



Fundamentals of Aseptic Processing

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**

12:45 Gowning

13:30 Gowning Demonstration

13:50 Gowning Qualification - **Manufacturing Training Facility (MTF)**

15:00 **Coffee/Tea Break**

15:15 Cleaning/Disinfecting the Cleanroom

14:30 **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 - **MFT Observation Area**

12:00 **Lunch**

13:00 Water/Compounding/Formulation

14:00 Cleanroom Controls – **MTF Observation Area**

15:00 **Coffee/Tea Break**

15:15 Operational Considerations (Human Behavior)

15:45 Airflow Visualization

14:30 **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

14:30 **End of Day 3**

DAY 4

8:30 **Recap Day 3**

8:45 Process Run – MTF Observation Area

12:00 **Lunch**

13:00 Visual Inspection

14:00 Batch Record Review

15:00 **Training Course Close Out (Final Q&A, Evaluation Forms)**

15:30 **End of Training Course**
