

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 & Richard Mühle, SKAN & Alex Kappani, SKAN
12:30	Lunch Break	
13:15	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 & Richard Mühle, SKAN & Alex Kappani, SKAN

14:45	Microbiological Monitoring on Gloves (Theory) <ul style="list-style-type: none"> Swab test- Microbiological testing 	Theresa Ladwig, SKAN
15:45	Coffee Break	
16:15	Gloves (Practice) <ul style="list-style-type: none"> Tightness Visual inspection 	Andreas Kindscher, SKAN & Richard Mühle, SKAN
17:15	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: Restaurant Schlüsselzunft Freie Str. 25 4001 Basel, Switzerland	
Day 2		
9:00	Recap Day 1	
9:05	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
09:50	Walk through the SKAN Assembly Hall showing Examples on Large Filling Lines, small scale filling lines, Material Transfer Systems.	
10:30	Coffee Break and walk to the Academy	
10:45	Practical Training Divided in Group 1 and Group 2	
	Get to Know the Isolator (Hall) <ul style="list-style-type: none"> Doors Gloves Ports/Locks Isolator in operation 	Alain Ribstein, SKAN & Yves Schöller, SKAN
	Gloves, Filters and Smoke Studies in Practice (Hall) <ul style="list-style-type: none"> How does a glove test work? HEPA filter, safe filter change, and test Airflow visualization and studies 	Michael Scheibel, SKAN & Florian Trommer, SKAN
12:30	Lunch Break	

<p>13:30</p>	<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 • Cycle development <ul style="list-style-type: none"> ○ Validation 	<p>Martin Novak, SKAN & Simone Eicher, SKAN & Christian Doriath, SKAN</p>
<p>14:30</p>	<p>Decontamination (Assembly Hall)</p> <ul style="list-style-type: none"> • Preparation for decontamination • Start cycle <p>Cleaning SKAN CleanIP (Assembly Hall)</p> <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 	<p>Martin Novak, SKAN & Simone Eicher, SKAN & Christian Doriath, SKAN</p> <p>Max Mittelviefhaus, SKAN</p>
<p>16:30</p>	<p>Q&A from Day 2</p>	
<p>16:45</p>	<p>End of Course</p>	