



Agenda

PDA Annex1 Implementation: Inspection Ready Workshop 2025

Tuesday, 17 June

08:00 – 09:00

Registration

09:00 – 10:15

Opening Session

09:00 – 09:15

Introduction by Program Chair

Richard Denk, Senior Consulting Aseptic Processing & Containment, *SKAN AG*

09:15 – 09:45

Keynote: How Are The Current Trade Policies Affecting The Industry Regionally

09:45 – 10:15

Regulatory Roundtable: Adoption and Implementation of PIC/S Annex 1, Successes and Challenges Two Years On

10:15 – 10:45

Coffee Break

10:45 – 12:15

Session 1

10:45 – 11:15

Understanding Annex 1: Key Requirements and Regulatory Updates

11:15 – 11:45

Developing a Robust Contamination Control Strategy (CCS) for Compliance

11:45 – 12:15

Cleanroom Design and Environmental Monitoring: Meeting Annex 1 Standards

12:15 – 13:15

Lunch Break



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13:15 – 14:15

Session 2

13:15 – 13:45

Personnel Training and Competency: Building a Culture of Compliance

13:45 – 14:15

Panel Discussion

14:15 – 15:00

PIC/s Annex 1 Workshop/Training Part 1

Richard Denk, Senior Consulting Aseptic Processing & Containment, *SKAN AG*

15:00 – 15:30

Coffee Break

15:30 – 17:00

PIC/s Annex 1 Workshop/Training Part 2

Somasundaram G., Associate Director, *Merck Life Science Private Limited*

Wednesday, 18 June

08:30 – 09:00

Registration

09:00 – 10:20

Session 3

09:00 – 09:40

Equipment Qualification and Validation for Sterile Manufacturing

09:40 – 10:20

Sterility Assurance and Process Validation: Ensuring Consistency



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10:20 – 10:50

Coffee Break

10:50 – 12:40

Session 4

10:50 – 11:30

Documentation, Batch Records, and Change Control for Inspection Readiness

11:30 – 12:10

GMP Inspections: Preparing for Success and Effective Response Strategies

12:10 – 12:40

Panel Discussion

12:40 – 13:40

Lunch Break

13:40 – 15:00

Mastering Contamination Control Strategy (CCS) for Annex 1 Compliance Part 1

15:00 – 15:30

Coffee Break

15:30 – 17:00

Mastering Contamination Control Strategy (CCS) for Annex 1 Compliance Part 2