

# PDA Annex 1 Implementation Works 2025

## Agenda

**Tuesday, 2 December**

EST Standard Time (UTC -5:00)

07:30 – 08:30 **Continental Breakfast**

07:30 – 16:30 **Registration Open**

### **P1: From Risk to Resilience: Building an Annex 1 Compliant Contamination Control Strategy**

In the wake of the revised EU GMP Annex 1, pharmaceutical manufacturers face heightened expectations for contamination control and risk management. Participants will explore the practical implementation of a robust, risk-based Contamination Control Strategy (CCS) that aligns with Annex 1 requirements, learning how to integrate CCS into existing quality systems, leverage cross-functional risk assessments, and apply science-based decision-making to proactively mitigate contamination risks.

Through real-world examples and actionable insights, the discussion will highlight key elements such as facility design, personnel practices, environmental monitoring, and the role of Quality Risk Management (QRM) in shaping a defensible CCS. Attendees will leave equipped with practical tools and strategies to move from compliance to operational excellence, whether preparing for regulatory inspections or refining their contamination control framework.

**Moderator: Richard Denk** , Senior Consultant Aseptic Processing, SKAN AG

#### **Welcome Remarks and Introduction from the Workshop Chair**

08:30 – 08:40 • **Chair: Frederic B. Ayers** , Senior Consultant - Microbiology, Va/Source, Inc.

#### **Annex 1 in Practice: A Strategic Framework for Contamination Control Excellence**

The revised EU GMP Annex 1 ushered in a transformative era for pharmaceutical manufacturing, emphasizing a comprehensive, risk-based approach to contamination control. This presentation explores a strategic framework for translating Annex 1 principles into practical, sustainable contamination control excellence across pharmaceutical operations.

• **Presenter: Frederic B. Ayers** , Senior Consultant - Microbiology, Va/Source, Inc.

#### **Control or Chaos? A Tabletop Exercise in Contamination Strategy Evaluation**

Step into the dynamic world of aseptic fill-finish manufacturing in this immersive exercise, where participants will take on the roles of Quality Assurance, Sterility Assurance, Operations, and Engineering to evaluate and enhance a fictional facility's Contamination Control Strategy (CCS). Set against the backdrop of a high-throughput sterile product line, teams will navigate realistic scenarios involving a failed Aseptic Process Simulation (APS) while evaluating the investigation related to a comprehensive CCS.

Participants will:

- Analyze investigation for CCS documentation and identify critical gaps
- Respond to simulated contamination events with cross-functional input
- Develop risk-based CAPAs aligned with regulatory expectations

This exercise emphasizes strategic decision-making, cross-disciplinary collaboration, and the practical application of contamination control principles in a high-risk aseptic environment.

• **Presenter: Frederic B. Ayers** , Senior Consultant - Microbiology, Va/Source, Inc.

09:55 – 10:15 **Report Out and Discussion**

10:15 – 10:45 **Networking Break in the Exhibit Area**

## P2: Closing the Gap: Annex 1-Compliant Barrier Technology for Modern and Legacy Operations

This session will guide participants through the practical implementation of barrier technology in both existing and new facilities, aligned with Annex 1 requirements. Using real-world scenarios, case studies, and group exercises, the session will address key operational challenges and proven best practices.

Participants will explore their own facility challenges, work through problem-solving exercises, and leave with actionable strategies to maintain compliance while optimizing operational performance.

**Moderator: Julian Petersen**, Head of Business Development Pharma, groningen & co gmbh

### Barrier Systems in Practice: Managing Doors, Gloves, Decontamination, Airflow, and Pressure Cascades

10:45 – 12:15

10:45 – 11:05

- **Presenter: Richard Denk**, Senior Consultant Aseptic Processing, SKAN AG

### Interactive Case Study: Barrier Doors – First Air and Air Flow Challenges

11:05 – 11:55

Join this interactive case study to explore two key challenges in Annex 1 implementation—first air practices and airflow control. Each table will choose which topic to tackle, engaging in discussion around best practices, common pitfalls, and practical approaches to maintaining aseptic conditions during operations. This hands-on session encourages collaboration and real-world problem-solving to strengthen your Annex 1 compliance strategies.

- **Presenter: Richard Denk**, Senior Consultant Aseptic Processing, SKAN AG

11:55 – 12:15 **Report Out and Discussion**

12:15 – 13:15 **Networking Lunch**

## P3: Uncovering Hidden Complexities in Redundant Sterilizing Filters, Pre-Use Post-Sterilization Integrity Testing, and Single-Use Systems

Redundant filtration, as recognized by Annex 1, promises business risk mitigation by allowing a contingency in the event your primary filter fails its integrity test. This hands-on workshop explores lesser-known implications of redundant filtration configurations, and challenges the audience to consider carefully how their designation of multiple filters in series affects the process.

Participants will debate the differences between pre-filtration, redundant filtration, and double filtration, and evaluate how the distinctions have trickle-down impacts on their integrity testing approach, PUPSIT, and single-use systems (SUS) design.

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

### Handling Multiple Filters as Close to the Point of Fill as Possible

13:15 – 14:45

13:15 – 13:35

- **Presenter: William Peterson**, Director, Global QA, Merck & Co., Inc.

### Interactive Case Study: Multiple Sterilizing Grade Filters

13:35 – 14:25

Dive deep into the differences between redundant filtration, bioburden reduction filtration, and double filtration. How does the distinction affect your process? This interactive case study will walk through nuances of redundant filtration you may not have considered: Which filter (upstream or downstream) should be primary? How do you handle the “inter-filter” region? What type of investigation is needed in the contingency scenario where your primary filter fails its integrity test, but the secondary passes? Walk away with a better understanding of sterilizing grade filter configurations, and confidence to navigate and defend your own program.

- **Presenter: William Peterson**, Director, Global QA, Merck & Co., Inc.

14:25 – 14:45 **Report Out and Discussion**

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

## P4: Day 1 Debrief: Key Themes and Takeaways

This interactive session invites participants to reflect on the day's key themes, share takeaways, and engage in open discussion. Bring your questions, ideas, and challenges to the group as we connect lessons across sessions and explore practical approaches to implementation in real-world sterile manufacturing environments.

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

15:15 – 16:15

#### Day 1 Reflections

15:15 – 15:25 • **Presenter: Brooke K. Higgins MS**, Senior Vice President, Regulatory Compliance, *ELIQUENT Life Sciences*

15:25 – 16:15 **Open Group Discussion: Turning Insight into Action**

16:15 – 17:30 **Networking Reception in the Exhibit Area**

## Wednesday, 3 December

EST Standard Time (UTC -5:00)

07:30 – 08:30 **Continental Breakfast**

07:30 – 16:15 **Registration Open**

#### **P5: The Wrapping Paradox: Annex 1-Compliant Strategies for Barrier Entry**

Transferring stopper equipment from the washing room to the isolator filling line may appear routine—but it's anything but simple. This session unpacks the complexity behind this critical process, drawing on recent cGMP observations, 483 findings, and industry insights to reveal evolving expectations for Annex 1 compliance.

Whether you're building a new facility or optimizing an existing one, this session will help you unwrap the paradox and repackage your approach to Annex 1 compliance.

**Moderator: Richard Denk**, Senior Consultant Aseptic Processing, *SKAN AG*

#### Day 1 Highlights

08:30 – 08:40 • **Chair: Frederic B. Ayers**, Senior Consultant - Microbiology, *ValSource, Inc.*

08:30 – 10:00

#### **Unwrapping the Risks: Annex 1-Compliant Approaches to Part Handling and Installation**

08:30 – 08:50 • **Presenter: Julian Petersen**, Head of Business Development Pharma, *groningen & co gmbh*

#### **From Equipment Washroom to Isolator: Designing Ideal SOPs for Stopper Equipment Transfer in Greenfield and Brownfield Projects**

08:50 – 09:45 In this hands-on presentation, you'll step into real-world sterile manufacturing scenarios to design high-level SOPs for transferring stopper equipment in both greenfield and brownfield settings. Collaborate with peers to map process flows, refine wrapping and gowning procedures, and strengthen aseptic handling and decontamination strategies. Through active problem-solving and discussion, you'll develop draft SOP frameworks—and walk away with practical tools to enhance contamination control and compliance at your own facility.

• **Presenter: Julian Petersen**, Head of Business Development Pharma, *groningen & co gmbh*

09:45 – 10:00 **Report Out and Discussion**

10:00 – 10:30 **Networking Break in the Exhibit Area**

#### **P6: Implementation of Aseptic Process Simulation Requirements in Compliance with Revised EU Annex 1**

APS Starts Here: From Planning to Inspection Ready!

Aseptic Process Simulations (APS) are far more than a regulatory requirement—they're a cornerstone of sterility assurance in aseptic manufacturing. This Annex 1-focused workshop breaks down the essentials of APS design, execution, and defense.

Gain practical, step-by-step guidance on risk-based planning, program execution, deviation handling, and inspection readiness aligned with the latest EU GMP standards. You'll leave equipped to build, validate, and confidently justify a robust APS program from start to finish.

**Moderator: Julian Petersen**, Head of Business Development Pharma, *groninger & co gmbh*

10:30 – 12:15

### Designing, Executing, and Defending APS Programs

10:30 – 11:00

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

### Uncovering APS Failures: A Hands-On Root Cause Investigation

11:00 – 11:55

Attendees will gain hands-on skills in uncovering the root causes of APS failures. Through simulated case studies, participants will learn how to identify root causes – whether they stem from utilities, equipment, or human factors, and develop effective CAPA strategies. Discover how multidisciplinary teams can collaborate to resolve complex contamination events and ensure your APS program stands up to regulatory scrutiny.

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

11:55 – 12:15

### Report Out and Discussion

12:15 – 13:15 **Networking Lunch**

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

EU GMP Annex 1 principles are increasingly relevant to drug substance operations where contamination risks impact product quality. This session applies a risk-based approach to help participants identify critical control points, assess risks, and implement effective controls. Topics include facility and equipment design, personnel practices, environmental monitoring, and integrating Quality Risk Management (QRM) into contamination control strategies. Real-world examples show how manufacturers adapt Annex 1 to non-sterile and hybrid operations. Ideal for quality, operations, and validation professionals, this session provides practical strategies to strengthen contamination control and stay ahead of regulatory expectations.

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

### A Risk-Based Approach to Annex 1 Requirements

13:15 – 13:35

- **Presenter: Michael Hendershot**, Director - API Contamination Control Steward, *Eli Lilly and Company*

### An Interactive Evaluation of Annex 1 Applicability to Drug Substance Manufacturing

13:35 – 14:25

During this interactive presentation, participants will work in teams to apply insights from the discussion and their own experiences to evaluate how Annex 1 requirements relate to various drug substance manufacturing processes. Each team will identify relevant Annex 1 provisions, justify their applicability, and then nominate a Subject Matter Expert to represent the team in a mock inspection to defend their decisions.

- **Presenter: Michael Hendershot**, Director - API Contamination Control Steward, *Eli Lilly and Company*

14:25 – 14:45

### Report Out and Discussion

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

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

This interactive session invites participants to reflect on the day's key themes, share takeaways, and engage in open discussion. Bring your questions, ideas, and challenges to the group as we connect lessons across sessions and explore practical approaches to implementation in real-world sterile manufacturing environments.

**Moderator: Frederic B. Ayers**, Senior Consultant - Microbiology, *Va/Source, Inc.*

## Day 2 Reflections

15:15 – 16:15

15:15 – 15:25 • **Panelist: Brooke K. Higgins MS**, Senior Vice President, Regulatory Compliance, *ELIQUENT Life Sciences*

15:25 – 16:10 **Open Group Discussion: Turning Insight into Action**

### Closing Remarks from Workshop Chair

16:10 – 16:15

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