

# 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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## AGENDA

(All times listed are in Eastern Standard Time)

### Day 1: Monday, December 4, 2023

Time	Session Title	Speakers
8:55 AM	Welcome and In Person Logistics	Mary Schwarz, Symposium Moderator
9:00 AM	Opening remarks	Vid Desai, FDA Chief Information Officer (ODT)
9:15 AM	Revealing the Road Ahead: A Preview of the FDA IT Strategy's Operating Plan	Jessica Berrellez, Joseph Montgomery, and Vid Desai (ODT)
10:00 AM	Managing the Business of Technology	Joseph Montgomery, General Lee, and Maria Shams-Ramsey (ODT/OEPM)
10:20 AM	Process Optimization at FDA: Update on Enterprise Transformation	James Mulholland (ODT) and Dr. Meredith Chuk (ETO)
10:50 AM	Break	
11:00 AM	CDRH Digital Transformation Moves to a Business Capability Driven Model	Elizabeth McNamara, William Lohnes, Anjila Merchant, and Linda Peters (CDRH)
11:30 AM	Our FDA Zero Trust Journey	Craig Taylor, FDA Chief Information Security Officer (ODT)
11:50 AM	HOLD FOR SPEAKER	
12:20 PM	Lunch	
1:00 PM	Modernizing Tobacco Registration & Listing – How Data Exchange and Information Sharing Supports CTP's Mission	Ele Ibarra-Pratt and James Bowling (CTP)
1:20 PM	On the Importance of Edge Computing: Service to the Cloud and to Public Health	Luis Santana-Quintero (CBER)
1:40 PM	Data Central: High Quality Study Data, in the Right Place at the Right Time	Matthew Wiley (CDER)
2:00 PM	Over-the-Counter Drugs: Modernizing Communications Between CDER and Industry	Athena Shry (CDER)
2:20 PM	Break	



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<b>2:30 PM</b>	Fireside Chat: The Direction of Information Technology in FDA	Dr. Robert Califf, FDA Commissioner; Dr. Janet Woodcock, FDA Principal Deputy Commissioner; Dr. Namandjé N. Bumpus, FDA Chief Scientist; and Mary Ann Slack, Director, CDER Office of Strategic Programs
<b>3:00 PM</b>	Data Analytics as a Service	Meghan Mariman (ODAR) and Brad Brown (CFSAN)
<b>3:15 PM</b>	Developing Enterprise Capabilities through Electronic Submission Gateway (ESG) Modernization	Binh Ta and Jessica Bernhardt (ODT)
<b>3:35 PM</b>	Sharing Data through the FDA Expertise and Research Portal	Ben Hope (ODT) and Alexis Norris (CVM)
<b>3:55 PM</b>	Bridging the Gaps Between Business and IT with the Focus on Cross Cutting Enterprise Services	Mohammed Sohail Chaudry, FDA Chief Technology Officer, Joshua Lehman, and Shellie Rogers (ODT)
<b>4:35 PM</b>	Closing Remarks	Mary Schwarz, Symposium Moderator

## Day 2: Tuesday, December 5, 2023

Time	Session Title	Speakers
9:00 AM	Welcome and In Person Logistics	Mary Schwarz, Symposium Moderator
9:05 AM	Data Modernization in the AI Era	Ram Iyer, FDA Chief Data Officer (ODT)
9:25 AM	DataForward: Applied Learning Tracks to Drive FDA Data Science	Raju Rayavarapu and Ian Edlund (CVM)
9:45 AM	Occupational Health and Safety Transformation Initiatives, Changing the Culture of Safety	Hollie Bodiford-Taylor (OLS), Jeffrey DeGrasse (OLS), Sacha H. Gutierrez (OHS) and LCDR Justin Perkins
10:15 AM	What's new in CDRH Data Modernization effort	Alison Russo, Randi Scott, and Charlie Haggart (CDRH)
10:40 AM	Break	
10:50 AM	Knowledge-aided Assessment & Structured Application (KASA)	Sunitha Mathews and Archana Narayanaswamy (CDER)
11:10 AM	Use of Machine Learning to Reduce State IT Burden of Regulatory Partner Submissions	Eugene Reilly (OISM)
11:30 AM	Putting the YOU in User – System for Agriculture, Food, Health, E-Inspections and Registration (SAFHER) Customer Experience	Kellie Isaac, Chief Innovation Officer Association of Food and Drug Officials and Sheri L. Morris, Assistant Director, PA Department of Agriculture, Bureau of Food Safety & Laboratory Services
12:00 PM	Lunch	
1:00 PM	Fireside Chat - Embracing the Future: Exploring the FDA's IT Strategy for Innovation and Emerging Technologies with Key Stakeholders	Kellie Isaac, Chief Innovation Officer of Association of Food and Drug Officials; Monica Mehta, Vice President of Biogen; Michelle Rohrer, Global Head of Product Development Regulatory of Genetech Roche; Vid Desai, and Jessica Berrellez (ODT)
1:30 PM	Cultivating Tomorrow: The Future of Nurturing Talent and Leadership in the Digital Era	Jessica Berrellez, ODT Executive Officer; Anjelica Dortch, Senior Director & Head of Global Cybersecurity Policy, SAP America, Inc.; and Kristy Daphnis, Chief, Federal Workforce Branch, Executive Office of the President, Office of Management and Budget
2:05 PM	PTS – Product Tracing System	Bhabani Das (CFSAN)
2:15 PM	Warp Intelligent Learning Engine (WILEE) Demonstration	Ernest Kwegyir-Afful (CFSAN)



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<b>2:25 PM</b>	CFSAN Analytical Product Survey (CAPS)	Christine Parker and Thomas Farrell (CFSAN)
<b>2:45 PM</b>	Break	
<b>3:00 PM</b>	CDER's Innovation Achievements in AI	Ethan Chen, Venu Boppana, and Zac Tillman (CDER)
<b>3:20 PM</b>	Driving Usable Innovation to Enhance Capabilities	Denny Skiles (NCTR)
<b>3:40 PM</b>	RAPID (Real Time Analytics Platform for Innovation and Discovery) for CDER Innovation Platform	Isaac Chang (CDER)
<b>4:00 PM</b>	Needle in a Haystack: Using Machine Learning for Improved Compliance Targeting in the Human Food Program	Chuck Hassenplug (CFSAN)
<b>4:20 PM</b>	Closing Remarks	Mary Schwarz, Symposium Moderator



## Day 3: Wednesday, December 6, 2023

Time	Session Title	Speakers
9:50 AM	Welcome and In Person Logistics	Mary Schwarz, Symposium Moderator
10:00 AM	Reverse Vendor Day Session: Industry Perspectives on Best Value Procurements for Complex Services	Kelly Morrison, Senior Vice President, HumanTouchLLC; Jill Kenney, Managing Director, Growth and Sales Lead, Accenture Federal Services; and Manu Uppal, Chief Executive Officer, Tyrula LLC
10:45 AM	Break	
11:00 AM	Reverse Vendor Day Session: Industry Perspectives on Best Value Procurements for Complex Services	Donald Thomas, Vice President, Customer Success, Ad Hoc LLC; Chris Schwalm, Senior Vice President, Technology Services, Customer Value Partners; Kishore Suresh, Senior Director, General Dynamics Informational Technology
11:45 AM	Lunch	
12:30 PM	How to do Business with FDA	Mahesh Choksi, Director, Division of Acquisition Innovation (ODT)
1:00 PM	Procurement Innovation Lab (PIL) Method for Agile Acquisition	Mahesh Choksi (ODT); Monica Taylor, Senior Innovation Coach, US Department of Homeland Security Procurement Innovation Lab; Andrew Jernell, Director, Division of IT Acquisitions (OAGS)
1:45 PM	Upcoming Acquisitions	Andrew Jernell (OAGS)
2:15 PM	Break	
2:30 PM	Importance of Small Business for Health and Human Services (HHS)	Shannon Jackson, Executive Director, HHS Office of Small and Disadvantaged Business Utilization (OSDBU)
3:00 PM	Break	
3:10 PM	Awards Ceremony	Vid Desai, FDA Chief Information Officer; Leonard Grant, Director, OAGS; Shannon Jackson (OSDBU)
3:30 PM	Closing Remarks	Mary Schwarz, Symposium Moderator