

**18th Annual PDA Metro Chapter Day - Aseptic Manufacturing and Beyond: Supporting Sterility, Compliance and Quality**

**Agenda**  
May 14, 2025

Approx. Start*	Speaker	Topic
8:15 – 8:35 am	Continental Breakfast, Registration & Vendor Show	
8:35 – 8:45 am	PDA Metro Chapter	Welcome & Announcements
8:45 - 9:20 am	Tyler Harris, Business Development Applications Engineering Manager, PTI	Navigating CCIT Regulations with Confidence: Building Framework & Strategies for Effective Implementation
9:20 – 9:50 am	Jennifer Metch, Senior Plant Microbiologist, J&J Innovative Medicine	Contamination Control Strategy - Retrospective Look at Annex 1
9:50 – 10:20 am	Waseem Ahmed, Global Vice President, Alutech Packaging	Innovations Ensuring Authenticity of Medicine Against Counterfeit Drugs and Combatting Supply Chain Disruptions
10:20 – 10:35 am	Morning Break	
10:35 – 11:25 am	Jim Agalloco Agalloco & Associates	Sterilization 2025
11:25 – 11:55 am	Daniel (Danny) Miranda, Associate Scientific Director for Device Development, Human Factors Engineering, and User Research within the Devices, Delivery, and Product Strategy group at Bristol Myers Squibb	Device Development: Enhancing Human Factors Workflows Using Non-Traditional Data Capture and Analysis Tools
12:00 – 12:55 pm	Lunch / Group Pictures Regulatory Inspection / Industry Insights (Discussion: Lara Soltis, Shaista Hasan, Luciana Sartor L. Mansolelli, Head of Regulatory Compliance, Advanced Therapies, J&J Innovative Medicine) Prizes	
1:00 – 1:45 pm	Ziva Abraham, CEO, Microrite, Inc.	Contamination Control Strategies and Mold Investigations
1:45 – 2:20 pm	Bob Seltzer, Manager, Supplier Quality Management, Otsuka Pharmaceutical Development and Commercialization (OPDC)	Preparation for Performing GMP Audits of Pharma Suppliers, CMOs, Contract Test Labs
2:20 – 2:50 pm	Phil DeSantis, DeSantis Consulting Associates	Thinking Outside the Box – When the Regulations are not Quite Enough
2:50 – 3:05 pm	Afternoon Break	
3:05 – 3:35 pm	Eric Thostesen, Sr. Director, Business Development, J&J Innovation Medicine	Current Inspection Trends
3:35 – 4:15 pm	Kelly Waldron, PhD, MBA, Business Unit Manager, ValSource	QRM and CCS: Overview of the PDA/ANSI Standard 03-2025 on QRM for Aseptic Processing
4:15 – 4:25 pm	PDA Metro Chapter	Panel Discussion / Q&A
4:25 - 4:30 pm	PDA Metro Chapter	Closing Remarks

\*Timing may shift accordingly.