DIGITAL TRANSFORMATION SYMPOSIUM 2023

Hosted by FDA's Office of Digital Transformation

December 4–6 | 2023

U.S. FOOD & DRUG ADMINISTRATION

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SPEAKERS AND BIOGRAPHIES

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Day 1: Monday, December 4, 2023

Jessica Bernhardt
IT Program Manager
Office of Digital Transformation (ODT)

Jessica Bernhardt currently is the Program Manager for the Electronic Submissions Gateway (ESG) and AdminApps programs at the Food and Drug Administration (FDA). She took on the role of ESG Program Manager at the start of 2023 and oversaw the successful completion of the ESG AWS Migration. Jessica joined the FDA in 2020 as the AdminApps Program Manager, which she has successfully managed for the past three years. Jessica started her career in Government nine years ago when she joined the Social Security Administration (SSA) as an IT Specialist. After a year working as an IT Specialist for a year, was assigned to lead and manage an IT Modernization project, promoting the use of the Agile development lifecycle. In 2016, she was promoted to Team Lead within the Enterprise Architecture (EA) and Software Governance group (SG). As a Team Lead in EA & SG she helped to define, promote, and manage the EA & SG program as well as various development projects at SSA. In 2020 she moved into a purely Project Management role, managing a large agile IT Modernization effort for several of SSA's core business systems. During her tenure at SSA, she helped to promote the EA Program, integrating it into both the Waterfall and Agile development lifecycles, mentored employees in EA and Project Management and managed several development projects.

Jessica Berrellez
Executive Officer
Office of Digital Transformation (ODT)

Jessica "Jess" N. Berrellez is the Executive Officer for the Office of Digital Transformation at the U.S. Food and Drug Administration. Jess has broad leadership experience in a variety of areas and currently oversees strategic initiatives, organizational effectiveness, strategic communications, high priority change initiatives, events and engagement, human capital management, learning and development, and administrative operations. She was previously ODT's Executive Director for Strategy and Operations, Senior Advisor to the Chief Information Officer, Senior Advisor to the Principal Deputy Commissioner, and Director for Program Evaluation and Process Improvement. Jess is the recipient of agency, federal, and industry honors and has received national recognition for her volunteer work. She is a graduate of the Senior Executive Fellows Program at Harvard University's Kennedy School of Government and earned an Executive Certificate in Public Leadership. Jess holds a Master of Arts and Master of Science from the University of Arizona and earned a Bachelor of Arts from Indiana University.

James Bowling, J.D.
Deputy Division Director, Division of Enforcement and Manufacturing (DEM),
Office of Compliance and Enforcement (OCE), Center for Tobacco Products (CTP)

Mr. Bowling is currently the Deputy Division Director of DEM. He joined CTP in 2014 and has served in various leadership and advisory positions throughout his CTP career. Prior to joining CTP, Mr. Bowling worked in private practice where he represented clients across a spectrum of legal matters, including personal injury, employment law, criminal law, bankruptcy, family law, and appellate advocacy. He has a Juris Doctorate from Florida Coastal School of Law and a Bachelor of Arts in Political Science from Virginia Commonwealth University.

J. Bradley Brown, Ph.D.
Senior Science Advisor
Center for Food Safety and Applied Nutrition (CFSAN)

Dr. J. Bradley Brown coordinates data and modeling efforts to economic and policy analysis and develops industry studies and analyses of novel policy issues. Dr. Brown joined FDA in 2002 as a staff economist at CFSAN. He was and Economics Team Lead at CFSAN during the development of the major FSMA regulations. He has performed analysis in support of The Egg Safety Rules, the HHS Task Force on Drug Reimportation, and the Bioterrorism Regulations. Dr. Brown earned his Ph.D. in Economics from The University of Texas, in Austin, with a concentration in the fields of Environmental and Natural Resource Economics, Computational Economics, and Econometrics.

Dr. Namandjé N. Bumpus
Chief Scientist
Office of the Chief Scientist

Dr. Namandjé N. Bumpus provides strategic leadership and expertise to support scientific excellence, innovation, collaboration, and capacity to achieve FDA's public health mission. Prior to this, Dr. Bumpus was on the faculty at Johns Hopkins University School of Medicine for 12 years, most recently as the E.K. Marshall and Thomas H. Maren Professor and chair of the Department of Pharmacology and Molecular Sciences. She also served previously as associate dean for basic research. Dr. Bumpus' research expertise is in pharmacology with a particular focus on drug metabolism, pharmacogenetics, bioanalytical chemistry, and infectious disease. She earned a BA in biology at Occidental College in 2003, a PhD in pharmacology at the University of Michigan in 2007 and completed a postdoctoral fellowship in molecular and experimental medicine at The Scripps Research Institute in La Jolla, CA in 2010.

Dr. Bumpus currently serves as president of the American Society for Pharmacology and Experimental Therapeutics (ASPET). She previously served as chair of the NIH Xenobiotic and Nutrient Disposition and Action study section.

Robert M. Califf, M.D.
Commissioner of Food and Drugs
Food and Drug Administration

Dr. Robert M. Califf was confirmed in 2022 as the 25th Commissioner of Food and Drugs. As Commissioner, Dr. Califf 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. Califf has had a long and distinguished career as a physician, researcher, and leader in the fields of science and medicine. He is a nationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research, and a leader in the growing field of translational research, which is key to ensuring that advances in science translate into medical care.

Mohammed Sohail Chaudhry
Chief Technology Officer
Director Office of Information Management and Technology (OIMT)
Office of Digital Transformation (ODT)

Mohammed Sohail Chaudhry is a strategic leader with progressive and vibrant ideology of transformative change in the delivery of technology and information management processes. Mr. Chaudhry has a proven record of saving millions in information technology (IT) expenses by leveraging secure innovation and business transformation. Currently serving as the Chief Technology Officer (CTO) at the United States Food and Drug Administration (FDA), he is responsible for the standardization and modernization of IT. Mr. Chaudhry is accomplishing this by leading the development of enterprise solutions that enables the Office of Information Management and Technology (OIMT) to align and integrate with the strategic business objectives of the agency. Prior to serving as the CTO, Mr. Chaudhry served as the Chief Technology Architect (CTA) and as the Director of the Division of Infrastructure Operations (DIO) leading the implementation, operations, and maintenance of enterprise IT.

Meredith Chuk, M.D.
Director, Enterprise Transformation Operation (ETO)
Office of the Commissioner (OC)

Dr. Meredith Chuk is the Director of the Enterprise Transformation Operation (ETO). She completed a pediatric hematology/oncology fellowship at Johns Hopkins/National Cancer Institute (NCI), and subsequently was an instructor in the Pediatric Oncology Branch of the NCI, an assistant professor of pediatrics at the Children's Hospital of Pittsburgh in the department of hematology/oncology before joining the FDA in 2013 as a medical officer. She has been in a variety of roles beginning as a medical officer in oncology then serving as the Acting Associate Director for Safety in the Office of Oncologic Diseases in CDER and in the Oncology Center of Excellence, which focuses on optimizing common business processes at FDA for improved efficiencies and better use of data and technology to support business needs.

Vid Desai
Chief Information Officer
Office of Digital Transformation (ODT)

Vid Desai is a seasoned technology leader who brings more than 30 years of experience in the information technology (IT) field, with over 26 years in the healthcare and life sciences industries. He has previous experience working for large Pharma, Clinical Research Organizations (CRO) and Medical Device companies. As the FDA's Chief Information Officer (CIO), Mr. Desai sets and leads the agency's IT strategy, as well as the agency's enterprise IT, data management, and cybersecurity in the Office of Digital Transformation (ODT). The ODT team oversees the overall FDA IT spend of more than $750M and a staff of around 2,500 employees and contractors. Prior to being named CIO, Mr. Desai served as the FDA's Chief Technology Officer, overseeing day-to-day technology operations as the leader of the Office of Information Management and Information Technology. Prior

to joining the FDA, Vid held the Chief Information Officer (CIO) roles at Vyaire Medical, a Respiratory Medical Device company formed from a divestiture from Becton Dickinson. He was CIO at Endochoice, a GI device and services provider, and Lake Region Medical, which was acquired by Greatbach to form Integer, a medical device, outsource manufacturer.

Ian Edhlund
Staff Fellow
Center for Veterinary Medicine (CVM)

Ian works as a toxicologist in CVM's Office of Surveillance and Compliance. In addition to compiling and reviewing surveillance data, he uses various techniques, including Physiologically based toxicokinetic (PBTK) and Adverse Outcome Pathway (AOP) models, to predict bioaccumulation and toxicity of contaminants, including per- and polyfluoroalkyl substances (PFAS). Prior to joining FDA, Ian completed his PhD in Environmental Toxicology at Clemson University, where he focused on biomarkers and PBTK and AOP modeling in fish. Ian is also a part-time lecturer at the University of Wisconsin-Stout where he teaches online computer science courses.

Ben Hope
Deputy Director
FDA Library

Ben Hope is a dedicated information professional who has made significant contributions to the fields of library science and healthcare. He holds a master's degree in library and information science and a bachelor's degree in computer science. With a career spanning several decades, Ben has become known for his unwavering commitment to providing top-notch information services to the scientific, medical, and regulatory communities within the NIH and FDA. Throughout his career, Ben's dedication to promoting open access to information, fostering innovation in library services, and serving the research and regulatory communities has been exemplary. Today, he is leading an ambitious effort, along with fellow Library staff, to represent FDA's Expertise and the significant contributions FDA has made to research and science through the FDA Expertise and Research Portal.

Ele Ibarra-Pratt, BSN, MPH
Deputy Director of Regulatory Affairs,
Office of Compliance and Enforcement (OCE)
Center for Tobacco Products (CTP)

Ms. Ibarra-Pratt is currently Deputy Director of Regulatory Affairs in OCE. She has contributed to FDA's public health mission for over 24 years. She joined OCE in 2010 to help lead the office and implement the new Family Smoking Prevention and Tobacco Control Act. She previously served as Division Director in OCE's Division of Promotion, Advertising and Labeling for over 10 years. Prior to joining CTP, Ms. Ibarra-Pratt served in leadership positions at the Center for Biologics Evaluation and Research (CBER), Advertising and Promotional Labeling Branch, the Center for Drug Evaluation and Research (CDER), Division of Drug Marketing, Advertising and Communications, and CDER's Division of Scientific Investigations. She has a Master of Public Health from San Diego State University in California and a Bachelor of Science in nursing from the University of Hawaii at Manoa.

General Lee
Senior IT Program Manager
Office of Enterprise Portfolio Management (OEPM)
Office of Digital Transformation (ODT)

General serves as the Food and Drug Administration Agency Lead for Technology Business Management within the Office of Enterprise Portfolio Management, providing governance oversight, strategic planning, and performance analysis expertise for all IT investments, projects, contracts, applications, and systems across FDA. He has been an FDA government employee for nearly 7 years, serving in various IT and regulatory science roles across FDA such as solutions architect, technical lead, project manager, health scientist, regulatory informatics specialist, Scientific Computing Board member, Big Data Interest Group Leader, and contracting officer's representative. General is dedicated to providing FDA staff involved in digital transformation with the right data to improve mission and business outcomes.

Joshua Lehman
Director, Office of Business and Customer Assurance (OBCA)
Office of Digital Transformation (ODT)

Joshua Lehman, PMP, is the Director, Office of Business and Customer Assurance (OBCA) and the Division of Business Partnership and Support (DBPS) in the Office of Information Management and Technology (OIMT) at the Food and Drug Administration. He is responsible for the Agency's collaboration services, FDA.gov, operational support, and end user IT equipment. Mr. Lehman is also the sponsor of FDA's User Experience Project Portfolio, which consists of 20+ information technology modernization projects to improve the day-to-day IT collaboration end user experience in a heightened telework environment. With over 23 years of extensive IT experience, Mr. Lehman excels in managing and developing information technology program solutions, project management, search engine optimization, web development as well as personnel management and mentoring.

William (Bill) Lohnes
Senior Program Manager, Office of Strategic Partnerships and Technology Innovation
Center for Devices and Radiological Health (CDRH)

Bill is a Senior Program Manager in the Center for Devices and Radiology Health, Office of Strategic Partnerships and Technology, Digital Transformation (DT) initiative. Bill has over 25 years of experience converting business vision into innovative, sustainable solutions. Prior to joining CDRH, Bill's roles have included Product Manager for CDER's Office of Business Informatics, New Drug Regulatory Program Modernization and Global IT Leader for Becton Dickinson, a medical device manufacturing company. Bill earned an MBA from Johns Hopkins University, bachelor's degree in information systems management from the University of Maryland, Baltimore County, and a bachelor's degree in political science and government from Loyola University.

Meghan Mariman
Supervisory IT Specialist
Office of Data, Analytics and Research (ODAR)
Office of Digital Transformation (ODT)

Meghan Mariman joined the FDA in June 2023 as the Service Owner for Data Analytics as a Service (DAaaS) in the Office of Digital Transformation (ODT). A Navy Veteran, Meghan previously led the Data Division for the U.S. Army in Washington, DC, where she led a team of military, civilians, and contractors in the Chief Information Office. Meghan was responsible for Data Strategy, Policy, and Governance. She brings extensive experience in Program Management, Strategic Communications, and Financial Management to the ODAR team. Before joining the Army Civilian Corps, Meghan held leadership positions at Raytheon and Lockheed Martin. Her Naval service includes tours as a Surface Warfare Officer, a Protocol Officer, and a Public Affairs Officer.

Elizabeth (Liz) McNamara
Associate Director, Office of Strategic Partnerships and Technology Innovation
Program Director, Digital Transformation
Center for Devices and Radiological Health (CDRH)

Liz Is an Associate Director in the Office of Strategic Partnerships and Technology Innovation at FDA's, Center for Devices and Radiology Health. Liz joined the FDA in 2019 as the Director of CDRH's Digital Transformation (DT) initiative. Liz has over 30 years of experience in the successful planning, development, and implementation of complex health information technology applications and solutions. Prior to joining FDA, her roles have included Director at Blue Cross Blue Shield Association, Program Manager at NIH, and Principal of Healthcare Consulting at CSC and Health IT Solutions LLC. Ms. McNamara earned a Master of Science in healthcare administration and a Bachelor of Science in decision and information systems both from the University of Maryland.

Anjila Merchant, MBA, PMP
Program Manager, Office of Strategic Partnerships and Technology Innovation
Center for Devices and Radiological Health (CDRH)

Anjila is an IT Program Manager in the Office of Strategic Partnerships and Technology Innovation at FDA's Center for Devices and Radiological Health. Anjila officially joined the FDA in August of 2023, after supporting the digital transformation and modernization journey as a contractor since early 2021. She has over 15 years of experience spanning from business analysis to leading product teams. She has expertise in defining and delivering efficient business processes, managing client relationships, and delivering high quality results. Prior to joining the FDA, her roles included Lead Associate at Booz Allen Hamilton and Senior Project Manager at AIG. Ms. Merchant earned her master's degree in business administration from the George Washington University and has an active Project Management Professional (PMP) License.

Joseph Montgomery
Director, Office of Enterprise Portfolio Management (OEPM)
Office of Information Management and Technology (OIMT)
Office of Digital Transformation (ODT)

Joseph Montgomery is the Director for the Office of Enterprise Portfolio Management (OEPM). In this role, he provides oversight for the Office of Digital Transformation's (ODT) IT portfolio, IT Governance, Finance, Acquisition, Enterprise Licenses, Human Resources, and Change Management functions. Joseph has over 28 years of experience in the IT field and has been with FDA for over 25 years. Prior to his time in ODT, Joseph served as the Director of BioInformatics and the Associate Deputy, Chief Information Officer for Center for Biologics Evaluation and Research. He managed the program at FDA that produced the first electronic submissions in CBER, developed international regulatory electronic submission standards, and established the Portfolio Management Office in OIMT. Joseph has received many certifications, awards, and citations but is most proud of the dedicated and talented individuals that he has had the opportunity to work with to support the FDA mission.

Jim Mulholland
Associate Director
Office of Digital Transformation (ODT)

Jim is the Portfolio Director for the Enterprise Transformation Operation (ETO). He has worked in various corporate and education roles during his 35+ year career, most recently instructor at Wake Tech Community College and consulting at several Life Sciences concerns in support of their data analytics initiatives. Prior to that, Jim enjoyed success working in various corporate roles delivering analytical solutions that drive business success. Jim was Chief Operating Officer and Life Sciences Partner at MSRCosmos LLC, an IT services and software company, and prior to that served as Vice President of Digital and Business Technology Innovation at Syneos Health, a leading contract research organization (CRO) and commercialization services (CCO) firm. Jim was named a top digital innovator in Databird Research Journal Digital Transformation 2018 guide and appeared in the PharmaVOICE publication article Artificial Intelligence Molecule to Market (Jan 2019).

Alexis Norris
Biologist
Center for Veterinary Medicine (CVM)

Alexis Norris joined CVM as a bioinformatics reviewer in 2018. Prior to that, she completed her PhD and postdoctoral training at Johns Hopkins School of Medicine where she used genomics, transcriptomics, proteomics, and metabolomics to study human cancer and psychiatric disorders. At CVM, Alexis evaluates next generation sequencing (NGS) data submitted to support new animal drug applications for genome edited animals, through an independent analysis of the raw NGS data. For the analysis, Alexis uses multiple bioinformatics platforms (precisionFDA, CDRH Betsy HPC, and Galaxy), and codes primarily in Linux/bash scripting and R. Alexis is actively involved in multiple omics and data science working groups at the FDA and currently co-chairs the FDA Omics Working Group.

Linda Peters
Program Manager, Office of Strategic Partnerships and Technology Innovation
Center for Devices and Radiological Health (CDRH)

Linda Peters is the Deputy Program Director for Digital Transformation program. Mrs. Peters serves as the Program Manager for the Customer Collaboration Portal, SBD, and Technical Architecture efforts. Most notably, she led the successful launch of the Customer Collaboration Portal which provides external stakeholders with the ability to view the status of their premarket medical device submissions and upload their 510(k) eSTAR and eCopy submissions electronically. Mrs. Peters has over 28 years of experience in Information Technology and Program Management in both the public and private sectors.

Shellie Rogers
Senior Advisor & Portfolio Manager
Office of Digital Transformation (ODT)

Shellie Rogers is a portfolio manager with over 20 years of experience in strategic planning, high impact business process improvement and stakeholder management. Shellie manages the FDA's User Experience Portfolio. User Experience applies a consistent framework to deliver the latest technology faster, while minimizing disruptions to FDA users carrying out the Agency's mission. In her current role, she is also responsible for managing at risk projects at the request of senior management, formulating communication strategies to impact stakeholders across the agency and policy formulation and implementation. Previously, she worked as a project manager in the Office of Operations, Immediate Office where she was responsible for projects on operational strategy and execution at the direction of the Chief Operating Officer.

Luis Santana-Quintero
Staff Fellow
Center for Biologics Evaluation & Research (CBER)

Luis Santana-Quintero is leading the CBER's bioinformatics group (HIVE) in the Division of Analytics and Benefit Risk Assessment in the Office of Biostatistics and Epidemiology. His research focused on multiple fields of computational biology including immune informatics, as well as artificial intelligence, and machine learning. He has co-developed the CBER HIVE platform and numerous algorithms and bioinformatic tools for large datasets. Also, he is an Associate Editor of the "IEEE Transactions on Evolutionary Computation", a scientific journal in the area of evolutionary computation. Before joining CBER in 2012, Dr. Santana-Quintero was a Postdoctoral Fellow in the Krasnow Institute for Advanced Study at the George Mason University.

Mary Schwarz
Symposium Moderator
Managing Partner, Division Lead
ICF Next Government

Mary Schwarz, Managing Partner, ICF Next Government, is a digital strategist and marketing technologist with a comprehensive range of experience in direct marketing, web development, community outreach, and analytics. Mary leads ICF Next's Government, federal digital and engagement practices. She brings over 20 years of experience providing strategic guidance for health, education, and social programs. Mary helps clients define their objectives and business goals; map user journeys; and develop incremental and iterative development plans. She also helps clients evaluate the impact and efficiency of their programs and revise and optimize their digital programs for

maximum impact. Mary has extensive experience crafting data-driven digital and engagement programs using a combination of on- and off-line tactics and strategies. Her work often calls upon deep data analytics to not only inform and tailor experiences, but to drive timing, frequency, and lasting behavior change.

Maria Shams-Ramsey
Senior Advisor
Office of Enterprise Portfolio Management (OEPM),
Office of Digital Transformation (ODT)

Maria Shams-Ramsey currently serves as the Food and Drug Administration's Lead for the Performance Monitoring and Oversight Team (PMOT) within the Office of Enterprise Portfolio Management (OEPM). She overseas multiple Office of Digital Transformation (ODT) agency-wide programs. Maria provides strategic and tactical guidance ensuring FDA's Technology Portfolio is in compliance with federal policies and enterprise-wide portfolio optimization efforts. In her current role, Maria serves as a strategic thought partner to FDA senior leadership, spearheading innovative initiatives that drive positive outcomes for the FDA. Maria has supported various federal agencies as a consultant for much of her career. She began her federal consulting career at the Pentagon with the Office of the Secretary of Defense (OSD) where she specialized in public affairs for high-visibility technology initiatives. Maria is a hands-on entrepreneurial leader with proven experience advancing enterprise-wide initiatives and is the recipient of numerous accolades.

Athena Shry
IT Program Manager
Center for Drug Evaluation and Research (CDER)

Athena Shry is currently serving as the IT program manager for the Over-the-Counter Monograph User Fee Program (OMUFA) in the Center for Drug Evaluation and Research (CDER). In this role, she balances the domains of technology, business analysis, and application design to help motivate business and technical teams, achieve FDA goals, as well as define and achieve overall project success. Prior to her work with OMUFA she spent two years as an ORISE Fellow within OBI's Division of Drug Quality working on the Quality Metric Pilot for partners in the Office of Pharmaceutical Quality (OPQ). In her short time here at FDA, Ms. Shry has received multiple Honors Awards for FDA Leveraging and Collaboration and FDA Group Recognition.

Mary Ann Slack
Director, Office of Strategic Programs
Center for Drug Evaluation and Research (CDER)

Ms. Slack has over 30 years of experience in both the public and private sectors developing informatics strategy and implementing solutions to business problems. She joined the FDA in 2003, where she currently serves as Director of FDA's CDER Office of Strategic Programs, charged with leading many of the Center's strategic initiatives such as decision support, data standards, program analysis, informatics, and governance. Ms. Slack has led numerous large, complex initiatives with broad stakeholder impact. She serves FDA's expert on multiple boards and committees focused on technology, standards, and governance.

Binh Ta
Senior Technical Advisor
Office of Digital Transformation (ODT)

Binh Ta has worked in the IT industry for over 30 years and possesses extensive experience in implementing IT projects. Prior to joining the FDA, Binh Ta worked for large corporations such as IBM, Lockheed Martin, and others. At FDA, he supported various informatics initiatives for the Center for Drug Evaluation and Research, Office of Regulatory Affairs, and Office of Information Management and Technology. His IT projects support included center-specific systems, enterprise platforms, as well as data standards such as the Structured Product Labeling. Currently, Binh Ta is with the Office of Digital Transformation as Senior Technical Advisor managing multiple enterprise efforts, including the next generation for the electronic submission gateway.

Craig Taylor
Chief Information Security Officer (CISO)
Director, Office of Information Security (OIS)
Office of Digital Transformation (ODT)

Selected to the Senior Executive Service in 2016, Mr. Taylor serves as the U.S. Food and Drug Administration (FDA) Chief Information Security Officer (CISO) where he leads and manages the FDA Cybersecurity, Counterintelligence, and Insider Threat Program. He ensures the confidentiality, integrity and availability of information and protects FDA's IT infrastructure, sensitive data, 23,000 end users, and 320 systems and applications. Also advises on cybersecurity, counterintelligence, insider threat, and operational matters to ensure situational awareness, compliance, and operational oversight.

Before joining the FDA, Mr. Taylor was an official at the Office of the National Counterintelligence Executive, under the Office of the Director of National Intelligence (ODNI). As a cybersecurity leader and veteran cryptologist, he built teams of counterintelligence, security, and cyber subject matter experts thwarting hackers and uncovering vulnerabilities, and risks exploited by foreign intelligence services, trusted insiders, transnational criminal organizations, and other adversarial threats. He also served at the Defense Intelligence Agency (DIA), the Defense Information Systems Agency (DISA), Office of Naval Intelligence (ONI) and at multiple overseas locations and aboard naval ships.

Janet Woodcock, M.D.
Principal Deputy Commissioner
Food and Drug Administration

Janet Woodcock is the FDA's Principal Deputy Commissioner. In this role she works closely with the Commissioner of Food and Drugs to develop and implement key public health initiatives and helps oversee the agency's day-to-day functions. She served as the Acting Commissioner of Food and Drugs from Jan. 20, 2021, until Feb. 17, 2022. Dr. Woodcock began her FDA career in 1986 at the Center for Biologics Evaluation and Research (CBER). At CBER, she served as Director of the Division of Biological Investigational New Drugs and as Acting Deputy Director. She later became Director of CBER's Office of Therapeutics Research and Review, which oversaw the approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis during her tenure.

Day 2: Tuesday, December 5, 2023

Hollie Bodiford-Taylor
Senior Program Manager
Office of Laboratory Safety (OLS)

Ms. Bodiford-Taylor is the Program Manager for the enterprise-wide Inventory Control and Information Management System (ICIMS), and for Diversity, Equity, Inclusion, and Accessibility program within the Office of Laboratory Safety. In this capacity she provides strategic direction for information technology, procurement, and acquisition management. Ms. Bodiford-Taylor has worked at the FDA for nearly ten years as a Leader in the areas of Business Informatics; Enterprise Applications; Human Centered Design; IT Modernizations; and Occupational Health and Safety. Under her leadership, the FDA has enhanced business operations, streamlined processes, and implemented new technological tools. And, in her role as the Program Manager for Diversity, Equity, Inclusion, and Accessibility, her primary focus has been on developing strategic initiatives fostering a workforce that reflects the diversity of the United States creating a strong culture of inclusion. Before joining the FDA, she served as a senior leader for the Central Intelligence Agency (CIA), as Chief Officer in the Directorate of Science and Technology. During her intelligence career, she shaped and enabled successful management, strategy, implementation, and administration of programs impacted throughout the intelligence community.

Venu Boppana
Senior Operations Research Analyst
Office of Strategic Programs (OSP)
Center for Drug Evaluation and Research (CDER)

Venu Boppana is a Senior Operations Research Analyst in the Division of Business Management Service and Solution (DBMSS) Office of Business Informatics (OBI), Office of Strategic Programs (OSP) in the Center for Drug Evaluation and Research (CDER). DBMSS is leading the modernization and operations of work management, business intelligence and infrastructure support of the CDER Informatics Platform. Since joining the FDA in 2013, Mr. Boppana has led several critical programs including CDER Drug Supply Chain, COVID IT projects, CDEROne Analytics Platform and Mercado Enterprise Data Warehouse. He has over 20-years' experience in Augmented Analytics, Enterprise Architecture, Applications Development and System Integration. Venu received a BS from University of Mysore, India.

Isaac Chang
Deputy Director
Center for Drug Evaluation and Research (CDER)

Isaac Chang is the Deputy Director of the Office of Computational Science (OCS) in the Office of Translational Sciences, Center for Drug Evaluation and Research. OCS leads and directly supports the modernization of CDER's scientific review capabilities. OCS innovates tools, technologies, and services specifically for drug product review and then provides these to reviewers with training and support. Dr. Chang received his Ph.D. in Bioengineering at the University of Pennsylvania. He was recognized as a fellow with the American Institute for Medical and Biological Engineering (AIMBE) for his scientific research contributions. Dr. Chang earned an FDA Commissioner Citation for helping establish the first high performance computing facility at FDA. He has served in both CDRH and CDER and joined FDA in 1995.

Ethan Chen
Director of Data Management Service and Solution (DDMSS)
Office of Strategic Programs (OSP)
Center for Drug Evaluation and Research (CDER)

Ethan Chen is the Director of the Division of Data Management Service and Solution (DDMSS), under his leadership, DDMSS provides overall leadership in streamlining electronic and traditional submissions and delivering solutions to enable rapid adoption of emerging electronic data standards. Since joining the FDA in 2012, Mr. Chen has led several critical initiatives as the CDER Informatics Architect, including Data Management, Business Intelligence programs, and CDEROne Enterprise Data Analytics programs. He has over 20-years' experience in Data Management, Enterprise Architecture, Solution Development and System Integration.

Kristy L. Daphnis
Chief, Federal Workforce Branch
Executive Office of the President, Office of Management and Budget (OMB)

Kristy Daphnis is a career Senior Executive in the Office of Performance and Personnel Management at the U.S. Office of Management and Budget (OMB), serving as Chief of the Federal Workforce Branch. The Federal Workforce Branch is focused on civil service innovation and reform, the future of work, employee engagement, the use of Federal human capital data and shared services, and effective management of the Federal workforce - comprised of over 2.1 million employees. Complementary to these priorities, she co-leads implementation of Priority 1 of the President's Management Agenda (Strengthening and Empowering the Federal Workforce); supports the Safer Federal Workforce Taskforce by providing government-wide guidance on Federal agency COVID-19 operations; and helps lead implementation of Executive Order 14035: Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce. Collectively, the work of Kristy's team involves collaboration with the U.S. Office of Personnel Management and General Services Administration agency leadership teams, and engagement with senior leaders and executives from agencies across the Government.

In her 20-years at OMB, Kristy has worked on a variety of government management topics including human capital and strategic workforce management, information technology and information security policy, health information technology, legislative review, and regulatory review and reform. Kristy began her career as a Presidential Management Fellow in the Justice Management Division at the U.S. Department of Justice, after receiving her Bachelor of Arts and Bachelor of Science from Michigan State University and her Master of Public Health from the University of Michigan School of Public Health (SPH). She also holds a certificate in Executive Leadership from American University's School of Public Affairs, and currently.

Bhabani Das
Supervisory Management Lead
Center for Food Safety and Applied Nutrition (CFSAN)

Bhabani Das is an IT Solution leader with over 30 years of technology experience, half of which has been spent supporting the FDA. He is a pioneer in providing leadership and IT solutioning for FDA's human food program. FDA's mission is his passion, and he considers technology and strategic thinking the nexus of his career. He holds a BS in Physics and an MS in Computer Applications. In his free time, he serves as a mentor for high school students and is a huge Cricket enthusiast.

Jeffrey DeGrasse, MS, PhD
Occupational Safety and Health Manager
Office of Laboratory Safety (OLS)

Mr. Degrasse is an Occupational Safety and Health Manager in the Office of Laboratory Safety (OLS). In this capacity, he is responsible for leading and coordinating OLS's cross-cutting laboratory safety and security policy efforts and other related initiatives. Jeff previously served in the Office of Scientific Integrity in FDA's Office of the Chief Scientist from 2015 to 2017. In 2008, Jeff joined FDA as a chemist in CFSAN's Office of Regulatory Science. He earned his BS in chemistry from The George Washington University, his MS from Cornell University, and his PhD in Chemical Biology from Rockefeller University.

Anjelica Dortch
Senior Director & Head of Global Cybersecurity Policy
SAP America, Inc.

Anjelica Dortch is Senior Director and Head of Global Cybersecurity Policy at SAP where she manages the company's cybersecurity, artificial intelligence, and workforce policy portfolio. Prior to joining SAP, Ms. Dortch led scale up of tech policy positions at IBM within the Government and Regulatory Affairs team with a focus on artificial intelligence, hybrid cloud, and intellectual property. Ms. Dortch spent 10 years working for a variety of U.S. federal agencies including the Executive Office of the President as a Senior Technology Advisor where she led coordination of several tech policy initiatives within the U.S. government. She has co-authored U.S. policies and strategies including the 2018 National Cyber Strategy, the Presidential Executive Order on America's Cybersecurity Workforce (EO 13870), the U.S. Federal Cloud Computing Strategy (or Cloud Smart), and the Administration's Report on Artificial Intelligence. Ms. Dortch is the recipient of the Office of Management and Budget Special Achievement award, Women Leading for Impact award, the University of Maryland Outstanding Alumnus award, and Federal Computer Week's Rising Star award. Ms. Dortch holds a Bachelor of Arts degree in philosophy and a Master of Science in financial management and information systems from the University of Maryland.

Thomas Farrell
Supervisory Information Technical Specialist
Center for Food Safety and Applied Nutrition (CFSAN)

Thomas Farrell has over 30 years of leadership and technical experience providing information technology (IT) services to the Federal Government and possesses a comprehensive understanding of IT systems. He is a seasoned executive experienced in all aspects of project management, customer relationship management, human resources, contract management, business development, and finance. Thomas served as a Vice President and Program Manager for HHS Accounts at both large and small businesses overseeing various IT programs at the NIH, FDA, HHS, MHS, and USCG and worked for the Federal Government overseeing data center operations for FDA, US Patent and Trademark Office and the IRS.

Sacha H. Gutierrez, MD, MS, FACOEM
Chief Medical Officer
Occupational Health Services (OHS)

Dr. Gutierrez graduated from Princeton University with a degree in chemistry. She completed medical school at the New Jersey Medical School and then served three years on active duty as an Army flight surgeon. Her time in service included one tour in Afghanistan in support of Operation Enduring Freedom. Sacha completed her residency training in occupational medicine at University of Texas at Tyler while also earning a Master of Science in environmental medicine at Stephen F. Austin State University. Before joining the staff at FDA in January 2016, Dr. Gutierrez worked for the US Army as a disability evaluation physician for five years and then moved on to manage a 24-hour urgent care and occupational health clinic for Concentra, a national healthcare company. In her seven-year tenure at FDA as Chief Medical Officer, Occupational Health Services, she has worked toward standardization of occupational health services provided across FDA, updating clinic procedures, and promoting employee health.

Charlie Haggart
Chief Data Steward, Office of the Center Director (OCD)
Center for Devices and Radiological Health (CDRH)

Charlie Haggart, Ph.D., is CDRH's Chief Data Steward. The Data Stewardship group sits in the Office of the Center Director and serves the Center's regulatory review, public health, and supporting business functions. The Data Stewardship group utilizes a comprehensive approach to defining and implementing enterprise data, improving data quality, and building and operating an effective data governance program. In his current role, Dr. Haggart and team lead development and implementation of CDRH's Enterprise Data Model. Leveraging Informatica data management tooling (EDC, IDQ, Axon), Dr. Haggart and team are spearheading CDRH's phased implementation of an enterprise business glossary, and a multi-domain Master Data Management (MDM) initially scoped for Regulated Entity data (organizations and individuals over which CDRH has regulatory oversight). Prior to his current role, Dr. Haggart has a range of experience at CDRH across quality management and organization excellence, medical device innovation, and pre-market review of cardiovascular devices.

Chuck Hassenplug
Senior Policy Analyst
Center for Food Safety and Applied Nutrition (CFSAN)
Office of Compliance

Chuck Hassenplug is currently a Senior Policy Analyst in CFSAN's Office of Compliance, Division of Field Planning. He leads modeling and analysis work to support risk-informed resource allocation for CFSAN Field Programs, to include cutting-edge compliance predictions using machine learning. Previously, he led cross-cutting projects across the Food Program within OFPR/OFVM, and before that served as the Director of ORA's Division of Planning, Evaluation, and Management. Chuck started his FDA career in 2007 working as an Operational Research Analyst conducting program evaluations across FDA's Product Centers. Chuck has a BSc. in Bioengineering and a MSc. in International Healthcare Management, Economics, and Policy.

Kellie P. Isaac
Chief Innovation Officer
Association of Food and Drug Officials (AFDO)

Kellie Isaac is AFDO's Chief Innovation Officer and SAFHER Director. Isaac is a highly creative and innovative, goal-oriented IT professional with more than 20 years of experience in the private and public sector. Isaac has significant experience in Program Management, Product Management, Project Management, Information Technology, International Product Delivery, Customer Experience, Aviation, and Business Finance. She has used these talents while serving companies such as Boeing, Amazon, Lloyd's Register, and the State of Colorado. Isaac gets great satisfaction partnering with stakeholders to turn their visions into reality by delivering valuable user-friendly products for their organization and end-users. Fluent in "tech speak," Isaac excels at translating technical information into relatable non-technical terms, while guiding customers, decision makers, and top executives to achieve business, organizational, and customer goals. She has extensive background in problem-solving, ideation, and strategy in support of customer solutions. Developing and delivering SAFHER has been the perfect opportunity to leverage Isaac's entrepreneurial spirit with her mission-driven experience supporting the public and private sector. Isaac finds great satisfaction in working with AFDO, the FDA, the States, and private sector to help improve inspections, facilitate data management and data sharing, and track and prevent food born illness.

Ram Iyer
Chief Data Officer
Director, Office of Data, Analytics, and Research (ODAR)
Office of Digital Transformation (ODT)

As the Chief Data Officer of the FDA, Ram C. Iyer has the accountability to develop and execute an agency wide data modernization strategy, building robust central functions that can be leveraged by the centers and the agency for high value decisions. The scope spans the entire stack from data identification to actionable decision, including data policies and governance. Ram is an industry and peer recognized data and technology professional with experience in the Pharma, Consulting, Telecom, and International Government organizations. His expertise includes Data and Decision Sciences, Digital and Technology Architecture, and Talent Development with a focus on building collaborative partnerships and ecosystems. Before joining the FDA, Ram was the Head of Enterprise Architecture and Executive Director of Analytics Center of Excellence at Bristol Myers Squibb (BMS). He helped jumpstart several Data and Analytic practices at BMS including enterprise class platforms for reproducible research, model management and visual analytics. He also built a thriving network of data scientists, data analysts, visual story tellers, and agile specialists to tackle urgent and complex problems in the organization. Ram received his Master of Science in computer science from the New Jersey Institute of Technology and Bachelor of Science in mathematics from the University of Madras, India. He is also trained in several complementary skills such as Enterprise Analytics, System Dynamics, and Design Thinking from leading institutions in the U.S.

Ernest K. Kwegyir-Afful, PhD, RAC
Senior Policy Advisor
Center for Food Safety and Applied Nutrition (CFSAN)

Ernest received his Ph.D. in Neuroscience from the University of Maryland, Baltimore, and a Certificate in Data Science from Georgetown University. His graduate work and subsequent post-doctoral work at the University of Pittsburgh School of Medicine focused on signal transformation in neuronal networks involved in somatosensory perception and memory consolidation. In 2010, he joined the U.S Food and Drug Administration as Commissioner's Fellow where he worked in the Office of Food Additive Safety serving as the technical lead on quantitative risk assessment projects.

Ernest has previously led CFSAN's efforts in designing an AI engine, "Emerging Chemical Hazard Intelligence Platform", to assist the pilot Chemical Signals Program in detecting and predicting the emergence of potential chemical hazards of concern in the food supply. This work was featured in a KM World publication and the Harvard Business Review. Ernest has had the privilege to advise and interact with various government organizations, including the Dutch and Swedish governments, on the use of effective and appropriate tools to successfully implement AI powered applications that address specific challenges. Ernest is currently leading an effort to build an intelligent analytic and knowledge discovery engine that will help streamline some of the Office's and Center's horizon scanning activities related to premarket submissions and post-market surveillance.

Sunitha Mathews
Director, Division of Drug Quality and Compliance Services and Solutions (DDQCSS), Office of Business Informatics (OBI), Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER)

Sunitha Mathews is the Director for Drug Quality and Compliance Services and Solutions (DDQCSS) in the Office of Business Informatics (OBI) and oversees large-scale informatics systems implementation for CDER. Under her leadership, DDQCSS provides product management and technology solution delivery services to modernize Generic Drug Review, Pharmaceutical Quality Review, and Compliance processes. This includes modernizing and streamlining regulatory review processes in a CDER-wide enterprise review platform, and delivering workflow, analytics, and knowledge management solutions to improve the efficiency of drug product assessments. Ms. Mathews has over 18 years of Information Technology experience and joined the FDA in 2015. She holds a Bachelor of Science in computer science and Master of Science in software engineering from George Mason University, Virginia.

Monica Mehta
Vice President
Biogen

Monica Mehta is VP, Head Global Pharmacovigilance, Regulatory Submission Management and PV/Regulatory Quality at Biogen. Prior to Biogen, Monica was at Genzyme and Sanofi in Regulatory Operations and RIM and PV Operations, respectively.

Sheri L. Morris
Assistant Director
PA Department of Agriculture
Bureau of Food Safety & Laboratory Services

Sheri has 15 years of experience in the food industry holding various quality assurance and sanitation management positions, in LACF, Dairy, Frozen & Dried Vegetable, and Snack Food manufacturing firms. Sheri also has 25 years with the PA Department of Agriculture, (PDA), Bureau of Food Safety & Laboratory Services. In her 25-year career at PDA Sheri has been involved with development of 3 successive inspection systems and was key in the development of the current PA Food Safety inspection system that was then opened for use by other state jurisdictions and currently known as US Food Safety. Sheri was the Principal Investigator on an FDA grant for PDA to implement the National Food Safety Data Exchange (NSFDX), for contract and non-contract inspections, as well as

laboratory data. Sheri is involved in the current SAFHER project as part of the multiple user groups and as a pilot state.

On a national level Sheri has on the Executive Board for the Conference for Food Protection (CFP), was Chair of the 2012 Conference and is the current CFP representative on the ACAC (ANAB-CFP Accreditation Committee). Sheri is the CASA Representative on the Executive Board of the Manufactured Food Regulatory Program Alliance (MFRPA) and the current Chair. Recently, Sheri facilitated the signing of a Partnership Agreement between FDA and PDA to advance mutual reliance between the agencies and further an integrated food safety system.

Archana Narayanaswamy
Business Informatics Specialist
Office of Business Informatics (OBI), Office of Strategic Programs (OSP)
Center for Drug Evaluation and Research (CDER)

Archana Narayanaswamy is leading several critical IT modernization projects in implementing IT solutions to support of CDER's GDUFA commitments, Center's first knowledge management and structured review system 'KASA' and enterprise workload management dashboard. Archana has more than 17 years of IT product management experience across the federal government and private sector. She brings in 12 years of strong IT consulting experience while working on variety of health care projects in one of the top consulting firms. Archana holds a Bachelor of Science in engineering from Visvesvaraya Technological University (VTU), and a Master of Science in information systems from University of Pittsburgh.

Christine Parker
Supervisory Chemist
Center for Food Safety and Applied Nutrition (CFSAN)

Christine Parker obtained her B.S. at Bucknell University and Ph.D. in Chemistry at the University of North Carolina at Chapel Hill. In 2010, Christine began her work at the U.S. Food and Drug Administration in the Center for Food Safety and Applied Nutrition (CFSAN). Today she supports FDA in leading the Bioanalytical Methods Branch (BMB) in the Office of Regulatory Science (ORS) on the development and validation of analytical methods and the collection of scientific data including the broad areas of chemical contaminants, natural toxins, and nutrients in food and dietary supplement products.

LCDR Justin Perkins, REHS, ASP
Health & Safety Manager
Center for Food Safety and Applied Nutrition (CFSAN)

Justin has over 20 years of diverse safety and health experience from their time in the US Army, private consulting, and the US Public Health Service. In these roles, they managed WMD response/defense programs during 9/11, overseen a dozen asbestos and lead contaminated demolitions, managed $70 million in retail tobacco inspection contracts, and ensured food safety standards through retail inspections at cafeterias in almost every federal building in the DC/MD/VA area including White House Executive Office Buildings, the Smithsonian, and White Oak Campus. LCDR Perkins currently serves as an Occupational Safety & Health Manager for FDA's Center for Food Safety and Applied Nutrition.

Their responsibilities include leading Center programs in the areas of Incident Investigation, Laboratory Safety Inspections, Safety Training, and Laser Safety. Additionally, they administer the

Center Safety Program's digital footprint; enhancing safety program effectiveness by managing online collaboration software, updating hardcopy processes into automated formats, and utilizing AI and LLM solutions to provide real-time leading and lagging indicator metrics. Outside of work, Justin enjoys researching and presenting on niche areas of Japanese history, culture, and travel, as well as hosting gaming night for friends.

Raju Rayavarapu
Staff Fellow/Technical Information Specialist
Center for Tobacco Products (CTP)

Raju comes to the FDA from the great state of Pennsylvania via South Bend, IN and Memphis, TN where he did his Ph.D. and post-doctoral work. He is the lead of ODAR's DataForward Initiative which is focused on upskilling FDA staff in data related skills and harnessing the power of the incredible existing FDA data science community to drive data literacy and the joy that comes from working with and understanding data. Raju is also the Lead Data Scientist for Data Analytics as a Service, one of the co-chairs of the Scientific Computing Board and loves to spend his time talking FOSS (Python/R/whatever), Natural Language Processing, artificial Intelligence (AI), and all things data science. He also spends any night he can staring into the universe with his two dogs and his telescope.

Eugene Reilly
Director of the Division of Enforcement Systems Solutions
Office of Information Systems Management

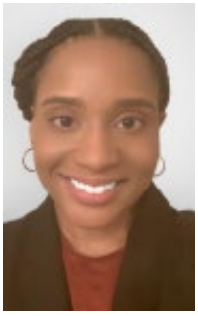
Eugene Reilly is the Director of the Division of Enforcement Systems which manages several systems that support operational staff conducting inspections, pursuing compliance actions, conducting sample collections and analysis, and managing recalls as well supporting systems involved with FDA's exchange of information with State, Local, Tribal, and Territorial (SLTT) regulatory partners. The Division also contains subject matter experts on the data from the systems the Division supports.

Michelle Rohrer
Global Head of Product Development Regulatory
Genetech Roche

Michelle Rohrer has been with Genetech Roche for 30 years, starting as a post-doctoral research fellow with subsequent roles as a clinical scientist, project team leader and regulatory strategist. Currently, she leads Roche's global regulatory organization responsible for the regulatory strategies and submissions supporting Roche's pharmaceutical development pipeline. Michelle is a member of TransCelerate Biopharma Inc's Board of Directors, until recently chaired the Charles Forum, is a founding member of Accumulus Synergy, serves as the executive sponsor of PhRMA's Regulatory IT Working Group, is the PhRMA representative to the ICH Management Committee and Assembly and co-chairs the ICH New Topic process. In 2015, she served as one of the industry representatives to the PDUFA VII negotiation team. Michelle views policy and molecule work as complementary. In her various roles, she strives to identify areas where policy can speed the development of innovative medicines for patients.

Ali Russo
Chief Data Officer
Office of Strategic Partnerships and Technology Innovation
Center for Devices and Radiological Health (CDRH)

Ali Russo is the Chief Data Officer in the Center for Center for Devices and Radiological Health. Ali joined the FDA in 2023 to lead the Data Modernization efforts within the center. She has over 25 years of experience in standing up successful data and analytic programs. Prior to the FDA, Ali served as the Chief Information Officer at FAIR Health, a non-profit organization with the mission to increase healthcare price transparency and the largest private healthcare claims repository in the United States. Ali has also served as the Director of Analytic Services for McKesson, Corp. She is currently pursuing a Master of Public Health at the George Washington University Milken School of Public Health.



Randi Scott
Data Scientist Lead, Office of Strategic Partnerships and Technology Innovation
Center for Devices and Radiological Health (CDRH)

Randi is an experienced and skilled leader in the healthcare analytics industry. Randi's most recent job was at FAIR Health where she was working as a Senior Healthcare Data Analyst leading statistical and descriptive custom analyses for diverse stakeholders in the healthcare ecosystem, including providers, government, academia, and others. She has also worked for the New York City Department of Health and Mental Hygiene where she was responsible for many of the data visualizations and innovation reporting that the department was responsible for. Randi has a Master of Science in quantitative methods in the social sciences from Columbia University.

Denny Skiles
Senior Executive for National Center for Toxicological Research (NCTR)
Associate Director of Operations
Office of Management (OM)

Denny Skiles maintains oversight of NCTR's support operations to include ethics, equal employment opportunity, human capital programs, communications, acquisition, and financial management oversight. Denny joined FDA in 2022, coming from USDA as Director of the Geospatial Enterprise Operations (GEO) Center located in Salt Lake City Utah, which provides enterprise level geospatial services and data in support of USDA programs. Mr. Skiles led the development of data materialization, curation, and distribution to millions of consumers daily, and the materialization of AI/ML tools for data analytics. Denny has served the federal government for over 20 years as a federal civilian after capping off a 27-year military career in the active duty and reserve forces.

Zac Tillman
Data Scientist
Office of Program and Strategic Analysis (OPSA), Office of Strategic Programs (OSP)
Center for Drug Evaluation and Research (CDER)

Zac Tillman is a Data Scientist on the Economics Staff in the Office of Program and Strategic Analysis (OPSA), Office of Strategic Programs (OSP) in the Center for Drug Evaluation and Research (CDER). OPSA provides a range of analytical services, project management support, and strategic and operational planning for CDER offices to improve the effectiveness and efficiency of regulatory functions. Since joining the FDA in 2017, Zac has led large scale data science and predictive modeling efforts on policy questions related to pharmaceutical product pricing, shortages, and supply

chains while contributing to efforts related to workforce planning and controlled substances. Zac received two bachelor's degrees from the University of Pittsburgh and Master of Science in public policy and management from Carnegie Mellon University's Heinz College where he focused on the intersection of data science and policy analysis.

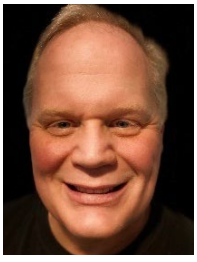
Day 3: Wednesday, December 6, 2023

Mahesh Kanubhai Choksi
Division Director, Division of Acquisitions Innovation
Office of Digital Transformation (ODT)

Mr. Mahesh Choksi is the Director of the Acquisition Strategies and Partnership (ASAP) Division, within the Office of Digital Transformation (ODT) at the Food and Drug Administration (FDA). He leads ODT-wide acquisitions support, including the development and implementation of ODT's Acquisition-as-a-Service (AaaS) model, vendor management program, small business participation support services, business process improvement, and CORs workforce development in overall acquisitions management. Mr. Choksi began his 14-year career with FDA as a deputy branch chief in Division of Application Services (DAS), supporting IT solutions for multiple FDA centers. He then moved on to the role of Director in the Division of Infrastructure Operations (DIO) with a focus on infrastructure management services.

Mr. Shannon C. Jackson
Director, U.S. Department of Health, and Human Services
The Office of Small and Disadvantaged Business Utilization (OSDBU)

Mr. Shannon Jackson is responsible for implementing the Department's small business procurement programs across the HHS portfolio valued at $9.4 billion in procurements, awarding contracts each year to small businesses. Mr. Jackson comes to HHS with a wealth of experience and is joining us from the Department of Defense (DoD) Office of Small Business Programs (OSBP) where he served in various roles to include Acting Director of OSBP, Deputy Director of OSBP, and Associate Director for the DoD Mentor Protégé Program and Senior Advisor to the Director of the DoD OSBP. Mr. Jackson has served over 29 years in the federal government and has held various leadership positions throughout his career, to include his military service retiring at the rank of Lieutenant Colonel in the U.S. Army. Mr. Jackson led a network of 700 full- and part-time small business professionals across the DoD. Noteworthy is that the work of DOD's small business workforce results in more than $50 billion in prime contract spending on contracts to small businesses and over $40 billion in subcontract spending for small businesses annually.



Andrew Jernell
Director of Division of Information Technology Acquisitions
Office of Acquisitions and Grant Management (OAGS)

Andrew Jernell has over 35-years of federal procurement, acquisition management, and consultant experience. Over his career he has acquired jet fuel, intelligence satellites & systems, and a wide range of information technology systems and solutions for federal agencies. He has spent time at the US Defense Logistics Agency, US National Reconnaissance Office, US Postal Service, US Department of Education's Federal Student Aid, US Coast Guard, and is currently working for the US Food and Drug Administration. Andrew led the effort in establishing the U.S. Coast Guard's new Command, Control, Communication, and Information Technology Service Center acquisition organization and became the Chief of Contract Office and was the Contracting Officer and Deputy Program Manager for the Postal Service Retail Modernization Program. He also has five years of consulting experiences with a leading federally- funded research and development center.

Monica Taylor
Senior Innovation Coach
U.S. Department of Homeland Security

Monica is a Senior Innovation Coach within the U.S. Department of Homeland Security's Procurement Innovation Lab (PIL). The PIL is a virtual lab that provides a "safe space" for acquisition teams to test innovative techniques to improve the efficiency and effectiveness of procurements. Monica works directly with procurement teams within DHS and external federal agencies, assisting teams in determining the contract method and strategy to be used while implementing procurement innovation techniques. Monica enjoys bridging the gap between federal contracting, the mission, and its customers, internal and external.