SPEAKER BIOGRAPHIES

Day 1 Keynote & Plenary Speakers

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.

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.

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.

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.

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

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

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

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 he has 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 29-year FDA career in 1994 and devoted the next 17 years in what is now the Office of Product Evaluation and Quality (OPEQ), responsible for scientific regulatory review and policy development for a diverse range of medical device programs, such as 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 such as 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 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.

Day 1 CDER Session Speakers

Stacey Ricci, M.Eng, ScD

Director of Scientific Review Staff (SRS)
Office of Therapeutic Biologics and Biosimilars (OTBB) | Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Dr. Ricci is the Director of Scientific Review Staff in the Office of Therapeutic Biologics and Biosimilars in CDER. Her work focuses on the scientific and regulatory review of biotechnology-derived therapeutic proteins and has made major contributions to FDA guidance and standards development for biosimilars and other protein therapeutics. Dr. Ricci leads a multidisciplinary team of scientists, clinicians, pharmacists, and project managers who oversee the review of biosimilar and interchangeable products at all stages of development and who advance biosimilar policy and scientific standards development through regulatory scientific research activities, facilitating scientific dialogue and stakeholder engagement, and providing educational and training opportunities.

Kimberly Maxfield, PhD

BsUFA Regulatory Science Program Coordinator
Office of Therapeutic Biologics and Biosimilars (OTBB) | Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Kimberly is a pharmacologist who focuses on the intersection between public health, drug development, policy, and regulation of therapeutic proteins. She is currently serving as the scientific lead in the FDA Office of Therapeutic Biologics and Biosimilars (OTBB) for the BsUFA III regulatory research pilot program. Prior to OTBB, Kimberly served as a 'guidance and policy lead' in the FDA Office of Clinical Pharmacology (OCP) where she led the CDER Immunogenicity Review Committee (IRC), a forum for defining multidisciplinary approaches to immunogenicity risk assessments. Kimberly received her PhD in Pharmacology from the University of North Carolina at Chapel Hill. Her doctorate focused on the systematic dissection of tumor cell biology through pan-genomic high throughput screening for the rational design of new therapeutic and dose combinations. She completed two post-doctoral fellowships at the National Academies of Sciences, Engineering, and Medicine (NASEM) and the FDA in health policy and regulatory science, respectively.

Elizabeth Thompson, MS

Chief, Project Management Staff
Division of Regulatory Operations for Nonprescription Drugs (DRO-NPD) | Office of Regulatory Operations (ORO)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Elizabeth (Beth) Thompson is the Chief Project Manager in the Division of Nonprescription Drugs 2 in the Office of Regulatory Operations (ORO) in FDA's Center for Drug Evaluation and Research (CDER). Beth Thompson joined the FDA in 2004 in the Division of Antiviral Products as a Regulatory Project Manager and then as the Chief Project Manager from 2012 until she joined the Division of Nonprescription Drugs in 2020. Beth received a BS in Microbiology from the University of Florida in 1992, and a MS in Biomedical Sciences from Hood College in 2005. She served in the U.S. Army from 1993-1999 where she worked on poxviruses and vaccine development for Ebola virus. She also served in the U.S. Public Health Service from 2006-2022 while working for the FDA.

Jessica Bernhardt, MS
AdminApps Program Manager, ESG Program Manager
Office of Information Management & Technology (OIMT)
Office of Digital Transformation (ODT)
Office of the Commissioner (OC)| US 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 dvelopment 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 husband and our 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.

Jonathon Resnick
Project Management Officer
Division of Data Management Services & Solutions (DDMSS) | Office of Business Informatics (OBI)
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.

Heather Crandall
Operations Research Analyst
Division of Data Management Services & Solutions (DDMSS) | Office of Business Informatics (OBI)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

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.

Hao (Ray) Wang
Director
Data Standards Staff (DSS) | Office of Strategic Programs (OSP)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Ray Wang serves as the Data Standards Staff Director within CDER's Office of Strategic Programs. In this role, he is responsible for managing CDER's Data Standards Program portfolio, which encompasses a range of projects related to the evaluation, development, and implementation of standards for various data domains such as Study Data, Quality Data, and Real-World Data initiatives, among others. The focus of the Data Standards Program is aimed at driving greater consistency and efficiency in submission data for regulatory review.

Andrew Potter
Mathematical Statistician
Division of Biometrics I (DBI) | Office of Biostatistics (OB) | Office of Translational Sciences (OTS)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Andrew Potter is a mathematical statistician in the Division of Biometrics I at the Center for Drug Evaluation and Research of the US Food and Drug Administration, supporting the review work in the Division of Psychiatry. He also leads digital health technology initiatives in the Office of Biostatistics at CDER. His research interests include the use of digital health technologies in clinical trials and the analysis of high-frequency outcome data. He is involved in FDA working groups on this topic.

Mary Ann Slack
Director
Office of Strategic Programs (OSP)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Mary Ann Slack serves as Director of CDER's Office of Strategic Programs (OSP). OSP plays a lead role in many of the center's strategic initiatives and modernization efforts, including development of benefit-risk and other decision support tools, data standardization, lean process management, program analysis, informatics, capacity planning, and major user fee negotiations. OSP leads implementation of CDER's business informatics governance function in support of business modernization objectives.

Since joining CDER in 2003, Ms. Slack has led numerous large, complex initiatives with broad stakeholder impact. She established and led CDER's data standards program, co-chairs FDA's Data Standards Advisory Board, and represents FDA's needs on HL7's.

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.

LaShawn Schnupp, PharmD
Senior Regulatory Health Project Manager
STAR Program Manager
Program Development, Implementation and Management Staff (PDIMS)
Office of Program Operations (OPO) | Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

LaShawn Schnupp is a Senior Regulatory Health Project Manager within the Center for Drug Evaluation and Research (CDER) Office of New Drugs (OND) in the Office of Program Operations (OPO) as a member of the Program Development, Implementation, and Management Staff (PDIMS). She has worked at the FDA since 2015 and is currently serving as the Program Manager for the Split Real Time Application Review (STAR) Pilot Program. She earned her Doctor of Pharmacy degree from the University of Maryland School of Pharmacy.

J. Paul Phillips, MS
Director
Office of Program Operations (OPO) | Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Mr. Phillips is the director of the Office of Program Operations (OPO) within the Office of New Drugs (OND) at FDA's Center for Drug Evaluation and Research. He began his career at FDA in 2008 as a project manager in an OND review division and has held various responsibilities and leadership positions since that time. Mr. Phillips was part of the FDA team that negotiated the PDUFA VII commitments as well as the FDA team that negotiated the BsUFA III commitments. He was responsible for overseeing the implementation of the new PDUFA VII programs in OND. Mr. Phillips received a bachelor's in biology from the University of Utah and a Master's in Bioscience and Regulatory Affairs from Johns Hopkins University. He also holds a certificate in Patient and Product Safety from The University of Southern California, as well as a certificate in Operations Management from Cornell University.

Lolita Sterrett, PharmD
Associate Director for Human Factors
Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM) | Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Lolita Sterrett is currently the Associate Director for Human Factors in the Division of Medication Error Prevention and Analysis2 in CDER's Office of Surveillance and Epidemiology (OSE). Dr. Sterrett joined the FDA as a Safety Evaluator in 2014 where she contributed to the review of new drug products, proposed proprietary drug names, container labels and other labeling, packaging, product design, and human factors submissions to prevent medication errors. In 2016, Dr. Sterrett moved to a Team Lead position over the newly formed DMEPA Human Factors Team. In 2019, as the team grew, Dr. Sterrett advanced to the Associate Director for Human Factors overseeing the human factors team. Dr. Sterrett received her Doctor of Pharmacy from Howard University College of Pharmacy in 1999. She completed her pharmacy residency at the Children's National Medical Center in Washington, DC. Since then, she has worked in Clinical Pharmacy, Ambulatory Care Pharmacy and Pharmacy Informatics.

Elizabeth L. Kunkoski
Health Science Policy Analyst
Clinical Methodologies
Office of Medical Policy (OMP)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Beth Kunkoski currently works in the FDA's Center for Drug Evaluation and Research (CDER), Office of Medical Policy (OMP). She oversees several projects involving digital health technologies and electronic records and storage in clinical investigations. She worked for 15 years in the Center for Devices and Radiological Health (CDRH) in guidance document development and as a branch chief overseeing the review of orthopedic devices. She earned a master's degree in biomedical engineering and a bachelor's degree in chemical engineering from the University of Michigan.

Kimberly Smith, MD
CAPT, USPHS
Real-World Evidence (RWE) Analytics
Office of Medical Policy (OMP)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Kimberly Smith is a nephrologist with the Real-World Evidence Analytics team in the Office of Medical Policy (OMP), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). In her current role, she develops and implements programs and policies related to the use of real-world evidence in drug development. Prior to her current role, Dr. Smith served at FDA as team leader for the Division of Clinical Trial Quality in OMP and as the nephrology team leader in the Division of Cardiology and Nephrology in CDER's Office of New Drugs. Before joining the FDA, she was with the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services.

Kathy Weil
Senior Science Policy Analyst and CDER's PMR/PMC Program Manager
Safety Policy Research and Initiatives Team (SPiRIT)
Immediate Office | Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Kathy Weil has been part of Center for Drug Evaluation and Research's (CDER) PMR/PMC Program and the Safety Policy Research and Initiatives Team (SPiRIT) since January 2017. She manages the PMR/PMC Program which includes responding to policy and process questions and Congressional inquiries, reviewing and clearing PMR/PMC-related letters, drafting new and updating current guidances, Manuals of Policies and Procedures (MAPPs), and Standard Operating Procedures (SOPs); providing training throughout the Center; drafting and clearing annual reports, OIG/GAO reports, and reports to Congress; overseeing the quarterly updates to the public and various data quality management processes. Most recently, Ms. Weil was the chair of the PDUFA VII PMR Commitments workgroup and implementation and participates on various workgroups related to new and current policies and processes.

In 2006, she started working in the Center for Devices and Radiological Health (CDRH) analyzing adverse event reports and then became a branch chief in the Office of Compliance, Bioresearch Monitoring division. In 2014, she moved to CDER's Office of Surveillance and Epidemiology (OSE). Ms. Weil has a Bachelor of Sciences in Nursing and a master's in applied communication. She has practiced clinically in hospitals (mostly ERs and ICUs), was a managing editor at a major medical publishing company, coordinated research studies in an academic environment, and was a nurse educator and project manager for a major healthcare company in Maryland.

Helen K. Edelberg, MD, MPH, FACP
Deputy Director of Safety
Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Dr. Helen Edelberg joined the Office of New Drugs (OND) in the US Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER) in 2021, after a career of more than 20 years in the pharmaceutical industry, having held many senior leadership positions in safety and in quality system management. As Deputy Director for Safety in the Immediate Office, Helen is focused on helping FDA to further develop its postmarket safety approach within OND, integrating efforts in OND with the evolving CDER-wide postmarket safety efforts and leading implementation of the New Drugs Regulatory Program (NDRP) postmarket safety modernization workstream. Helen oversees the OND Safety, Policy, Research, and Initiatives Team, works closely with the OND Deputy Directors for Safety and Safety Regulatory Program Managers, and closely collaborates with other CDER superoffices, especially with colleagues in the Office of Surveillance and Epidemiology (OSE) and the CDER postmarket safety group. Helen graduated from the University of Michigan with a degree in philosophy and received her medical degree from McGill University. She completed her training in internal medicine at Beth Israel Hospital in the Harvard medical system. After her fellowship in geriatrics and gerontology at the Harvard Division on Aging, she joined the faculty at Harvard Medical School/Beth Israel Deaconess Medical Center in Internal Medicine and Geriatrics. In 1999, Helen joined the faculty of Mount Sinai School of Medicine as an assistant professor of medicine. During her time in New York, Helen obtained a Master of Public Health (MPH) degree in health policy and management at Columbia University. She is a Fellow of the American College of Physicians.

Kerry Jo Lee, MD
Associate Director for Rare Diseases
Rare Diseases Team
Division of Rare Diseases and Medical Genetics (DRDMG)
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORDPURM) | Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Kerry Jo Lee, MD, is currently the acting Associate Director for Rare Diseases in the Division of Rare Diseases and Medical Genetics, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER). Dr. Lee joined the FDA as a medical officer in 2014 with the former the Division of Gastroenterology and Inborn Errors Products, OND, CDER, where she led and contributed to external efforts and publications to advance drug development in pediatric gastrointestinal disease in the areas of inflammatory bowel disease and biologic therapy, pediatric trial design, and the expedition of pediatric drug development. Dr. Lee then moved to a position as a clinical advisor for the Office of New Drug Policy, CDER, where she served as a lead in the areas of benefit-risk assessment, modernization efforts (including the Integrated Assessment), and real-world data/evidence programming.

Dr. Lee is a graduate of Princeton University and the New York University School of Medicine with an honors degree conferred in microbiology. She completed her residency in pediatrics at the Children's Hospital of Los Angeles followed by a post-doctoral clinical fellowship in Pediatric Gastroenterology, Hepatology, and Nutrition at Columbia University College of Physicians and Surgeons in New York. She completed published research involving the microbiome and viral pathogens from her time at the Center for Infection and Immunity of Columbia University Medical Center. Dr. Lee also maintains a steadfast interest in international policy and bioethics and worked for several years at the National Bioethics Advisory Commission on reports advising the executive branch on ethical and policy issues in both international and domestic clinical trials as well as interning at the World Health Organization.

Paresma Patel, PhD
Division Director
Division of New Drug API (DNDAPI) | Office of New Drug Products (ONDP) | Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Paresma Patel, PhD is a Division Director for the Division of New Drug API in CDER's Office of New Drug Products, Office of Pharmaceutical Quality. She started at the FDA in 2015 as a review chemist supporting the oncology divisions. She has worked across multiple clinical divisions as a drug substance and drug product chemistry, manufacturing, and controls (CMC) reviewer and served as a Quality Lead for two years prior to transitioning to a role as Branch Chief in 2021. Prior to FDA, she worked as a medicinal chemist at the National Institutes of Health with a focus on target validation and lead optimization of small molecule kinase inhibitors. Dr. Patel completed her Ph.D. in organic chemistry at The Scripps Research Institute in 2010 and completed a postdoctoral fellowship at the California Institute of Technology in 2012.

Doris Chin, RPh
Consumer Safety Officer
Incidents, Recalls and Shortages Branch (IRSB) | Division of Supply Chain Integrity (DSCI)
Office of Drug Security, Integrity, and Response (ODSIR) | Office of Compliance (OC)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Doris Chin has been with the FDA since 2009, working in CDER's Office of Compliance, Recalls and Shortages Team. She currently focuses on classifying recalls and providing recall strategy guidance to firms through the Office of Regulatory Affairs, Division of Pharmaceutical Quality Operations. She also coordinates responses within OC related to shortages which may include regulatory discretion review of proposals if a market action will cause or exacerbate a drug shortage.

Joel Welch, PhD
Associate Director for Science & Biosimilar Strategy
Chair for Emerging Technology Team
Office of Biotechnology Products (OBP) | Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Joel Welch is the Associate Director for Science and Biosimilar Strategy in the Office of Biotechnology Products in the Office of Pharmaceutical Quality at the US Food and Drug Administration. He assessed complex or precedent-setting issues impacting science policies of the office with particular emphasis on the biosimilar program. He also serves as the Rapporteur for The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) revision to Q5A(R1) and the Chair for the Emerging Technology Team. He previously served as a Review Chief, regulatory project manager, product quality reviewer, and a product quality team leader. He received a B.S. in Chemistry from the University of Kansas in 1999, and a Ph.D. in bioinorganic chemistry in 2004 from the University of Iowa. Prior to joining FDA in 2010, he spent six years in the industry supporting analytical development.

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

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

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

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

Day Three CDRH Session Speakers

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

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 he has 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 29-year FDA career in 1994 and devoted the next 17 years in what is now the Office of Product Evaluation and Quality (OPEQ), responsible for scientific regulatory review and policy development for a diverse range of medical device programs, such as 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 such as 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 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.

Kendra Holter, MSN, RN
Consumer Safety Officer
Premarket Programs Branch
Division of Industry and Consumer Education (DICE) | Office of Communication and Education (OCE)
Center for Devices and Radiological Health (CDRH) | Food and Drug Administration (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 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.

Jennifer Goode
Biocompatibility Program Advisor
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiologic Health (CDRH) | Food and Drug Administration (FDA)

Jennifer L. Goode has served as the Biocompatibility Program Advisor for OPEQ (formerly ODE) since 2015, and most recently has been providing biocompatibility technical and regulatory policy input for the ASCA Biocompatibility Testing Laboratory Accreditation process. Ms. Goode began her career at CDRH in 1994, as a premarket reviewer responsible for the review of medical devices and combination products for obstetrics and gynecology treatment, and surgical and interventional treatment of the peripheral vasculature, as well as cardiac monitoring, pacing, and neurology devices.

Beginning in 2007, Ms. Goode served as an FDA liaison to and International Expert for several ISO Working Groups responsible for the development of international standards for the biocompatibility evaluation of medical devices, including ISO 10993-1, ISO 10993-4, and ISO 10993-18. Since 2017, Ms. Goode has represented CDRH on the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), a committee responsible for coordination of review and acceptance of fit for purpose new or revised toxicology test methods that reduce, refine, or replace the use of animals. In 2018, Ms. Goode was selected as FDA's Alternate Agency Representative to ICCVAM. Since 2018, Ms. Goode has also served as the CDRH regulatory expert for the USP Biocompatibility Expert Panel tasked with revision of General Chapters <87>, <88>, and <1031>, and in 2020, she was identified as an expert government liaison to USP's Packaging Expert Committee. Since 2018, Ms. Goode has also served as the regulatory co-chair for the US AAMI Biological Evaluation (BE) mirror committee to ISO/TC 194. The AAMI/BE committee is responsible for coordinating US positions on all ISO standards related to biocompatibility evaluation of medical devices. Since 2008, Ms. Goode has also served as one of two OPEQ representatives to the Biocompatibility Standards Task Group (STG) at CDRH. This Biocompatibility STG is responsible for coordinating FDA input to, and scientific review and recognition of all biocompatibility standards used by CDRH.

Jennifer earned a Bachelor of Science in Biomedical Engineering from Boston University.

Scott A. Colburn
Director
Standards and Conformity Assessment Program | Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health (CDRH) | Food and Drug Administration (FDA)

Scott A. Colburn is the Director of the Standards and Conformity Assessment Program at CDRH's Office of Strategic Partnerships and Technology Innovation (OST). In this role, Scott is responsible for the CDRH standards recognition and related development activities in over 600 national and international consensus standards committees. In addition, Scott oversees the program's new Accreditation Scheme for Conformity Assessment (ASCA) Pilot program and CDRH's efforts to optimize standards for regulatory use within the International Medical Device Regulators Forum.

Scott has served in numerous roles in premarket review and voluntary consensus standards development and implementation for medical devices. He is a member of many national and international standards organizations and serves on several policy and leadership committees.

Scott earned his BSN from Marquette University in 1999 and a Master of Science in Biomedical Technology Development and Management from Georgetown University and Virginia Polytechnic Institute and State University. Scott recently retired from active duty after 23 years of service with the US Army and US Public Health Service Commissioned Corps.

Andrew Sprau
Consumer Safety Officer
Premarket Programs Branch
Division of Industry and Consumer Education (DICE) | Office of Communication and Education (OCE)
Center of Devices and Radiological Health (CDRH) | Food and Drug Administration (FDA)

Andrew Sprau is currently a Consumer Safety Officer in the Division of Industry and Consumer Education (DICE) in CDRH's Office of Communication and Education (OCE). Previously, he was a Medical Device Lead Reviewer in the Office of Product Evaluation and Quality (OPEQ), Division of Health Technology (DHT3A) Obesity and Hepatobiliary Devices Team (THT3A3). He has experience and expertise in the review of 510(k)s, IDEs, Q-Submissions, 513(g)s and recalls. He joined the FDA in August of 2020. Prior to joining the FDA, he was with the Centers for Medicare and Medicaid Services for 4 years in the Office of Information Technology. Additionally, he was a Clinical Research Coordinator at Washington University in St. Louis with the Bone Marrow Transplant Team. He obtained a Bachelor of Science in Physiology from Michigan State University and his Master of Science. in Cellular Metabolism and Molecular Nutrition from the University of Chicago.

Nelson Anderson, B.S.
Platform Owner, CDRH Portal
Division of Regulatory Systems, Tools, and Data Management | Office of Regulatory Programs (ORP)
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH) | Food and Drug Administration (FDA)

Nelson Anderson is a Biomedical Engineer and the Information Technology (IT) Product Owner in CDRH's Office of Product Evaluation and Quality (OPEQ), Office of Regulatory Programs (ORP), Division of Regulatory Systems, Tools, and Data Management (also known as Division of Regulatory Programs 4 [DRP 4]). Prior to this role, he was a lead reviewer in CDRH for cardiovascular devices for 13 years before moving into the IT realm 7 years ago and is now the platform owner for the CDRH Portal, among other IT duties. Nelson has been with the Food and Drug Administration for approximately 20 years. He received a Bachelor of Science in Biomedical Engineering from Tulane University.

Jason Brookbank
Assistant Division Director
Division of Financial Management | Office of Management (OM)
Center for Devices and Radiologic Health (CDRH) | Food and Drug Administration (FDA)

Jason Brookbank is the Assistant Division Director, Division of Financial Management, Office of Management (OM), FDA, Center for Devices and Radiologic Health (CDRH). In this role over the past 9 years, he has served as a leader and Assistant Director in managing and overseeing CDRH's financial accountability including the Reduced Medical Device User Fees: Small Business Determination (SBD) Program. He joined the FDA approximately 16 years ago, initially in the Office of Compliance (OC) as a Consumer Safety Officer before transitioning over to, and helping establish, CDRH's Emergency Preparedness/Operations and Medical Countermeasures (EMCM) program. Prior to joining the FDA, he worked for a biomedical test equipment manufacturer and had his own design and consulting company. Jason earned a bachelor's degree in biomedical engineering from Wright State University and a Graduate Certificate in Biohazardous Threat Agents and Emerging Infectious Disease from Georgetown 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) | Food and Drug Administration (FDA)

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 17-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 29 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.

Ruth Bediakoh
Consumer Safety Officer
Postmarket and Consumer Branch
Division of Industry and Consumer Education (DICE) | Office of Communication and Education (OCE)
Center for Devices and Radiological Health (CDRH) | Food and Drug Administration (FDA)

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.

Tonya A. Wilbon
Branch Chief
Postmarket and Consumer Branch
Division of Industry and Consumer Education (DICE) | Office of Communication and Education (OCE)
Center for Devices and Radiological Health (CDRH) | Food and Drug Administration (FDA)

Tonya A. Wilbon is the Branch Chief for the Postmarket and Consumer Branch, Division of Industry and Consumer Education (DICE), in CDRH's Office of Communication and Education. 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 23 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 (now known as the Office of Health Technology 7 or OHT7 in the Office of Product Evaluation and Quality) and served as the Quality System Specialist in that Office.

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).

Day Four CDRH Session Speakers

Joseph Tartal

Deputy Director
Division of Industry and Consumer Education (DICE) | Office of Communication and Education (OCE)
Center for Devices and Radiological Health (CDRH) | Food and Drug Administration (FDA)

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 17-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 29 years of experience in the medical device industry, including premarket submissions. Mr. Tartal received a Bachelor Degree in Biology from Pennsylvania's Slippery Rock University.

Alexej Gossmann, PhD

Staff Fellow
Division of Imaging, Diagnostics, and Software Reliability (DIDSR) | Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH) | Food and Drug Administration (FDA)

Alexej Gossmann is a Staff Fellow in the Division of Imaging, Diagnostics, and Software Reliability (DIDSR) at CDRH's Office of Science and Engineering Laboratories, where he splits his time evenly between regulatory science research and regulatory review of device submissions with an artificial intelligence (AI) or machine learning (ML) component. His current research interest is in topics adjacent to performance evaluation of medical AI/ML algorithms with many peer-reviewed publications in prominent journals and venues. At DIDSR, Alexej is coordinating the Fundamental AI research subprogram. Alexej received his PhD degree in 2018 from the interdisciplinary Bioinnovation Program at Tulane University, New Orleans, LA, coming from a prior background in mathematics and statistics.

Laurel Burk, PhD

Director
Division of Radiological Imaging Devices and Electronic Products
Office of Radiological Health (Office of Health Technology 8) | Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH) | Food and Drug Administration (FDA)

Laurel Burk is the Division Director of the Division of Radiological Imaging Devices and Electronic Products in the Office of Radiological Health (also known as the Office of Health Technology 8) in CDRH's Office of Product Evaluation and Quality (OPEQ). Laurel joined CDRH in 2014 as a lead reviewer of diagnostic x-ray devices and later served as the Assistant Director of the Diagnostic X-ray Systems Team. With a background in computed tomography (CT), her professional interests include artificial intelligence (AI)/machine learning (ML) software device applications in radiology, radiation safety in pediatric x-ray imaging, and CT reconstruction methods. Prior to joining CDRH in 2014, Laurel earned her Ph.D. in Physics from the University of North Carolina at Chapel Hill, where she specialized in the development and preclinical evaluation of novel micro-CT technology.

Yvette Montes
Consumer Safety Officer
Imports and Registration and Listing Team (IRLT) | Division of Regulatory Programs 2 (DRP2)
Office of Regulatory Programs (ORP) | Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH) | Food and Drug Administration (FDA)

Yvette Montes is a Consumer Safety Officer within the Office of Regulatory Programs, Division of Regulatory Programs 2, Imports and Registration & Listing Team (IRLT) in CDRH's Office of Product Evaluation and Quality (OPEQ). She has served the agency for fourteen years and has a vast knowledge in import operations specializing in medical devices and radiological health products.

Ms. Montes started her career with the FDA in 2009 in the Division of Southwest Imports (DSWI), in 2015 she moved to the Division of Import Operations (DIO) Import Operations Branch (IOB) and recently, she started a new career chapter in the Center.

Ms. Montes has played an integral role in FDA operational activities with different partner governing agency's (PGA) such as Customs and Border Protection (CBP), Homeland Security Investigations (HIS), 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. Ms. Montes is recognized as a subject matter expert in the importation of medical devices and radiological health products.

Ms. Montes earned her Bachelor of Science in Microbiology with a minor in Chemistry and Biochemistry from New Mexico State University and a Post bachelor's degree in Cytogenetics from the University of Texas Health Science Center at San Antonio.

William Chang, MBA, PE
Lieutenant Commander, US Public Health Service
Office of Medical Device and Radiological Health Operations (OMDRHO)/Division 1 - East
Office of Regulatory Affairs (ORA) | Food and Drug Administration (FDA)

William Chang is a Medical Device Specialist in the FDA Office of Medical Device and Radiological Health Operations and has been an officer in the US Public Health Service Commissioned Corp for the past 5 years. Lieutenant Commander Chang performs inspections and investigations in the field for the New Jersey District. He previously worked in industry as an engineer in research, development, and manufacturing, where he has earned two United States Patents. He obtained his master's in business administration and Bachelor of Science in biomedical engineering, both from Rutgers University. He is also a licensed professional engineer in the state of Maryland.

Day Four CBER Session Speakers

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, Center for Biologics Evaluation and Research, Food and Drug Administration. Dr. Lapteva is a physician with long-standing experience in clinical research with novel drugs and biological products, including cell and gene therapies. Prior to her work at 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.

Mara Miller, MA

Division Director
Division of Review Management and Regulatory Review 2 | Office of Review Management and Regulatory Review
Office of Therapeutic Products (OTP)
Center for Biologics Evaluation and Research (CBER) | Food and Drug Administration (FDA)

Mara Miller is the acting Division Director in the Office of Review Management and Regulatory Review (ORMRR) in the Office of Therapeutic Products (OTP) in FDA's Center for Biologics Evaluation and Research. She joined OTP in 2019 as the Associate Director within the Division of Regulatory Project Management. In 2011, Ms. Miller joined the FDA in the Division of Hematology Products within Office of New Drugs in CDER as a Regulatory Health Project Manager and served as the Lead Regulatory Health Project Manager from 2015 to 2019. From 2019- 2021, prior to joining OTP, Ms. Miller served as the Product Specific Guidance (PSG) Program Manager within the Office of Generic Products (OGD) in CDER. For 11 years prior to coming to the FDA, Ms. Miller worked in data management and clinical trials in hospital settings and Contract Research Organizations. She has a master's degree from UNC-Chapel Hill and a BS degree from Indiana University.

Adrienne Hornatko-Munoz, RAC-US

Senior Project Manager
Office of the Regulatory Operations (ORO)
Center for Biologics Evaluation and Research (CBER) | Food and Drug Administration (FDA)

Adrienne Hornatko-Munoz is a Senior Project Manager in the Office of Regulatory Affairs (ORO) in the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA). Adrienne serves as the Senior Advisor for Pediatric Regulatory Review for the Center and the Project Manager for CBER's Pediatrics Working Group. She is a voting member of the FDA Pediatric Review Committee (PeRC), and liaison between CBER and the Office of Pediatric Therapeutics for the coordination of all CBER products going before the FDA Pediatric Advisory Committee (PAC).

Adrienne began her FDA career in CBER in 2002, as the one of the Center's first "bioterrorism hires" after 9-11 due to her experience as a DoD-contractor on the Anthrax Vaccine Immunization Program. In her first position, she worked in the Consumer Affairs Branch (OCOD) responding to public inquiries. Adrienne went to serve as Branch Chief for Manufacturers Assistance and Technical Training Branch (MATTB) in OCOD, as well as Special Assistant to CBER's former Deputy Director for Operations.

Adrienne received her degree in Animal Science from the University of Maryland at College Park. In her years after college, and a brief stint in vet school across the pond, she managed 2 university- based animal research facilities in the

Baltimore-Washington area as well as a private primate toxicology facility. She holds a US Regulatory Affairs certification (RAC) as well as a master's Certificate in Project Management.

Ernesto F. Moreira, MD
Biologist
Pharmacology/Toxicology Branch I
Office of Pharmacology/Toxicology Office of Therapeutic Products
Center for Biologics Evaluation and Research (CBER) | Food and Drug Administration (FDA)

Dr. Moreira is a Pharmacology/Toxicology reviewer in the Office of Pharmacology/Toxicology, Office of Therapeutic Products in CBER. Prior to his FDA appointment, Dr. Moreira was an Assistant Professor of Ophthalmology at the Medical University of South Carolina, where he studied the molecular and cellular mechanisms involved in the pathogenesis of age-related macular degeneration, the leading cause of blindness in individuals over 60 years of age in the U.S. Prior to that, he performed postdoctoral training in Cellular, Molecular, and Developmental Biology at the National Eye Institute, NIH and the Wilmer Eye Institute, Department of Ophthalmology, Johns Hopkins University School of Medicine. Dr. Moreira is a graduate of the University of Buenos Aires, School of Medicine, Argentina.

Gregory Conway, PhD, MA
Biological Reviewer
Office of Pharmacology and Toxicology (OPT) | Office of Therapeutic Products (OTP)
Center for Biologic Evaluation and Research (CBER) | Food and Drug Administration (FDA)

Dr. Gregory Conway is a Biological Reviewer in the Office of Pharmacology and Toxicology (OPT), Office of Therapeutic Products (OTP) in FDA's Center for Biologic Evaluation and Research (CBER). Prior to joining FDA in 2022, Dr. Conway worked as a Scientist in the Manufacturing Science and Technology Department at American Type Culture Collection (ATCC). Dr. Conway completed post-doctoral training at Fox Chase Cancer Center in Philadelphia where he was a NIH T32 trainee in Cancer Biology. Dr. Conway received a BA in Biochemistry and Molecular Biology from Boston University, an MA in Pharmacology and Toxicology from SUNY Buffalo, and a PhD in Molecular Medicine from the University of Maryland, Baltimore. He has prior research experience in ovarian cancer, homologous recombination, protease biology, and stem cell biology.

Shelby Elenburg, MD
Medical Officer
Division of Clinical Evaluation General Medicine (DCEGM)
Office of Therapeutic Products (OTP)
Center for Biologics Evaluation and Research (CBER) | Food and Drug Administration (FDA)

Dr. Shelby Elenburg is a medical officer in the Office of Therapeutic Products (OTP) in FDA's Center for Biologics Evaluation and Research (CBER). Prior to joining FDA in 2021, Dr. Elenburg was in Allergy/Immunology clinical practice in Maryland and DC for 6 years. Dr. Elenburg received a BS in Psychology from The Ohio State University in 2006 and an MD from University of Cincinnati College of Medicine in 2010. She completed her pediatric residency at Phoenix Children's Hospital in 2013 and her fellowship in Allergy/Immunology at The University of Tennessee Health Science Center in 2015. She is Board Certified in Pediatrics and Allergy/Immunology. Her primary work is in the clinical review of cell and gene therapy products for rare diseases; she also participates in several policy and regulatory science working groups and committees across the FDA. She has presented at an FDA Cellular Tissues and Gene Therapies Advisory Committee (CTGTAC) meeting in 2022 and at the American Society for Gene and Cell Therapies (ASGCT) Annual Meeting in 2023.

Day Five CBER Session Speakers

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, Center for Biologics Evaluation and Research, Food and Drug Administration. Dr. Lapteva is a physician with long-standing experience in clinical research with novel drugs and biological products, including cell and gene therapies. Prior to her work at 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.

Ramjay Vatsan Ph.D., CQA

Associate Director for Policy
Office of Gene Therapy | Office of Therapeutic Products (OTP)
Center for Biologics Evaluation and Research (CBER) | Food and Drug Administration (FDA)

Dr. Ramjay Vatsan is an Associate Director for Policy in the Office of Gene Therapy, OTP in CBER/FDA. He joined CBER in 2006 and served as a Team leader in the Gene Therapy Branch, Acting Branch Chief in the Cell Therapy Branch before taking up his current position. Prior to joining FDA, he had worked in basic and translational research at National Cancer Institute/NIH and Washington University in St. Louis. Dr. Vatsan has extensive research experience in viral and bacterial vector development, gene delivery and cancer immunotherapy. Dr. Vatsan is an expert in the CMC aspects of Cell and Gene Therapy and has co-authored several regulatory articles and CMC guidance documents. Dr. Vatsan is an ASQ Certified Quality Auditor and a full-time CMC Master Reviewer at FDA.

Wen (Aaron) Seeto, PhD

Staff Fellow
Tissue Engineering Branch 2, Division of Cell Therapy 2
Office of Cellular Therapy & Human Tissue CMC (OCTHT) | Office of Therapeutic Products (OTP)
Center for Biologics Evaluation and Research (CBER) | Food and Drug Administration (FDA)

Dr. Wen (Aaron) Seeto is a cell therapy CMC reviewer in the Office of Therapeutic Products (OTP) in FDA's Center for Biologics Evaluation and Research (CBER). Dr. Seeto obtained his PhD in Chemical Engineering at Auburn University with a research focus in cell-biomaterial interaction. Prior to joining the FDA, he worked as a Research Scientist at the Marcus Center for Cell Characterization and Manufacturing (MC3M) in Georgia Institute of Technology researching on therapeutic cell characterization for predictive clinical application and improvement of therapeutic cell manufacturing. In 2018 he joined FDA's Office of Tissues and Advanced Therapies, now OTP, and has reviewed a wide variety of tissue engineered products, cell-based therapy products, including stem/somatic cell, extracellular vesicle, and lyophilized tissue products.

Matthew Klinker, PhD
Biologist/CMC Reviewer
Cell Therapy Branch 2 (CTB2)
Office of Cell Therapy and Human Tissue (OCTHT) Office of Therapeutic Products (OTP)
Center for Biologics Evaluation and Research (CBER) | US Food & Drug Administration (FDA)

Dr. Matthew Klinker is a cell therapy product reviewer in the Office of Therapeutic Products (OTP) in FDA's Center for Biologics Evaluation and Research (CBER). Dr. Klinker joined the FDA in 2014 as a postdoctoral fellow in CBER's Division of Cellular and Gene Therapy, where his research focused on developing potency assays and new approaches for cell-based product characterization. He became a product reviewer in 2018 and has since reviewed regulatory submissions for a diverse array of cell and gene therapy products throughout the product development lifecycle. Prior to joining the FDA, he completed graduate studies at the University of Michigan, receiving a PhD in Immunology in 2013 for his work on cellular immunomodulatory mechanisms in autoimmune disorders. Dr. Klinker has represented FDA at liaison meetings, public workshops, and panel discussions, and routinely presents to industry stakeholders on topics related to development of cell and gene therapy products, including potency assay development and phase-specific manufacturing expectations.

John Scott, PhD, AM
Director
Division of Biostatistics (DB) | Office of Biostatistics and Pharmacovigilance (OBPV)
Center for Biologics Evaluation and Research (CBER) | Food and Drug Administration (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 and 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 the 21st Century Cures Act 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 ICH E20 expert working group on adaptive designs. 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.

Meghna Alimchandani, M.D.
Deputy Director
Division of Pharmacovigilance (DPV) | Office of Biostatistics and Pharmacovigilance (OBPV)

Center for Biologic Evaluation and Research (CBER) 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.

Dr. Alimchandani 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 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.

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Lei Xu, MD, PhD, serves as the Chief of General Medicine Brach 2 in the FDA's Division of Clinical Evaluation General Medicine (DCEGM) of Office of Clinical Evaluation (OCE), Office of Therapeutic Products (OTP) at Center for Biologics Evaluation and Research (CBER). Dr. Xu is responsible for overseeing the branch in review of clinical trial protocols, clinical trial conduct and evaluation of trial data with investigational biologics (e.g., gene therapy, cellular therapy and plasma-derived products) and devices in several therapeutic areas, including Neurology, Ophthalmology, Dermatology, and burn and wound care. Staff from Dr. Xu's branch reviewed the clinical data that led to the regulatory approval of the first two adeno-associated virus-based gene therapy products: voretigene neparvovec (Luxturna) for the treatment of retinal dystrophy due to RPE65 mutation, and onasemnogene abeparvovec (Zolgensma) for the treatment of spinal muscular atrophy. In addition to the regulatory responsibilities, Dr. Xu is actively involved in FDA guidance development, including the Guidance for Industry: Expedited Programs for Serious Conditions, Guidance for Industry: Human Gene Therapy for Retinal Disorders, and Guidance for Industry: Human Gene Therapy for Neurodegenerative Diseases.

Dr. Xu received her M.D. from Central South University Xiangya School of Medicine in China, and her Ph.D. in neuroscience from Yale University. She completed residency training in Neurology at Loyola University Chicago. She is board-certified in Neurology by the American Board of Psychiatry and Neurology.

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Wei Wang is a Microbiologist at Food and Drug Administration (FDA)/Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ), Division of Manufacturing and Product Quality (DMPQ). Wei has a B.A. and a M.A. in Engineering of Industrial Microbiology from South China Institute of Technology (Guangzhou, China) and a Ph.D. in Biology from New York University (New York, NY). Wei has performed regulatory review of different types of submissions, including Biologics License Applications (BLA) and Investigative New Drug (INDs), and conducted pre-license inspections and pre-approval inspections in support of the review BLA and prior-approval supplements.

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(See biography on above page)

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