

Training Course Agenda

Title: Fundamentals of Aseptic Processing

PDA # 800

DAY 1	
8:30	Welcome and Introductions
9:00	Aseptic Processing Overview
9:45	Microbiology
10:30	Coffee/Tea Break
10:45	Environmental Monitoring Sampling
12:00	Lunch
13:00	Gowning
13:45	Gowning Demonstration
14:30	Coffee/Tea Break
14:45	Gowning Qualification - Manufacturing Training Facility (MTF)
16:30	End of Day 1

DAY 2	
8:30	Recap Day 1
8:45	Filtration
10:30	Coffee/Tea Break
10:45	Clean/Disinfect the Cleanroom
12:00	Lunch
13:00	Clean/Disinfect the Cleanroom - MFT Observation Area
14:00	Water/Compounding/Formulation
15:00	Coffee/Tea Break
15:15	Cleanroom Controls + Airflow Visualization – MTF Observation Area
16:30	End of Day 2



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DAY 3	
8:30	Recap Day 2
8:45	Components, Containers, Closures, Audits and Agreements
9:30	Operational Considerations, (Interventions and Station Walkthrough) – MTF Observation Area
10:30	Coffee/Tea Break
10:45	Aseptic Fill Room Activities – MTF Observation Area
12:00	Lunch
13:00	Component Preparation and Wrapping – Micro Lab II
14:45	Break
15:00	Component Wrapping and Sterilization – Micro Lab I
15:30	Media Fills/Aseptic Process Simulation
16:30	End of Day 3

DAY 48:30Recap Day 38:45Process Run – MTF Observation Area12:00Lunch13:00Visual Inspection14:00Batch Record Review15:00Training Course Close Out (Final Q&A, Evaluation Forms)15:30End of Training Course