

PDA Manage Your Isolator for Aseptic Processing Training Course

Agenda

Wednesday, 11 March

CET Standard Time (UTC +1:00)

08:30 – 09:00 **Welcome and Introduction of Trainers and Participants**

Isolator Basics (Theory)

- Application of isolators
 - Technical basics
 - Components
 - Annex 1
 - Containment/ Cleaning
 - Gloves
 - Ports
 - Process components
- 09:00 – 09:15

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

Regulatory View on Annex 1

- Principles
 - Key Changes
 - Points to Consider
- 09:15 – 10:30

Tracy Moore , CEO, *TM Pharma Group*

10:30 – 11:00 **Coffee Break and walk to the Academy**

Workshop in 2 Groups

Get to Know the Isolator (Academy)

- Doors
 - Gloves
 - Ports/Locks
- 11:00 – 11:45
- **Alain Ribstein** , Sales Manager, *SKAN AG*
- 11:00 – 12:30

Filters in Practice (Academy)

- HEPA filter, safe filter change, and test
- 11:45 – 12:30
- **Jörg Kettner** , CQE Coordinator, *SKAN AG*

12:30 – 13:30 **Lunch Break**

Walk through the SKAN Assembly Hall

- Showing examples on large filing lines, small scale filing lines, and material transfer systems
- Short presentation on ebeam

13:30 – 14:30 **Richard Denk** , Senior Consultant Aseptic Processing, *SKAN AG*

Alain Ribstein Sales Manager *SKAN AG*

Requirements for Environmental Monitoring

14:30 – 16:00

- What are the GMP Requirements?
- Find the right Position in the Isolator System

Tracy Moore , CEO, *TM Pharma Group*

16:00 – 16:30 **Coffee Break**

SKAN Transfer Solutions

16:30 – 17:00

- Discover the SKAN transfer solutions to safely introduce your product and materials inside your isolator, ensuring the aseptic continuity of your process. The following transfer solutions will be introduced: AT-Port for liquids, ABC Transfer ports for materials.

17:00 – 17:30 **Attendee Questionnaire and Q&A from Day 1**

Thursday, 12 March

CET Standard Time (UTC +1:00)

08:30 – 08:45 **Recap Day 1**

Gloves on the Isolator (Theory)

08:45 – 10:00

- Requirements for gloves
 - Tightness (pressure drop test)
 - Handling by operator
- How to differentiate glove types
 - Manufacturing
 - Material, size, etc.
- Glove Risk Management
- Microbiological Monitoring on Gloves (Theory/Practical)

Andreas Kindscher , , *SKAN Germany*

Alex J. Kappani Product Management SKAN AG

10:00 – 10:30 **Coffee Break and walk to the Academy**

Gloves on the Isolator (Practice)

10:30 – 12:00

- Types of gloves (different examples)
- Positioning of gloves in the isolator (various examples)
- Positioning in the isolator through mock-up studies
- Mock-up study (example)
- Installation and removal of the gloves
- Working with/in the gloves on practical examples
- Tightness
- Visual inspection

Andreas Kindscher , , *SKAN Germany*

Alex J. Kappani Product Management SKAN AG

Clean @ SKAN

12:00 – 12:45

- Key considerations when building cleaning process
- How to clean an isolator
- What about toxic isolators and cleaning
- How to quantify clean

Lilia Lahouel , Cleaning Validation Manager, SKAN AG

12:45 – 13:30	Lunch Break
13:30 – 14:00	<p>Biological Indicators (BI's) for Bio-Decontamination with Hydrogen Peroxide</p> <ul style="list-style-type: none"> • Specifications, requirements, suitability assessment tests and challenges for use <p>Veronika Zysk , Administrative Laboratory Specialist, <i>SKAN AG</i></p>
14:00 – 14:30	<p>Decontamination (Theory)</p> <ul style="list-style-type: none"> • H2O2 as decontaminating agent <ul style="list-style-type: none"> ◦ Properties ◦ Concentration ◦ Interaction with water <p>Martin Novak MSc, Technology Lead, <i>SKAN AG</i></p>
14:30 – 15:00	<p>Cycle Development</p> <ul style="list-style-type: none"> • Validation <p>Theresa Ladwig , Sterility Assurance Service Manager, <i>SKAN AG</i></p>
14:50 – 15:05	<p>Decontamination (Praxis Academy)</p> <ul style="list-style-type: none"> • Preparation for decontamination • Start cycle <p>Vincent Guilhou , , <i>SKAN AG</i></p> <p>Theresa Ladwig Sterility Assurance Service Manager <i>SKAN AG</i></p>
16:30 – 17:15	Attendee Questionnaire and Q&A from Day 2
17:15 – 17:15	End of Training Course