

PDA SO CAL CHAPTER MICROBIAL CONTAMINATION 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	<b>Amy Stanton</b> , Quality Compliance Sr. Manager, Amgen
<b>Annex 1</b>		
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 <b>Vanessa Figueroa</b> , Founder & Chief Executive Microbiologist, VVF Science (virtual attendee)
9:30 AM	EU GMP Annex 1	<b>Alvaro Yepes</b> , Technical Director, Contamination Control, Alsico Iberia Group
<b>Contamination Control Strategy (CCS)</b>		
10:00 AM	A Roadmap to Digitalized CCS	<b>Sheba Zaman</b> , Head of Product Specialists and Training Services, Novatek International
10:30 AM	CCS Case Study, Takeda	<b>Liz Brockson</b> , Takeda Global Sterility Assurance Lead
11:00 AM	BREAK	
<b>Rapid Micro Methods (RMM)</b>		
11:30 AM	Modern Microbial Method in Support of CCS	<b>Allison Scott</b> , 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	<b>Mike Brewer</b> , Director, Global Principal Consultant, Regulatory, Thermo Fisher Scientific
12:30 PM	LUNCH and Networking	
<b>Annex 1 Hot Topics for Aseptic Processing</b>		
1:30 PM	Smoking Hot Topics in Airflow Visualization Studies	<b>Erwin Andrews</b> , CEO & Founder, Andrews Professional Services

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