

# PDA Manage Your Isolator for Aseptic Processing Training Course

## Agenda

**Wednesday, 11 March**

CET Standard Time (UTC +1:00)

08:30 – 09:00	<b>Welcome and Introduction of Trainers and Participants</b>				
09:00 – 09:45	<p><b>Isolator Basics (Theory)</b></p> <ul style="list-style-type: none"><li>• Application of isolators</li><li>• Technical basics</li><li>• Components<ul style="list-style-type: none"><li>◦ Annex 1</li><li>◦ Containment/ Cleaning</li><li>◦ Gloves</li><li>◦ Ports</li><li>◦ Process components</li></ul></li></ul> <p><b>Richard Denk</b> , Senior Consultant Aseptic Processing, <i>SKAN AG</i></p>				
09:45 – 10:40	<p><b>Regulatory View on Annex 1</b></p> <ul style="list-style-type: none"><li>• Principles</li><li>• Key Changes</li><li>• Points to Consider</li></ul> <p><b>Andrew D. Hopkins PGDip</b>, Senior Director, <i>Lachman Consultants</i></p>				
10:40 – 11:10	<b>Coffee Break and walk to the Academy</b>				
11:10 – 13:00	<p><b>Workshop in 2 Groups</b></p> <table><tr><td>11:10 – 12:05</td><td><p><b>Get to Know the Isolator (Academy)</b></p><ul style="list-style-type: none"><li>• Doors</li><li>• Gloves</li><li>• Ports/Locks</li></ul><p>• <b>Alain Ribstein</b> , , <i>SKAN</i></p></td></tr><tr><td>12:05 – 13:00</td><td><p><b>Filters in Practice (Academy)</b></p><ul style="list-style-type: none"><li>• HEPA filter, safe filter change, and test</li><li>• <b>Guido Herzberg</b> , , <i>SKAN Switzerland</i></li></ul></td></tr></table>	11:10 – 12:05	<p><b>Get to Know the Isolator (Academy)</b></p> <ul style="list-style-type: none"><li>• Doors</li><li>• Gloves</li><li>• Ports/Locks</li></ul> <p>• <b>Alain Ribstein</b> , , <i>SKAN</i></p>	12:05 – 13:00	<p><b>Filters in Practice (Academy)</b></p> <ul style="list-style-type: none"><li>• HEPA filter, safe filter change, and test</li><li>• <b>Guido Herzberg</b> , , <i>SKAN Switzerland</i></li></ul>
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13:00 – 13:45	<b>Lunch Break</b>				
13:45 – 14:30	<p><b>Walk through the SKAN Assembly Hall</b></p> <p>Showing examples on large filling lines, small scale filling lines, and material transfer systems.</p> <p><b>Richard Denk</b> , Senior Consultant Aseptic Processing, <i>SKAN AG</i></p> <p><b>Alain Ribstein</b> <i>SKAN</i></p>				

<b>Requirements for Environmental Monitoring</b>	
14:30 – 15:45	<ul style="list-style-type: none"> <li>• What are the GMP Requirements?</li> <li>• Find the right Position in the Isolator System</li> </ul> <p><b>Tracy Moore</b> , CEO, <i>TM Pharma Group</i></p>
<b>15:45 – 16:30 Coffee Break</b>	
<b>Cleaning SKAN CleanIP - SKANalytix</b>	
16:30 – 17:00	<ul style="list-style-type: none"> <li>• What is important to prepare cleaning</li> <li>• What is the right method to perform cleaning and how to quantify clean</li> </ul> <p><b>Max Mittelviefhaus</b> , Research Manager, <i>SKAN AG</i></p>
<b>17:00 – 17:30 Q&amp;A from Day 1</b>	

## Thursday, 12 March

CET Standard Time (UTC +1:00)

<b>09:00 – 09:10 Recap Day 1</b>	
09:10 – 10:15	<b>Theory/Practical</b>
	<div> <div> <b>Gloves on the Isolator (Theory)</b> </div> <div> 09:10 – 09:35 <ul style="list-style-type: none"> <li>• Requirements for gloves <ul style="list-style-type: none"> <li>◦ Tightness (pressure, liquid)</li> <li>◦ Insensitivity to media</li> <li>◦ Handling by operator</li> </ul> </li> <li>• Positioning in the isolator through mock-up studies</li> <li>• How do different gloves and designs look like <ul style="list-style-type: none"> <li>◦ Manufacturer</li> <li>◦ Materials</li> </ul> </li> </ul> </div> </div>
	<ul style="list-style-type: none"> <li>• <b>Andreas Kindscher</b> , , <i>SKAN Germany</i></li> <li>• <b>Alex J. Kappani</b> , Product Management, <i>SKAN AG</i></li> </ul>
	<div> <div> <b>Microbiological Monitoring on Gloves (Theory/Practical)</b> </div> <div> 09:10 – 10:15 <ul style="list-style-type: none"> <li>• Swab test - Microbiological testing</li> <li>• <b>Andreas Kindscher</b> , , <i>SKAN Germany</i></li> <li>• <b>Alex J. Kappani</b> , Product Management, <i>SKAN AG</i></li> </ul> </div> </div>
<b>10:15 – 10:45 Coffee Break and walk to the Academy</b>	
10:45 – 12:30	<b>Gloves on the Isolator (Practice)</b>
	<ul style="list-style-type: none"> <li>• Explanation of technical specification of the isolator</li> <li>• Material and design of gloves</li> <li>• Positioning of gloves in the isolator (various examples)</li> <li>• Mock-up study (example)</li> <li>• Installation and removal of the gloves</li> <li>• Working with/in the gloves on practical examples <ul style="list-style-type: none"> <li>◦ "Easy" example</li> <li>◦ "Difficult" example</li> </ul> </li> <li>• Tightness</li> <li>• Visual inspection</li> </ul> <p><b>Andreas Kindscher</b> , , <i>SKAN Germany</i></p> <p><b>Alex J. Kappani</b> Product Management <i>SKAN AG</i></p>

12:30 – 13:30	<b>Lunch Break</b>
13:30 – 13:50	<b>Biological Indicators BI's</b> <ul style="list-style-type: none"> <li>• What is important to consider using BI's for the validated decontamination cycle</li> </ul> <b>Chantal Past</b> , , <i>SKAN</i>
13:50 – 14:50	<b>Decontamination (Theory)</b> <ul style="list-style-type: none"> <li>• H2O2 as decontaminating agent <ul style="list-style-type: none"> <li>◦ Properties</li> <li>◦ Concentration</li> <li>◦ Interaction with water</li> </ul> </li> <li>• Cycle development <ul style="list-style-type: none"> <li>◦ Validation</li> </ul> </li> </ul> <b>Martin Novak MSc</b> , Technology Lead, <i>SKAN AG</i> <b>Theresa Ladwig Dipl Ing, MASBEM</b> Sterility Assurance Service Manager <i>SKAN AG</i>
14:50 – 15:05	<b>Decontamination (Praxis Academy)</b> <ul style="list-style-type: none"> <li>• Preparation for decontamination</li> <li>• Start cycle</li> </ul> <b>Mathilde Jemelen</b> , Sales Engineer, <i>SKAN AG</i> <b>Theresa Ladwig</b> Sales Engineer <i>SKAN AG</i>
15:05 – 15:45	<b>Q&amp;A from Day 2</b>