SESSION SUMMARIES

(all times listed are in Eastern Standard Team)

Day 1: Monday, December 5, 2022

Monday, 9:15 AM: "Keynote: Holistic Modernization"
Chief Information Officer Vid Desai's keynote session will talk about how:

- Our modernization is customized to the issues we face at the FDA and is not the typical "cookbook" type approach. It's been a very thoughtful process aligning IT with a business plan that covers people, processes, and technology.
- Our modernization is aimed to be sustainable. It's not a project but a culture change. We should not need to keep initiating new modernization projects every few years. It should be able to continue regardless of organizational and leadership changes.
- It's evolved over several years and is still evolving as we learn more about what works and what does not work within our environment. We are happy to share some of what we have learned and are learning as we progress our modernization journey
- "Hard things are hard but they're worth doing right." Embracing the mindset, technology, and capabilities to drive change through collaboration, trust and unity is improving in FDA IT.
- FDA IT are far more than technology experts; we are business change leaders and drivers transforming one of the most trusted Federal agencies to new heights.

Monday, 9:45 AM: "Building a Digital Future: Cloud Forward"
This session will talk about how:

- Our cloud modernization effort is geared towards providing choice and flexibility in the placement of workloads. A Multi-Cloud model will streamline the delivery of value creation for the Agency.
- The Agency will establish a centralized IT service delivery model equipped to provide deployment services with automated capabilities in the most cost-effective, secure, and agile way.
- We plan to enhance the existing and new Infrastructure as a Service (IaaS), Software as a Service (SaaS) and containerization of workloads to provide the Agency with greater flexibility and standardization in moving workloads between on-premise data center and cloud deployment targets.

Monday, 10:25 AM: "Making the difference: Journey to a new operating model- Keynote Media Bytes"
Chief Technology Officer Mohammed Sohail Chaudhry will talk about how:

- Our journey to a new operating model is all about making service modernization investments that offer the FDA greater choice in services that are easy to use, secure, reliable, and modern.
- We are focused on building a workforce and workplace modernization pathway that, by design, puts business and users first by being accessible and inclusive.
- We are focused on business centricity, cost efficiency, and striving towards developing our solutions that are being built to adapt vs. build to last.

- The future we aspire to is ambitious! It requires accountable leadership and a clear vision. It demands the unique contributions of all members of our dedicated workforce "Feds and Contractors." It calls for close collaboration with our partners "Sponsors and Industry" to transform how we deliver value added services on behalf of the American people.

Monday, 10:45 AM: "Center for Devices and Radiological Health (CDRH) Digital Transformation: Successes and Challenges"
You will learn how:

- CDRH has been working on its Digital Transformation initiative since 2016. We continue to identify and overcome the many challenges associated with moving from siloed, custom systems to COTS platforms providing common features and data to meet similar business needs
- From the start, we have managed this as a Business-led initiative. While focusing on promising new technologies is exciting, we must focus on defining holistic, best-value solutions that allow us to meet the many aspects of our public health mission
- Data Modernization is at the core of our digital transformation. Technology changes, data persists
- One of our many successes is implementing program, IT, and data governance to ensure we are aligned with center and agency goals to make the most of our IT and resource investments
- Like all Centers, we struggle with finding dedicated, knowledgeable resources to work with us on the effort due to the pandemic, the volatility of the healthcare ecosystem, and US labor shortages

Monday, 11:40AM: "Revolutionizing IT Portfolio Management through Technology Business Management"
This session covers how:

- FDA will be showcasing their application of Technology Business Management (TBM) through a capability demonstration.
- The FDA is committed to continuing to improve their TBM capabilities through additional data fidelity and advanced business intelligence capabilities. This work will help to provide further insights into IT spending thus strengthening the organization's ability to drive strategic decision making.
- The FDA's TBM architecture has enabled the organization to more rapidly respond to key data calls and leadership requests. Tasks that would historically take hours to compile can now be accomplished in minutes, with a much higher degree of accuracy.
- The FDA has been on this TBM journey since 2019 and has invested in building an architecture that will scale as the program matures. The FDA will demonstrate planned future data analytics capabilities.

Monday, 12:45 PM: "CDEROne Analytics Enterprise Platform Overview"
This session is about:

- The CDEROne Enterprise Analytics Platform Overview will provide a high-level understanding of CDER's journey to data analytics. Attendees will understand how CDEROne aligns with the FDA's Technology Modernization Action Plan, Data Modernization Action Plan, and the Enterprise Modernization Action Plan. An overview of CDEROne's challenges, technologies, and achievements will culminate into a discussion on the Drug Supply Chain.

Monday, 1:30 PM: "FDA IT Acquisition Strategies and Goals"
You will learn how:

- The FDA is implementing an Acquisition-as-a-Service model to strategize, simplify, standardize, consolidate, and expedite IT acquisitions to bring efficiencies and cost savings.
- The FDA is committed to the socioeconomic goals and promotes Small Business vendor community by leveraging their capabilities and set aside contracts for Small Business vendors.
- In order to leverage potential and expertise of industry partners and develop talent network, ODT, the technical arm of FDA, is determined to collaborate strategically with industry partners to exchange and share knowledge, experiences, know-how, and expertise through strategic contracting and vendor partnership.
- The FDA has initiated a Vendor Management program to promote agility, efficiencies, and innovations.

Day 2: Tuesday, December 6, 2022

Tuesday, 9:15 AM: "Keynote: Connecting the Dots: Building a Data and Talent Ecosystem"
Chief Data Officer Ram Iyer will discuss how:

- Our Data Modernization approach is built on creating a network of talent, capabilities and processes.
- We are balancing the value to the organization with the need to build sustainable foundational capabilities.
- Our approach is based on strong and enduring partnerships within the agency, across our federal and industry partners.

Tuesday, 9:45 AM: "Executive Perspectives on Data Modernization – A Panel Discussion"
This executive panel will explore:

- Importance of data modernization for regulatory operations and food safety
- Emergency preparedness and data needs
- Ability to connect disparate data sets through MDM

Tuesday, 10:15 AM: "Enterprise Modernization in Action"
This session covers:

- The Enterprise Transformation Operation (ETO) was established within the Office of the Commissioner to carry out the Agency's Enterprise Modernization Action Plan (EMAP) aimed at implementing optimized enterprise business processes that solve cross-agency problems and improve operational efficiency.
- The EMAP is the backbone of the Agency's Data Modernization Action Plan (DMAP) and Technology Modernization Action Plan (TMAP) such that the business needs drive enterprise change in data management and technology.
- To operationalize optimized business processes, ETO is partnering with the Office of Digital Transformation in projects to modernize and enhance FDA's technical capabilities and data management in support of FDA's public health mission.
- An example of enterprise modernization in action can be seen with the current inspection modernization pilot.

Tuesday, 11:00 AM: "Realizing the Value of FDA Data: Bridging the Gaps"
This session will present a:

- Demo and discussion on use cases delivered through the data modernization program in collaboration with FDA program areas and external experts

Tuesday, 1:00 PM: "Keynote: The Art and Science of Racing"
For this session, you will meet racecar driver Robert Megennis and:

- Dive into the world of motor racing and explore what it takes to win races.
- Learn how racing teams rely on technology and data to make real time decisions and gain important milliseconds on track.
- See how Robert and his team collaborate, adapt, and make changes to attack every challenge and maximize every advantage throughout the race weekend.
- Trust the data and trust your team – keys to success for my team on track and your team at the office.

Tuesday, 1:45 PM: "Transforming How the FDA Foods Program Receives and Uses Data"
This session is about:

- The complexity of the health and safety objectives of the Foods Program requires a modern IT environment that supports data interoperability, data discovery, and data exchange.
- To this end, the FDA is investing in modernization of data, applications, and technology architectures that support advanced data collection and analytics, including AI and ML, in support of the food safety mission.

Tuesday, 2:45 PM: "Research-to-Review (R2R) to Empower Digital Transformation"
The R2R Program:

- Provides an agile and collaborative platform for translating NCTR research to regulatory application.
- Often employs AI/ML technologies and secure gov cloud environment.
- Utilizes extensive skillsets across regulatory research and system development to support regulatory application and empower digital transformation.

Tuesday, 3:30 PM: "Center for Veterinary Medicine (CVM) Modernization: One Health"
This presentation why:

- Partnership is key to the success of modernization (business, enterprise, technology)
- Business is first – understand and drive business needs (learn the business process)
- Think holistically! Combine the end-to-end process and an enterprise approach to maximize modernization efforts

Day 3: Wednesday, December 7, 2022

Wednesday, 9:15 AM: "Evolution of the FDA Cybersecurity Counterintelligence & Insider Threat Program"

Session summary:
Cybersecurity is among the top priorities of the FDA and the Office of Digital Transformation (ODT) takes its responsibility seriously to protect people and data in today's environment of increased cybersecurity threats.

As the cyber threat landscape evolves globally, threat actors present ever-changing challenges. FDA will modernize our cyber defenses and will continue to invest in and prioritize our cybersecurity workforce in order to meet current and future cybersecurity needs. Our recently published Cybersecurity Modernization Action Plan (CMAP) outlines steps the FDA Office of Digital Transformation is taking to modernize our cyber defenses and implement enhanced security measures of Zero Trust. FDA is strengthening our ability to protect sensitive information and improve operational capacity to reduce security risks and facilitate more seamless and secure data sharing across our global regulatory environment.

The FDA Chief Information Security Officer and Director, Counterintelligence and Insider Threat will present an overview and evolution of FDA Cybersecurity, Counterintelligence, and Insider Threat Program include the following audience take-aways as follows:

- Introduction of FDA Cyber Leaders and Cyber Organization
- Global Cyber Threat Landscape
- FDA Cybersecurity Modernization Action Plan and Zero Trust
- FDA Cybersecurity Workforce

Strengthening FDA's network environment, identity capabilities, and data protections are critical as the Agency continues to modernize and deploy new digital services and facilitate more seamless data sharing across its global regulatory environment. Our CMAP will support the Agency in building a modern security architecture that will expedite digital transformation and directly support FDA's mission to protect and promote U.S. public health.

Wednesday, 9:45 PM: "CTP Rhapsody: Supporting Tobacco Product Marketing Application and Review"

The CTP Rhapsody solution is:

- Envisioned as a one-stop marketing application review with the data and tools to accelerate review processes.
- Helps route the application through the relevant pathway to make a final determination on a given tobacco product(s).
- A regulatory review management system built to support CTP regulatory project managers, scientific discipline reviewers, leadership, and compliance staff.
- A comprehensive, integrated submissions document review environment for different marketing pathways and tracked regulatory functions of the Office of Science (OS) and Office of Compliance and Enforcement (OCE).

- Built on OpenText Appworks and OpenText Content Server with data linkages to multiple CTP systems.

Wednesday, 10:45 AM: "Building the Federal IT Workforce of the Future"
This session will explore how:

- People are the key to success or failure of modernization initiatives. An agile, future-ready workforce is needed to advance modernization efforts.
- The path to transformation is paved by strong leaders and changemakers.
- ODT is releasing the Leadership Modernization Action Plan, the last installation of FDA's Modernization Frameworks.
- The LMAP highlights the role of leadership strategic alignment continuity, IT strategic planning, and the importance of building a diverse pipeline of change-adept leaders. Successful digital transformation requires leaders that can translate technology potential into business value.

Wednesday, 12:45 PM: "Research into the Use of Artificial Intelligence/Machine Language Models and Technology to Produce Resource Efficiencies in Office of Regulatory Affairs (ORA) Processes"
This session will present how:

- The FDA has established an environment where Artificial Intelligence/Machine Learning (AI/ML) research can be explored. Initial research shows that using ML in conjunction with the current rules-based tool boosts performance of import screening.

Wednesday, 2:00 PM: "Modernizing Identify and Access Management: Implementing Role-Based Access Management at the Center for Biologics Evaluation and Research (CBER)"

- Modernizing Identity and Access Management (IAM) will provide a high-level overview of CBER's modernization efforts and a comprehensive understanding of how CBER modernized access to business functions. After defining IAM, attendees will learn why CBER chose IAM as a priority, how IAM was implemented, and what improvements were made for granting access. Users will also understand how CBER overcame obstacles and ongoing enhancements for future capabilities.

Wednesday, 2:45 PM: Modernization of Support for a Dispersed Workforce
This session is about:

- The journey of supporting FDA's global workforce through a cultural change. Discussing the rapid technology changes implemented throughout the pandemic to stabilize and allow FDA to thrive remotely.