



PDA EU00179 Best Practice and Points to Consider in Aseptic Processing

Thursday, 22 September 2022	
09:00	Welcome and Collection of Participants' Expectations
09:30	Team Exercise 1: Discussion of Selected Hot Topics in Aseptic Processing
10:15	Coffee Break
10:45	Important Aspects of Sterilization, Cleaning and Disinfection, Gowning Procedures <ul style="list-style-type: none"> • Steam & Dry Heat Sterilization • Key elements for Cleaning & Disinfection in cleanrooms • Gowning steps for entering grade A/B area VR Simulator-Session <ul style="list-style-type: none"> • Introduction to VR Simulator and human error analysis
12:30	Lunch Break
13:30	Aspects of Clean Room Concepts and Good Aseptic Working Practices <ul style="list-style-type: none"> • Conventional filling lines • RABS systems and Pharmaceutical isolators • Understanding First Air and barrier concepts • Points to Consider for Aseptic Processing • Smoke Study learnings • Good Aseptic Working Practices • Examples, demonstrations, and Videos VR Simulator-Session <ul style="list-style-type: none"> • Understanding Human Errors and gaining hands-on experience
14:45	Team Exercise 2: How to build- up an Aseptic Manufacturing Facility
15:45	Coffee Break
16:15	Effective Oversight at the Shop Floor, Good Training Methods <ul style="list-style-type: none"> • Regulatory requirements and framework • Sharing our best practices and effectiveness • Examples from the shop floor worldwide VR Simulator-Session Understanding Human Errors and gaining hands-on experience
17:15	Q&A
17:30	End of Training Course Day 1



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Friday, 23 September 2022	
09:00	<p>Best Practices in Aseptic Processing Simulation</p> <ul style="list-style-type: none"> • Basic Concepts and Regulatory Framework about Process Simulations • Best Practices in Media Fills for Finished Dosage Form and API <ul style="list-style-type: none"> - TR 22 Process Simulation for Aseptically Filled Products (under revision) - TR 28 Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals (PDA survey results) • (Re)Qualification of Operators • Categorization of Interventions <p>VR Simulator-Session Understanding Human Errors and gaining hands-on experience</p>
10:30	Coffee Break
11:00	<p>Important Aspects in Environmental Monitoring</p> <ul style="list-style-type: none"> • TR 13 Fundamentals of an Environmental Monitoring Program • Regulatory requirements and expectations • Rationale for sample locations and frequency • How to proceed in case of excursions <p>VR Simulator-Session Understanding Human Errors and gaining hands-on experience</p>
11:45	<p>Team Exercise 3: Set-up an EM Program for Cleanrooms/Isolators</p>
12:30	Lunch Break
13:30	<p>Continue Team Exercise 3: Presentation of Results</p>
14:00	Coffee Break
14:30	<p>Team Exercise 4: Share your own experience and challenges in aseptic processing</p> <ul style="list-style-type: none"> • find resolutions as a team
15:30	Q&A & completion of participants' expectations
17:00	End of Training Course