



PDA EU00179 Best Practice and Points to Consider in Aseptic Processing

Thursday, 14 September 2023	
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 – Part I <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 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
16:00	Aspects of Clean Room Concepts and Good Aseptic Working Practices – Part II <ul style="list-style-type: none"> • Smoke Study learnings • Good Aseptic Working Practices • Examples, demonstrations, and Videos 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, 15 September 2023

09:00	Best Practices in Aseptic Processing Simulation <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 VR Simulator-Session Understanding Human Errors and gaining hands-on experience
10:30	Coffee Break
11:00	Important Aspects in Environmental Monitoring <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 VR Simulator-Session Understanding Human Errors and gaining hands-on experience
11:45	Team Exercise 3: Set-up an EM Program for Cleanrooms/Isolators
12:30	Lunch Break
13:30	Continue Team Exercise 3: Presentation of Results
14:00	Coffee Break
14:30	Team Exercise 4: Share your own experience and challenges in aseptic processing <ul style="list-style-type: none">• find resolutions as a team
15:30	Q&A & Completion of Participants' Expectations
16:30	End of Training Course