

Training Course Agenda

PDA EU00180 Manage Your Isolator for Aseptic Processing

Day 1		
8:30	Welcome and Introduction of Trainers and Participants	
9:00	Isolator Basics (Theory) <ul style="list-style-type: none"> • Application of isolators • Technical basics • Components <ul style="list-style-type: none"> ○ Annex 1 ○ Containment/ Cleaning ○ Gloves ○ Ports ○ Process components 	Richard Denk, SKAN
9:45	Regulatory View on Annex 1	Andrew Hopkins, Abbvie
10:20	Coffee Break	
10:50	Relevant Guidelines and Regulations for Gloves <ul style="list-style-type: none"> • PDA Paper 	Andreas Kindscher, SKAN
11:20	Gloves on the Isolator (Theory) <ul style="list-style-type: none"> • Requirements for gloves <ul style="list-style-type: none"> ○ 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 <ul style="list-style-type: none"> ○ Manufacturer ○ Materials 	Andreas Kindscher, SKAN & Alex Kappani, SKAN
12:30	Lunch Break	
13:15	Get to Know the Isolator (Hall) <ul style="list-style-type: none"> • Doors • Gloves • Ports/Locks • Isolator in operation 	Ruben Rizzo, SKAN Harald Kiesel, SKAN
15:00	Gloves, Filters and Smoke Studies in Practice (Hall) <ul style="list-style-type: none"> • HEPA filter, safe filter change, and test 	Guido Herzberg, SKAN

	Airflow visualization and studies	
15:00	Coffee Break	
15:30	Gloves on the Isolator (Practice) <ul style="list-style-type: none"> • Explanation of technical specification of the isolator • Material and design of gloves (different examples) • 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 <ul style="list-style-type: none"> ○ "easy" example ○ "difficult" example 	Andreas Kindscher, SKAN & Alex Kappani, SKAN
17:00	Q&A from Day 1	
17:30	End of Day 1 & Networking Event	
17:30 – 20:30	Meeting Point for Networking Event: SKAN Reception Dinner: Baracca Zermatt	

Day 2		
9:00	Recap Day 1	
9:05	Microbiological Monitoring on Gloves (Theory) Swab test- Microbiological testing	Theresa Ladwig, SKAN
10:05	Gloves (Practice) <ul style="list-style-type: none"> • Tightness • Visual inspection 	Andreas Kindscher, SKAN
11:05	Coffee Break	
11:30	Requirements for Environmental Monitoring <ul style="list-style-type: none"> • What are the GMP Requirements • Find the right Position in the Isolator System 	Tracy Moore, TM Pharma Group Ltd Former MHRA Inspector
12:15	Lunch Break	
13:15	Walk through the SKAN Assembly Hall showing Examples on Large Filling Lines, small scale filling lines, Material Transfer Systems.	Ruben Rizzo Richard Denk
14:00	Decontamination (Theory)	Martin Novak, SKAN &

	<ul style="list-style-type: none"> • H2O2 as decontaminating agent <ul style="list-style-type: none"> ○ Properties ○ Concentration ○ interaction with water • Cycle development <ul style="list-style-type: none"> ○ Validation 	Theresa Ladwig, SKAN
15:00	Decontamination <ul style="list-style-type: none"> • Preparation for decontamination • Start cycle 	Martin Novak, SKAN & Theresa Ladwig Mathilde Jemelen, SKAN
15:45	Cleaning SKAN CleanIP - SKANalytix <ul style="list-style-type: none"> • What is important to prepare Cleaning • What is the right method to perform cleaning and how to quantify clean 	Max Mittelviefhaus, SKAN
16:30	Q&A from Day 2	
16:45	End of Course	