



# Training Course Agenda

PDA 800 - Fundamentals of Aseptic Processing

## DAY 1

8:30 M1: Welcome and Introductions

9:00 M2: Aseptic Processing Overview

9:45 M3: Microbiology

10:30 Coffee/Tea Break

10:45 M4: Environmental Monitoring Sampling

12:00 Lunch

13:00 M5: Gowning

13:45 M6: Gowning Demonstration

14:30 Coffee/Tea Break

14:45 M7: Gowning Qualification - **Manufacturing Training Facility (MTF)**

16:30 End of Day 1

## DAY 2

8:30 Recap Day 1

8:45 M8: Filtration

10:30 Coffee/Tea Break

10:45 M9: Clean/Disinfect the Cleanroom

12:00 Lunch

13:00 M10: Clean/Disinfect the Cleanroom - **MFT Observation Area**

14:00 M11: Water/Compounding/Formulation

15:00 Coffee/Tea Break

15:15 M12: 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      M13: Components, Containers, Closures, Audits and Agreements

9:30      M14: Operational Considerations, (Interventions and Station Walkthrough) – **MTF Observation Area**

**10:30**      **Coffee/Tea Break**

10:45      M15: Aseptic Fill Room Activities – **MTF Observation Area**

**12:00**      **Lunch**

13:00      M16: Component Preparation and Wrapping – **Micro Lab II**

**14:45**      **Coffee/Tea Break**

15:00      M17: Component Wrapping and Sterilization – **Micro Lab I**

15:30      M18: Media Fills/Aseptic Process Simulation

**16:30**      **End of Day 3**

## DAY 4

**8:30**      **Recap Day 3**

8:45      M19: Process Run – **MTF Observation Area**

10:15      Coffee/Tea Break

10:30      M19: Process Run – **MTF Observation Area**

**12:00**      **Lunch**

13:00      M20: Visual Inspection – **Training Room C**

14:00      M21: Container Closure Integrity Testing

**14:45**      **Coffee/Tea Break**

15:00      M22: Container Closure Integrity Testing – **CIP Room**

**16:15**      **Training Course Evaluations**

**16:30**      **End of Training Course**