SPEAKER BIOGRAPHIES

Keynote & Welcome

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) and holds a RAC-US certificate. CAPT Stodart has had experience in hospital and retail pharmacy before joining the FDA.

Patrizia Cavazzoni, MD
Director
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Patrizia Cavazzoni, MD, is the director of the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration. The Center's mission is to ensure that safe, effective, and high-quality drugs are available to the public. To achieve this, CDER regulates the medical products under its jurisdiction throughout their lifecycle, oversees the development of new and generic drugs, evaluates applications to determine whether drugs should be approved, monitors the safety of drugs after they are marketed, conducts research to advance regulatory science and takes enforcement actions to protect the public from harmful products. Dr. Cavazzoni joined the FDA in January 2018 as CDER's Deputy Director for Operations where she has led several key initiatives on behalf of the organization. She also served as Acting Principal Deputy Commissioner of Food and Drugs from January 2019 to February 2019.

Dr. Cavazzoni received her medical degree at McGill University and completed a residency in psychiatry and a fellowship in mood disorders at the University of Ottawa. During her training, she was an investigator in clinical trials of novel antipsychotic and antidepressant medications and became a research collaborator within the International Group for The Study of Lithium Treated Patients. She subsequently received a full-time appointment to the Faculty of Medicine at the University of Ottawa and joined the Mood Disorders Program at the Royal Ottawa Hospital, where she treated patients suffering from severe mood disorders, taught students and conducted research on genetic predictors of bipolar disorder as part of a multidisciplinary international collaborative effort, authoring numerous peer-reviewed scientific publications.

After her tenure in academic medicine, Dr. Cavazzoni worked in the pharmaceutical industry for several years and held senior executive positions in clinical development, regulatory affairs, and safety risk management in large companies across multiple therapeutic areas, until she joined the FDA.

Dr. Cavazzoni obtained certification by the American Board of Neurology and Psychiatry in 1997 and 2008 and is a fellow of the Canadian Royal College of Physician and Surgeons. She is a fellow of the Canadian College of Neuropsychopharmacology and a recipient of the American College of Psychiatrists' Laughlin Fellowship.

Jeff Shuren, MD, JD
Director
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration (FDA)

Jeffrey E. Shuren, MD, JD became the director of the Center for Devices and Radiological Health at the Food and Drug Administration (FDA) in January 2010. He previously served as Acting Center Director, beginning in September 2009. The center is responsible for assuring the safety, effectiveness, and quality of medical devices; assuring the safety of radiation-emitting products (such as cell phones and microwave ovens); and fostering device innovation. "Our center experts and programs help get safe and effective technology to patients and health care professionals on a daily basis," says Dr. Shuren. "Rapid technological advances enable us to approve such innovations as a diagnostic test for the H1N1 influenza virus, an expandable prosthetic rib for children with abnormal growth conditions, and a test that can help detect ovarian cancer."

Dr. Shuren received his B.S. and M.D. degrees from Northwestern University under its Honors Program in Medical Education. He completed his medical internship at Beth Israel Hospital in Boston, his neurology residency at Tufts New England Medical Center, and a fellowship in behavioral neurology and neuropsychology at the University of Florida. He received his J.D. from the University of Michigan. Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including acting deputy commissioner for policy, planning, and budget; associate commissioner for policy and planning; special counsel to the principal deputy commissioner; assistant commissioner for policy; and medical officer in the Office of Policy.

Dr. Shuren has served in a leadership role at FDA or on behalf of the agency on numerous initiatives, including:

- reauthorization of the Medical Device User Fee Act, which dramatically shortens review times for device applications.
- creation of the Sentinel Initiative, which works toward a national electronic system for monitoring medical product safety.
- development of FDA's Pandemic Influenza Preparedness Strategic Plan
- development of FDA's Counterfeit Drug Task Force Report
- development of the Interagency Food Safety Working Report to the President
- implementation of FDA provisions of the Medicare Prescription Drug Improvement and Modernization Act
- development and implementation of the Interagency Import Safety Working Group's Report to the President: Action Plan for Import Safety 4

From 1999 to 2000, Dr. Shuren served as a detailee on Senator Edward Kennedy's staff on the Senate Health, Education, Labor, and Pensions Committee. From 1998 to 2003, he also was a staff volunteer in the National Institutes of Health's Cognitive Neuroscience Section where he supervised and designed clinical studies on human reasoning. As director of the Division of Items and Devices, Coverage and Analysis Group at the Centers for Medicare and Medicaid Services, Dr. Shuren oversaw the development of Medicare national coverage determinations for drugs, biologics, and non-implantable devices.

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Peter Marks, MD, PhD is the director of the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration. The center is responsible for assuring the safety and effectiveness of biological products, including vaccines, allergenic products, blood, and blood products, and cellular, tissue, and gene therapies.

Dr. Marks and center staff are committed to facilitating the development of biological products and providing oversight throughout the product life cycle. Examples of these activities include:

- reviewing and providing advice during product development
- evaluating applications and making approval decisions based on safety and effectiveness data.
- monitoring the safety of biological products
- conducting research that supports product development and characterization.

"The center regulates and does research on complex biologic products that touch people's lives on a daily basis," says Dr. Marks. "Many of the products that we regulate are vital for promoting and protecting the public health, including vaccines, blood products, and tissues for transplantation. I'm very proud to lead a team of highly committed individuals whose efforts help to ensure the timely development of safe and effective products to meet important medical needs."

Dr. Peter Marks received his graduate degree in cell and molecular biology and his medical degree at New York University. Following this, he completed an Internal Medicine residency and Hematology/Medical Oncology fellowship at Brigham and Women's Hospital in Boston, where he subsequently joined the attending staff as a clinician-scientist and eventually served as Clinical Director of Hematology.

He then moved on to work for several years in the pharmaceutical industry on the clinical development of hematology and oncology products prior to returning to academic medicine at Yale University where he led the Adult Leukemia Service and served as Chief Clinical Officer of Smilow Cancer Hospital. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in 2016. Dr. Marks is board certified in internal medicine, hematology and medical oncology, and is a Fellow of the American College of Physicians. In 2022, he became a Member of the National Academy of Medicine, one of the highest honors in the fields of health, science and medicine.

Plenary Session Moderator

Elias Mallis
Director
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
Center for Devices and Radiological Health (CDRH)

Elias Mallis is the Director of the Division of Industry and Consumer Education (DICE) in the Office of Communication and Education (OCE), in the Center for Devices and Radiological Health (CDRH), a position held since 2011. Mr. Mallis provides strategic leadership, vision, and oversight to educate industry and consumer stakeholders with understandable and accessible science-based regulatory information about medical devices and radiation-emitting electronic products. He's a member of the Regulatory Affairs Professionals Society (RAPS) education committee.

Mr. Mallis began his three-decade FDA career in 1994 and devoted the next 17 years in the Office of Product Evaluation and Quality (OPEQ), responsible for scientific regulatory review and policy development for diverse medical device program areas, including 510(k)s, IDEs, PMAs and HDEs. As an Electrical Engineer in the Gastroenterology and Renal Devices Branch, he was responsible for lead, engineering, and software review of medical products in the fields of hemodialysis, extracorporeal therapeutics, gastric motility and incontinence, and endometrial ablation. He was Branch Chief of the Cardiac Electrophysiology and Monitoring Branch, responsible for cardiovascular disciplines including cardiac ablation for treatment of atrial fibrillation, implantable heart failure diagnostics, and non-invasive cardiac monitors. Mr. Mallis served as a Policy Analyst contributing to the 510(k) Program, Clinical Studies, Device Reclassifications and De Novo policy. Mr. Mallis received a Bachelor of Science in Electrical Engineering at the University of Maryland at College Park.

Mary T. Thanh Hai, MD
Deputy Director for Clinical
Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Dr. Thanh Hai is currently the Deputy Director for Clinical in the Office of New Drugs Immediate Office. She works directly with the OND Director to oversee the development programs of drugs and biologics regulated by the Center of Drug and Evaluation and Research across 27 review divisions. She also oversees the Office of Drug Evaluation Science including the Drug Development Tool Qualification Programs. Dr. Thanh Hai is an internist/endocrinologist receiving her medical degree from Georgetown University. Over the past 24 years, she has held several leadership positions in FDA including Director of Division of Metabolism and Endocrinology Products from 2006-2013. She served as the rapporteur for the development of ICH E19 Guidelines.

Kevin Bugin, PhD, MS, RAC
Deputy Director
Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Dr. Kevin Bugin is the Deputy Director of Operations in the Office of New Drugs (OND) in FDA's Center for Drug Evaluation and Research (CDER). Prior to his current role, from May 2020 through May 2021, Dr. Bugin served as the Chief of Staff for the Therapeutics Response Efforts as part of the US Government's HHS and DOD operation formerly known as Operation Warp Speed. Dr. Bugin is an adjunct faculty at the George Washington University in the Clinical Leadership Program, focusing on areas of clinical research and medicines development. Dr. Bugin joined the FDA in 2008 in the Office of Business Process Support, then joined the Division of Gastroenterology and Inborn Errors Products within OND as a Regulatory Health Project Manager in 2010, and as the Chief of Project Management from 2015 to 2017. From 2017 until 2020, he served as the Director of Special Programs and the lead of CDER's New Drugs Regulatory Program Modernization. Prior to joining the FDA, Dr. Bugin held roles in multiple areas and phases of drug development, including discovery (molecular biology) at the Virginia Bioinformatics Institute, translational research and technology transfer at the National Institute of Health's Office of Technology Transfer, safety and pharmacovigilance with NIH's National Cancer Institute's Cancer Therapy Evaluation Program, and regulatory affairs and quality assurance at Amarex Clinical Research. Kevin received a BS in Biology and Chemistry from Virginia Tech in 2005, a MS in Biotechnology from American University in 2006, and a PhD in translational health science from George Washington University in 2020, with a focus on the Science of Team Science in drug development and regulatory science teams. He is certified in US regulatory affairs (RAC) and participates in numerous policy and regulatory science program working groups across the FDA.

Tala Fakhouri, PhD, MPH
Associate Director for Policy Analysis
Office of Medical Policy (OMP)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Tala H. Fakhouri PhD MPH is the Associate Director for Policy Analysis at the Food and Drug Administration. Dr. Fakhouri manages a team tasked with developing, coordinating, and implementing medical policy with a focus on the use of Artificial Intelligence (AI) in drug development. She also contributes to the development of medical policy related to real-world evidence (RWE) for medical product development. In 2023, She was selected by the Office of Management and Budget to serve on the Federal Committee for Statistical Methodology for her expertise in statistical methods.

Prior to joining FDA, Dr. Fakhouri served as Chief Statistician for the CDC's flagship population survey, the National Health and Nutrition Examination Survey (NHANES), which is recognized as the premier source of nationally representative data on the health of the nation. Prior to NHANES, she served as an Epidemic Intelligence Service Officer with the CDC, and deputy lead for health surveys at ICF-Macro International. Dr. Fakhouri published over 30 government reports, peer-reviewed papers, and book chapters.

Dr. Fakhouri earned a Ph.D. in Oncological Sciences from The Huntsman Cancer Institute at the University of Utah, an MPH in Epidemiologic and Biostatistical Methods from the Johns Hopkins University School of Public Health, and a postdoctoral fellowship in molecular biology and genetics from Harvard University, and holds a BSc Medical Technology form the Jordan University of Science and Technology

Laurie Muldowney, MD
Deputy Director
Office of Scientific Investigations (OSI)
Office of Compliance (OC)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Dr. Laurie Muldowney serves as the Deputy Director of the Office of Scientific Investigations (OSI) in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration. In this role, she works collaboratively with the Office Director to manage the development and implementation of patient focused, risk-based inspection, compliance, and enforcement activities under the Agency Bioresearch Monitoring Program.
Dr. Muldowney joined the FDA/CDER in 2009 as a medical officer and has served in multiple positions across CDER, including clinical team leader with the Division of Gastroenterology and Inborn Errors Products in the Office of New Drugs and associate director for medical policy in the Office of Translational Science. Dr. Muldowney received a B.S. in chemistry from the College of William and Mary and earned her medical doctorate from Jefferson Medical College in Philadelphia, PA. Following additional postgraduate training, Dr. Muldowney served as a primary care physician with the United States Navy and worked in medical communications.

Aden S. Asefa, MPH
Drug Trials Snapshot Lead
Office of Drug Evaluation Sciences (ODES)
OND
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Aden started her FDA career as an ORISE Fellow with the Center for Food Safety and Applied Nutrition. From 2012-2014, she worked in Tobacco regulation in which she managed portfolio applications of Tobacco companies under the Family Smoking Prevention & tobacco Control Act. In 2015, Ms. Asefa switched gears again at the Agency and worked for Center for Devices and Radiological Health (CDRH) and managed Advisory Committee Public Meetings. Before starting her career in diversity in Clinical trials in 2022, she worked in the Office of Commissioner supporting Commissioner Dr. Califf in various FDA issues.

Kristina Lauritsen, PhD
Combination Product Regulatory Advisor
Product Jurisdiction and Combo Product Team
Office of Executive Programs (OEP)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Kristina Lauritsen, PhD serves as a Combination Product Policy Advisor and Product Jurisdiction Officer within the Center for Drug Evaluation and Research (CDER) at the FDA. In this role, she is responsible for engaging in development of CDER's policies related to combination product review and regulation, including activities such as guidance development, facilitating coordination with the FDA's Office of Combination Products, CBER and CDRH, and representing CDER in cross-center combination product working groups. Kristina originally joined FDA in 2003 as a device reviewer in CDRH. She later joined the Office of Combination Products and spent several years there prior to joining CDER in 2014. She holds a B.S. in Biology from Shippensburg University, and a Ph.D. in tumor biology from Georgetown University.

CDER SBIA Host

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

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

Day Two CDER Session Speakers

Renu Lal, PharmD, BCACP
Lieutenant Commander, USPHS
Team Leader
Division of Drug Information (DDI) | Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

LCDR Renu Lal currently serves as a Team Leader and Deputy Director of SBIA. In addition to growing and expanding the services SBIA provides to the regulated pharmaceutical industry, she leads a team that responds to drug related inquiries from the public regarding a wide range of topics and managing outreach and educational programs.

Renu is an officer of the United States Public Health Service and has been with CDER's Division of Drug Information since 2002, and SBIA since 2010. She has also worked in retail and hospital pharmacy, and in the pharmaceutical industry. Renu received her Doctor of Pharmacy from the Medical University of South Carolina, and her bachelor's degree in pharmacy from the University of Connecticut.

Alyson Karesh, MD
Senior Clinical Advisor
Office of Medical Policy (OMP)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Dr. Alyson Karesh is currently Director, Division of Clinical Trial Quality, Office of Medical Policy, Food & Drug Administration (FDA). She served as Pediatric Team Leader in the Division of Pediatric and Maternal Health in the Center for Drug Evaluation and Research (CDER) at the FDA. Dr. Karesh and her team provided scientific and regulatory advice regarding the development of drugs and biologic products in the pediatric population to FDA review divisions, pharmaceutical companies, and other agencies. Dr. Karesh received her medical degree from Medical College of Virginia and completed her pediatric residency at Children's Hospital of Pittsburgh.

Suzanne R. Pattee, JD
Regulatory Counsel
Office of Clinical Policy (OCP)
Office of Clinical Policy and Programs (OCPP)
Office of the Commissioner (OC) |
Food and Drug Administration (FDA)

Suzanne Pattee is a regulatory counsel with the Office of Clinical Policy in the Office of the Commissioner where she addresses policy for the ClinicalTrials.gov data bank, clinical trial design, and informed consent. She previously worked in CDER for the Division of Clinical Trial Quality in the Office for Medical Policy (OMP), and in the Office of Policy in the Office for Pharmaceutical Quality (OPQ).

Before joining FDA in 2009, Suzanne was a vice president at a rare disease foundation where she led policy initiatives in clinical trials, orphan drug policies, and many others. She also led bioethics issues and outreach for a biotechnology trade association and addressed health policy for a biotechnology company. Suzanne was a member of the Secretary's Advisory Committee for Human Research Protections and served on the board of an accreditation association. Suzanne earned her law degree from George Washington University, and her bachelor's degree in biology from The College of William and Mary.

Jonathan Resnick
Project Management Officer
Division of Data Management Services and Solutions
(DDMSS) | Office of Business Informatics (OBI)
Office of Strategic Programs (OSP)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

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.

Seyoum Senay
Supervisory Operations Research
DDMSS | OBI | OSP
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Mr. Senay is leading the FDA CDER mission-critical Informatics initiatives in support of human drug regulatory review process with a customer focus through analysis and pragmatic solutions that work to advance CDER's public health mission. He represents CDER in the FDA cloud strategy working group for decision making, collaboration, coordination, and execution of programs. Mr. Senay earned a reputation among many clients for ensuring customer satisfaction and delivering desired outcomes. Currently, Mr. Senay is leading innovative cloud transformation effort to enable collaboration and improve operational efficiency. This capability continues to reduce regulatory overhead for sponsors, research institute, academia, and small businesses. In addition, Mr. Senay successfully completed the U.S Excellence in Government Leadership Fellow (EIG) program to solve national problems by driving innovation, inspiring employees, and delivering results.

Mr. Senay holds a master's degree in Information Systems from The Johns Hopkins University and a Certified Program Manager by Federal Acquisition Institute.

Jessica Bernhardt, MS
ESG Program Manager
Division of Application Services (DAS)
Enterprise Application Branch (EAB)
Office of Digital Transformation (ODT)
Office of Information Management and Technology (OIMT)
Food and Drug Administration (FDA)

Jessica Bernhardt currently is the Program Manager for the Electronic Submissions Gateway (ESG) and AdminApps programs at the Food and Drug Administration (FDA). She took on the role of ESG Program Manager at the start of 2023 and oversaw the successful completion of the ESG AWS Migration. Jessica joined the FDA in 2020 as the AdminApps Program Manager, which she has successfully managed for the past three years.

Jessica started her career in Government nine years ago when she joined the Social Security Administration (SSA) as an IT Specialist. After a year working as an IT Specialist for a year, was assigned to lead and manage an IT Modernization project, promoting the use of the Agile development lifecycle. In 2016 she was promoted to Team Lead within the Enterprise Architecture (EA) and Software Governance group (SG). As a Team Lead in EA & SG she helped to define, promote, and manage the EA & SG program as well as various development projects at SSA. In 2020 she moved into a purely Project Management role, managing a large agile IT Modernization effort for several of SSA's core business systems. During her tenure at SSA, she helped to promote the EA Program, integrating it into both the Waterfall and Agile development lifecycles, mentored employees in EA and Project Management and managed several development projects. Additionally, while working at SSA she obtained her Master of Science in Information Systems Management with a concentration in Project Management. Prior to joining SSA, Jessica worked for five years in private industry IT at the International Union of Painters and Allied Trades (IUPAT) as a Business Analyst/Project Manager. While at the IUPAT, she helped with the IT Modernization of their Membership, Education and Dues system providing Analytical, Testing, Training and Project Management support. Prior to leaving she and her team successfully rolled out the application to multiple District Councils and Local Unions throughout the country.

Jessica currently lives in Gambrills, Maryland with her husband and their four children. When she is not busy working and continuing to advance her knowledge in IT you can usually find her at the dirt bike track watching either her husband or their twin boys ride.

Bin Duan
ESG NextGen Lead Architect
CTO | Precise Software Solutions Inc.
FDA Contractor
Division of Application Services (DAS)
Enterprise Application Branch (EAB)
Office of Digital Transformation (ODT)

Office of Information Management and Technology (OIMT) | FDA

Dr. Duan is a visionary and result focused IT executive with 20 years of progressive responsibility leading IT strategy, architecture, technology innovation, business operation, and delivering strategic product offerings and large-scale IT programs. He is the Chief Technical Officer of Precise Software Solutions. Prior to Precise, Dr. Duan held leadership roles in Oracle, CSRA and Nielsen. Dr. Duan has a PhD degree in Aerospace Engineering and an MBA. He is currently an Adjunct Professor at George Mason University teaching graduate level classes on Big Data and Advanced Data Analytics.

Qi Liu, PhD, MStat, FCP
Associate Director for Innovation & Partnership
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Qi Liu, PhD, MStat, FCP, is the Associate Director for Innovation & Partnership in OCP, OTS/CDER/FDA. She leads OCP's innovative initiatives through strategic partnership. She has helped develop OCP's portfolio on machine learning/artificial intelligence, real-world evidence, and digital health technologies, collaborating with internal and external experts. She led OCP's Physiologically Based Pharmacokinetic Modeling and Simulation Oversight Board and co-led the Biologics Oversight Board. She was also a co-lead initiating the Real-Time Oncology Review and Assessment Aid Pilot Programs. During her career at the FDA, she also contributed to over 200 NDA/sNDA reviews, 20 BLA/sBLA reviews, and numerous IND reviews to support drug development. She worked on working groups for FDA guidance documents and Manual of Policies & Procedures. She is an Associate Editor of Clinical Translational Science and on the editorial board of five scientific journals. Before joining FDA, Dr. Liu was a senior pharmacokineticist at Merck & Co. Inc. She obtained her PhD degree in Pharmaceutics and a concurrent Master's degree in Statistics from the University of Florida in 2004. In addition, she has a Master's degree in Pharmaceutics and a Bachelors' degree in Clinical Pharmacy from West China University of Medical Sciences.

Dave Burrow, PharmD, JD
Director
Office of Scientific Investigations (OSI)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Dr. David Burrow serves as the Director of the Office of Scientific Investigations (OSI), within the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Compliance (OC). In this role, Dr. Burrow leads efforts to shield the American public from unsafe and ineffective drug products. His leadership in the Agency's Bioresearch Monitoring (BIMO) program includes the development and implementation of policies, surveillance activities, and compliance strategies for CDER-regulated products. Additionally, he oversees the enforcement of clinical and non-clinical drug product studies, bioequivalence studies, human subject protections, post-market adverse drug experience reporting requirements, risk evaluation and mitigation strategies, and post marketing requirements. Dr. Burrow holds a Doctor of Pharmacy from Duquesne University, and a Juris Doctorate from Widener University School of Law. He is licensed to practice law in the State of Maryland.

Ranjani Prabhakara, PhD
Policy Lead
Office of Policy for Pharmaceutical Quality (OPPQ)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Ranjani Prabhakara, PhD is Policy Lead in the Office of Policy for Pharmaceutical Quality (OPPQ), Office of Pharmaceutical Quality (OPQ) in the Center for Drug Evaluation & Research at the FDA. Ranjani was a Team Leader in CDER/ Office of Compliance/ Office of Manufacturing Quality. Ranjani earned her PhD in immunology from the University of Maryland Medical School in 2009. She also holds a BS in Microbiology and a BA in Psychology.

Prior to joining CDER in 2013 (in what was previously the Office of Manufacturing and Product Quality), Ranjani was a Researcher and CMC Reviewer at CBER's Office of Vaccine Research and Regulation, where her research and review work focused on protein vaccines against bacterial infections. Before joining FDA, Ranjani worked at the NIH Vaccine Research Center studying HIV vaccines.

Jill P. Furman, JD
Director
Office of Compliance (OC)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Jill Furman, J.D., serves as the Director of the Office of Compliance in the Center for Drug Evaluation and Research (CDER). The Office of Compliance is charged with protecting the public from poor quality, unsafe, and ineffective drug products through proactive compliance strategies and risk-based enforcement actions.

Ms. Furman joined FDA in 2020 as the Office of Compliance Deputy Director after more than 22 years with the U.S. Department of Justice's (DOJ) Consumer Protection Branch, where she handled a wide range of consumer protection matters, including civil and criminal litigation under the Food, Drug, and Cosmetic Act. In her last eight years at DOJ, Ms. Furman served as the Deputy Director of that office, supervising litigation, and providing leadership and direction to attorneys and staff.

Before joining DOJ, Ms. Furman served as an Assistant District Attorney with the Suffolk County District Attorney's Office in Boston, Massachusetts, where she prosecuted criminal cases in state appellate and trial courts.

Ms. Furman earned her law degree from Boston University School of Law and her bachelor's degree from the University of Pennsylvania.

Kim Piermatteo, MHA
CDR | USPHS
Education Program Administrator
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE) | CDRH

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.

Kendra Holter, MSN, RN
Consumer Safety Officer
Premarket Programs Branch
DICE | OCE | CDRH

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 such information on the CDRH website for the purpose of industry education. She joined FDA in September 2022.

Prior to her FDA career, Ms. Holter served as the National Educator in the care and management of reusable medical devices for the Veterans Health Administration (VHA) 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 in Marine Biology from the College of Charleston, a Bachelor of Science in Nursing from the Medical University of South Carolina, and a Master of Science in Nursing Informatics from Walden University.

Edward Margerrison, PhD
Director
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

Ed Margerrison is the Director of CDRH's Office of Science and Engineering Laboratories (OSEL) at the U.S. Food and Drug Administration. The Office is responsible for providing technical expertise and analyses in support of the regulatory processes within CDRH. Previously, he was President and CEO of Ortho Regenerative Technologies, a biotech startup focused on developing novel biomaterial approaches to surgical soft tissue repair. Dr. Margerrison has held senior positions at Zimmer Biomet, Akela Pharma and Smith and Nephew. He graduated in Biochemistry from the University of Oxford and gained his PhD in Molecular Genetics from St. George's Hospital Medical School in London UK.

Simon Choi, MPH, PhD
Senior Policy Advisor
Division of Standards and Conformity Assessment (DSCA)
Office of Readiness and Response (ORR)
Office of Strategic Partnerships and Technology Innovation (OST)
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Simon Choi is a Senior Policy Advisor with the Division of Standards and Conformity Assessment (DSCA) in CDRH's Office of Readiness and Response (ORR), in the Office of Strategic Partnerships and Technology Innovation (OST). He has led major public health projects and initiatives at FDA for medical imaging, directed computed tomography (CT) medical imaging safety investigations and developed regulatory policies for Digital Health. Previously, Dr. Choi was Director of the Master of Public Health program at the University of Kansas Medical Center and served as Assistant Professor in the Department of Preventive Medicine. Dr. Choi received a Masters and PhD in Public Health from the University of Southern California.

Christina Savisaar, PhD
Policy Analyst
Policy and Operations Team 1
Division of Clinical Evidence and Analysis (DCEA1)
Office of Clinical Evidence and Analysis (OCEA)
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Christina Savisaar currently serves as a Policy Analyst on a team within the Office of Clinical Evidence and Analysis (OCEA) within the US Food and Drug Administration's Center for Devices and Radiologic Health (CDRH). This team serves CDRH, and CDRH's vision to provide all patients in the US with access to high-quality, safe and effective medical devices of public health importance first in the world, by providing regulatory guidance to both internal and external stakeholders regarding the interpretation and application of policies and procedures related to the Investigational Device Exemption, Expanded Access, Breakthrough, and Safer Technologies Programs, as well as to clinical trial and human subject protection matters in device investigations. Before joining OCEA in 2020, Christina had been with CDRH in various capacities for over 13 years, where her responsibilities have included leading premarket reviews of medical device submissions and developing and implementing regulatory policy for the rollout of the Unique Device Identification Program. Christina received a bachelor's degree in biomedical engineering from Rensselaer Polytechnic Institute and a doctoral degree in biomedical engineering from the University of Iowa. Prior to her career in public service, Christina had a number of research roles in the medical device industry and in academia.

Kathryn J. De Laurentis, PhD
Policy Analyst
Pre-Market Notification Team (PMNT)
Office of Regulatory Programs (ORP)
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

Kathryn J. De Laurentis has been a Policy Analyst since 2020 on the 510(k), De Novo, 513(g), Device Determinations and Custom Devices Lifecycle Team. She contributes to several pre-market programs and currently is the primary 510(k) team lead for eSTAR submissions, the CDRH Portal, and Least Burdensome flags.

Kathryn began her tenure at the FDA in 2014 as a Biomedical Engineer/Scientific Medical Device Lead Reviewer in the Division of Neuromodulation and Rehabilitation Devices, Office of Neurological and Physical Medicine Devices (OHT5). She evaluated numerous physical medicine devices, such as, exoskeletons, prosthetic devices, and wheeled mobility devices, through a variety of submission types (that is, Premarket Approvals, Premarket Notifications (510(k)), Q-Submission Requests, and 513(g) Requests for Designation). Dr. De Laurentis continues to be an instructor for internal educational programs including the Reviewer Certification Program and OPEQ-wide training for new initiatives, as well as participating in external outreach education regarding medical device premarket activities.

Prior to joining the FDA, she designed and developed assistive and medical technologies as a research professor, project/program manager, and small business owner. Her major areas of interests are the advanced design and development of robotic, mechatronic, and mechanical technologies; the development of layered/additive manufacturing technologies and techniques; the creation of smart material actuation schemes and actuated devices; and human factors.

Dr. Kathryn De Laurentis has patented and widely published her work. She received honors from organizations such as the National Science Foundation, was named a Pinellas County Emerging Entrepreneur, and is a member of the National Academy of Inventors. She earned a PhD in Mechanical and Aerospace Engineering from Rutgers, the State University of New Jersey, and has a background as a behavioral and mental health professional.

Hina Pinto, MSE
Associate Director
Regulatory Policy and Combination Products
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

Hina M. Pinto is the Associate Director for Regulatory Policy and Combination Products in CDRH's Office of Product Evaluation and Quality (OPEQ). In this role, Hina collaborates across the Agency on cross-cutting regulatory and policy matters, many of which apply to the review and regulation of combination products. Hina also oversees complex regulatory projects, provides leadership and regulatory support on the development and implementation of regulations and guidances, and serves as a focal point for product classification and jurisdiction questions.

Hina joined CDRH in 2001 as a lead and engineering reviewer of various life-supporting and life-sustaining anesthesiology, respiratory, and interventional cardiology medical devices. Hina has also served as Team Lead and Regulatory Advisor in the Regulation, Policy, and Guidance (RPG) team, where she was involved in a range of regulatory and scientific issues in OPEQ, including development and implementation of product-specific and cross-cutting policies for device regulation. Prior to her current role, Hina served as Deputy Division Director within the Office of Clinical Evidence and Analysis, where she provided leadership support and oversight to policy and operations teams, which are responsible for the IDE, Breakthrough Devices, Safer Technologies, and Expanded Access Programs, as well as the Postmarket Mandated Studies and RWE Programs. Hina received her B.S. in Applied Science from the University of North Carolina-Chapel Hill and M.S.E. in Biomedical Engineering from Tulane University.

Joseph Tartal
Deputy Director
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
Center for Devices and Radiological Health (CDRH)

Joseph Tartal is Deputy 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 18-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.

Tonya A. Wilbon
Branch Chief
Postmarket and Consumer Branch
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
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Tonya A. Wilbon is the Branch Chief for the Postmarket and Consumer Branch, Division of Industry and Consumer Education (DICE), Office of Communication and Education (OCE), 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 24 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 the Quality System Specialist within OIR.

Ms. Wilbon also currently serves as an FDA instructor for the Association for the Advancement of Medical Instrumentation (AAMI) and serves on FDA's Content Advisory Group as an instructor for FDA Investigators and Staff. 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).

Indira Rao Konduri, MS
Deputy Director
FDA UDI Implementation Lead
Division of Regulatory Programs 3 (DRP3)
Office of Regulatory Programs (ORP)
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

Indira Rao Konduri serves as the Deputy Director for the Division of Regulatory Programs 3 (DRP3) in the Office of Regulatory Programs (ORP), Office of Product Evaluation and Quality (OPEQ) in CDRH. Indira is responsible for leading the UDI program, and oversees Medical Device Adverse Events, Recalls, Device Allegation programs.

Indira joined the FDA in 2000 as an IT Specialist. She later became Chief of the Information Analysis Branch, where she initiated and led the successful launch of the electronic Medical Device Reporting (eMDR) Program. From 2010-2011, Indira worked at Health Resources and Services Administration (HRSA) as Chief of the Compliance Branch in the Division of Practitioner Data Banks (DPDB). In 2011, Indira returned to CDRH to work on the Unique Device Identification (UDI) Program and served as the Program Manager for the Global Unique Device Identification Database (GUDID) until 2019, when she left to work for FDA's Office of Regulatory Affairs. At ORA, she worked as the Business Process Manager for the FDA ACE/IWS system, which receives, and processes FDA regulated imported products. Prior to her work with the FDA, Indira's work experience includes working as a Software Engineer at Verizon; Medical Technologist at two community hospital laboratories. Indira earned a B.S. in Clinical Laboratory Science from the University of Nevada, Reno in 1994 and an M.S. in Information Systems and Accounting from Virginia Polytechnic Institute and State University in 1998.

Ruth Bediakoh
Consumer Safety Officer
Postmarket and Consumer Branch
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
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Ruth Bediakoh is a Consumer Safety Officer in the Postmarket and Consumer Branch, Division of Industry and Consumer Education (DICE), Office of Communication and Education (OCE), 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 FDA's Center for Tobacco Products. Ruth has a Bachelor of Science degree from Pennsylvania State University.

Dianna Kenner-Staves, PharmD
Consumer Safety Officer
Postmarket and Consumer Branch
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Dianna Kenner-Staves is a Consumer Safety Officer (CSO) in the Division of Industry and Consumer Education (DICE) in CDRH's Office of Communication and Education (OCE). In her role as a CSO, she assists with DICE's efforts to educate the medical device and radiological health industry on FDA regulatory requirements for marketing medical devices and radiation-emitting products. She uses the latest regulatory information to develop and maintain educational content on CDRH's Device Advice webpages.

Prior to joining the FDA, Dianna worked as a clinical pharmacist at the VA Northern California Healthcare System, serving our nation's military veterans. In her role as a pharmacist for the Veterans Health Administration (VHA), she worked directly with patients and their caregivers to provide comprehensive education about their medication regimens. Additionally, she provided patient counseling services which often included demonstrating the use of combination products, such as drug products contained in and administered by a medical device. Before beginning her career as a pharmacist, she served in the United States Air Force as a Cryptologic Language Analyst and provided translation services to military leaders. Dianna earned her Doctor of Pharmacy degree from the University of Maryland School of Pharmacy and is a licensed pharmacist in Maryland and Delaware.

Katelyn Bittleman, PhD
Policy Analyst
Compliance and Quality Staff
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

Katelyn Bittleman is Policy Analyst in the Compliance and Quality Staff in CDRH's Office of Product Evaluation and Quality (OPEQ). She is responsible for developing and managing initiatives to strengthen OPEQ's compliance skill sets and promote the importance of quality in medical devices. Katelyn joined FDA/CDRH in 2015 as a compliance reviewer and has extensive experience in post-market compliance, cross-cutting policy initiatives, and collaborating with external stakeholders.

Katelyn earned a BS degree in Bioengineering at SUNY Binghamton before attending the Virginia Tech-Wake Forest University School of Biomedical Engineering and Sciences to obtain a PhD in Biomedical Engineering.

LCDR Sara Onyango, DHSc, MPH, MSN
United States Public Health Service Commissioned Corps
Medical Device Specialist
Investigator
Medical Device and Radiological Health Operations/Division I
Office of Regulatory Affairs

LCDR Sara Onyango is a Medical Device Investigator with the U.S. Food and Drug Administration and is stationed at the New England District Office in Winchester, MA. She's been on active duty in the U.S. Public Health Service Commissioned Corps for the past twelve years, with deployments to a federal prison and long-term care facility to assist with the COVID-19 pandemic, Liberia to assist with an Ebola outbreak, and Puerto Rico to provide medical care following hurricane Maria. She became a Women's Health Nurse Practitioner in 2021 and volunteers as a clinician at two community clinics serving uninsured women. She received her Doctorate in Health Science from Nova Southeastern University, her Master of Science in Nursing from Frontier Nursing University, her Master of Public Health from the University at Albany, her Bachelor of Science in Nursing from Villanova University, and her Bachelor of Science in International Health Science from SUNY Cortland. She is a Certified Health Education Specialist (CHES) and a former high school health science teacher. She and her husband are currently working to open a women's preventive health clinic in rural Kenya.

Joseph Hillring, MS
Consumer Safety Officer
Postmarket and Consumer Branch
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Joseph Hillring is a Consumer Safety Officer in the Postmarket and Consumer Branch, Division of Industry and Consumer Education (DICE), in Center for Devices and Radiological Health's (CDRH's) Office of Communication and Education (OCE). His work focuses on helping external stakeholders locate and understand various regulatory resources and requirements established by FDA, with a specialization in Quality System regulation (Title 21 Code of Federal Regulation Part 820). In 2016, Mr. Hillring began working for OCE as a Staff Fellow in DICE. 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 Bachelor's 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 Degree from Northeastern University Majoring in Regulatory Affairs for Drugs, Biologics, and Medical Devices.

Larissa Lapteva, MD, MHS, MBA
Associate Director
Division of Clinical Evaluation General Medicine (DCEGM) Office of Clinical Evaluation (OCE)
Office of Therapeutic Products (OTP)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Larissa Lapteva, M.D., M.H.S., M.B.A. is the Associate Director in the Division of Clinical Evaluation, Office of Therapeutic Products, CBER, FDA. Dr. Lapteva is a physician with long-standing experience in clinical research with novel drugs and biological products, including cell and gene therapies and products developed for rare diseases. Prior to her work at the FDA, Dr. Lapteva served as a clinical investigator in clinical studies conducted at the National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS), National Institutes of Health (NIH). Since joining FDA in 2006, Dr. Lapteva has held review and supervisory positions in the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and provided scientific and regulatory advice for clinical development programs with investigational products across different therapeutic areas. Dr. Lapteva received her degrees of Master of Health Sciences from Duke University and Master of Business Administration from R.H. Smith School of Business.

Brian Stultz
Chief, Gene Therapy Branch 2 (GTB2)
Division of Gene Therapy 1 (DGT1) Office of Gene Therapy CMC (OGT) Office of Therapeutic Products (OTP)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Brian Stultz is the Chief of Gene Therapy Branch 2 located in the Office of Gene Therapy CMC, Office of Therapeutic Products, Center for Biologics Evaluation and Research. Brian has over 19 years of experience with cell and gene therapy CMC review including expertise in plasmids, peptides, mRNA, genome editing, and AAV based products. He received a Master of Science with training in Biochemistry and Molecular Biology from the University of Virginia. Since joining the FDA in 2000, Brian worked in the lab of Dr. Hursh publishing multiple papers on the regulation of the TGF-β signaling pathway and identifying critical quality attributes of mesenchymal stem cells (MSCs). In addition to lab research, he participated in reviewing gene therapy CMC and eventually transitioned to full time review of gene therapy products.

Gopa Raychaudhuri, PhD
Associate Director for Special Programs
Office of the Director (OD)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Gopa Raychaudhuri, PhD is the Associate Director for Special Programs in the Office of the Director, Center for Biologics Evaluation and Research. Dr. Raychaudhuri is engaged in facilitating development of gene therapies for rare diseases including engagement in the public-private partnership – the Bespoke Gene Therapy Consortium (BGTC). Additionally, Dr. Raychaudhuri is CBER's liaison to the World Health Organization (WHO) providing strategic direction and overseeing CBER's scientific collaborations with the WHO. Dr. Raychaudhuri has a long-standing interest in the development of and access to essential medical products that promote national and global public health. She received her BSc and MSc degrees in Biochemistry from the University of Toronto and received a PhD in Microbiology from the University of Virginia. Her post-doctoral training at NIH/NIAID focused on vaccine development research. Since 2010, she has been in her current position implementing strategic programs that advance CBER priorities, including the development gene therapies for rare diseases.

Lorrie McNeill
Director
Office of Communication, Outreach and Development (OCOD) Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Lorrie McNeill is the director of the Office of Communication, Outreach and Development (OCOD) in FDA's Center for Biologics Evaluation and Research. Prior to becoming Office director, she was the director of the Division of Communication and Consumer Affairs in CBER/OCOD. She has been with the Center since 1992, and with the FDA since 1990. Before joining the FDA, she worked as a public health advisor for the Centers for Disease Control and Prevention in Atlanta and Baltimore. She holds a BA degree in industrial relations from the University of North Carolina at Chapel Hill.

Scott A. Brubaker
Director
Division of Human Tissues (DHT)
Office of Cellular Therapy and Human Tissue (OCTHT) Office of Therapeutic Products (OTP)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Scott A. Brubaker is the Director of the Division of Human Tissues, Office of Cellular Therapy and Human Tissue, in the Office of Therapeutic Products, at the Center for Biologics Evaluation and Research, FDA. Prior to selection in October 2016 as the Director of the Division of Human Tissues, Mr. Brubaker served 12 years as Sr. Vice President of Policy at the American Association of Tissue Banks where his duties included the development and management of Association policies, professional standards and guidance documents, and oversight of the Accreditation Program. Prior to that, Scott acquired 18 years of practical experience involving organ donation and tissue banking while holding various management positions at an organ procurement organization/tissue bank in Virginia. Scott has authored or co-authored more than 40 publications and is co- editor of 3 essential guides (books) for tissues and cells that cover donation, processing, and clinical use.

Cara Pardon, MS
Regulatory Project Manager (RPM)
Division of Review Management and Regulatory Review 1 (DRMRR1) Office Review Management and Regulatory Review (ORMRR)
Office of Therapeutic Products (OTP)
Center for Biologics Evaluation and Research (CBER)
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Cara Pardon, M.S. is a Regulatory Project Manager (RPM) in the Office of Review Management and Regulatory Review, Office of Therapeutic Products, Center for Biologics Evaluation and Research. Cara is a regulatory expert and project manager, with a passion for protecting public health and safety. Since joining FDA as an RPM in November of 2020, Cara has provided review management throughout the product life cycle, from pre-submission meetings to post-marketing submissions. As an RPM, Cara also acts as the liaison between FDA and industry, managing all communications and meetings. Prior to her work at FDA, Cara served as a Biologist at the National Cancer Institute (NCI), National Institutes of Health (NIH). Cara received her Bachelor of Science from The University of Wisconsin-La Crosse and her Master of Science from Cornell University.

Karen Jackler
Program Manager – Patient Engagement
Office of the Director
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration (FDA)

Karen Jackler is the program manager for the Center for Biologics Evaluation and Research (CBER) Patient Engagement Program. She works with patient organizations and with her FDA colleagues to coordinate patient engagement activities and to facilitate information sharing and collaboration. Ms. Jackler joined the FDA in 2009. Prior to joining CBER in 2018 she served as a strategic communication advisor and project manager for the FDA Center for Drug Evaluation and Research and the FDA Center for Devices and Radiological Health. Her experience also includes communication research and outreach roles with the National Institutes of Health and the Centers for Disease Control and Prevention. She holds a Master of Public Health with a concentration in Health Communication and Education and a Bachelor of Science in Cellular and Molecular Biology; both degrees are from Tulane University.

Hector S. Izurieta, MD, MPH, PhD
Associate Director
Novel Clinical Investigations Office of Vaccines Research and Review (OVRR)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Hector S. Izurieta, MD, MPH, PhD, is Associate Director for Novel Clinical Investigations at the Office of Vaccine Research and Review (OVRR), CBER, FDA. He has extensive U.S. and international vaccine research and public health experience, having previously worked at CDC (including in the EIS program), PAHO, WHO, Médecins Sans Frontières and other international organizations. He has authored around 100 manuscripts on real-world evidence studies of vaccine safety and effectiveness, methods for observational study research, and on the natural history of pandemics and epidemics including COVID-19, Influenza, Measles, Tetanus, Diphtheria, Pertussis, and others. His investigations have been cited extensively and were used for regulatory- decision making and public health recommendations by FDA, CDC, PAHO/WHO, and multiple national authorities.

Peter J. Weina, PhD, MD
Associate Director for Medical Countermeasures and Scientific Affairs
Office of Vaccines Research and Review (OVRR)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Peter J. Weina, PhD, MD, FACP, FIDSA is the Associate Director for Medical Countermeasures and Scientific Affairs in the Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA). Prior to this position, Dr. Weina retired as a Colonel after 46 years with the U.S. Army where he was last assigned as the Director of the Office of Research Protections for the Defense Health Agency. Dr. Weina is a clinically active Infectious Diseases Staff at A.T. Augusta Military Medical Center and a Full Professor at the Uniformed Services University of the Health Sciences. Dr. Weina is board certified in Internal Medicine and Infectious Diseases and holds a Certificate of Knowledge in clinical tropical medicine and travelers' health. He was Chief of Pharmacology and Director of Viral Diseases with the Army. A Fellow of the American College of Physicians, a Fellow of the Infectious Diseases Society of America, Dr. Weina has more than 75 scholarly articles in peer-reviewed journals, 2 books and 5 book chapters. Dr. Weina worked on the availability and licensure of intravenous artesunate since 1988 and continued serving until its licensure in 2020. He is a world-recognized expert in leishmaniasis and former Director of the only College of American Pathologists-accredited leishmania diagnostics laboratory. Dr. Weina is the former Director of the WRAIR Tropical Medicine Course that educates medical personnel from around the world in tropical medicine competency. Dr. Weina's distinguished recognitions include the Federal CDC Silo Buster's Collaborative Award of Excellence in 2008, the Colonel George W. Hunter III Certificate in 2011, the Major Jonathan Letterman Medical Excellence Award in 2014, the USUHS Alumni Association Lifetime Achievement Award in 2015, the BEYA Modern Day Technology Leader Award in 2020, and the Federal Laboratory Consortium Excellence in Technology Transfer in 2021. Dr. Weina's military awards include the Expert Field Medical Badge, the Order of Military Medical Merit, the Bronze Star for Service in Iraq during the first year of Operation Iraqi Freedom, the Soldier's Medal for Heroism, the Legion of Merit Medal, and the Defense Superior Service Medal.

Sudhakar Agnihothram, B.Pharm., Ph.D
Associate Director
Office Regulatory Initiatives Office of Vaccines Research and Review (OVRR)
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U.S. Food and Drug Administration (FDA)

Sudhakar Agnihothram, B.Pharm., Ph.D is the Associate Director of Office Regulatory Initiatives, at the Office of Vaccines Research and Review, CBER, FDA with extensive experience in the product life cycle regulation of vaccines for prevention of infectious diseases. He served as the chair of FDA multidisciplinary review committees responsible for Emergency Use Authorization for Moderna COVID-19 vaccine and Janssen COVID-19 Vaccine, and review committee for Moderna COVID-19 Vaccine for SPIKEVAX Biological License Application (Moderna COVID-19 Vaccine). Dr. Agnihothram is the Office lead in managing several programmatic regulatory initiatives including activities on frontline COVID-19 vaccines and has been involved in advancing stakeholder partnerships in these areas.

Meghna Alimchandani, M.D.
Deputy Director
Division of Pharmacovigilance (DPV)
Office of Biostatistics and Pharmacovigilance (OBPV)
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration (FDA)

Meghna Alimchandani, M.D., serves as the Deputy Director of the Division of Pharmacovigilance (DPV), Office of Biostatistics and Pharmacovigilance (OBPV) at FDA's Center for Biologics Evaluation and Research (CBER), where her work focuses on pharmacovigilance planning, and passive and active postmarketing safety surveillance for products regulated by the Center. She supervises DPV staff in pharmacovigilance plan reviews for Biologics License Application (BLAs), including original submissions and supplements. The pharmacovigilance review encompasses evaluation of safety-related postmarketing requirement/commitment (PMR/PMC) studies, Risk Evaluation and Mitigation Strategy (REMS), and spontaneous adverse event data.

She joined FDA in 2014 as a medical officer in DPV, OBPV and her past roles have included serving as the Branch Chief in DPV, and Associate Director in OBPV. She also gained experience in regulatory review of investigational biologics and clinical trial data while serving as a medical officer in the Office of Tissues and Advanced Therapies (now Office of Therapeutic Products) in CBER. Prior to FDA, Dr. Alimchandani received her medical degree from the Albert Einstein College of Medicine of Yeshiva University, Bronx, NY and completed her residency in Anatomic Pathology at the National Institutes of Health, Bethesda, MD.

Craig Zinderman, MD, MPH
Associate Director for Medical Policy
Office of Biostatistics and Pharmacovigilance (OBPV)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Craig Zinderman, MD, MPH is the Associate Director for Medical Policy in the Office of Biostatistics and Pharmacovigilance (OBPV) at FDA's Center for Biologics Evaluation and Research. He serves on inter- and intra-Center working groups developing FDA regulations and guidance on post-market safety and adverse event reporting for regulated industry. Dr. Zinderman also provides expertise and advice to Office and Division Leadership on medical product safety surveillance and the management of product safety issues.

Dr. Zinderman has served as a Medical Officer in OBPV since 2004, including serving as Associate Director of the Division of Epidemiology from 2012 to 2020. He has a Bachelor of Science in Biology from the University of Maryland, a Medical Doctorate from the University of Maryland School of Medicine, and a Master in Public Health from the Uniformed Services University of Health Sciences. He is Board certified in General Public Health and Preventive Medicine.

Orieji Illoh, MD
Director
Division of Blood Components and Devices (DBCD)
Office of Blood Review and Regulation (OBRR)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Dr Illoh joined FDA in 2009. Currently, she serves as the Director, Division of Blood Components and Devices in the Office of Blood Research and Review. She oversees regulatory activities related to blood and blood components for transfusion, plasma for fractionation, blood collection containers and storage solutions, devices used in the manufacture of blood and blood components, plasma volume expanders and oxygen carrying solutions. Prior to joining the FDA, Dr Illoh practiced Clinical Pathology and Transfusion Medicine at the University of Virginia, Charlottesville, and then at the University of Texas Medical School in Houston.

Julia Tait Lathrop, PhD
Associate Deputy Director
Division of Emerging and Transfusion-Transmitted Diseases (DETTD) Office of Blood Research and Review (OBRR)
Center for Biologics Evaluation and Review (CBER)
Food and Drug Administration (FDA)

Julia Tait Lathrop, PhD is the Associate Deputy Director in the Division of Emerging and Transfusion-Transmitted Diseases (DETTD), Office of Blood Research and Review (OBRR) in the Center for Biologics Evaluation and Review. DETTD has responsibility for regulating retroviral diagnostics, including all HIV devices, as well as devices for screening blood donors for infectious disease. In her current position Dr. Lathrop is responsible for developing and implementing regulatory and review policies for the Division. She joined FDA in 2012 and held roles in the Center for Devices and Radiological Health (CDRH), Office of In Vitro Diagnostics and Radiological Health (OIR, now OHT7) as a Scientific Reviewer and as Acting Chief of the Immunology and Flow Cytometry Branch in the Division of Immunology and Hematology Devices until 2016, when she joined DETTD. She holds a Ph.D. in Biology from the University of Virginia.

Triet M. Tran, PharmD, BCSCP
Regulatory Officer
Bioresearch Monitoring Branch (BMB)
Division of Inspections and Surveillance (DIS)
Office of Compliance and Biologics Quality (OCBQ)
Center for Biologics Evaluation and Research (CBER)
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Lieutenant Triet M. Tran, PharmD, BCSCP, is a regulatory officer in the Bioresearch Monitoring Branch, Division of Inspections and Surveillance, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research. Prior to his work at the FDA, Dr. Tran served as an inpatient pharmacist, nuclear pharmacist, and radiation safety officer. Since joining the FDA in 2021, Dr. Tran has served as a bioresearch and monitoring reviewer, collaborating with different product offices within CBER to review drug applications and with the Office of Regulatory Affairs (ORA) to issue and review inspections. Dr. Tran earned his Doctorate of Pharmacy from the University of Maryland School of Pharmacy in 2018.

Seth Schulte, M.S.
Biologist
Division of Biological Standards and Quality Control (DBSQC) Office of Compliance and Biologics Quality (OCBQ)
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Seth Schulte, M.S. is a Biologist in the Division of Biological Standards and Quality Control, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research.
Prior to his work at FDA, Seth worked in various industry settings in quality control, analytical development, and small-scale production. Since joining FDA in 2021, Seth has been involved in the operation of the lab clean suite, execution of sterility testing, and regulatory review of microbiological methods for multiple FDA offices.

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