

PDA SO CAL CHAPTER MICROBIAL CONTAMINTION CONTROL ANNEX 1 EVENT

DECEMBER 4, 2025

ABBVIE IN IRVINE, CA

| Time | Session Title | Speaker |
|--|---|--|
| 7:30 AM | Vendor Arrival and Setup | Vendors and PDA BOD |
| 8:00AM | Arrival and Breakfast | ALL |
| 9:00 AM | PDA SoCal Chapter President Welcome | Amy Stanton , Quality Compliance Sr. Manager, Amgen |
| Annex 1 | | |
| 9:05 AM | A Milestone Revision: What the Latest PDA TR22 Means for Aseptic Processing <i>Overview of the newly published PDA Technical Report 22 on APS</i> | PDA TR 22 team members Vanessa Figueroa , Founder & Chief Executive Microbiologist, VVF Science (virtual attendee) |
| 9:30 AM | EU GMP Annex 1 | Alvaro Yepes , Technical Director, Contamination Control, Alsico Iberia Group |
| Contamination Control Strategy (CCS) | | |
| 10:00 AM | A Roadmap to Digitalized CCS | Sheba Zaman , Head of Product Specialists and Training Services, Novatek International |
| 10:30 AM | CCS Case Study, Takeda | Liz Brockson , Takeda Global Sterility Assurance Lead |
| 11:00 AM | BREAK | |
| Rapid Micro Methods (RMM) | | |
| 11:30 AM | Modern Microbial Method in Support of CCS | Allison Scott , Principal Scientist, BWT Pharma & Biotech Inc |
| 12:00 PM | Leveraging the Capabilities of qPCR in Rapid Mycoplasma Validation Study Design and Execution Including a Case Study on Application in Investigation of a Contamination Event | Mike Brewer , Director, Global Principal Consultant, Regulatory, Thermo Fisher Scientific |
| 12:30 PM | LUNCH and Networking | |
| Annex 1 Hot Topics for Aseptic Processing | | |
| 1:30 PM | Smoking Hot Topics in Airflow Visualization Studies | Erwin Andrews , CEO & Founder, Andrews Professional Services |

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| 2:00 PM | Developing a Successful CCS: Updates on Cleaning and Disinfection and Materials Transfer | Jim Polarine , Principal Consultant, Steris |
| 2:30 PM | EU Annex 1 Regulator Roundtable Report Out and Inspection Trends ISPE Florence, Italy Oct 2025 | Marsha Steed , CEO & Founder Steed MicroBio LLC |
| 3:00 PM | Break and Sponsor Raffle | |
| Environmental Monitoring | | |
| 3:30 PM | Global Risk-Based Approach for Sample Location Selection in Personnel Monitoring | Hilary Chan , Global Sterility Assurance & Microbiology Lead, Takeda |
| Regulatory Compliance Panel | | |
| 4:00 PM | Inspection Readiness, Quality Culture, Inspection Trends | Jeff Yuen , CEO Jeff Yuen & Associates & former FDA, Beth Blomquist , Director GxP Global Compliance at Vertex Tim Werner , Sr. Manufacturing Specialist at Amgen Moderator: Marsha Steed |
| 5:00 PM | Close Out | |