SPEAKER BIOGRAPHIES

Keynote & Plenary Speakers

Janet Woodcock, MD
Acting Commissioner of Food and Drugs
Food and Drug Administration (FDA)

Janet Woodcock was named Acting Commissioner of Food and Drugs on January 20, 2021.

As Acting Commissioner, Dr. Woodcock oversees the full breadth of the FDA portfolio and execution of the Federal Food, Drug, and Cosmetic Act and other applicable laws. This includes assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices; the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation; and the regulation of tobacco products.

Dr. Woodcock began her FDA career in 1986, joining the agency's Center for Biologics Evaluation and Research (CBER) as Director of the Division of Biological Investigational New Drugs, as well as serving as CBER's Acting Deputy Director for a period of time. She later became Director of the Office of Therapeutics Research and Review in CBER, which included the approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis during her tenure.

In 1994, Dr. Woodcock was named Director of the FDA's Center for Drug Evaluation and Research (CDER), overseeing the center's work that is the world's gold standard for drug approval and safety. There she led many of the FDA's drug initiatives, including introducing the concept of risk management as a new approach to drug safety; modernizing drug manufacturing and regulation through the Pharmaceutical Quality for the 21st Century Initiative; advancing medical discoveries from the laboratory to consumers more efficiently under the Critical Path Initiative; and launching the Safety First and Safe Use initiatives designed to improve drug safety management within and outside the FDA, respectively.

In 2004, Dr. Woodcock became Deputy Commissioner and Chief Medical Officer in the Office of the Commissioner. Later she took on other executive leadership positions in the Commissioner's Office, including Deputy Commissioner for Operations and Chief Operating Officer.

In 2007, Dr. Woodcock returned as Director of CDER until she was asked to lend her expertise to "Operation Warp Speed" for developing therapeutics during the COVID-19 pandemic, such as evaluating the potential benefits of monoclonal antibody treatments for certain COVID-19 patients. From late 2020, she split her time advising "Operation Warp Speed" on advancing COVID-19 therapeutics while also serving as the Principal Medical Advisor to the Commissioner on key priorities on behalf of the Office of the Commissioner.
Dr. Woodcock holds a Bachelor of Science in chemistry from Bucknell University (Lewisburg, PA), and a Doctor of Medicine from the Feinberg School of Medicine at Northwestern University Medical School (Chicago). She also completed further training and a fellowship in rheumatology, as well as held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She is board certified in internal medicine.

Dr. Woodcock has been bestowed numerous honors over her distinguished public health career, most notably: a Lifetime Achievement Award in 2015 from the Institute for Safe Medication Practices; the Ellen V. Sigal Advocacy Leadership Award in 2016 from Friends of Cancer Research; the Florence Kelley Consumer Leadership Award in 2017

from the National Consumers League; and the 2019 Biotechnology Heritage Award from the Biotechnology Innovation Organization and Science History Institute.

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.

Jeffrey E. 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

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.

Center Drug Evaluation and Research (CDER) Speakers

Virginia L. Behr
Ombudsman
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

As the CDER Ombudsman since 2007, Virginia addresses questions and complaints from CDER-regulated industry and informally resolves disputes between those entities and CDER. She is an active Coalition of Federal Ombudsman member; she currently chairs the Mentoring Committee and served on its Executive Committee for three years. She mediates cases as a collateral duty for the federal government-wide Shared Neutrals program and FDA's Conflict Prevention and Resolution Program.

After a brief research position at the NIH and USUHS, Virginia started her FDA career as a regulatory project manager in CDER's Division of Antiviral Products in 1999, later becoming its Chief of Project Management Staff. She provided regulatory expertise for multi-disciplinary teams and supervised the management of Investigational New Drug Applications (IND), Biologic Licensing Applications (BLA), and New Drug Applications (NDA) for the treatment and/or prevention of HIV/AIDS, herpes, influenza, hepatitis, and other viruses.

Virginia earned her B.S. degree in psychology from Washington and Lee University. When off duty, Virginia explores new places near and far with her family, kayaks, flexes her creative side in the kitchen, and plays competitive volleyball.

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

Dr. Kevin Bugin is the acting 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 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.

John Concato, MD, MS, MPH
Associate Director of Real World Evidence Analytics (Acting)
Office of Medical Policy (OMP)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

John Concato is the Associate Director for Real-Word Evidence Analytics in the Office of Medical Policy (OMP) at the Center for Drug Evaluation and Research (CDER), US Food and Drug Administration. In seeking to enhance policies related to drug development and regulatory review in CDER, his responsibilities include serving as the Chair of RWE Subcommittee, supporting RWE guidance development and demonstration projects, interacting with external stakeholders regarding RWE, and developing internal Agency processes related to RWE. Prior to joining FDA in 2019, his career focused on generating research as an independent investigator and research center director at Yale University School of Medicine and the U.S. Department of Veterans Affairs (VA), including serving as one of two founding principal investigators of the VA Million Veteran Program. He received M.D. and M.S. degrees from New York University and an M.P.H. degree from Yale University.

Andrea Gormley, PharmD, JD, BCACP
Associate Director for Regulatory Affairs
Counterterrorism & Emergency Coordination Staff (CTEC)
Office of the Center Director (OCD)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Andrea Gormley serves as the Associate Director for Regulatory Affairs in FDA's Center for Drug Evaluation and Research, Counterterrorism and Emergency Coordination Staff, where she works on emergency response activities involving CDER-regulated products, facilitates the development of medical countermeasures under CDER's jurisdiction, and liaises with federal partners in the emergency preparedness and response space. She has spent the last year working on CDER's COVID-19 response, including facilitating access to investigational treatments and the issuance of EUAs in the drug and biologics space. Andrea is a Board-Certified Ambulatory Care Pharmacist. She holds a PharmD and JD from Ohio Northern University.

John Ibrahim, PharmD, BCPS
Associate Director for Regulatory Affairs
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

John Ibrahim is the Associate Director for Regulatory Affairs for the Office of Regulatory Operations in the Office of Generic Drugs. John received his Doctorate in Pharmacy from St. John's University in 2006 and became a Board-Certified Pharmacotherapy Specialist in 2014.

Prior to joining the FDA, John practiced in community pharmacy, clinical pharmacy in the hospice setting, and clinical pharmacy in the hospital setting.

Sevan Kolejian, PharmD, MBA, BCPPS
CDER Division of Medication Error Prevention and Analysis (DMEPA) Team Leader
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)

Sevan Kolejian has over 15 years of combined FDA and clinical pharmacy medication safety experience. Sevan is currently Team Leader in the FDA's Division of Medication Error Prevention and Analysis (DMEPA). In this role, she is responsible for leading and advising a team of medication safety evaluators about the pre- and post-marketing medication error prevention activities related to drug proprietary name, labels, labeling, human factors and product design and packaging. Dr. Kolejian received her undergraduate degree in Biochemistry & Molecular Biology from University of Maryland Baltimore County. She earned her Doctor of Pharmacy degree and Graduate Certificate of Aging Studies from Virginia Commonwealth University. Sevan has a Master of Business Administration (MBA) from Johns

Hopkins University and completed Executive Fellowship in Patient Safety at VCU Williamson Institute for Healthcare Leadership. She most recently completed the American Course on Drug Development and Regulatory Sciences certificate and the ASHP Medication Safety Certificate program in 2020. Prior to joining FDA in 2014, Sevan was a full time clinical pediatric pharmacist and medication safety facilitator at Johns Hopkins Hospital Children's Center.

Stephanie Kraus, JD
Senior Regulatory Counsel
Office of Regulatory Policy (ORP)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Stephanie Kraus is a Senior Regulatory Counsel in the Center for Drug Evaluation and Research's (CDER) Office of Regulatory Policy (ORP) at the Food and Drug Administration (FDA). She received her J.D. from Brooklyn Law School and her MPH from the Harvard T.H. Chan School of Public Health. In her position, Ms. Kraus leads ORP's work on clinical trials and drug development standards, real-world evidence, regulatory science research, and artificial intelligence. Ms. Kraus works on developing policy and regulatory standards and serves on several key steering committees at CDER, including the Real-World Evidence Subcommittee of the Medical Policy Program and Review Counsel, the Artificial Intelligence Steering Committee, the Research Governance Council, the Complex Innovative Trial Design Steering Committee, and the Model Informed Drug Development Steering Committee. Ms. Kraus also serves as one of the leads for ORP's COVID-19 pandemic response efforts, including policy development around the continuing conduct of clinical trials, development of therapeutics to treat or prevent COVID-19, and Emergency Use Authorizations.

Kristina J. Lauritsen, PhD
CDER Combination Products Regulatory Policy Advisor
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.

Alison Lyndaker
Operations Research Analyst, Resource Capacity Planning Staff
Office of Program and Strategic Analysis (OPSA)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Alison Lyndaker is the team lead for Resource Forecasting in the Office of Strategic Programs and Analysis (OPSA) in the Center for Drug Evaluation and Research (CDER) in the U.S. Food and Drug Administration (FDA). Alison oversees the reporting and communications for the CDER time reporting system and leads the Resource Forecasting team. Alison has 13 years of experience as a contractor and employee in the federal workforce with experience ranging from financial management systems to activity-based costing resource models.

Qi Liu, PhD, M.Stat, FCP
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Dr. Qi Liu has developed her scientific expertise through a combination of broad training in multiple scientific fields, industry experience, and her 15-year career at the FDA. She earned a B.S in Clinical Pharmacy and a Master's degree in Pharmaceutics from West China University of Medical Sciences. She obtained her Ph.D. in Pharmaceutics and a concurrent master's degree in Statistics from the University of Florida in 2004. After graduation, she worked as a senior PK scientist at Merck. In 2006, Dr. Liu joined FDA, working first as a reviewer and then as a team leader, in Division 5 (now the Divisions of Cancer Pharmacology) in OCP. During this period, she contributed to over 200 NDA/sNDA reviews, 20 BLA/sBLA reviews, and numerous IND reviews to support oncology drug development. In 2019, she joined OCP immediate office as a Senior Science Advisor. She helped developing OCP's capacity/portfolio on real world data/evidence, machine learning/artificial intelligence and digital biomarker/mobile health, collaborating with internal and external experts to help keep the Office and the Center stay abreast of current trends in innovative approaches. In 2021 she was named OCP's Associate Director for Innovation & Partnership. In her new position she will continue to lead OCP's innovative initiatives through strategic partnership.

Dr. Liu has co-authored about 50 manuscripts and presented on many topics at FDA Advisory Committee meetings and scientific conferences. She worked on several working groups for FDA guidance documents and Manual of Policies & Procedures (MAPP) development. She also leads OCP's Innovative Data Analytics program. Dr. Liu is a Fellow of the American College of Clinical Pharmacology. She is also on the editorial board of the American Association of Pharmaceutical Scientists Journal, Clinical Pharmacology and Therapeutics, and Clinical and Translational Science. Dr. Liu is interested in the application of clinical pharmacology principles, innovative tools (e.g., modeling/simulation, machine learning, digital health tools), big data and real-world evidence to facilitate drug development and advance precision medicine.

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.

Kelly Ngan, PharmD, MPH, CPH
CDR, USPHS
Project Management & Emergency Coordination Team Leader
Counterterrorism & Emergency Coordination Staff (CTEC)
Office of the Center Director (OCD)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

CDR Kelly Ngan holds a PharmD from the University of North Carolina - Chapel Hill and an MPH from the University of Minnesota – Twin Cities. Prior to focusing her career on public health, Dr. Ngan was an assistant professor of pharmacotherapy at the University of Maryland School of Pharmacy. She joined the FDA in 2009, working on post-

marketing safety activities, and she was commissioned into the U.S. Public Health Service Commissioned Corps in 2010. Since 2014, she has worked with CDER's Counter-Terrorism and Emergency Coordination Staff, which specializes in medical countermeasure drug development and public health emergency responses.

Jonathon Resnick
Project Management Officer
Cloud Collaboration Capability Team
Division of Data Management Services & Solutions
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 FDA since 2011. Prior to joining FDA, Jonathan spent 18 years working in IT project management supporting federal and private sector clients.

Seyoum Senay, MS
Supervisory Operations Research Analyst
Office of Business Informatics (OBI)
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.

Jacqueline Ware, PharmD
CAPT | USPHS
Deputy Director
Office of Regulatory Operations (ORO)
Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Jacqueline Ware, PharmD, is the Deputy Director of the newly formed Office of Regulatory Operations (ORO) in CDER's Office of New Drugs (OND). In partnership with ORO's Director, she is responsible for oversight of OND's regulatory review processes and regulatory project management (RPM) staff, who co-lead OND's regulatory review activities. Jackie has 25 years of senior regulatory project management experience, and currently serves/has served on many policy and process committees, including the group that established the first iteration of the 21st Century Review Guide. Before FDA, Jackie was a clinical pharmacist at Children's National Hospital and Texas Children's Hospital. She received her Doctor of Pharmacy degree from UNC-Chapel Hill.

Wendy Wilson-Lee, PhD
Division Director
Office of New Drug Products (ONDP)

Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Wendy Wilson-Lee, PhD is a Division Director in the Office of New Drug Products (ONDP), within CDER's Office of Pharmaceutical Quality (OPQ). She joined FDA in September 2006, after working as a formulation scientist in the pharmaceutical industry.

Dr. Wilson-Lee earned her Doctorate in Pharmaceutical Science at the University of Maryland – Baltimore under Dr. Larry Augsburger. She holds dual Bachelor of Science degrees in Chemical Engineering and Chemistry from North Carolina A&T State University. In addition to her academic honors, Wendy also is a graduate of the Partnership for Public Service Excellence in Government Leadership Program.

Dr. Wilson-Lee is currently using her role as Division Director to help shape the culture and review operations of ONDP and OPQ. She was the project lead for ONDP's Product Quality Benefit Risk Framework and has given several presentations on linking product quality to patient outcomes. Wendy is a wife and a mother and enjoys sharing her love of S.T.E.M and leadership development as a speaker and coach for elementary, middle, and high school minority girls.

James-Denton (JD) Wyllie
Director
Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

James-Denton (JD) Wyllie is Director of CDER's Office of Communications (OCOMM). He oversees CDER's public outreach and internal communications programs. His expertise includes public affairs program management, strategic communications planning, organizational marketing, digital communication operations, community communications outreach, writing and editing, media relations and crisis communications.

Before joining CDER, Mr. Wyllie served as Director for the Office of Communications at the U.S. Department of Agriculture's (USDA) Agricultural Research Service (ARS) – the nation's premiere agricultural research agency. At ARS, he managed communication efforts to inform the public about USDA-led solutions to global agricultural challenges and gained support for agency programs among the media, industry, Congress, and other ARS stakeholders. He also managed the agency's internal communications program.

Prior to his time at USDA, Mr. Wyllie served as Deputy Director for the U.S. Navy Office of Information's External Communications Division, overseeing headquarter digital engagement operations and leading global strategy development for online and social media outreach and content marketing. He also served as the Marketing Officer for the U.S. Department of Homeland Security's U.S. Immigration and Customs Enforcement and as the Command Information Officer for the U.S. Army's Fort McPherson and Fort Gillem.

Mr. Wyllie holds a bachelor's degree in public relations from Florida International University and earned a Certificate of Mastery from the Federal Executive Institute. He is also a U.S. Army veteran, completing public affairs missions in the Philippines, Honduras, Alaska and Afghanistan. Mr. Wyllie is a member of the Senior Executive Service.

Center for Biologics Evaluation and Research (CBER) Speakers

Jennifer Hsu Albert, BSN, RN
Regulatory Project Manager
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Jennifer Hsu Albert manages Investigation New Drugs, device submissions, and formal meetings with industry.

Ms. Albert holds a Bachelor of Science in Nursing from Salisbury University. She is a Registered Nurse and has experience in critical care and oncology. Prior to working at the FDA, she worked at the Clinical Center of the National Institutes of Health for 11 years. Jen has certifications in oncology nursing (OCN) and blood and marrow transplantation (BMTCN).

In 2012, she joined the National Cancer Institute (NCI) as a Clinical Research Nurse Specialist where she was responsible for managing phase 1 and 2 clinical trials involving stem cell transplantation and immunotherapies for hematological malignancies, multiple myeloma, and metastatic solid tumors. She was involved in the design, implementation, and evaluation of clinical research protocols and managed the implementation of multiple trials and the patient population studied. She also directed and performed quality assurance and quality control activities as they related to protocol adherence, monitoring, data collection, abstraction and analysis at NCI.

Ekaterina Allen, PhD, RAC
Team Lead (Acting)
Division of Manufacturing and Product Quality (DMPQ)
Office of Compliance and Biologics Quality (OCBQ) | CBER | US FDA

Ekaterina Allen, PhD, earned her M.S. in Medical Biology from Novosibirsk State University, Russia and her Ph.D. in Pharmacology from the University of Minnesota, Twin Cities. She joined FDA in 2014 as Interagency Oncology Task Force Fellow with the Division of Viral Products within CBER's Office of Vaccines Research and Review. In 2016 Ekaterina joined the Division of Manufacturing and Product Quality (DMPQ), first as a Regulatory Project Manager and later as a facility and equipment Reviewer and Inspector. She currently provides leadership to review/inspection staff as the acting Team Lead within DMPQ's Manufacturing and Review Branch 2.

Danielle Brooks, PhD
Biologist
Pharmacology Toxicology Branch (PTB)
Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT)
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Danielle Brooks is a pharmacology/toxicology reviewer in the Office of Tissues and Advanced Therapies. She received her Ph.D. in Biomedical Sciences with a concentration in Cancer and Developmental Biology at The University of Tennessee Health Science Center in Memphis, TN. Following her graduate training, Dr. Brooks completed her post-doctoral training in the Women's Malignancies Branch of the National Cancer Institute. In 2017, she joined the NCI-FDA Interagency Oncology Task Force Fellowship program as a product quality research/review fellow in the Cellular and Tissues Therapies Branch of OTAT. At the completion of her fellowship, Dr. Brooks joined PTB where she now focuses on the review of preclinical toxicology and pharmacology data to support the safety of cell and gene therapies, tissue-engineered products, devices and combination products.

Scott A. Brubaker
Director
Division of Human Tissues (DHT)
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Scott A. Brubaker serves as Director, Division of Human Tissues (DHT) in the Office of Tissues & Advanced Therapies (OTAT) within the Center for Biologics Evaluation & Research (CBER) at the Food & Drug Administration (FDA). In this position he leads the Division in the maintenance of existing, and development of new, federal policies in support of the regulations in 21 CFR part 1271 and associated guidance documents governing the oversight of human cells, tissues, and cellular and tissue-based products (HCT/Ps). Additional responsibilities include serving as Chairperson of the Tissue Reference Group and the Tissue Safety Team. Prior to working at FDA, he was the Senior Vice President of Policy at the American Association of Tissue Banks (AATB) for 12 years where duties included oversight of the Accreditation Program and the development and management of the Association's policies, professional standards and guidance documents. Before joining AATB, 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 is co-editor of three "Essential Guide" books covering cell and tissue donation, processing, and clinical use, and has authored or co-authored more than 40 scientific publications.

Wilson Bryan, MD
Director
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Wilson Bryan is a neurologist who graduated from the University of Chicago Pritzker School of Medicine. He served on the neurology faculty of the University of Texas Southwestern Medical School for 13 years. He has been an investigator on clinical trials in cerebrovascular disease and neuromuscular disorders, particularly amyotrophic lateral sclerosis. Dr. Bryan joined the United States Food and Drug Administration (FDA) in 2000, and now serves as Director of the Office of Tissues and Advanced Therapies (OTAT) in the Center for Biologics Evaluation and Research (CBER).

Asha Das, MD
Physician
Oncology Branch | DCEPT
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Asha Das, MD serves as a Physician in FDA's Oncology Branch in the Center for Biologics Evaluation and Research.

Dr. Das earned her bachelor's and medical degrees from Cornell University. Following internship and residency in internal medicine and neurology at New York-Presbyterian Hospital/Weill Cornell Medicine, she completed a fellowship in neuro-oncology at Massachusetts General Hospital. Certified in neurology by the American Board of Psychiatry and Neurology and in the sub-specialty of neuro-oncology by the United Council for Neurologic Subspecialties, Dr. Das has held academic appointments at the University of California, Los Angeles, University of California, San Francisco, and the National University of Singapore.
Previously, she was Head of the Neuro-oncology Program at Cedars-Sinai Medical Center. Prior to joining the FDA, Dr. Das held positions of increasing responsibility and leadership at several pharmaceutical and biotechnology companies.

Donald Ertel, MS, MT (ASCP)
CDR, USPHS
Division of Manufacturing and Product Quality (DMPQ)
Office of Biologics Compliance and Quality (OCBQ)
CBER | US FDA

Commander Donald Ertel received his B.S. Degree in Medical Technology from the University of Maryland and his master's degree in Regulatory Affairs / Quality Assurance from Temple University School of Pharmacy. CDR Ertel currently serves in the role of Team Lead for DMPQ. For over 11 years, CDR Ertel's primary duty has been scientific review (manufacturing and controls) of BLAs and PMAs. As a CBER lead inspector, he performs, and trains new inspectors in pre-license/approval inspections for BLAs and supplements; and has performed numerous facility inspections, domestically and internationally. CDR Ertel has over 29 years of experience working in quality assurance and compliance in and with regulated industries of blood banking & cell therapy (prior employment at Johns Hopkins Hospital), biotechnology, and pharmaceuticals (prior employment at Shire Pharmaceuticals). As an USPHS officer, CDR Ertel has participated in multiple deployments in support national crisis including twice to the COVID-19 global response.

Tom Finn, PhD
Product Quality (Chemistry, Manufacturing, and Control- CMC) Reviewer
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Tom Finn, PhD is a CMC reviewer in the Division of Cell and Gene Therapy within the Office of Tissues and Advanced Therapies at FDA/CBER. He joined the FDA in 2006, where he reviews regulatory submissions at all stages of product development, from pre-pre-IND advice to post-licensure supplements, and performs pre-licensure and biannual facility inspections. Dr. Finn reviews a wide range of cellular therapies, such as cancer immunotherapies and regenerative medicine products, including neural and cardiovascular stem-cell based products, and immunomodulatory therapies. Dr. Finn has regulatory expertise in bioassays, product comparability, product stability, and process validation. In addition to regulatory review, he is involved in the development of several guidance documents and numerous CBER internal working groups, such as CBER's CMC Coordinating Committee. He received his PhD in Cell Biology from Oregon Health & Science University, did postdoctoral work in neuroimmunology at the Portland VA Medical Center, and was a research assistant professor in the Department of Neuroscience at Georgetown University.

Basil Golding, MD, MBBCh
Director
Division of Plasma Protein Therapeutics
Office of Tissues and Advanced Therapies (OTAT)
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Dr. Golding graduated from the University of Witwatersrand, South Africa, in 1968 and received a medical degree, M.B.B.Ch. In 1975 he worked as a Fellow in Immunology at the University of Oregon Health Sciences Center, and in 1982 as a Fellow at the NIH. He joined FDA in 1985, progressing from a Research Fellow, to a Branch Chief, and to presently serving as Director of the Division of Plasma Derived Therapeutics in OTAT, CBER. Highlights of his research include: (i) development of the first in vitro antigen specific B cell responses in humans; (ii) discovering which Toll Receptors were triggered by Brucella abortus; and (iii) showing molecular mimicry to HIV antigens. Recently he has been studying the immunogenicity of FVIII-Fc fusion proteins, and the possibility that this protein may engage Fc□RIIIa receptors on NK cells and target FVIII-specific B cells.

Andrea Gray, PhD
Biomedical Engineer
Cell Therapy Branch (CTB)
Division of Cellular and Gene Therapies (DCGT)
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Andrea Gray is a Biomedical Engineer and the Devices and Combination Products Team Lead in the Cell Therapy Branch of the Division of Cellular and Gene Therapies (DCGT) in the Office of Tissues and Advanced Therapies (OTAT)/Center for Biologics Evaluation and Research (CBER). She specializes in regulatory review of medical devices and combination products, including tissue engineered/regenerative medicine products. Andrea earned her B.S. in Chemical Engineering from the University of Maryland, College Park and earned her Ph.D. in Biomedical Engineering from Rutgers, the State University of New Jersey.

Elizabeth Hart, MD
Branch Chief
General Medicine 1
Division of Clinical Evaluation and Pharmacology/Toxicology
Office of Tissues and Advanced Therapies
CBER | US FDA

Elizabeth Hart, MD is the Branch Chief of General Medicine Branch 1 in the Office of Tissue and Advanced Therapies (OTAT) in the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA). Dr. Hart completed her undergraduate medical training at the University of Pennsylvania, a residency in pediatrics at Rainbow Babies and Children's Hospital, and a fellowship in pediatric endocrinology at Boston Children's Hospital. She provided clinical care, taught and conducted clinical and translational research prior to joining the FDA in 2014. Upon joining the FDA, she initially served as a medical officer in the Division of Gastroenterology and Inborn Errors Products where she developed expertise in innovative clinical trial design and analysis for products aimed to treat rare diseases. She joined OTAT in 2019 and currently supervises a team of medical officers who are responsible for regulating cellular and gene therapies for a variety of medical conditions. Dr. Hart has served at multiple committees within FDA and authored and edited multiple FDA Guidances, book chapters, and presented at national and international meetings.

Safa Karandish
Consumer Safety Officer
Division of Human Tissues (DHT)
Office of Tissues and Advanced Therapies
CBER | US FDA

Safa Karandish is a Consumer Safety Officer with FDA's Office of Tissues and Advanced Therapies (OTAT) in the Division of Human Tissues (DHT). Her primary focus in DHT/OTAT is related to tissue regulations, policies, stakeholder outreach, and review of certain cellular and tissue products. She joined FDA in 2010 with over 24 years of experience in cellular therapy product manufacturing and cord blood banking in academic and industry settings. She has a Bachelor of Science in Medical Technology from Catholic University of America.

Niloofar Kennedy, MS
Regulatory Project Manager
Division of Regulatory Project Management (DRPM)
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Niloofar Kennedy, MS is a Regulatory Project Manager in the Center for Biologics Evaluation and Research (CBER) Office of Tissues and Advanced Therapies (OTAT), at the US Food and Drug Administration (FDA). She manages Investigation New Drugs, device submissions, and formal meetings with industry. She holds a Bachelor of Science in Cell Biology and Genetics and Master of Science in Bioengineering from University of Maryland College Park. Prior to working at the FDA, she worked at private biotech industry for 5 years. Niloofar is also a certified embryologist.

Anna Kwilas, PhD
Biologist
Division of Cellular and Gene Therapies
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Anna Kwilas received her Ph.D. in Biomedical Science from The Ohio State University in 2010 with an emphasis in Molecular Virology & Gene Therapy and Translational Science. She performed her graduate research at the Research Institute at Nationwide Children's Hospital examining the potential application of respiratory syncytial virus as a gene therapy vector for the treatment of cystic fibrosis.

Dr. Kwilas performed her post-doctoral research at the National Cancer Institute investigating the efficacy of modified vaccinia virus Ankara and adenovirus-based cancer vaccines alone and in combination with other approved and investigational cancer therapeutics.

Dr. Kwilas joined FDA in 2015 on an Interagency Oncology Task Force Fellowship. During her fellowship she was involved in the CMC review of gene therapy products and the generation of safer vector producing cells with the use of CRISPR/Cas9 genome editing technology. In 2016, Dr. Kwilas became a full-time gene therapy CMC reviewer in the Gene Therapy Branch of CBER OTAT and in 2019 was promoted to a Team Lead in the Gene Therapy Branch.

Larissa Lapteva, MD, MHS, MBA
Associate Director
Division of Clinical Evaluation, Pharmacology, and Toxicology
Office of Tissues and Advanced Therapies (OTAT)
Center for Biologics Evaluation and Research
US Food and Drug Administration

Larissa Lapteva, MD, MHS, MBA, is the Associate Director in the Division of Clinical Evaluation, Pharmacology, and Toxicology, Office of Tissues and Advanced Therapies, 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.

Malcolm Moos Jr., MD, PhD
Medical Officer
Senior Investigator
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Malcolm Moos Jr majored in Biological Sciences at Stanford University and obtained his M.D. and Ph.D. at the University of Minnesota. His graduate major was pharmacology, with a supporting program in biophysics and spectroscopy. He completed residency training in Laboratory Medicine and Pathology, with a fellowship in Clinical Chemistry, at the same institution. Dr. Moos then came to FDA/CBER to continue his work in the area of cyclic nucleotide-mediated signal transduction, and became a recognized expert in protein microsequencing, separation techniques, and protein analytical biochemistry. His current research interests are to define how evaluating the status of major cell signaling pathways (BMP, Wnt, etc.) can be used in conjunction with recent developments in systems biology, single cell analytical

technology, and computational biology to characterize cell- based products more accurately to facilitate improved product design and testing. His work has resulted in seven patents issued, one allowed, and two pending. While at CBER, he has been CMC reviewer on IND submissions (Original Submissions plus Amendments) and BLAs, been primary or contributing author on various FDA and International Council on Harmonization guidance documents dealing with recombinant protein and cellular products, organized various meetings on cell and gene therapy regulatory topics, and participated in criminal investigations with the Office of Compliance. Dr. Moos has been FDA/CBER liaison to the ASTM subcommittee on Tissue Engineered Medical Products for approximately twenty years. His awards include the Harvey W. Wiley Medal, the FDA Award of Merit, the Center Director's Targeted Research Award (twice), the Center Director's Distinguished Service Award, the American Society for Testing and Materials Robert E. Fairer, and Manny Horowitz Awards, and forty others.

Graeme Price, PhD
Research Microbiologist
Division of Cellular and Gene Therapies
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Graeme Price, PhD, is a research microbiologist and CMC reviewer in the Division of Cell and Gene Therapy. After receiving a Ph.D. in Biological Sciences from the University of Birmingham, UK for studies on the mechanism of fever in influenza, he continued to pursue his research interests in viral pathogenesis and antiviral immunity in the Molecular Immunology Program at the Medical College of Georgia. Dr. Price joined CBER as a staff fellow in 2006. His expertise is in immunology and virology, with research interests focused on universal vaccine approaches to influenza. His regulatory role is to review IND and BLA submissions for human cell and gene therapy products, particularly CAR T cells and cancer vaccines. He serves on the FDA Institutional Biosafety Committee and multiple CBER internal working groups.

Tejashri Purohit-Sheth, MD, FACAAI, CQIA
Director
Division of Clinical Evaluation and Pharmacology/Toxicology
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Dr. Tejashri Purohit-Sheth is currently the Director of the Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT) in the Office of Tissues and Advanced Therapies (OTAT) in the Center for Biologics Evaluation and Research at the Food and Drug Administration. She provides supervisory oversight for the clinical and pharmacology/toxicology review of submissions to OTAT. She previously served as the Clinical Deputy Director in DAGRID/ODE/CDRH/FDA as well as Acting Division Director and Branch Chief in Office of Scientific Investigation in CDER/FDA and as a Medical Officer in the Division of Pulmonary and Allergy Products (CDER/FDA).

She completed an Internal Medicine Residency at Naval Medical Center Portsmouth followed by a fellowship in Allergy/Immunology at Walter Reed Army Medical Center. Following fellowship, she took over as Service Chief of the Allergy/Immunology clinic at National Naval Medical Center in Bethesda, MD. Following her end of obligated service as an active-duty Naval Officer, she transferred her commission to the U.S. Public Health Service and began her FDA career; currently she has served for 26+ years as an active duty Uniformed Service Officer.

Daniel J. Urban, PhD
Biologist
Pharmacology / Toxicology Branch 1
Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT)
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Daniel J. Urban holds a Ph.D. degree in pharmacology and currently serves as a pharmacology/ toxicology reviewer in the Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT) in the Office of Tissues and Advanced Therapies (OTAT) in the Center for Biologics Evaluation and Research (CBER) at the USFDA. He is responsible for evaluating the preclinical studies conducted to support administration of cellular therapy products, gene therapy products, hemostatic products, selected plasma derivatives, and/or tissue-engineered products in investigational clinical trials under the auspices of FDA/CBER. Prior to joining the FDA, Dr. Urban served as a senior scientist and scientific program manager for the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH), where he managed/reviewed drug discovery/development projects involving small molecules, enzymes, antibodies, stem cell therapies, and gene therapies. Dr. Urban's graduate and post-doctoral work focused on evaluating the chemogenetic modulation of the serotonin and dopamine networks utilizing AAV-based gene delivery vectors.

Lei Xu, MD, PhD
Chief
General Medicine Brach 2 (GMB2)
DCEPT
Office of Tissues and Advanced Therapies (OTAT)
CBER | US FDA

Lei Xu, MD, PhD, serves as the Chief of General Medicine Brach 2 in the FDA's Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT) of Office of Tissue and Advanced Therapies (OTAT) at Center for Biologics Evaluation and Research (CBER).

Her Branch is responsible for reviewing clinical trial protocols, overseeing clinical trial conducts and evaluating trial data of investigational biological products (e.g., gene therapy, cellular therapy and plasma-derived products) in several clinical areas, including Neurology, Ophthalmology, Pulmonology, Dermatology, and burn and wound care. Her Branch reviewed all the clinical data that led to FDA-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, she is actively involved in FDA guidance development, including the Guidance for Industry: Expedited Programs for Serious Conditions, Guidance for Industry: Gene Therapy for Retinal Disorders, and draft Guidance for Industry: 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.

Center for Devices and Radiological Health (CDRH) Speakers

Meredith Andress, MPH
Recall Coordinator
Division 2
Office of Medical Devices and Radiological Health (OMDRHO)
Office of Regulatory Affairs (ORA) | US FDA

Meredith Andress serves as a Recall Coordinator for medical device recalls under the Compliance Branch, OMDRHO Division 2. Currently she is one of 9 recall coordinators for the medical device program and responsibilities include reviewing and recommending new recalls for classification by CDRH, monitoring ongoing recalls within Division 2, terminating those recalls, and advising follow up as needed. She became a Recall Coordinator in March 2015 and has been a frequent speaker of recall-related topics with industry for Medical Devices, and Food in the past. She has been with the FDA for 11 years and prior to her current position as Recall Coordinator, served as a Consumer Safety Officer, performing inspections in multiple commodity areas. Ms. Andress received a Master's degree in Public Health, with a specialization in Veterinary Public Health, from The Ohio State University.

Matthew Di Prima, PhD
Research Materials Scientist/Additive Manufacturing Program Area Coordinator
Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
CDRH | US FDA

Matthew Di Prima is a Research Materials Scientist in the Division of Applied Mechanics (DAM), Office of Science and Engineering Laboratories (OSEL), in FDA's Center for Devices and Radiological Health. He is currently serving as the Coordinator for the Additive Manufacturing Program Area as well as Chairing the CDRH Additive Manufacturing Working Group and the Agency Advanced Manufacturing Technology Working Group. Dr. Di Prima is involved in many research efforts to improve device testing and the understanding of material processing on device performance. He earned his Ph.D. in Materials Science from the Georgia Institute of Technology in 2009.

Adam Donat, MS, JD
Deputy Director
Division of Clinical Evidence and Analysis 1 (DCEA1)
Office of Clinical Evidence (OCEA)
Office of Product Evaluation and Quality (OPEQ)
CDRH | US FDA

Adam Donat is Deputy Director for the Division of Clinical Evidence and Analysis 1 (Clinical Science and Quality), Office of Clinical Evidence (OCEA), Office of Product Evaluation and Quality (OPEQ), in FDA's Center for Devices and Radiological Health. In this role, he helps manage issues related to clinical research policy, clinical data reliability, and human subject protections throughout the Total Product Life Cycle for devices. Prior to this, he worked in the Bioresearch Monitoring compliance programs in CDRH and CDER, as both a reviewer and a Branch Chief. His earlier experience outside FDA included managing the regulatory aspects of clinical trials for NIH's Division of AIDS and working in the lab for a local biotech company. Mr. Donat has a Bachelor of Science in Integrated Science and Technology from James Madison University with concentrations in biotechnology and telecommunications. He also has an Master's of Science in Bioscience Regulatory Affairs from Johns Hopkins University and a JD from University of Maryland School of Law.

Jake Dyer, PE, PMP
Lieutenant Commander, US Public Health Service
Senior Regulatory Officer, Regulatory Inspections and Audits Team
Division of Regulatory Programs 2 (DRP2)
Office of Regulatory Programs (ORP)
Office of Product Evaluation and Quality (OPEQ)
CDRH | US FDA

LCDR Jake Dyer is a Senior Regulatory Officer in the Regulatory Inspections and Audits Team in the Division of Regulatory Programs 2 (DRP2), Office of Regulatory Programs (ORP), Office of Product Evaluation and Quality (OPEQ), in FDA's Center for Devices and Radiological Health (CDRH). He is currently serving as a Program Analyst and Accessor for the Medical Device Single Audit Program (MDSAP) where he leads efforts associated with MDSAP development and implementation with other regulatory authorities and industry. LCDR Dyer began his career with the FDA over 5 years ago as an FDA Medical Device Investigator and is a licensed Professional Engineer, Lean Design for Six Sigma Black Belt, Certified Project Management Professional. Certified Quality Auditor, and a level 2 certified FDA medical device investigator. LCDR Dyer earned his degree in Mechanical Engineering from the University of Rochester.

Susannah Gilbert, MS
Policy Analyst/Q-Submission Program Lead
Division of Regulatory Programs 1 (DRP1)
ORP
Office of Product Evaluation and Quality (OPEQ)
CDRH | US FDA

Susannah Gilbert is a Policy Analyst acting as the Q-Submission Program Lead in the Office of Regulatory Programs (ORP) in CDRH's Office of Product Evaluation and Quality (OPEQ). In this position, she works to support Q-Submission Program development, manage daily program operations, and support both FDA review teams and external stakeholders by answering questions and providing information about Q-Sub policy and practices. Susannah joined CDRH in 2014, and prior to joining ORP she worked as a Biomedical Engineer in the Division of Orthopedic Devices and in the Division of Manufacturing and Quality. Susannah received her bachelor's and master's degrees in Biomedical Engineering from Brown University.

Vidya Gopal, MS
Consumer Safety Officer
Postmarket and Consumer Branch (PCB)
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
CDRH | US FDA

Vidya Gopal is a Consumer Safety Officer in the Postmarket and Consumer Branch (OCB), Division of Industry and Consumer Education (DICE), Office of Communication and Education (OCE), in FDA's Center for Devices and Radiological Health (CDRH). Her work consists primarily of helping external stakeholders locate and understand various regulatory resources and requirements established by FDA, with a specialization in Quality System regulation (21 CFR 820).

Ms. Gopal also currently serves as an FDA instructor for the Association for the Advancement of Medical Instrumentation (AAMI) Quality System Requirements and Industry Practice Course, Design Controls Course and Corrective and Preventive Action (CAPA).

In 2012, Ms. Gopal began working in the FDA's Office of Compliance as a senior reviewer in the cardiovascular devices branch. Prior to her FDA career, Ms. Gopal has over 15 years of experience in FDA-regulated device industry. She worked as a Research and Development engineer in Cardiovascular and Women's health device companies primarily responsible for design and clinical trials.

Ms. Gopal received a Bachelor Degree in Engineering (Polymer Science) from India, and a Master of Science in Material Science from University of Utah.

Melissa Hall, MS
Consumer Safety Officer
Premarket Programs Branch (PPB)
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
CDRH | US FDA

Melissa Hall is a Consumer Safety Officer in the Premarket Programs Branch (PPB), Division of Industry and Consumer Education (DICE), Office of Communication and Education (OCE), in FDA's Center for Devices and Radiological Health (CDRH). Her work consists primarily of educating external stakeholders about the various regulatory resources and requirements established by FDA. Prior to her joining DICE, she was an Assistant Director for the Spinal Devices Division in the Office of Orthopedic Devices within CDRH for two and a half years. Prior to that she was a lead reviewer for four and a half years within the same Division.

Ms. Hall received her Master of Science in Biomedical Engineering at the New Jersey Institution of Technology (NJIT), and a Bachelor of Science in Biological Sciences from the University of Maryland Baltimore County (UMBC).

Elias Mallis
Director
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
CDRH | US 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 leads a division whose mission is 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 27-year FDA career in 1994 and devoted the next 17 years in the Office of Device Evaluation (ODE) where he conducted regulatory review and developed policy 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 in the ODE Immediate Office, contributing to 510(k) Program, Clinical Studies, Device Reclassifications and De Novo policy. Mr. Mallis received a Bachelor of Science Degree in Electrical Engineering at the University of Maryland at College Park.

Fariba Maramkhah, MS
Consumer Safety Officer
Monitoring eMDR helpdesk
Division of Regulatory Programs 3 (DRP3)
Office of Regulatory Programs (ORP)
Office of Product Evaluation and Quality (OPEQ)
CDRH | US FDA

Fariba Maramkhah is a Consumer Safety Officer for the Medical Device Reporting (MDR) team in the Division of Regulatory Programs 3 (DRP3), Office of Regulatory Programs (ORP), Office of Product Evaluation and Quality (OPEQ), in FDA's Center for Devices and Radiological Health (CDRH). Her primary role includes supporting manufacturers through the eMDR (Electronic Medical Device Reporting) helpdesk. As the primary eMDR Helpdesk manger, she provides manufacturers with guidance and support with electronic account creation, report submission and troubleshooting. She also provides guidance to manufacturers related to navigating existing data systems for MDR reports, such as the public facing MAUDE (Manufacturer and User Facility Device Experience) database on FDA.gov. Her expertise has supported many efforts to improve post-market surveillance at CDRH, though the eMDR system enhancements. Ms. Maramkhah earned her Master's degrees in Health Systems Management from George Mason University in 2006, and Health Care Services Administration from Iran University in 1999 with Nursing background.

Edward Margerrison, PhD
Director
Office of Science and Engineering Laboratories (OSEL)
CDRH | US FDA

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.

Diane Nell, PhD
Consumer Safety Officer
PPB
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
CDRH | US FDA

Diane Nell is a Consumer Safety Officer and Mechanical Engineer in the Premarket Programs Branch (PPB), Division of Industry and Consumer Education (DICE), Office of Communication and Education (OCE), in FDA's Center for Devices and Radiological Health (CDRH). Dr. Nell presently educates medical device industry stakeholders on regulatory and policy matters pertaining to medical devices and electronic products. She also develops, maintains and updates such information on the CDRH website for the purpose of industry education. Over the course of her 20+ years with the agency, Dr. Nell also conducted research in the Center's Science and Engineering Laboratories and served as a regulatory reviewer and technical advisor of scientific, regulatory, administrative and procedural aspects of the PMA and Humanitarian Device Exemption (HDE) Programs. As a lead reviewer, Dr. Nell was responsible for the management, review, evaluation, and determination for premarket notifications (510(k)), investigational device exemptions (IDE), and premarket approval applications (PMA), submitted by manufacturers and clinical sponsors seeking to commercially distribute or conduct clinical investigations of circulatory support and prosthetic cardiovascular devices. Dr. Nell obtained her undergraduate degree in Mechanical Engineering from the University of Maryland and her Masters and Doctorate degrees from the George Washington University.

Geeta Pamidimukkala, MS
Deputy Director (Acting)
DRP1
Office of Regulatory Programs (ORP)
Office of Product Evaluation and Quality (OPEQ)
CDRH | US FDA

Geeta Pamidimukkala is Acting Deputy Division Director of pre-market programs in the Office of Regulatory Programs (ORP), Office of Product Evaluation and Quality (OPEQ), in FDA's Center for Devices and Radiological Health (CDRH). Since joining CDRH over 10 years ago, she has served in a variety of roles, including Assistant Director of a Total Product Lifecycle (TPLC) review team. She has extensive experience drafting policies, processes, and guidance documents to enhance consistency and efficiency in the pre-market programs. Ms. Pamidimukkala earned a BS degree in electrical engineering from Tufts University and an MS degree in biomedical engineering from New Jersey Institute of Technology.

Joseph Tartal
Deputy Director
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
CDRH | US 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 serve 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 15-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 27 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.

Tonya A. Wilbon
Branch Chief
PCB
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
CDRH | US FDA

Tonya A. Wilbon is the Branch Chief for the Postmarket and Consumer Branch (PCB), Division of Industry and Consumer Education (DICE), Office of Communication and Education (OCE), in FDA's Center for Devices and Radiological Health. Ms. Wilbon 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 21 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) new Quality System Regulation 21 CFR 820 and ANSI/AAMI/ISO 13485: Navigating Regulatory Requirements, Integrating Risk Management into the Product Life Cycle Course, and Design Control Requirements-Integrating the QSR and AAMI/ANSI/ISO 13485 Course. She assisted with updating the course ancillary document, The Quality System Compendium. She also serves on FDA's Content Advisory Group and serves as an instructor for the FDA Basic Medical Device Course for FDA Investigators and Staff. Ms. Wilbon has previously served as a member of the Consensus Committee for Quality System and Laboratory Practices and the Subcommittee on Antimicrobial Susceptibility testing of Human Mycoplasmas for the Clinical and Laboratory Standards Institute (CLSI).
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).