



Training Course Agenda

PDA 100 Aseptic Processing

WEEK 1

DAY 1

8:00 **Welcome and Introductions**

9:00 Types of Aseptic Processing

10:00 **Coffee/Tea Break**

10:15 Basic Microbiology

12:15 **Lunch**

12:45 Velocity Testing and Airflow Studies

16:15 **Coffee/Tea Break**

16:30 EM and Pass-through SOPs

18:30 **End of Day 1**
(optional gowning training after)

DAY 2

7:30 **Optional Gowning Training**

8:00 Filtration

10:15 **Coffee/Tea Break**

10:30 Water Fill

12:45 **Lunch**

13:15 Facility Cleaning and Sanitization

15:45 **Coffee/Tea Break**

16:00 Environmental Monitoring

18:30 **End of Day 2**
(optional gowning training after)



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DAY 3

7:30	Optional Gowning Training
8:00	Gowning Commodities
9:00	Gowning Training and Qualification
12:00	Lunch
12:30	Aseptic Technique Qualification
15:15	Coffee/Tea Break
15:30	Performing Aseptic Process Simulations
18:30	End of Day 3 (optional gowning training after)

DAY 4

8:00	Lyophilization
10:15	Coffee/Tea Break
10:30	Particle Monitoring
12:45	Lunch
13:15	Media Fill
16:15	Coffee/Tea Break
16:30	Media Fill (cont.)
18:30	End of Day 4

DAY 5

8:00	Evaluate Media Fill
10:00	Coffee/Tea Break
10:15	Container Closure Integrity Testing
12:15	Training Course Evaluations
12:30	End of Training Course



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WEEK 2

DAY 1

8:00 **Welcome Back!**

8:45 Read Media Fills

10:15 **Coffee/Tea Break**

10:30 New Process and Facility Technology

12:30 **Lunch**

13:15 Water Fill

15:15 **Coffee/Tea Break**

15:30 HVAC & HEPA Filters

17:30 **End of Day 1**

DAY 2

8:00 Manufacturing Documentation/QC Plan

10:00 **Coffee/Tea Break**

10:15 Moist Heat Sterilization

12:15 **Lunch**

12:45 Review Autoclave Cycle

13:15 Rapid Microbial Identification

15:15 **Coffee/Tea Break**

15:30 Prep of Fill Components

17:30 **End of Day 2**



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DAY 3

8:00 Product Fill

10:15 Coffee/Tea Break

10:30 Product Fill (cont.)

12:15 Lunch

12:45 Industry Hot Topics

14:45 Coffee/Tea Break

15:00 Environmental Excursions

17:00 End of Day 3

DAY 4

8:00 Isolators/Bio-Decontamination

10:15 Coffee/Tea Break

10:30 Intervention Risk Evaluation Method

12:45 Lunch

13:15 Media Fill

15:30 Coffee/Tea Break

15:45 Media Fill (cont.)

18:00 End of Day 4

DAY 5

8:00 Sterility Testing

09:15 Coffee/Tea Break

09:30 Liquid Particle Testing

10:45 Current FDA Perspectives

12:45 Training Course Evaluations

13:00 End of Training Course