



Training Course Agenda

PDA 100 Aseptic Processing

WEEK 1

DAY 1

8:00 Welcome and Introductions

8:45 Microbiology (Lecture)

9:55 Break

10:05 Group 1: Airflow + Water Fill
Group 2: Microbiology (Activity)

12:00 Lunch

13:00 Group 1: Microbiology (Activity)
Group 2: Airflow + Water Fill

14:55 Break

15:05 Aseptic Gowning (Lecture + Practice)

17:00 End of Day 1

DAY 2

8:00 Group 1: Environmental Monitoring – Viable
Group 2: Water Fill

9:55 Break

10:05 Group 1: Water Fill
Group 2: Environmental Monitoring – Viable

12:00 Lunch

13:00 Group 1: Filtration
Group 2: Cleaning and Disinfection

14:55 Break

15:05 Group 1: Cleaning and Disinfection
Group 2: Filtration

17:00 End of Day 2



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DAY 3

8:00 Group 1: Aseptic Gowning (Activity)
Group 2: Aseptic Technique

9:55 Break

10:05 Group 1: Aseptic Technique
Group 2: Aseptic Gowning (Activity)

12:00 Lunch

13:00 Performing Aseptic Process Simulations

14:55 Break

15:05 Performing Aseptic Process Simulations (cont.)

16:10 Media Fill Attendee Prep

17:00 End of Day 3

DAY 4

8:00 Group 1: Media Fill
Group 2: Lyophilization

9:55 Break

10:05 Group 1: Media Fill (cont.)
Group 2: Environmental Monitoring – Total Particulates

12:00 Lunch

13:00 Group 1: Lyophilization
Group 2: Media Fill

14:55 Break

15:05 Group 1: Environmental Monitoring – Total Particulates
Group 2: Media Fill (cont.)

17:00 Post Fill Environmental Monitoring

17:45 End of Day 4



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DAY 5

8:00 Group 1: Visual Inspection
 Group 2: Container Closure Integrity Testing

9:55 **Break**

10:05 Group 1: Container Closure Integrity Testing
 Group 2: Visual Inspection

12:00 **Lunch**

13:00 Elastomers and Closures

15:00 Wrap-Up

15:15 **End of Training Course**



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WEEK 2

DAY 1

8:00 Read Media Fill Results

9:55 Break

10:05 Investigation Process and Technique

12:00 Lunch

13:00 Investigation Process and Technique (cont.)

14:55 Break

15:05 Investigation Process and Technique (cont.)

17:00 End of Day 1

DAY 2

8:00 Group 1: Rapid Microbial Identification
Group 2: EM Trending

9:55 Break

10:05 Group 1: EM Trending
Group 2: Rapid Microbial Identification

12:00 Lunch

13:00 Group 1: Isolator Technology
Group 2: Water Fill + Quantifeel

14:55 Break

15:05 Group 1: Water Fill + Quantifeel
Group 2: Isolator Technology

17:00 End of Day 2



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DAY 3

8:00 Group 1: Sterilization
Group 2: IREM

9:55 Break

10:05 Group 1: Sterilization (cont.)
Group 2: IREM (cont.)

12:00 Lunch

13:00 Group 1: IREM
Group 2: Sterilization

14:55 Break

15:05 Group 1: IREM (cont.)
Group 2: Sterilization (cont.)

17:00 End of Day 3

DAY 4

8:00 Group 1: CSS
Group 2: Media Fill

9:55 Break

10:05 Group 1: CSS (cont.)
Group 2: Media Fill (cont.)

12:00 Lunch

13:00 Group 1: Media Fill
Group 2: CSS

14:55 Break

15:05 Group 1: Media Fill (cont.)
Group 2: CSS (cont.)

17:00 End of Day 4

17:30 Happy Hour – Please join us for appetizers and drinks at Uncle Julio’s!



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DAY 5

8:00 Investigation

9:55 Break

10:05 Investigation – Report Out

12:00 Lunch

13:00 Regulatory Perspectives

15:00 Wrap-Up and Evaluations

15:15 End of Training Course