



PDA Fundamentals of Aseptic Processing

Tuesday, 30 July 2024	
09:00	Welcome and Collection of Participants' Expectations
09:30	Fundamentals of cleaning and disinfection <ul style="list-style-type: none">• Key elements for cleaning & disinfection in cleanrooms• Regulatory requirements and expectations• Hazard scenarios in cleaning and disinfections• <i>VR Simulator Session (hands-on): Avoiding risks during disinfection procedures</i>
11:15	Coffee Break
11:30	Fundamentals of gowning in cleanrooms <ul style="list-style-type: none">• Key elements for gowning in different cleanroom grades• Demonstration of risks and possible errors during gowning
12:30	Lunch Break
13:30	Fundamentals of microbiology and environmental monitoring <ul style="list-style-type: none">• Background on key concepts of microbiology• Regulatory requirements and expectations• Overview on environmental monitoring programs (air, surfaces, personnel)• <i>VR Simulator Session (hands-on): Avoiding risks in environmental monitoring</i>
15:15	Coffee Break
15:30	Cleanroom controls, operations and behavior <ul style="list-style-type: none">• Background on key concepts on cleanroom controls• Introduction to correct cleanroom behavior• Regulatory requirements and framework• <i>VR Simulator Session (hands-on): Train how to move correctly in cleanrooms</i>
17:00	Q&A
17:30	End of Training Course Day 1



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Wednesday, 31 July 2024	
09:00	Wrap-up day 1 and Q&A
09:30	Fundamentals of first air <ul style="list-style-type: none">• Key elements first air and how it protects critical surfaces• <i>VR Simulator Session (hands-on): Understanding hoe to interact with first air</i>
10:45	Coffee Break
11:00	Fundamentals of aseptic processing, material transfer and equipment setup <ul style="list-style-type: none">• Background on different cleanroom technologies (RABS; isolator, closed systems/robotics)• Principles of material transfer and equipment setup• Regulatory requirements and expectations• Most common hazard scenarios and errors during material transfer and equipment setup
12:30	Lunch Break
13:30	Fundamentals of aseptic interventions <ul style="list-style-type: none">• Background on common aseptic interventions• Regulatory requirements and expectations• Most common hazard scenarios and errors during aseptic interventions• <i>VR Simulator Session (hands-on): Avoiding risks in aseptic interventions</i>
15:15	Coffee Break
15:30	How to design effective training and oversight <ul style="list-style-type: none">• Background on knowledge management and training• Guidelines on how to design great training materials• Background on effective QA oversight• Regulatory requirements and framework
17:00	Q&A & Completion of Participants' Expectations
17:30	End of Training Course