FDA

DIGITAL TRANSFORMATION SYMPOSIUM 2022

Hosted by FDA's Office of Digital Transformation

DECEMBER 5–7 | 2022

Table of Contents

KEYNOTE SESSIONS

(All times listed are in Eastern Standard Time)

Day 1 Monday, December 5, 2022

9:15 AM	***Holistic Modernization***	Vid Desai, FDA Chief Information Officer (ODT)
10:25 AM	***Making the Difference: The Journey to a New Operating Model***	Mohammed Sohail Chaudhry, FDA Chief Technology Officer (ODT/OIMT)

Day 2 Tuesday, December 6, 2022

9:15 AM	***Connecting the Dots: Building a Data and Talent Ecosystem***	Ram Iyer, Chief Data Officer (ODT/ODAR)
1:00 PM	***The Art and Science of Racing***	Robert Megennis

Day 3 Wednesday, December 7, 2022

12:00 PM	***Emerging Technologies Trends***	David Groombridge, VP (Gartner)

AGENDA

(All times listed are in Eastern Standard Time)

Day 1: Monday, December 5, 2022

Time	Session Title	Speakers
9:00 AM	Welcome	Mary Schwarz, Symposium Moderator
9:15 AM	***Keynote: Holistic Modernization***	Vid Desai, FDA Chief Information Officer (ODT)
9:45 AM	Building a Digital Future: Cloud Forward	Farhan Khan, Mark Kennedy, and Beth Wisneski (ODT/OTD)
10:15 AM	Break	
10:25 AM	***Keynote: Making the Difference: The Journey to a New Operating Model***	Mohammed Sohail Chaudhry, FDA Chief Technology Officer (ODT/OIMT)
10:45 AM	CDRH's Digital Transformation: Success and Challenges	Daniel Montgomery, Elizabeth McNamara, Jerry Logue, Charlie Haggart, Poonam Sachdeva, and Kenneth Sullivan (CDRH)
11:30 AM	Break	
11:40 AM	Revolutionizing IT Portfolio Management Through Technology Business Management	Joseph Montgomery and Maria Shams-Ramsey (ODT/OEPM)
12:20 PM	Lunch	
12:45 PM	CDEROne Analytics Enterprise Platform Overview	Ethan Chen and Venu Boppana (CDER)
1:30 PM	FDA IT Acquisition Strategies and Goals	Mahesh Choksi (ODT) and Andrew Jernell (OAGS)
2:00 PM	Break	
2:15 PM	***Fireside Chat: The Direction of IT in FDA***	Dr. Robert Califf, FDA Commissioner; Dr. Janet Woodcock, FDA Principal Deputy Commissioner; and Erica Jefferson, Associate Commissioner for External Affairs
2:45 PM	Moderator Closing Remarks	Mary Schwarz, Symposium Moderator

Day 2: Tuesday, December 6, 2022

Time	Session Title	Speakers
9:00 AM	Welcome	Mary Schwarz, Symposium Moderator
9:15 AM	***Keynote: Connecting the Dots: Building a Data and Talent Ecosystem***	Ram Iyer, Chief Data Officer (ODT/ODAR)
9:45 AM	Executive Perspectives on Data Modernization – A Panel Discussion	Carol Cave, Deputy Associate Commissioner for Regulatory Affairs; Frank Yiannas, Deputy Commissioner for Food Policy and Response, and Aloka Chakravarty
10:15 AM	Enterprise Modernization in Action	Dr. Meredith Chuk and Adele Nguyen (ETO)
10:45 AM	Break	
11:00 AM	Realizing the Value of FDA Data: Bridging the Gaps	Ram Iyer, Elaine Johanson, Swati Kulkarni (ODT/ODAR); Jason Cober (CDER); and Brandon Gallas (CDRH)
12:00 PM	Lunch	
1:00 PM	***Keynote: The Art and Science of Racing***	Robert Megennis
1:45 PM	Transforming How the FDA Foods Program Receives and Uses Data	Bhabani Das, Pedram Farid, Lauren Gortenburg, Robyn Barringer (CFSAN)
2:30 PM	Break	
2:45 PM	Research-to-Review Program to Empower Digital Transformation	Joshua Xu (NCTR)
3:30 PM	CVM Modernization: One Health	Douglas Margulies (CVM)
4:15 PM	Moderator Closing Remarks	Mary Schwarz, Symposium Moderator

Day 3: Wednesday, December 7, 2022

Time	Session Title	Speakers
9:00 AM	Welcome	Mary Schwarz, Symposium Moderator
9:15 AM	Evolution of the FDA Cybersecurity Counterintelligence and Insider Threat Program	Craig Taylor, Chief Information Security Officer, and Leah Buckley (ODT/OIS)
9:45 AM	CTP Rhapsody: Supporting Tobacco Product Marketing Application and Review	Susan Tam, Deborah Sholtes, and Vijay Dharmavaratha (CTP)
10:30 AM	Break	
10:45 AM	Building the Federal IT Workforce of the Future	Jess Berrellez, Executive Officer (ODT); Melanie Keller, Chief Talent Officer; and Jordan Parsons (ICF)
11:30 AM	Lunch	
12:00 PM	***Keynote: Emerging Technologies Trends***	David Groombridge (Gartner)
12:45 PM	Research into the Use of Artificial Intelligence/Machine Language Models and Technology to Produce Resource Efficiencies in ORA Processes	Indu Konduri, Greg Parcover, and Eugene Reilly (ORA)
1:45 PM	Break	
2:00 PM	Modernizing Identity and Access Management: Implementing Role-Based Access Management at CBER	Maryland Hatch (CBER)
2:45 PM	Modernization of Support for a Dispersed Workforce	Joshua Lehman (ODT/OBCA)
3:15 PM	Moderator Closing Remarks	Mary Schwarz, Symposium Moderator

SPEAKERS AND BIOGRAPHIES

(Listed in alphabetical order by last name, by day of presentation)

Day 1: Monday, December 5, 2022

Venu Boppana
Operations Research Analyst, Division of Data Management Service and Solution (DDMSS), Office of Business Informatics (OBI), Office of Strategic Programs (OSP)
Center for Drug Evaluation and Research (CDER)

Venu Boppana is an 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 for 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.

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

Dr. Robert M. Califf was confirmed earlier this year 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. This is Dr. Califf's second stint as Commissioner. He also served in 2016 as the 22nd Commissioner. Before assuming the position at that time, he served as the FDA's Deputy Commissioner for Medical Products and Tobacco.
Prior to rejoining the FDA in 2022, Dr. Califf was head of medical strategy and Senior Advisor at Alphabet Inc., contributing to strategy and policy for its health subsidiaries Verily Life Sciences and

Google Health. He joined Alphabet in 2019, after serving as a professor of medicine and vice chancellor for clinical and translational research at Duke University. He also served as director of the Duke Translational Medicine Institute and was the founding director of the Duke Clinical Research Institute.
Dr. Califf is a graduate of Duke University School of Medicine. He completed a residency in internal medicine at the University of California, San Francisco, and a fellowship in cardiology at Duke.

Mohammed Sohail Chaudry
Chief Technology Officer and 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. Additionally, he has led the Risk and Compliance Division of OIMT at the FDA as the Deputy Chief Information Security Officer (D-CISO) and as a Senior Technical Advisor, where he established the foundation for FDA's cloud, mobile technology, and multiple security initiatives for the development and execution of processes that enable the FDA to efficiently leverage emerging solutions. He systematically developed and implemented enterprise technology programs, which reduced disruptions to business systems by nearly 80% and modernized the operational functionality and stability across FDA's IT enterprise.

Ethan Chen
Director, Division of Data Management Service and Solution (DDMSS), Office of Business Informatics (OBI), 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), Office of Business Informatics (OBI), Office of Strategic Programs (OSP) in the Center for Drug Evaluation and Research (CDER). 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. Ethan received a Bachelor of Science from Shanghai Jiao Tong University, a Master of Science Engineering from Temple University, and a Master of Business Administration from University of Maryland at College Park.

Mahesh Kanubhai Choksi
Division Director, Acquisition Strategies and Partnership Division (ASAP)
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. Choksi possesses a Bachelor of Science in Mechanical Engineering and Master of Business Administration in Finance and Marketing. He also holds several certifications: CISSP, PMP, CEH, and COBIT V. In 2022, Mr. Choksi was the recipient of the Star OSDBU award for outstanding support to the Small Business community. In his free time, Mr. Choksi enjoys traveling, exploring new cultures and food, kayaking, hiking, and cycling.

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. Vid's previous experience includes IT leadership roles with large clinical research organizations and pharmaceuticals, including Quintiles Transnational, where he served as executive director, Global IT Infrastructure. Prior to

Quintiles, Vid held several leadership positions of increasing responsibility with GlaxoSmithKline. Vid started his career in IT as a software engineer at Digital Equipment Corporation in Reading, U.K. Vid holds a Bachelor of Science degree in Computer Science (first class with honors) from Royal Holloway College, University of London.

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.

Erica Jefferson
Associate Commissioner for External Affairs
Office of the Commissioner

Erica Jefferson is the Associate Commissioner for External Affairs (OEA) within the Office of the Commissioner at the U.S. Food and Drug Administration. In this role, Ms. Jefferson oversees agency-wide communications activities regarding the FDA's public health and regulatory activities. This includes the development, coordination, and leadership of all FDA communications as well as outreach efforts to the news media, health professionals, patient advocates, industry, states, consumer groups and the general public. OEA also serves as the focal point for speechwriting, creative and editorial services, and best practices for the agency for digital and web technology and social media.
Ms. Jefferson has more than 17 years of progressive communications, patient advocacy and public affairs experience across the federal government, professional association, and private sector industries. She previously served at the FDA as the Acting Assistant Commissioner for Media Affairs. Prior to joining the agency, she held positions of increasing responsibility at a boutique crisis communications agency, a health care professional society and a leading biotechnology company. Before returning to the agency, Ms. Jefferson worked in communications and public affairs leadership roles at several clinical and commercial stage biotechnology companies focused on developing novel therapeutics for various diseases.

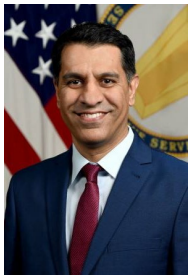
She holds a bachelor's degree in Communication with a minor in Sociology from the University of Maryland, College Park and master's degree in Health Communication from The Johns Hopkins University.

Andrew Jernell
Director, Division of Information Technology Acquisitions
Office of Acquisitions and Grant Management

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. Andrew was a University of Virginia Adjunct Professor for 20-years in their Procurement Management Certificate Program and assisted in establishing and taught in their Project Management Certificate Program.

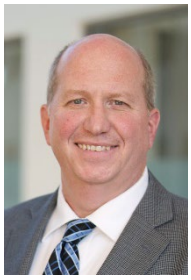
Mark Kennedy
IT Sr. Technical Advisor, Office of Technology & Delivery (OTD)/Division of Infrastructure & Operations (DIO)
Office of Digital Transformation (ODT)

Mark Kennedy is an accomplished IT professional with over 25 years' experience in adding business value through planning, design, and implementation of transformational IT systems and services. His previous experience includes global Contract Research Organizations (CROs), large Pharma, IT service providers, and self-owned IT consulting businesses. As the FDA's Division of Infrastructure's Sr. Technical Advisor, Mr. Kennedy supports strategic planning for IT transformation and modernization initiatives and leads highly effective teams in operational effectiveness to engineer and implement IT solutions in support of FDA business requirements.
Prior to joining the FDA, Mark held senior IT roles at INC Research (now Syneos Health) and Quintiles Transnational (now IQVIA), both global CROs. Other roles included Sr. Program Manager for multiple merger & acquisition activities and IT transformations for medical device and information management corporations. As an IT consultant Mark provided IT planning, design, and implementation management for local and state government agencies, financial institutions, and educational institutions. Mark holds a Bachelor of Science in Electrical Engineering and holds certifications as a Project Management Professional (PMP), and Registered Communications Distribution Designer (RCDD).



Farhan Khan
Technical Lead, Division of Regulatory Science Informatics
Office of Information Management and Technology (OIMT)
Office of Digital Transformation (ODT)

Farhan Khan is the Director of the Office of Technology and Delivery (OTD) in ODT's Office of Information Management and Technology (OIMT). His areas of expertise include Infrastructure Operations, Technology Innovation, Capacity Management, Contract Management, and more. Farhan's previous roles include principal advisor to the Army CIO on IT, business, architecture policy and process related improvements as the Director of Architecture and Integration, Chief of IT Infrastructure and Operations at The Federal Deposit Insurance Corporation (FDIC), Chief Technology Officer at the FDA, Director of IT Infrastructure at the U.S. Department of Transportation, and Acting CIO for the US Department of Justice Criminal Division. He's a strategic business and technical executive with a track record of saving millions in IT expenses through business transformation and process redesign. Farhan holds a Master of Information Management Systems (MIS) from George Washington University.



Jerry Logue
Senior Project Manager, Office of Product Evaluations & Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

Jerry Logue brings nearly 30 years' experience solving complex business problems using technology and data. Mr. Logue joined the FDA in 2015 and has been working on CDRH's Digital Transformation (DT) initiative since 2017, serving as the chair of the Business Owner Board (BOB) and Business Review Board (BRB). In this role, he works to align the business needs across the Center to help technical teams define optimal technical and data solutions. He also leads the Organizational Change Management (OCM) team that helps accelerate the adoption of changes being made in our transformation. Prior to joining the FDA, Mr. Logue worked 22 years as a consultant delivering solutions and served as a developer, technical lead, business analyst lead, and project manager. He earned his MBA from Loyola University Maryland, MS Comp Sci from Johns Hopkins University, and BSEE from the University of Maryland.

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

Liz McNamara brings nearly 30 years' experience solving complex business problems using technology and data. Liz joined the FDA in 2019 and is the director of CDRH's Digital Transformation (DT) initiative since 2018. Ms. McNamara has over 25 years of increasing responsibility and a proven track record in the planning, development, and implementation of complex health information technology applications and solutions. Liz has functional expertise in digital transformation, product development, program management, organizational change

management, enterprise analytics, IT service management, and system selection. 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's degree in Healthcare Administration and a bachelor's degree in Decision and Information Systems from the University of Maryland and is a certified ITIL and Agile Professional.

Daniel Montgomery
Deputy Director of Operations, Office of Product Evaluations & Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

Daniel Montgomery is the Executive Sponsor of CDRH's Digital Transformation since 2016 and the Deputy Director of Operations for the Office of Product Evaluation and Quality since 2020. Mr. Montgomery previously served as the Associate Director for Operations and the Deputy Executive Officer in CDRH's Office of Management. Mr. Montgomery started his career with CDRH in 2004 and has become a recognized expert in government budget and human capital management. Mr. Montgomery was selected to lead CDRH's Digital Transformation initiative because of his executive experience overseeing large efforts with significant funding. He earned his master's degree in HR from Towson University and his Bachelor of Arts from University of Maryland Baltimore County.

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.

Poonam Sachdeva
Digital Transformation Program Manager, Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health (CDRH)

Poonam Sachdeva is the Program Manager for CDRH Digital Transformation program. Mrs. Sachdeva serves as the Program Manager for the Decision Management Portal, Policy Guidance Development, ASCA, Advanced workflows and CDRH Acquisition and Administrative Planning System (CAAPS) efforts. Decision Management Portal provides a platform to CDRH staff to access their work assignments to perform their job duties. CAAPS is CDRH's Budget & Acquisition and Human Resources system. She has led successful delivery of new capabilities such as Policy Guidance Development workflow and making CAAPS-HR functions available to all CDRH offices. She is leading the development of Advanced workflows for the Total Product Lifecycle (TPLC) to help Reviewers perform reviews more efficiently. Mrs. Sachdeva has over 25 years of experience in Information Management Systems and Program Management in both the public and private sectors.

Maria Shams-Ramsey
Office of Enterprise Portfolio Management (OEPM), Performance Monitoring and Oversight Team
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. Maria obtained a Bachelor of Science in Public Affairs from Indiana University in 2009 and became a Certified Technology Business Management Executive in 2019.

Mary Schwarz, FDA Digital Transformation 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.

Kenneth Sullivan
Principal, Booz Allen Hamilton

Kenneth is a seasoned Program Manager with more than 20 years of Federal and commercial experience leading program management for large scale systems development, system integration, and digital solutions programs. He successfully transforms organizations by envisioning future state capabilities and driving operational performance and efficiency, meeting program objectives through automation, business intelligence and technical innovation. Mr. Sullivan defined and led a multi-year strategic modernization effort to lower IT costs, leading teams of 200+ team members. He led the development of a blueprint for cloud migration as well as the creation and implementation of Continuous Integration/Continuous Delivery (CI/CD) toolsets. He implemented an operating culture of DevSecOps to improve time to delivery and reduce security vulnerabilities. In addition, his programs implemented a Scaled Agile Framework (SAFe), modernizing their approach to software delivery. Under his leadership, the organization began pilot migrations to AWS and started shifting from proprietary software platforms to lower cost, open source alternatives. Mr. Sullivan earned his bachelor's degree in Decision and Information Systems from the University of Maryland, and is a Certified AWS Solution Architect.

Beth Wisneski
IT Program Manager, Office of Technology & Delivery (OTD)/Division of Infrastructure & Operations (DIO)
Office of Digital Transformation (ODT)

Beth Wisneski is an accomplished IT professional with over 15 years of experience as a Technical Project manager following 10 years as a Network Engineer. Her previous experience includes mid-level and large government infrastructure projects.

Ms. Wisneski has most recently been serving as the FDA Cloud Team Lead, which is responsible for supporting Amazon Web Services (AWS) and Azure at FDA. In that role, Ms. Wisneski utilizes her broad knowledge of Information Technology, cloud computing, and usage to manage multiple complex cross-team initiatives from analysis, architecture and design, through development and implementation. Prior to joining the FDA, Beth held senior project manager and network engineering roles at DRT Technologies, Unisys, and EDS. Beth holds a Bachelor of Arts degree in Criminal Justice from the University of Delaware, previously has held Microsoft and Cisco certifications, and currently holds certifications as a Project Management Professional (PMP), and AWS Cloud Practitioner.

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.
In 1994, Dr. Woodcock was named Director of the FDA's Center for Drug Evaluation and Research (CDER), leading the Center's work that is the world's gold standard for drug approval and safety. There she conceived and implemented 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; launching the Safety First and Safe Use initiatives designed to improve drug safety management within and outside the FDA, respectively; developing the Sentinel Network for drug safety and spearheading CDER efforts on patient-focused drug development.
In 2004, Dr. Woodcock became the FDA's Deputy Commissioner and Chief Medical Officer. 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 be the therapeutics lead for "Operation Warp Speed" in early 2020. This entailed supporting the development, evaluation, and availability of treatments such as monoclonal antibodies and antiviral drugs for patients with COVID-19.
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: the Nathan Davis award from the American Medical Association in 1999; the Roger W. Jones Award for executive leadership from American University in 2000; the VIDA award from the Society for Hispanic Health and the first Leadership Award in Personalized Medicine from the Coalition for Personalized Medicine in 2005; the Garry Neil prize for Innovation in Drug Development in 2009; a Lifetime Achievement Award in 2015 from the Institute for Safe Medication Practices; 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.

Day 2: Tuesday, December 6, 2022

Robyn Barringer
Associate Deputy CIO for Food Safety and Applied Nutrition
Director, Division of Information Technology Management (DITM)
Center for Food Safety and Applied Nutrition (CFSAN)

Ms. Robyn Barringer possesses more than 16 years of strategic IT leadership, technology management, and innovative solution-oriented technology implementation expertise spanning both federal and private sectors.
Robyn served as the Assistant Deputy Chief Information Officer (ADCIO) and Division of Information and Technology Management Director for the Center for Food Safety and Applied Nutrition. In this capacity, Ms. Barringer has responsibility for a $60 million dollar IT budget and provides oversight for the Center's more than 70+ IT systems, applications and scientific infrastructure. She is adept at implementing cross-cutting business-driven digital technology transformation campaigns that improve business automation, enable mobility solutions, and resolve complex data collaboration obstacles.
Robyn holds a Master's degree in Executive Leadership from Liberty University and a Bachelor's degree in Computer Science with a concentration in Applied Mathematics from the University of North Carolina Fayetteville State. Robyn has been recognized for the FDA CIO's Award of Excellence, FDA Leveraging Collaboration as well as the HHS Strategic Leader's Award of Leveraging Excellence in Acquisition Development. She brings a wealth of business acumen, diverse and emerging IT strategic insight coupled with a passionate approach for transformative IT initiatives.

Carol Cave
Deputy Associate Commissioner for Regulatory Affairs
Office of Regulatory Affairs

Ms. Cave serves as the Deputy Associate Commissioner for Regulatory Affairs within the Office of Regulatory Affairs in the Food and Drug Administration. In this role she supports the Associate Commissioner for Regulatory Affairs with activities including enforcement, regulatory science implementation, import operations, global/federal/state collaborations, implementation of new laws and regulations, and overall strategic planning and prioritizations.
She previously served as the Assistant Commissioner of the Office of Enforcement and Import Operations and had responsibility for providing direction and oversight of the Food and Drug Administration's field import operations. This included reviewing prior notice and intelligence data on human and animal food and leading the development, implementation, and evaluation of laws, regulations, and policies as they related to broad global and national programs and activities.
Prior to this position, she served as the Deputy Director for the Office of Compliance and Field Operations in the Consumer Product Safety Commission (CPSC) where she worked with other federal government agencies to identify unique approaches and solutions to identify potentially defective consumer products. Ms. Cave had an extensive career with the CPSC having served as the Director of

Field Investigations, and as part of the Office of Compliance's Special Investigations Unit. She holds a Bachelor of Science from the University of Maryland, College Park.

Aloka Chakravarty
Director, Data Staff
Office of Data, Analytics, and Research (ODT/ODAR)

Dr. Aloka Chakravarty joined FDA in 1992 and brings extensive organizational experience having served in various leadership roles. Prior to this appointment, she was the Deputy Director and Acting Director of the Office of Biostatistics in the Center for Drug Evaluation and Research.
She is an internationally recognized thought leader in real world data and evidence, multi-regional clinical trials, quantitative safety evaluation, surrogate makers and biomarkers in drug development. Dr. Chakravarty served as an Adjunct Faculty in the Department of Statistics, Foundation for Advanced Education in the Sciences at the National Institutes of Health, and also served on advisory boards of multiple academic institutions.
Dr. Chakravarty has received numerous awards, notably the FDA Award of Merit and Dr. Frances O. Kelsey Drug Safety Excellence Award. She is a Fellow of the American Statistical Association and an Associate Editor of Statistics in Biomedical Research.

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.

Jason Cober
Lead Project Manager, Office of Prescription Drug Promotion
Center for Drug Evaluation and Research (CDER)

Jason Cober is the Lead Project Manager in the Office of Prescription Drug Promotion and has served in that role since 2016. He joined FDA in 2008 and was previously a Project Manager in the Office of Strategic Programs (OSP). Before joining FDA, Jason was a software developer and contractor for two community behavioral health clinics in

Northeast Florida where he developed and maintained EHR systems. Jason holds a Master in Public Administration (MPA) from the University of North Florida in Jacksonville, Florida.

Bhabani Das
Deputy Director, Division of Information Technology Management (DITM)
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 food program. FDA's mission is his passion, and he considers technology and strategic thinking the nexus of his career. He holds a Bachelor of Science in Physics and Master of Science in Computer Applications. In his free time, he serves as a mentor for high school students and is a huge cricket enthusiast.

Pedram Farid
Acting Branch Chief, Division of Information Technology Management (DITM)
Center for Food Safety and Applied Nutrition (CFSAN)/DITM

Pedram Farid is a strategic leader with a progressive and transformative approach to the delivery of technology, data, and information management processes with a specific emphasis on application and platform solutions, application reengineering, and regulatory business innovation. Pedram oversees enterprise technology planning, data warehousing and management, cloud provisioning, program and project oversight, and enterprise architecture.

Brandon Gallas
Research Mathematical Statistician, Division of Imaging, Diagnostics, and Software Reliability
Center for Devices and Radiological Health (CDRH)

Brandon D. Gallas is a Research Mathematical Statistician in the Division of Imaging, Diagnostics, and Software Reliability in the Office of Science and Engineering Laboratories of the Center for Devices and Radiological Health.

Dr. Gallas provides mathematical, statistical, and modeling expertise to the regulatory review of medical imaging devices at the FDA. His main areas of research are image quality, computer-aided diagnosis, imaging physics, and the design, execution, and statistical analysis of reader studies. This work is summarized and realized as a regulatory science tool, "iMRMC: Software for the Statistical Analysis of multi-reader multi-case studies, and is available as a package of the R statistical programming language. Recently, he has been investigating pathologist performance and agreement using whole slide imaging devices and the microscope. These studies are enabled by an evaluation environment that registers the digital images to the glass slides. Dr. Gallas also participates in the Pathology

Innovation Collaborative Community, a regulatory science initiative to harmonize and standardize digital pathology processes to speed up innovation to patients.

Lauren Gortenburg
IT Program Manager, Data Warehouse Program
Center for Food Safety and Applied Nutrition (CFSAN)/DITM

Lauren Gortenburg is currently serving as the IT program manager for the Data Warehouse program in the Center for Food Safety and Applied Nutrition (CFSAN). In this role, she applies business analysis and enterprise architecture principles to define and solve key data related challenges to protect and promote public health. Prior to her work with the CFSAN Data Warehouse, she spent five years leading key IT modernization initiatives in support of the Food Safety Modernization Act (FSMA). Ms. Gortenburg holds a bachelor's degree from The Ohio State University and is a certified Project Management Professional (PMP). She deeply enjoys whiteboarding and is able to find reasons to do so in both her personal and professional life.

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's degree in Computer Science from the New Jersey Institute of Technology and bachelor's degree 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.

Elaine Johanson
Director, Health Informatics
Office of Data, Analytics, and Research (ODT/ODAR)

Elaine Johanson serves as the Director for Health Informatics in FDA's Office of Data, Analytics, and Research and Program Manager for precision FDA, a collaborative multi-omics site engaging experts around the world in evolving areas of science. She has thirty-seven years' experience in information technology (IT) including eighteen years in senior leadership, six of these leading FDA Health Informatics.
She has extensive leadership experience as well as technical knowledge in scientific computing, health informatics, cloud computing, crowd sourcing, international data standard management, data harmonization, data analysis, strategic planning, software development, infrastructure operations, budget formulation and execution, governance, project, risk, program and portfolio management.

Swati Kulkarni
Director, Data and Analytics Platform Engineering
Office of Data, Analytics, and Research (ODT/ODAR)

Swati Kulkarni joined Food and Drug Administration (FDA) in 2009. Swati is a seasoned modern data management leader with wide ranging expertise in data management and operations including data integration, data analytics, document management, contact management, data modeling, information technology (IT) service management, program and project management, and database administration.
Currently serving as the Director, Data, Analytics Platform Engineering where she is leading the development of integrated enterprise modern data analytics platforms solutions in FDA's cloud environment.
Prior to this role, Swati served as a Data Management and Operations Branch Chief within Division of Application Services (DAS) where she led 4 diversified teams consisting of 26 full time employees (FTEs) and 70+ contractors. She has been recognized multiple times for her contributions through Office of Operations (OO) Award for Creativity and Innovation, CIO's Award of Excellence.
Swati is a proud mom of teenage daughter, Preeti (16). She loves evening walks, and her hobbies include cooking, creating short videos, and writing.

Douglas Margulies
IT Specialist, Office of Management
Center for Veterinary Medicine (CVM)

Doug Margulies, DVM, MBA, is an Information Specialist in the Office of Management within FDA's Center for Veterinary Medicine. He has been leading CVM's modernization efforts since joining the FDA in June of 2019. As a licensed veterinarian and IT professional, Dr. Margulies is able to draw from over 20 years of Federal Health IT and clinical practice experience. Since 1999, he has been supporting Health IT and modernization efforts with clients such as NIH, HRSA, and CDC. He received his Doctorate of Veterinary Medicine from the Virginia-Maryland College of Veterinary Medicine, his Masters in Business

Administration from the Robert H. Smith School of Business at the University of Maryland, and his Bachelor of Arts in Business and Management from Goucher College.

Robert Megennis
Race Car Driver
Pilots the #39 CarBahn with Peregrine Racing Lamborghini Huracán GT3 Evo

Robert Megennis is a race car driver piloting the #39 CarBahn with Peregrine Racing Lamborghini Huracán GT3 Evo. With a deep appreciation for wheel-to-wheel racing, world-class racing drivers, and iconic tracks, Robert joined Lamborghini in 2022 to contest the full season of the prestigious IMSA WeatherTech SportsCar Championship. Collecting more than 25 podium finishes over his six years of racing in single-seaters, sports cars, and prototypes, he most recently competed in the Indy Lights Championship with Andretti Autosport in 2019 and 2021. Robert's two-year tenure included a win at the iconic Indianapolis Motor Speedway and pole position at the Freedom 100.
With the cancellation of the Indy Lights season in 2020 due to the Covid-19 epidemic, Robert turned his attention to endurance racing. Broadening his previous open wheel experience, he contested two rounds of the European Le Mans Series as well as the Intercontinental GT Challenge Indianapolis 8 Hour with Acura. In 2021, Robert joined Lexus for four endurance races which included a third place finish at the 10 hour season finale at Road Atlanta.
For the last five years, Robert has partnered exclusively with technology companies, including his 2022 sponsors Optimizely, DataRobot, Palantir, Gigamon, and SailPoint.
When he's not on track, Robert serves as an ambassador for Starlight Children's Foundation, meeting with children with extended hospital stays and fundraising for a variety of their programs. In 2020-2021, he was also an advisor to West Point/Purdue University as they competed to build an autonomous version of his race car. Residing in New York City, Robert is currently pursuing a Bachelor of Arts in Philosophy at Fordham University.

Adele Nguyen
Senior Technical Advisor, Enterprise Transformation Operation (ETO)
Office of the Commissioner (OC)

Adele Nguyen is a Senior Technical Advisor and program manager for cross cutting initiatives within the Enterprise Transformation Operation (ETO). She has over 20 years of experience in the IT field across multiple industries and has been with FDA for over 10 years. Prior to her time in ETO, Adele managed large complex projects and programs at the Agency within CDER Office of Business Informatics, ODT Office of Enterprise Portfolio Management, and the Office of Performance Evaluation and Risk Management.

Joshua Xu
Branch Chief for Research-to-Review and Return (R2R)
National Center for Toxicological Research (NCTR)

Dr. Joshua Xu received his Ph.D. degree in electrical engineering from Texas A&M University with research in medical image analysis. Currently he is the Branch Chief for Research-to-Review and Return (R2R) at the Division of Bioinformatics and Biostatistics of FDA's National Center for Toxicological Research (NCTR). He specializes in bioinformatics, text mining, image analysis, artificial intelligence, and informatics system development. He leads the Division's efforts in developing regulatory informatics applications and systems. Some ongoing projects are Data Analysis and Search Host (DASH), Breakthrough Therapy Designation (BTD), Safety Policy and Research Team (SPRT), Smart Template System (STS) and FDA drug labeling documents (FDALabel) in collaboration with CDER. The R2R program has also supported ORA in developing the Automated Laboratory Information System (ALIS), a customizable system that can be tailored to specific needs across all ORA laboratories; and CTP in creating ASSIST4Tobacco, which uses NLP for deeper searching of documents concerning tobacco products.

Frank Yiannas
Deputy Commissioner for Food Policy and Response
Office of Food Policy and Response

Frank Yiannas is the Deputy Commissioner for Food Policy and Response, a position he assumed in December of 2018. He is the principal advisor to the FDA Commissioner in the development and execution of policies related to food safety, including implementation of the landmark FDA Food Safety Modernization Act (FSMA). His leadership role within the Agency covers a broad spectrum of food safety priorities, such as outbreak response, traceback investigations, product recall activities, and supply chain innovation across the full spectrum of FDA-regulated products.
Mr. Yiannas is, in effect, the Agency's chief ambassador to reduce food safety risks and achieve high rates of compliance with FDA food safety standards. Mr. Yiannas also works diligently to develop innovative collaborations with external partners and stakeholders and effective relationships with government and industry leaders, as well as consumer groups.
A renowned food safety expert and author, Mr. Yiannas came to FDA from leadership roles with two industry giants: Walmart and the Walt Disney Company. Through his career, he's been recognized for his role in elevating food safety standards and building effective food safety management systems based on modern science and risk-based prevention principles.
At Walmart, which he joined in 2008 and served for over a decade, Mr. Yiannas was the Vice President for Food Safety. In this role, he led the effort to make Walmart the first U.S. retailer to require suppliers to achieve certification against one of the Global Food Safety Initiative (GFSI) benchmarked food safety schemes. More recently, he has become a globally recognized pioneer in using blockchain technology to create a more digital and transparent food system. His work has shown that by leveraging technology, the amount of time taken to trace the origin of food back to the source can be reduced from

weeks and days down to seconds. Based on his work, other major food companies are now exploring the use of this technology.

His experiences in the food safety arena have also made him an advocate for the promotion of a Food Safety Culture to protect the world's food supply, arguing that science and policy alone are not enough. Advancing food safety also requires an understanding of organizational culture and principles of human behavior. Engaging on this level to help shape an organization's culture is the subject of his books Food Safety Culture, Creating a Behavior-based Food Safety Management System, and Food Safety = Behavior, 30 Proven Techniques to Enhance Employee Compliance.

At Disney, where he worked for 19 years, he was the Director of Safety and Health. During his tenure, Disney received the prestigious Black Pearl Award for corporate excellence in food safety from the International Association for Food Protection.

The recipient of numerous awards, in 2007, he received the National Science Foundation's International Lifetime Achievement Award for Leadership in Food Safety. He is also the recipient of the Collaboration Award by FDA in 2008 and he was named the 2015 Industry Professional Food Safety Hero Award by STOP Foodborne Illness, a consumer advocacy group.

Mr. Yiannas is a past president of the International Association for Food Protection and a past vice-chairman of the Global Food Safety Initiative. He is also an adjunct Professor in the Food Safety Program at Michigan State University, and in 2017 was awarded the MSU Outstanding Faculty Award.

A microbiologist, Mr. Yiannas received a Bachelor of Science in microbiology from the University of Central Florida and a Master of Public Health from the University of South Florida.

Day 3: Wednesday, December 7, 2022

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 also 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.

Leah Buckley
Director, Counterintelligence and Insider Threat
Director, Office of Information Security (OIS)
Office of Digital Transformation (ODT)

Ms. Leah Buckley is the Director, Counterintelligence and Insider Threat, U.S. Food and Drug Administration (FDA). In this role, she oversees the Counterintelligence Team, Advanced Forensics Team, Foreign Travel Security Operations and Support Services Team, and the Cyber Threat Hunt capability. Prior to arriving at the FDA, Ms. Buckley worked as a consultant, helping both private and public sector entities develop, improve, and execute their insider threat programs. During 2022, she also retired as a Special Agent with the Air Force Office of Special Investigations, after serving 21 years in a variety of active duty and reserve roles. Ms. Buckley has a CISSP certification as well as a Master of Arts in National Security Affairs from the U.S. Naval Postgraduate School and a Bachelor of Science in Foreign Area Studies from the U.S. Air Force Academy.

Vijay Dharmavaratha
Technical Lead, Division of Regulatory Science Informatics (DRSI)
Center for Tobacco Products (CTP)

Vijay Dharmavaratha is a technical lead and product owner within CTP Office of Science, Division of Regulatory Science Informatics (DRSI) since August of 2020. Prior to joining FDA, Vijay worked at NIH/NIAID (National Institute for Allergies and Infectious Diseases), where he worked for 14 years. Vijay was a hands-on technical project manager in NIH/NIAID and enjoyed piloting new technologies. Vijay's career in IT has spanned multiple positions including, Application Developer, DB Developer, Systems Analyst and Project Manager. Vijay's current position enables him to work on what he enjoys most, hands on technical leadership, and working to ensure all stakeholders understand technology and are able to use IT tools and systems effectively. Vijay has a Bachelor of Science in Computer Science.

David Groombridge
Distinguished Vice President Analyst, IT Leaders and Tech Professionals
Gartner

David Groombridge is a Distinguished Vice President Analyst within the Sourcing, Procurement and Vendor Management team in Gartner Research. Mr. Groombridge undertakes analysis on all phases of the IT sourcing cycle, with a particular focus on best practices in the sourcing of managed workplace services, hybrid infrastructure services and hosting of SAP systems. He provides guidance for clients on vendor selection, contract pricing, structure and terms, and commercial negotiations.
Mr. Groombridge has over 20 years of experience in the IT industry. Prior to joining Gartner, he reported to the CIO of Eversheds, a global law firm. In this role, he managed a number of strategic vendor relationships, led the successful negotiation of the firm's largest outsourcing deal, and managed the implementation of multiple data center outsourcing, BPO and SaaS initiatives, and also won the firmwide innovation award in 2011. Prior to his time at Eversheds, he held a range of IT program and product manager roles, spanning the insurance, financial services, and enterprise software industries.

Maryland Hatch
IT Project Manager, Office of Regulatory Operations (ORO)/Division of Informatics and Information Technology (DIIT)/Information Technology Branch
Center for Biologics Evaluation and Research (CBER)

Maryland Hatch has been with the FDA since 2015. She transferred to the Information Technology Branch in 2017, where she served as the CBER IT Liaison. She shares, "In this position, I learned a lot about CBER technology, old and new, and slowly began working with others on projects to modernize our systems." Previously, Maryland served as the Business Lead on the Identity and Access Management (IAM) Initiation project. She is now the Project Lead of future enhancements for IAM.

Melanie Keller
Chief Talent Officer
Office of Talent Solutions

Melanie Keller serves as Chief Talent Officer for the U.S. Food and Drug Administration, a global federal Agency with nearly 19,000 employees. In this position Melanie is responsible for all talent acquisition operations for the FDA with nine different hiring and pay authorities. She leads her office of ~260 staff to achieve hiring goals based on legal, timely, efficient, and transparent hiring processes. The FDA hires a world-class workforce of scientific, technical, and professional experts that will work hard to promote and protect the public health of all Americans.

Previously, Melanie served as the Associate Director for Management for the Center for Drug Evaluation & Research (CDER) at the U.S. Food and Drug Administration (FDA) for seven years. She led all aspects of the Center's administrative operations which included human capital services and programs, facilities management, ethics management, financial management (including user-fee collection), employee safety and logistics management for over 5,500 employees, and directs procurement, budget formulation and execution for a budget of $1.2 billion. She has been with the Department of Health and Human Services for 26 years. Just prior to FDA, she was at the National Institutes of Health for 11 years.

She has played key leadership roles on the local, regional, and national level of the International Public Management Association for Human Resources (IPMA-HR) since 1997 working hard to promote education and professional development of human resources professionals in the public sector. She is a Past-President of IPMA-HR Montgomery County and has served on the IPMA-HR Eastern Region Board multiple times. Melanie holds a Bachelor of Science in Management Studies and Human Resources and an MBA from the University of Maryland Global Campus.

Indu Konduri
AI/ML Project Lead, Office of Partnerships and Operational Policies (OPOP)/Office of Information Systems Management (OISM)/Division of Import Systems Solutions
Office of Regulatory Affairs (ORA)

Indu is currently overseas and leads AI/ML, process automation, and data science initiatives for the Office of Information Systems Management (OISM) in ORA in support of the 'New Era of Smarter Food Safety and Data Modernization Action Plan'. He is the project manager for the RAPID AI/ML Capabilities initiative, which has gained significant interest and attention from many offices across the Agency. His work includes analyzing prioritized business use-cases to support post-market regulatory actions within the purview of ORA, to develop, test, evaluate, assess, and deploy AI/ML models, where needed.

Indu participates and provides direction in several other ORA lead cross-agency data science and AI projects such as Filer Evaluation, Health Fraud surveillance System, Foreign Supplier Verification Program (FSVP) and development of the FDA AI/ML Playbook. He assists in project management tasks for the current risk-based expert informed risk screening tool. He is also collaborating with different offices within ORA and the agency to explore, design and develop next generation import

screening tools/systems using AI/ML. He currently holds Federal Acquisition Certifications (FAC) for Contracting Officer Representative (COR) Level II and Senior Level Program and Project Managers (P/PM).
Prior to joining FDA, Indu worked as a Project Manager at Nuclear Regulatory Commission (NRC) for 13 years. At NRC, his work involved managing and supporting major IT investments in operating and new nuclear power reactor business lines, software modernization & development, and budget execution & formulation. Before NRC, Indu served as a Software Developer for the US Department of Commerce, Bureau of Economic Analysis (BEA), where he worked on modernization of the import and export trade data tracking and verification system. Prior to joining federal service, Indu worked in traffic demand modeling & forecasting, and application development areas at ACS-Xerox's EZ Pass System, Verizon, and TEMS Inc. Indu has a Ph.D. in mining & minerals engineering from Virginia Tech.

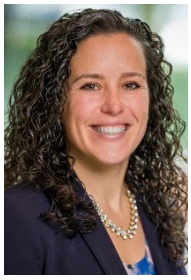
Joshua Lehman
Director, Office of Business and Customer Assurance (OBCA)
Office of Digital Transformation (ODT)

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.

Greg Parcover
Director, Office of Partnerships and Operational Policies (OPOP)/Office of Information Systems Management (OISM)/Division of Import Systems Solutions
Office of Regulatory Affairs (ORA)

Gregory Parcover started his professional career over twenty years ago as a programmer for an ATM company that manufactured machines for local businesses. After several years, Gregory joined the Food and Drug Administration (FDA) as a tech liaison for the Office of Regulatory Affairs. Then, he moved directions to support import IT work within the Division of Import Operations and Policy. In this role, Gregory helped support the development and maintenance of mission critical system and data entry. Along with working directly with import systems, he helped develop an imports data warehouse and supported tools in order to pull and display data. Later in his career, he was promoted to a new branch that oversaw systems that impacted case development, recalls, and inspections. Currently, Gregory is the Director of Import System Solutions. The division plays multiple roles in support of FDA's import mission by supporting the development and maintenance of critical import admissibility systems. Along with the system

aspect, the division is also responsible for the data the system store for reporting purposes. Lately, the division has expanded to include research into newer technologies such as artificial intelligence, machine learning, and natural language processing. All in support of FDA's crucial mission to protect public health.



Jordan Parsons
Vice President, FDA & NIH Account Executive
ICF

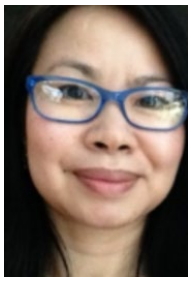
Jordan is an account executive with 16+ years of experience supporting federal civilian and defense clients in a variety of account strategy and management roles, and extensive experience supporting National Institutes of Health (NIH) and Food and Drug Administration (FDA) public health programs.
Jordan leads ICF's NIH and FDA solution strategies to bring the company's unique combination of deep domain expertise and digital modernization capabilities to achieve these clients' missions and improve public health outcomes. She is hyper focused on delivering measurable impact for her clients and building long-lasting relationships to help advance their missions.
Prior to ICF, Jordan served as director of public health at LMI, preceded by account director for the Department of Health and Human Services at Suntiva, which was acquired by LMI in 2021. In these roles, she led portfolios valuing $100M+, overseeing all aspects of account success. In previous roles, she was a business financial manager with Booz Allen Hamilton where she served the Defense Advanced Research Projects Agency, Defense Sciences Office. She also served as a project manager for the Presidential Helicopter Program at Sikorsky Aircraft.

Eugene Reilly
Director, Office of Partnerships and Operational Policies (OPOP)/Office of Information Systems Management (OISM)/Division of Import Systems Solutions
Office of Regulatory Affairs (ORA)

Eugene Reilly is the Director of the Division of Enforcement Systems Solutions in ORA's Office of Information Systems Management which manages several systems that support operational staff conducting inspections, pursuing compliance actions, conducting sample collections and analysis, and managing recalls. The Division also contains subject matter experts on the data from the systems the Divisions support. He has a role in this panel because of his interest in AI/ML and data analysis and wants to highlight the work Greg, Indu, and others have been researching in the AI/ML space.

Deborah Sholtes
Branch Chief, Division of Regulatory Science Informatics (DRSI)
Center for Tobacco Products

Deborah Sholtes is a Branch Chief with the Division of Regulatory Science Informatics, Office of Science, Center for Tobacco Products. As Chief of the Data and Systems Branch, Ms. Sholtes oversees development of innovative technology solutions to improve the use of regulatory and research data for hundreds of tobacco scientists and regulators. Ms. Sholtes is an FDA leader with over 20 years of FDA experience and 12 years of prior experience as a federal contractor. Ms. Sholtes has been with CTP since 2010 and has prior experience working at CDER and the FDA Office of the Chief Information Officer. Ms. Sholtes holds a Master of Science from Washington University in St. Louis and a Bachelor of Science from Beloit College.



Susan Tam
IT Project Manager, Division of Regulatory Science Informatics (DRSI)
Center for Tobacco Products (CTP)

Susan Tam is an IT Project Manager in the Division of Regulatory Science Informatics within the FDA's Center for Tobacco Products (CTP). She has served as the program/project manager for CTP's strategic Rhapsody program since joining the FDA in November 2020. Susan believes the key to any successful project lies in collaboration, stakeholder engagement, and detailed planning. With over 20 years in the investment banking industry based in New York, Susan has implemented mission-critical trading systems and client onboarding projects at Deutsche Bank, JP Morgan, and UBS. She previously served as Vice President at Deutsche Bank in the Global Technology & Infrastructure Division. As an avid world traveler, Susan has lived and worked abroad in Germany and India. Susan received her Master of Science in Information Systems from New York University and her Bachelor of Science in Industrial Engineering & Operations Research from Cornell University.

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.
Mr. Taylor served twenty-one years in the United States Navy as a Cryptologic Technician (Communications) Master Chief Petty Officer. He holds a Master of Science, Telecommunications from George Mason University and Bachelor of Science, Information Systems Management from the University of Maryland, University College.