



## PDA Fundamentals of Aseptic Processing

**Thursday, 23 October 2025**

09:00	Welcome and Collection of Participants' Expectations
09:30	<p>Fundamentals of cleaning and disinfection</p> <ul style="list-style-type: none"><li>• Key elements for cleaning &amp; disinfection in cleanrooms</li><li>• Regulatory requirements and expectations</li><li>• Hazard scenarios in cleaning and disinfections</li><li>• <i>2 Groups:</i></li><li>• <i>VR Simulator Session (hands-on): Avoiding risks during disinfection procedures</i></li><li>• <i>Practical: Disinfection with UV &amp; GMP-conforming cleaning</i></li></ul>
11:15	Coffee Break
11:30	<p>Fundamentals of gowning in cleanrooms</p> <ul style="list-style-type: none"><li>• Key elements for gowning in different cleanroom grades</li><li>• Demonstration of risks and possible errors during gowning</li></ul> <p><i>Practical Part: Correct Gowning (different gowning f.e. beard etc.)</i></p>
12:30	Lunch Break
13:30	<p>Fundamentals of microbiology and environmental monitoring</p> <ul style="list-style-type: none"><li>• Background on key concepts of microbiology</li><li>• Regulatory requirements and expectations</li><li>• Overview of environmental monitoring programs (air, surfaces, personnel)</li><li>• <i>VR Simulator Session (hands-on): Avoiding risks in environmental monitoring</i></li></ul>
15:15	Coffee Break
15:30	<p>Cleanroom controls, operations and behavior</p> <ul style="list-style-type: none"><li>• Background on key concepts on cleanroom controls</li><li>• Introduction to correct cleanroom behavior</li><li>• Regulatory requirements and framework</li><li>• <i>VR Simulator Session (hands-on): Train how to move correctly in cleanrooms</i></li><li>• <i>Exchange with the experts</i></li></ul>
17:00	Q&A
17:30	End of Training Course Day 1



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### Friday, 24 October 2025

09:00	Wrap-up day 1 and Q&A
09:30	Fundamentals of first air <ul style="list-style-type: none"><li>• Key elements first air and how it protects critical surfaces</li><li>• VR Simulator Session (<i>hands-on</i>): <i>Understanding how to interact with first air</i></li></ul>
10:45	Coffee Break
11:00	Fundamentals of aseptic processing, material transfer and equipment setup <ul style="list-style-type: none"><li>• Background on different cleanroom technologies (RABS; isolator, closed systems/robotics)</li><li>• Principles of material transfer and equipment setup</li><li>• Regulatory requirements and expectations</li><li>• Most common hazard scenarios and errors during material transfer and equipment setup</li></ul>
12:30	Lunch Break
13:30	Fundamentals of aseptic interventions <ul style="list-style-type: none"><li>• Background on common aseptic interventions</li><li>• Regulatory requirements and expectations</li><li>• Most common hazard scenarios and errors during aseptic interventions</li><li>• VR Simulator Session (<i>hands-on</i>): <i>Avoiding risks in aseptic interventions</i></li><li>• <i>(Practical Glove Interventions)</i></li></ul>
15:15	Coffee Break
15:30	How to design effective training and oversight <ul style="list-style-type: none"><li>• Background on knowledge management and training</li><li>• Guidelines on how to design great training materials</li><li>• Background on effective QA oversight</li><li>• Regulatory requirements and framework</li></ul>
17:00	Q&A & Questionnaire
17:30	End of Training Course