within the Premarket Industry Education Team (PIET) in the Division of Industry and Consumer Education (DICE) at the FDA's Center for Devices and Radiological Health (CDRH). In this role, she assists external stakeholders in navigating regulatory resources and understanding requirements for medical devices and radiation-emitting electronic products. She also develops and updates DICE's educational materials to support industry compliance. Prior to joining DICE, she served as a research scientist at the Center for Veterinary Medicine (CVM), where she conducted Good Laboratory Practice (GLP) validation studies, animal testing studies, and gene editing safety studies. Her responsibilities included contributing to protocol and study design development to advance regulatory science initiatives. Ms. Blanco earned a Master of Science in Biochemistry, Molecular, Cellular and Developmental Biology from the University of California Davis, and a Bachelor's in Biotechnology with a minor in Chemistry from California State Polytechnic University, Pomona.

Kenneth Chen, CDR, USPHS, M.S.
Assistant Director
Regulator Inspections and Audits Team
Office of Regulatory Programs
Office of Product Evaluation and Quality
CDRH | FDA

CDR Kenneth Chen is the Lead Project Manager of the Medical Device Single Audit Program, and Assistant Director of the FDA's Regulatory Inspections and Audits Team, Division of Regulatory Programs 2: Establishment Support, ORP, OPEQ, CDRH. He leads efforts associated with MDSAP development and implementation with other regulatory authorities and industry. He began with the FDA over 18 years ago as a Biomedical Engineer for the Office of Compliance, CDRH, specializing in orthopedic devices. CDR Chen received a Bachelor of Science degree in Biomedical Engineering from Rutgers University and Master of Science degree from Johns Hopkins University

Aneesh Deoras
Acting Division Director for Digital Health Technology Assessment
Digital Health Center of Excellence
Office of Strategic Partnerships and Technology Innovation
CDRH | FDA

Aneesh Deoras is a biomedical engineer within the Digital Health Center of Excellence (DHCoE) at the FDA's Center for Devices and Radiological Health (CDRH). He has served in this role since March 2026. His current work involves supporting pilot programs such as TEMPO and developing training to support review of digital health products. Since beginning at the Agency in 2015, he has primarily served as a reviewer and later Assistant Director for the Cardiac Ablation, Mapping, and Imaging Devices Team in the Office of Cardiovascular Devices, Office of Product Evaluation and Quality (OPEQ). In that role, he oversaw development of novel ablation and imaging technologies, including pulsed field ablation (PFA) systems. Aneesh Deoras earned an M.S.E. in Bioengineering from the University of Pennsylvania and a B.S. in Electrical Engineering from the Pennsylvania State University.

Robert Fink
Advisor
On detail to Office of Operations
Office of Finance, Budget, and Acquisitions
CDRH | FDA

Robert Fink serves as an Advisor in the Office of Operations, where he leads the Medical Device User Fee Amendments (MDUFA) Small Business Determination (SBD) Program. He also serves as a liaison to the Center for Devices and Radiological Health (CDRH), facilitating coordination of user fee matters.
In these roles, Robert provides guidance to industry stakeholders, develops program policy, and helps small businesses understand their eligibility for fee benefits and waivers under MDUFA, supporting their access to FDA's regulatory process.

Michelle Gabriele Sandrian
Assistant Director
Premarket Industry Education Team
Division of Industry and Consumer Education
CDRH | FDA

Michelle Gabriele Sandrian is the Assistant Director of the Premarket Industry Education Team, Division of Industry and Consumer Education (DICE), Center for Devices and Radiological Health (CDRH). She joined DICE in April 2024 and leads the team in the development of premarket medical device industry educational resources. Dr. Gabriele Sandrian started at FDA in 2015 as a Biomedical Engineer on the Retinal and Diagnostic Devices Team. As part of the Ophthalmic Devices Division in the Office of Health Technologies 1 (OHT1), she served as a lead and consulting reviewer, overseeing the full product lifecycle of medical devices under review, evaluating a broad range of submission types, including Premarket Approvals, Premarket Notifications (510(k)), De Novo Classification Requests, Investigational Device Exemption Studies**,** and Pre-Submission Requests, among others. She contributed to public workshops, FDA guidance documents**,** and international consensus standards.

Prior to joining FDA, Dr. Gabriele Sandrian was an Assistant Professor in the Departments of Ophthalmology and Bioengineering at the University of Pittsburgh. She earned a doctoral degree in bioengineering (neural engineering concentration) from the University of Pittsburgh and was Whitaker Foundation International Postdoctoral Research Scholar at the Medical University of Vienna Center for Medical Physics and Biomedical Engineering in Vienna, Austria.

Vidya Gopal
Senior Consumer Safety Officer
Division of Industry and Consumer Education
CDRH | FDA

Vidya Gopal is a Senior Consumer Safety Officer in the Division of Industry and Consumer Education (DICE), in CDRH. Her work consists primarily of managing the telephone industry and consumer stakeholder system, including maintaining the ACD system for the DICE call center, while helping external stakeholders locate and understand various regulatory resources and requirements established by FDA, including the transition to the new QMSR. Ms. Gopal currently serves as an FDA instructor for the Association for the Advancement of Medical Instrumentation (AAMI) Quality System Requirements and Industry Practice Course and Design Controls Course.

Ms. Gopal joined FDA in 2012 as a senior reviewer in the cardiovascular devices branch within the then Office of Compliance. Prior to her FDA career, she spent over 15 years in the FDA-regulated device industry, working as a Research and Development engineer in cardiovascular and women's health device companies, where she was primarily responsible for design and clinical trials. Ms. Gopal holds a Bachelor's degree in Engineering (Polymer Science) from India and a Master of Science in Materials Science from the University of Utah.

Joseph Hillring
Consumer Safety Officer
Postmarket Industry Education Teams
Division of Industry and Consumer Education
CDRH | FDA

Joseph Hillring is a Consumer Safety Officer in the Postmarket Branch of the Division of Industry and Consumer Education (DICE). His work focuses on helping external stakeholders locate and understand various regulatory resources and requirements established by FDA, with a specialization in Quality Management System Regulation (21 CFR 820). In 2016, Mr. Hillring began working in the FDA's Office of Communication and Education as a Staff Fellow in the Division of Communication and Education.

Prior to his FDA career, Mr. Hillring worked for several consulting firms working across the spectrum of Medical Devices including developing submissions and Quality Systems. Mr. Hillring received his Bachelors Degree in Arts and Science, Majoring in Biology with a Minor in Public Health from the University of South Florida and a Master of Science from Northeastern University Majoring in Regulatory Affairs for Drugs, Biologics, and Medical Devices.

Kendra Holter
Consumer Safety Officer
Premarket Industry Education Team
Division of Industry and Consumer Education
CDRH | FDA

Kendra Holter is a Consumer Safety Officer in the Division of Industry and Consumer Education (DICE), in CDRH's Office of Communication and Education. In this role, Ms. Holter educates stakeholders with understandable and accessible science-based regulatory information about medical devices and radiation-emitting electronic products. She also develops, maintains, and updates educational content on the CDRH website for industry audiences. She joined FDA in September 2022.

Before joining FDA, Ms. Holter served as the National Educator in the care and management of reusable medical devices for the Veterans Health Administration as an agent for infection prevention. She served with VHA for a total of 15 years in various roles to include those at the facility level as manager, educator, business liaison for purchase and repair of medical devices, and operating room nurse. Ms. Holter received a Bachelor of Science Degree in Marine Biology from the College of Charleston, a Bachelor of Science Degree in Nursing from the Medical University of South Carolina, and a Master of Science Degree in Nursing Informatics from Walden University.

Yvette Montes
Consumer Safety Officer
Office of Regulatory Programs
Office of Product Evaluation and Quality
CDRH | FDA

Yvette Montes is a Consumer Safety Officer within the Center for Devices and Radiological Health (CDRH), in the Office of Regulatory Programs, Division of Regulatory Programs 2, Imports and Registration & Listing Team (IRLT). She has served the FDA for seventeen years and has extensive knowledge of import operations specializing in medical devices and radiological health products. Yvette started her career with the FDA in 2009 as a Consumer Safety Officer, in the Division of Southwest Imports (DSWI). In 2015, she moved to the Division of Import Operations (DIO) Import Operations

Branch (IOB), and in 2023, she began a new role in the center. She earned her Bachelor of Science in Microbiology with a minor in Chemistry and Biochemistry from New Mexico State University and an additional bachelor's degree in Cytogenetics from the University of Texas Health Science Center at San Antonio.

Yvette has played an integral role in FDA operational activities with different partner government agencies (PGAs) such as Customs and Border Protection (CBP), Homeland Security Investigations (HSI), U.S. Department of Agriculture, U.S. Fish and Wildlife, and state and local agencies. She has served in many roles throughout her career and has experience in both operations and policy in the world of imports. Yvette is recognized as a subject matter expert in the importation of medical devices and radiological health products.

LCDR Morgan Lee, PE, CSP
Consumer Safety Officer
Premarket Industry Education Team
Division of Industry and Consumer Education
CDRH | FDA

LCDR Morgan Lee is a Consumer Safety Officer within the Premarket Industry Education Team (PIET) in the Division of Industry and Consumer Education (DICE) at the FDA's Center for Devices and Radiological Health (CDRH), a role she has held since June 2023. She brings extensive experience in both premarket reviews and emergency response operations from her previous roles across the agency. Since beginning her FDA career in 2016, she has held several key positions, including Emergency Coordinator in the Office of Emergency Operations, where she helped manage the FDA's response to major public health events like the COVID-19 pandemic. Her foundational experience at the agency was forged in the Anesthesiology Devices Branch within the Office of Product Evaluation and Quality (OPEQ).

As a reviewer, she was responsible for the scientific and regulatory evaluation of medical products in the anesthesiology field, including devices such as anesthesia gas machines and pulse oximeters. Following this role, she also served with the Center for Tobacco Products as a reviewer focusing on Electronic Nicotine Delivery Systems. LCDR Lee earned a Master of Engineering in Engineering Management from the University of Louisville and a Bachelor of Science in Bioengineering from the University of Maryland.

CDR Kimberly Piermatteo, MHA, CPH
Education Program Administrator
Division of Industry and Consumer Education (DICE)
CDRH | FDA

CDR Kimberly Piermatteo is a Commissioned officer in the United States Public Health Service and currently serves in the Center for Devices and Radiological Health's Office of Communication and Education, Division of Industry and Consumer Education as the Education Program Administrator who is responsible for leading and directing the CDRH External Webinar Program. She has been with the FDA in various capacities since 2006 spanning premarket review and postmarket adverse event and compliance work. CDR Piermatteo received her Bachelor of Science degree in Engineering Science and Minors in Bioengineering and Mathematics from the Pennsylvania State University and her Master of Health Administration (MHA) from the University of Maryland.

Justin Post
Cybersecurity Specialist
Division of Medical Device Cybersecurity
Office of Readiness and Response
Office of Strategic Partnerships and Technology Innovation
CDRH | FDA

Cybersecurity Focal Point Program Advisor
Office of Product Evaluation and Quality
CDRH | FDA

Justin Post is a Cybersecurity Specialist in the FDA's Center for Devices and Radiological Health (CDRH) Office of Strategic Partnerships and Technology Innovation (OST) and serves as the Cybersecurity Focal Point Program Advisor in the FDA's CDRH Office of Product Evaluation and Quality (OPEQ). In these roles, he advises senior leadership and review teams on medical device cybersecurity policy, guidance, and regulatory implementation, ensuring consistent, science-based oversight across the entire product life cycle to protect patient safety in an increasingly connected healthcare ecosystem. Mr. Post's responsibilities span both premarket and postmarket cybersecurity review, contributing to the modernization of FDA cybersecurity guidance.

A key part of his work is leading the OPEQ cybersecurity focal point program, an initiative designed to promote consistency in review practices and policy for complex topics, like cybersecurity, that span across multiple device types and Office of Health Technologies (OHTs) within OPEQ. Through this program, he helps ensure that all staff are appropriately trained and that subject matter experts are available to provide expertise to both internal and external stakeholders, which improves the quality, consistency, and efficiency of regulatory reviews. He regularly engages with external stakeholders to clarify FDA expectations and advance public health protections.

Janet Pulver
Medical Device Senior Operations Officer
Office of Medical Device and Radiological Health Inspectorate
Office of Inspections and Investigations (OII) | FDA

Janet Pulver is a Senior Operations Officer with the FDA's Office of Inspections and Investigations and serves as National Expert in the Medical Device and Radiological Health program areas. Mrs. Pulver joined the FDA in 2008 and has since conducted more than 200 medical device inspections (domestic and international), including inspections covering Human Tissue and Radiological Health regulations. She came to the FDA with more than 10 years of experience in FDA-regulated industry, working in quality and regulatory positions in clinical research, tissue banking and medical devices.

Prior to that, she spent eight years as a Chemistry Medical Technologist working with IVDs. Mrs. Pulver holds Certifications from ASQ (Certified Manager of Quality and Organizational Excellence, Certified Quality Auditor and Certified Six Sigma Green Belt), RAPS (Regulatory Affairs Certification), and AATB (Certified Tissue Bank Specialist). She is also an instructor and content advisor for the FDA's national Medical Device courses, and a core member of the QMSR transition team. Mrs. Pulver earned a Bachelor of Science from the University of Puerto Rico, a Master of Science in Administration from Central Michigan University and is currently pursuing a Juris Doctor from the California School of Law.

Michelle Rios
Assistant Director
Office of Regulatory Programs
Office of Product Evaluation and Quality
CDRH | FDA

Michelle Rios serves as Assistant Director of the Medical Device Reporting (MDR) Team in the Office of Regulatory Programs (ORP), Office of Product Evaluation and Quality (OPEQ), at the FDA's Center for Devices and Radiological Health (CDRH). In this role, she leads the development, implementation, and communication of policies, processes, and procedures governing MDR review, reportability determinations, postmarket IT system maintenance, and associated contracts that support OPEQ's premarket and postmarket decision-making and signal detection activities.

As a member of ORP's leadership team, Ms. Rios contributes to Agency-wide consolidation efforts and responds to inquiries from Congress, the media, patient advocacy groups, and other stakeholders on reportability policy, systems, MDR regulations, and guidance. She also advises Center leadership on the development and implementation of Agency-level adverse event reporting initiatives. Ms. Rios has played a key role in developing and implementing MDR-related policies, including those supporting the COVID-19 emergency response, summary reporting programs for device

malfunctions, and reporting frameworks for events identified through Real-World Data (RWD) sources. As a microbiologist, Ms. Rios has served at the FDA since 2004.

Joseph Tartal
Acting Director
Division of Industry and Consumer Education (DICE)
CDRH | FDA

Joseph Tartal is Acting Director of the Division of Industry and Consumer Education (DICE), Office of Communication and Education (OCE), in FDA's Center for Devices and Radiological Health (CDRH). In this role, he directs the division's effort to educate the medical device industry to understand its regulatory requirements and responsibilities with medical devices. Mr. Tartal serves as FDA faculty for the Association for the Advancement of Medical Instrumentation (AAMI) and is a member of the Regulatory Affairs Professionals Society (RAPS) education committee. Prior to his 19-year FDA career, Mr. Tartal served as a Quality Assurance Manager for small medical device manufacturers, primarily responsible for implementing and maintaining compliant quality management systems. He has over 30 years of experience in the medical device industry, including premarket submissions. Mr. Tartal received a bachelor's degree in biology from Pennsylvania's Slippery Rock University.

James Nick Walter
Assistant Director
Medical Device Recalls Team
Office of Regulatory Programs
Office of Product Evaluation and Quality
CDRH | FDA

James Nicholas (Nick) Walker earned degrees in physics and engineering from the University of South Carolina and South Carolina State University. Interested in the life cycle of medical devices, he joined the U.S. Food and Drug Administration (FDA) and has become a valuable resource in the medical device and electronic product areas. Currently, Mr. Walker is the Assistant Director of the Medical Device Recalls Team within the Office of Regulatory Programs (ORP) in the Center for Devices and Radiological Health (CDRH). Prior to this role, he served as a senior Total Product Life Cycle (TPLC) Reviewer and Electronic Product Radiation Control Expert within several Offices in CDRH.

As a TPLC reviewer, he led reviews for premarket, compliance, and postmarket assignments (including recall reviews and MDR evaluations) in the medical device and electronic product specialty areas. During his 25 years with CDRH, Mr. Walker developed specialized experience in leading policy and regulation amendments. This deep knowledge steered him to becoming a compliance mentor, radiological health course developer and instructor, and a technical writer for several FDA publications. In addition, he has performed both foreign and domestic regulatory inspections, and trained FDA investigators. Mr. Walker has received multiple CDRH and FDA excellence awards in premarket review, compliance and postmarket reviews, training and development, and communication.

Tonya A. Wilbon
Assistant Director
Postmarket Industry Education and Consumer Education Teams
Division of Industry and Consumer Education
CDRH | FDA

Tonya A. Wilbon is the Assistant Director for the Postmarket Industry Education and Consumer Education Teams, Division of Industry and Consumer Education (DICE), Center for Devices and Radiological Health (CDRH). Tonya leads DICE's efforts to educate and inform the medical device and radiological health industry on its FDA regulatory requirements for marketing medical devices and radiation-emitting products. In addition, she leads the division's efforts

to educate and inform consumers, health care professionals, and patients on issues with these medical devices and radiation-emitting products. Ms. Wilbon has been with FDA for over 26 years with more than 10 years of clinical laboratory experience. She initially began with the FDA as a Microbiology Scientific Reviewer for CDRH's Office of *In Vitro* Diagnostics and Radiological Health (OIR) and served as one of CDRH's Quality System Specialist. Ms. Wilbon currently serves as an FDA instructor for the Association for the Advancement of Medical Instrumentation (AAMI) and serves in FDA's Content Advisory Group. Ms. Wilbon received a Bachelor of Science Degree in Microbiology from Howard University and is a certified Microbiologist by the American Society of Clinical Pathology (ASCP).

CBER – Biologics Track (Last Name Alphabetical Order)

Holly Brevig, PhD
Quality Assurance Specialist
Division of Manufacturing and Product Quality (DMPQ)
Office of Compliance and Biologics Quality (OCBQ)
CBER | FDA

Dr. Holly Brevig is a Quality Assurance Specialist in the Division of Manufacturing and Product Quality (DMPQ), in the Office of Compliance and Biologics Quality (OCBQ) in FDA's Center for Biologic Evaluation and Research (CBER). In her current role, she performs inspections of facilities manufacturing biological products. She is a regulatory professional with over a decade of experience spanning biologics, pharmaceuticals, and medical devices in both government and private industry. Dr. Brevig first joined the FDA in 2015 as an ORISE Regulatory Science Fellow. She has since held several positions across the agency, including roles in the Center for Devices and Radiological Health (CDRH), Center for Drug Evaluation and Research (CDER), and previous appointments within CBER.

Throughout her career, she has participated in or led numerous domestic and international inspections of facilities that manufacture biological products (monoclonal antibodies, vaccines, gene therapies). She also served on a working group tasked with developing a compliance manual that guides FDA staff on conducting inspections of CDER regulated biologics. Her private sector experience includes serving as a Senior Biologics and Medical Device Regulatory Expert at Hyman, Phelps and McNamara, LLC, where she conducted informal audits of biologic and medical device manufacturing facilities, and advised clients on responding to FDA inspectional observations. She has also held roles as a Regulatory Intelligence Manager for US Pharmacopeia, and as an FDA Regulatory Science Fellow at Avalere. Dr. Brevig earned a Ph.D. in Pharmacology from the University of Michigan, Ann Arbor and a Bachelor of Science in Biological Sciences from the University of California, Irvine.

Yongwook Choi, PhD
Bioinformatics Reviewer
Division of Cell Therapy 1 (DCT1)
Office of Cellular Therapy and Human Tissue CMC (OCTHT)
Office of Therapeutic Products (OTP)
CBER | FDA

Dr. Yongwook Choi joined the FDA in 2022 and serves as a Bioinformatics Reviewer in the Office of Cellular Therapy and Human Tissue (OCTHT) within the Office of Therapeutic Products (OTP) at the Center for Biologics Evaluation and Research (CBER). In this role, he reviews next-generation sequencing, bioinformatics analysis, and AI/ML applications in cell and gene therapy product submissions. Dr. Choi also serves on multiple working groups focused on developing guidance for these emerging technologies. Prior to joining the FDA, he was a Bioinformatics Scientist at the J. Craig Venter Institute (JCVI) in Rockville, MD, and a Senior Computational Scientist at the Translational Genomics Research Institute (TGen) in Arizona. He earned his Ph.D. in Computer Science from Purdue University and holds undergraduate

and master's degree in Electrical Engineering from Seoul National University in South Korea. In 2025, Dr. Choi also earned a Master of Science in Artificial Intelligence from the University of Texas at Austin.

Silvia De Paoli, PhD
Biological Reviewer
Clinical Review Staff (CRS)
Division of Blood Components and Devices (DBCD)
Office of Blood Research and Review (OBRR)
CBER | FDA

Dr. Silvia H. De Paoli is a Biological Reviewer in CBER at the U.S. FDA, where she has extensive experience in both Chemistry, Manufacturing, and Controls (CMC) review and pharmacology/toxicology review. She received her Ph.D. in Chemistry from the University of São Paulo, Brazil, and has over 12 years of research experience in nanomaterial toxicology and blood product safety assessment, with 45 peer-reviewed publications. During her 14 years at the FDA, she has applied expertise across both CMC and pharmacology/toxicology disciplines to the evaluation of the safety, quality, and manufacturing of biologics and medical devices. Dr. De Paoli also serves as Deputy Topic Lead for the ICH Q3E guideline, supporting global harmonization of standards for extractables and leachables.

Christine Harman, PhD
Lead Consumer Safety Officer
Division of Manufacturing and Product Quality (DMPQ)
Office of Compliance and Biologics Quality (OCBQ)
CBER | FDA

Dr. Christine Harman is a CMC/facilities team lead in the Division of Manufacturing and Product Quality (DMPQ), in the Office of Compliance and Biologics Quality (OCBQ)/CBER/FDA. Dr. Harman received B.Sc. Degrees in Chemistry and Biology at Wright State University and received her Ph.D. in Biochemistry and Molecular Biology from Michigan State University. In 2009, she joined CBER in the Office of Blood Research and Review (OBRR) in which she performed regulatory review, in addition to conducting research. Her research area focused on antibody neutralization of Hepatitis C virus, resulting in several publications. In 2014, Dr. Harman moved to OCBQ in which she is responsible for the review of Investigational New Drug (INDs) applications, Biologics License Applications (BLAs) and manufacturing supplements for a variety of biological products, which include bacterial and viral vaccines, cell and gene therapies, hematologic recombinants, blood fractionation products, in-vitro diagnostics and combination (device) products. In addition to regulatory review activities, Dr. Harman also performs inspections of facilities manufacturing biological products.

Susan Lehman, PhD
Senior Staff Fellow
Office of Vaccine Research and Review (OVRR)
CBER | FDA

Dr. Susan Lehman is researcher and product reviewer in the Office of Vaccines Research and Review (OVRR) in FDA's Center for Biologics Evaluation and Research (CBER). She has an extensive background in phage and bacterial biology and reviews CMC packages for Investigational New Drug applications across a range of product types such as phage therapy, live biotherapeutics, and fecal microbiome transplant. She also conducts original research focusing on factors that affect phage antibacterial activity and on preclinical tools to support phage therapy product development.

She serves on policy working groups within FDA and on the International Committee for the Taxonomy of Viruses. Prior to joining FDA, she led the US research lab for AmpliPhi Biosciences, a biotech company developing phage therapeutics for use in a variety of clinical indications. Dr. Lehman received a BSc in Biology from McMaster University and a PhD in Ecology and Evolution from Brock University. Her research background includes positions at Agriculture and Agri-Food Canada, the US Centers for Disease Control and Prevention, and the Georgia Institute of Technology.

Meghan Maguire Thon, PhD
Lead Biologist
Regulatory Review Branch 3
Division of Review Management and Regulatory Review
Office of Vaccines Research and Review
CBER | FDA

Dr. Meghan Maguire Thon is a Regulatory Project Manager Team Lead in Regulatory Review Branch 3 of the Division of Review Management and Regulatory Review (DRMRR) in the Office of Vaccines Research and Review (OVRR) in the Center for Biologics Evaluation and Research (CBER). Prior to joining the FDA, Meghan gained post-doctoral experience at the University of Maryland College Park in the Department of Avian and Animal Sciences and as an ORISE Fellow in the Molecular Methods & Subtyping Branch within the Division of Microbiology at what was formerly the Center for Food Safety and Applied Nutrition [formerly CFSAN, now Human Foods Program (HFP)]. Meghan also currently serves as co-chair of the DRMRR Process Improvement Committee and as a representative on the CBER Process Improvement and Implementation Team. Meghan earned a B.S. in Biology from Ursinus College in 2007, a M.Sc. with Distinction in Biomedical Science from Edinburgh Napier University in 2008 and a Ph.D. in Endocrinology and Reproductive Physiology from the University of Wisconsin-Madison in 2017.

Ujwani Nukala, PhD
Visiting Associate
Division of Analytics and Benefit-Risk Assessment
Office of Biostatistics and Pharmacovigilance
CBER | FDA

Dr. Ujwani Nukala serves as a reviewer and researcher in the Division of analytics and Benefit-Risk Assessment in the Office of Biostatistics and Pharmacovigilance in FDA's Center for Biologic Evaluation and Research (CBER). In this role, she is responsible for review of Digital Health Technologies, Quantitative Benefit-Risk assessments and Real-World Evidence. Ujwani joined FDA in 2019 as an ORISE Fellow working on QSP/mechanistic models of immuno-therapy. She joined Office of Biostatistics and Pharmacovigilance in 2022 as a reviewer. She has master's degree in Biochemistry from Osmania University, India, and a second MS degree and Ph.D. in Bioinformatics from University of Arkansas.

Wendy Paul, M.D.
Director
Division of Blood Components and Devices (DBCD)
Office of Blood Research and Review (OBRR)
CBER | FDA

Dr. Wendy Paul is the Director of the Division of Blood Components and Devices (DBCD) in FDA's Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER). She has over 15 years of clinical experience in blood banking and transfusion medicine and 12 years' federal regulatory experience at CBER. Dr.

Paul joined the FDA in 2014, as a medical officer in CBER's Office of Biostatistics and Epidemiology bringing a wealth of analytical and administrative skills. In 2016, she joined OBRR as the Deputy Director of DBCD and accepted the position of Director in 2026, overseeing the regulatory work of approximately 50 scientific and clinical staff. The division is engaged in the evaluation of applications related to blood products for transfusion, devices for collection and processing of blood and blood components, pathogen reduction methodologies for blood components intended for transfusion, plasma volume expanders (e.g., albumin, dextrans, and hetastarches), hemoglobin-based oxygen carriers.

Prior to joining FDA, Dr. Paul held an academic appointment as Assistant Professor of Pediatrics and Pathology at The George Washington University School of Medicine, while serving clinically as Medical Director, Point of Care and Satellite Testing; Associate Medical Director, Transfusion Medicine; and Attending Physician, at Children's National Medical Center, Washington, D.C. Dr. Paul completed her undergraduate education at the University of Colorado Denver, and received her medical degree from the University of Maryland, Baltimore, MD. She completed an Internal Medicine internship at the Washington Hospital Center, and residency training in Anatomic and Clinical Pathology at Howard University Hospital, Washington DC. Following residency, she completed two fellowships: Diagnostic Immunology at the Johns Hopkins Medical Institutes and Blood Banking/Transfusion Medicine at the University of Virginia, Charlottesville, VA. Dr. Paul is double boarded by the American Board of Pathology in Clinical Pathology, and in Transfusion Medicine/Blood Banking. She is currently licensed to practice Medicine in the District of Columbia.

Luis Santana-Quintero, PhD
Data Scientist, HIVE Lead
Analytics and Real-World Evidence Branch (ARWEB)
Division of Analytics and Benefit-Risk Assessment (DABRA)
Office of Biostatistics and Pharmacovigilance (OBPV)
CBER | FDA

Dr. Luis Santana-Quintero has served with the Center for Biologics Evaluation and Research (CBER) since 2012, leading the HIVE bioinformatics group and key initiatives in computational biology, artificial intelligence (AI), and machine learning. He specializes in immune-informatics, transcriptomics, metagenomics, and the application of AI to analyze large biological datasets. Prior to CBER, he worked as a Postdoctoral Fellow at George Mason University, where he utilized computational methods to study the effects of complex operators in evolutionary algorithms. He holds M.Sc. and Ph.D. degrees in Computer Science from the Center for Research and Advanced Studies in Mexico.

Kimberly Schultz, PhD
Director
Division of Gene Therapy 2 (DGT2)
Office of Gene Therapy CMC (OGT)
Office of Therapeutic Products (OTP)
CBER | FDA

Dr. Kimberly Schultz is the Director of Division 2 (DGT2) of the Office of Gene Therapy (OGT) in Office of Therapeutic Products (OTP) in FDA's Center for Biologics Evaluation and Research (CBER). She oversees the product review for pre-IND, IND, and BLA submissions for gene therapy products. In addition to contributing to stakeholder outreach and regulatory guidance documents, Dr. Schultz serves on working groups related to Advanced Manufacturing initiatives within CBER and across the FDA. Dr. Schultz originally joined the FDA in 2015 as a Commissioner's Fellow to conduct a cross-study analysis of CAR T cell manufacturing and product data and then transitioned to a full-time reviewer in 2016 and Branch Chief in 2021. Prior to joining the FDA, she received her PhD from the University of

Wisconsin (2008) and conducted postdoctoral studies at Johns Hopkins Bloomberg School of Public Health specializing in virology and immunology.

John Scott, PhD, AM
Acting Director, OBPV
Director, Division of Biostatistics (DB)
Office of Biostatistics and Pharmacovigilance (OBPV)
CBER | FDA

Dr. John Scott is Director of the Division of Biostatistics in the FDA's Center for Biologics Evaluation and Research, where he has also served as a statistical reviewer for blood products and for cellular, tissue and gene therapies. Prior to joining the FDA in 2008, he worked in psychiatric clinical trials at the Western Psychiatric Institute and Clinic of the University of Pittsburgh Medical Center. He has authored or co-authored numerous articles in areas including Bayesian and adaptive clinical trial design and analysis, vaccine and drug safety, data and text mining, and benefit-risk assessment. He is the CBER lead for 21st Century Cures and PDUFA efforts in Complex and Innovative Trial Design and has been heavily involved in a number of FDA's statistical policy and outreach projects, including the 2019 Adaptive Design Guidance for Drugs and Biologics, the 2020 Guidance on Interacting with the FDA on Complex Innovative Trial Design, the ICH E9(R1) expert working group on estimands and sensitivity analyses, and the FDA draft guidance on the Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products. Dr. Scott holds a Ph.D. in Biostatistics from the University of Pittsburgh, an A.M. in Mathematics from Washington University in St. Louis, and a B.A. in Liberal Arts from Sarah Lawrence College. He is a Fellow of the American Statistical Association and is a past Editor of the journal, Pharmaceutical Statistics.

Nadia Whitt, MS
Branch Chief
Regulatory Review Branch 1
Division of Review Management & Regulatory Review 1
Office of Review Management and Regulatory Review (ORMRR)
Office of Therapeutic Products
CBER | FDA

Nadia Whitt is a Branch Chief in the Office of Review Management and Regulatory Review in the Office of Therapeutic Products at FDA's Center for Biologics Evaluation and Research (CBER), a position she has held since 2024. Prior to this role, she served as a Lead Regulatory Project Manager, where she trained new regulatory project managers and provided regulatory expertise to her team. Ms. Whitt joined the FDA in August 2019 as a Regulatory Project Manager in the Office of Tissues and Advanced Therapies, directing the review process for multiple application types including BLAs, INDs, IDEs, and 510Ks while serving as the primary point of contact between FDA and sponsors.

Before joining the FDA, Ms. Whitt worked as a Biochemist at the National Institutes of Health's National Center for Advanced Translational Sciences (NCATS), where she participated in genome-wide screening projects and contributed to multiple scientific publications. Nadia received a B.S. in Biology from the University of Maryland, Baltimore County in 2009 and an M.S. in Biotechnology with a Regulatory Affairs emphasis from the University of Maryland, Global Campus in 2021. She has completed FDA's Project Management Certification Program through Duke Corporate Education and has received multiple CBER Group Recognition Awards.

Hong Yang, PhD
Director
Division of Analytics and Benefit-Risk Assessment (DABRA)
Office of Biostatistics and Pharmacovigilance (OBPV)
CBER | FDA

Dr. Hong Yang is an acting director of Division of Analytics & Benefit-Risk Assessment, Office of Biostatistics and Pharmacovigilance, CBER, FDA. She is an expert in quantitative benefit-risk assessments and has led benefit-risk assessments in CBER to inform regulatory decisions. She is active in research and collaboration to develop novel benefit-risk approaches, as well as training and outreaching for implementation of benefit-risk framework. She was a member of FDA Benefit-Risk Guidance Working Group as well as FDA Benefit-Risk Framework Implementation team. She made major contributions to CIOMS (COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES) report for Benefit-Risk Balance for Medicinal Products. She is actively engaging with multiple working groups of professional societies including American Statistical Association and International Society for Pharmacoepidemiology in activities of Benefit-Risk Assessment Planning, methodology and tool development.