

# PDA Annex 1 Implementation Workshop 2025

## Agenda



**Tuesday, 2 December**

EST Standard Time (UTC -5:00)

07:30 – 08:30	<b>Continental Breakfast</b>
07:30 – 16:30	<b>Registration Open</b>
<b>P1: From Risk to Resilience: Building an Annex 1 Compliant Contamination Control Strategy</b> <b>Moderator:</b> Richard Denk , Senior Consultant Aseptic Processing, SKAN AG	
08:30 – 10:15	<div><div>08:30 – 08:40</div><div><b>Welcome Remarks and Introduction from the Workshop Chair</b><ul style="list-style-type: none"><li>• <b>Chair:</b> Frederic B. Ayers , Senior Consultant - Microbiology, ValSource, Inc.</li></ul></div></div>
	<div><div>08:40 – 09:00</div><div><b>Annex 1 in Practice: A Strategic Framework for Contamination Control Excellence</b><ul style="list-style-type: none"><li>• <b>Presenter:</b> Frederic B. Ayers , Senior Consultant - Microbiology, ValSource, Inc.</li></ul></div></div>
	<div><div>09:00 – 09:55</div><div><b>Control or Chaos? A Tabletop Exercise in Contamination Strategy Evaluation</b><ul style="list-style-type: none"><li>• <b>Presenter:</b> Frederic B. Ayers , Senior Consultant - Microbiology, ValSource, Inc.</li></ul></div></div>
	<div><div>09:55 – 10:15</div><div><b>Report Out and Discussion</b></div></div>
10:15 – 10:45	<b>Networking Break in the Exhibit Area</b>
<b>P2: Closing the Gap: Annex 1-Compliant Barrier Technology for Modern and Legacy Operations</b> <b>Moderator:</b> Julian Petersen , Head of Business Development Pharma, groninger & co gmbh	
10:45 – 12:15	<div><div>10:45 – 11:05</div><div><b>Barrier Systems in Practice: Managing Doors, Gloves, Decontamination, Airflow, and Pressure Cascades</b><ul style="list-style-type: none"><li>• <b>Presenter:</b> Richard Denk , Senior Consultant Aseptic Processing, SKAN AG</li></ul></div></div>
	<div><div>11:05 – 11:55</div><div><b>Interactive Case Study: Barrier Doors – First Air and Air Flow Challenges</b><ul style="list-style-type: none"><li>• <b>Presenter:</b> Richard Denk , Senior Consultant Aseptic Processing, SKAN AG</li></ul></div></div>
	<div><div>11:55 – 12:15</div><div><b>Report Out and Discussion</b></div></div>
12:15 – 13:15	<b>Networking Lunch</b>
<b>P3: Uncovering Hidden Complexities in Redundant Sterilizing Filters, Pre-Use Post-Sterilization Integrity Testing, and Single-Use Systems</b> <b>Moderator:</b> Frederic B. Ayers , Senior Consultant - Microbiology, ValSource, Inc.	
13:15 – 14:45	<div><div>13:15 – 13:35</div><div><b>Handling Multiple Filters as Close to the Point of Fill as Possible</b><ul style="list-style-type: none"><li>• <b>Presenter:</b> William Peterson , Director, Global QA, Merck &amp; Co., Inc.</li></ul></div></div>

	<b>Interactive Case Study: Multiple Sterilizing Grade Filters</b>	
	13:35 – 14:25	<ul style="list-style-type: none"> <li><b>Presenter:</b> William Peterson , Director, Global QA, <i>Merck &amp; Co., Inc.</i></li> </ul>
	14:25 – 14:45	<b>Report Out and Discussion</b>
14:45 – 15:15	<b>Networking Break in the Exhibit Area</b>	
15:15 – 16:15	<b>P4: Day 1 Debrief: Key Themes and Takeaways</b>	
	<b>Moderator:</b> Frederic B. Ayers , Senior Consultant - Microbiology, <i>ValSource, Inc.</i>	
	<b>Day 1 Reflections</b>	
	15:15 – 15:25	<ul style="list-style-type: none"> <li><b>Presenter:</b> Brooke K. Higgins MS, Senior Vice President, Regulatory Compliance, <i>ELIQUENT Life Sciences</i></li> </ul>
	15:25 – 16:15	<b>Open Group Discussion: Turning Insight into Action</b>
16:15 – 17:30	<b>Networking Reception in the Exhibit Area</b>	

## Wednesday, 3 December

EST Standard Time (UTC -5:00)

07:30 – 08:30	<b>Continental Breakfast</b>	
07:30 – 16:15	<b>Registration Open</b>	
08:30 – 10:00	<b>P5: The Wrapping Paradox: Annex 1-Compliant Strategies for Barrier Entry</b>	
	<b>Moderator:</b> Richard Denk , Senior Consultant Aseptic Processing, <i>SKAN AG</i>	
	<b>Day 1 Highlights</b>	
	08:30 – 08:40	<ul style="list-style-type: none"> <li><b>Chair:</b> Frederic B. Ayers , Senior Consultant - Microbiology, <i>ValSource, Inc.</i></li> </ul>
	08:30 – 08:50	<b>Unwrapping the Risks: Annex 1-Compliant Approaches to Part Handling and Installation</b> <ul style="list-style-type: none"> <li><b>Presenter:</b> Julian Petersen , Head of Business Development Pharma, <i>groninger &amp; co gmbh</i></li> </ul>
	08:50 – 09:45	<b>From Equipment Washroom to Isolator: Designing Ideal SOPs for Stopper Equipment Transfer in Greenfield and Brownfield Projects</b> <ul style="list-style-type: none"> <li><b>Presenter:</b> Julian Petersen , Head of Business Development Pharma, <i>groninger &amp; co gmbh</i></li> </ul>
	09:45 – 10:00	<b>Report Out and Discussion</b>
10:00 – 10:30	<b>Networking Break in the Exhibit Area</b>	
10:30 – 12:15	<b>P6: Implementation of Aseptic Process Simulation Requirements in Compliance with Revised EU Annex 1</b>	
	<b>Moderator:</b> Julian Petersen , Head of Business Development Pharma, <i>groninger &amp; co gmbh</i>	
	<b>Designing, Executing, and Defending APS Programs</b>	
	10:30 – 11:00	<ul style="list-style-type: none"> <li><b>Presenter:</b> Sarah Elliott , Senior Director, Technical Center of Excellence, <i>Emergent BioSolutions Inc.</i></li> </ul>
	<b>Uncovering APS Failures: A Hands-On Root Cause Investigation</b>	

11:00 – 11:55	<ul style="list-style-type: none"> <li>• <b>Presenter: Sarah Elliott</b> , Senior Director, Technical Center of Excellence, <i>Emergent BioSolutions Inc.</i></li> </ul>
11:55 – 12:15	<b>Report Out and Discussion</b>

12:15 – 13:15 **Networking Lunch**

**P7: Implementation of Annex 1 in Drug Substance Processes**

**Moderator: Sarah Elliott** , Senior Director, Technical Center of Excellence, *Emergent BioSolutions Inc.*

13:15 – 14:45	<b>A Risk-Based Approach to Annex 1 Requirements</b>	
	13:15 – 13:35	<ul style="list-style-type: none"> <li>• <b>Presenter: Michael Hendershot</b> , Director - API Contamination Control Steward, <i>Eli Lilly and Company</i></li> </ul>
	<b>An Interactive Evaluation of Annex 1 Applicability to Drug Substance Manufacturing</b>	
	13:35 – 14:25	<ul style="list-style-type: none"> <li>• <b>Presenter: Michael Hendershot</b> , Director - API Contamination Control Steward, <i>Eli Lilly and Company</i></li> </ul>
	14:25 – 14:45	<b>Report Out and Discussion</b>

14:45 – 15:15 **Networking Break in the Exhibit Area**

**P8: Day 2 Debrief: Key Themes and Takeaways**

**Moderator: Frederic B. Ayers** , Senior Consultant - Microbiology, *ValSource, Inc.*

15:15 – 16:15	<b>Day 2 Reflections</b>	
	15:15 – 15:25	<ul style="list-style-type: none"> <li>• <b>Panelist: Brooke K. Higgins MS</b>, Senior Vice President, Regulatory Compliance, <i>ELIQUENT Life Sciences</i></li> </ul>
	15:25 – 16:10	<b>Open Group Discussion: Turning Insight into Action</b>
	<b>Closing Remarks from Workshop Chair</b>	
	16:10 – 16:15	<ul style="list-style-type: none"> <li>• <b>Chair: Frederic B. Ayers</b> , Senior Consultant - Microbiology, <i>ValSource, Inc.</i></li> </ul>