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**

09:00 – 09:15	**Isolator Basics (Theory)**
	• Application of isolators
	• Technical basics
	• Components
	  ◦ Annex 1
	  ◦ Containment/ Cleaning
	  ◦ Gloves
	  ◦ Ports
	  ◦ Process components
	Richard Denk , Senior Consultant Aseptic Processing, *SKAN AG*

09:15 – 10:30	**Regulatory View on Annex 1** • Principles • Key Changes • Points to Consider **Andrew D. Hopkins PGDip**, Senior Director, *Lachman Consultants*
10:30 – 11:00	**Coffee Break and walk to the Academy**
11:00 – 12:30	**Workshop in 2 Groups** 11:10 – 12:05: **Get to Know the Isolator (Academy)** • Doors • Gloves • Ports/Locks • **Alain Ribstein** , , *SKAN* 12:05 – 13:00: **Filters in Practice (Academy)** • HEPA filter, safe filter change, and test • **Guido Herzberg** , , *SKAN Switzerland*
13:00 – 13:45	**Lunch Break**
13:45 – 14:30	**Walk through the SKAN Assemly Hall** Showing examples on large filing lines, small scale filing lines, and material transfer systems. **Richard Denk** , Senior Consultant Aseptic Processing, *SKAN AG* **Alain Ribstein** *SKAN*

14:30 – 15:45	**Requirements for Environmental Monitoring** • What are the GMP Requirements? • Find the right Position in the Isolator System **Tracy Moore** , CEO, *TM Pharma Group*
15:45 – 16:30	**Coffee Break**
16:30 – 17:00	**Cleaning SKAN CleanIP - SKANalytix** • What is important to prepare cleaning • What is the right method to perform cleaning and how to quanitfy clean **Max Mittelviefhaus** , Research Manager, *SKAN AG*
17:00 – 17:30	**Q&A from Day 1**

Thursday, 12 March

CET Standard Time (UTC +1:00)

09:00 – 09:10	**Recap Day 1**	
09:10 – 10:15	**Theory/Practical**	

	09:10 – 09:35	**Gloves on the Isolator (Theory)**
		• Requirements for gloves
		  ◦ Tightness (pressure, liquid)
		  ◦ Insensitivity to media
		  ◦ Handling by operator
		• Positioning in the isolator through mock-up studies
		• How do different gloves and designs look like
		  ◦ Manufacturer
		  ◦ Materials
		• **Andreas Kindscher** , , *SKAN Germany*
		• **Alex J. Kappani** , Product Management, *SKAN AG*

	09:10 – 10:15	**Microbiological Monitoring on Gloves (Theory/Practical)** • Swab test - Microbiological testing • **Andreas Kindscher** , , *SKAN Germany* • **Alex J. Kappani** , Product Management, *SKAN AG*
10:15 – 10:45	**Coffee Break and walk to the Academy**	

10:45 – 12:30	**Gloves on the Isolator (Practice)**
	• Explanation of technical specification of the isolator
	• Material and design of gloves
	• Positioning of gloves in the isolator (various examples)
	• Mock-up study (example)
	• Installation and removal of the gloves
	• Working with/in the gloves on practical examples
	  ◦ "Easy" example
	  ◦ "Difficult" example
	• Tightness
	• Visual inspection
	Andreas Kindscher , , *SKAN Germany*
	Alex J. Kappani Product Management *SKAN AG*	

12:30 – 13:30	**Lunch Break**
13:30 – 13:50	**Biological Indicators BI's** • What is important to consider using BI's for the validated decontamination cycle **Chantal Past** , , *SKAN*

13:50 – 14:50	**Decontamination (Theory)**
	• H2O2 as decontaminating agent
	  ◦ Properties
	  ◦ Concentration
	  ◦ Interaction with water
	• Cycle development
	  ◦ Validation
	Martin Novak MSc, Technology Lead, *SKAN AG*
	Theresa Ladwig Dipl Ing, MASBEM Sterility Assurance Service Manager *SKAN AG*

14:50 – 15:05	**Decontamination (Praxis Academy)** • Preparation for decontamination • Start cycle **Mathilde Jemelen** , Sales Engineer, *SKAN AG* **Theresa Ladwig** Sales Engineer *SKAN AG*
15:05 – 15:45	**Q&A from Day 2**