



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 (Activity)
Group 2: Microbiology (Activity)

12:00 Lunch

13:00 Group 1: Microbiology (Activity)
Group 2: Airflow (Activity)

14:55 Break

15:05 Aseptic Gowning (Lecture)

17:00 Gowning Practice (Activity)

18:00 End of Day 1

DAY 2

8:00 Group 1: Environmental Monitoring – Viable
Group 2: Cleanroom Operations

9:55 Break

10:05 Group 1: Cleanroom Operations
Group 2: Environmental Monitoring – Viable

12:00 Lunch

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

14:55 Break

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

17:00 End of Day 2



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PDA 100 Aseptic Processing

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.)

17:00 End of Day 3

17:30 Please join us for drinks at **World of Beer** (more information will be given Day 1 of the training)!

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 End of Day 4



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PDA 100 Aseptic Processing

DAY 5

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

9:45 **Break**

9:55 Group 1: Container Closure Integrity Testing
 Group 2: Visual Inspection

11:40 **Elastomers and Closures (during lunch)**

13:10 Wrap-Up

13:15 **End of Training Course**



Training Course Agenda

PDA 100 Aseptic Processing

WEEK 2

DAY 1

8:00 Read Media Fill Results

9:55 Break

10:05 Group 1: EM Trending
Group 2: Cleanroom Operations + Quantifeel

12:00 Lunch

13:00 Group 1: Cleanroom Operations + Quantifeel
Group 2: EM Trending

14:55 Break

15:05 Regulatory Perspectives

17:00 End of Day 1

DAY 2

8:00 Group 1: Microbial Data Deviations
Group 2: Sterilization

9:55 Break

10:05 Group 1: Microbial Data Deviations (cont.)
Group 2: Sterilization (cont.)

12:00 Lunch

13:00 Group 1: Sterilization
Group 2: Microbial Data Deviations

14:55 Break

15:05 Group 1: Sterilization (cont.)
Group 2: Microbial Data Deviations (cont.)

17:00 End of Day 2



Training Course Agenda

PDA 100 Aseptic Processing

DAY 3

8:00 Group 1: Isolator Technology
Group 2: Rapid Microbial Identification

9:55 Break

10:05 Group 1: Rapid Microbial Identification
Group 2: Isolator Technology

12:00 Lunch

13:00 Investigation

15:00 Break

15:10 Investigation – Report Out

17:00 End of Day 3

DAY 4

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

9:55 Break

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

12:00 Lunch

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

14:55 Break

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

17:00 End of Day 4

17:30 Please join us for dinner and drinks at Uncle Julio's (more information will be given Day 1 of the training)!



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PDA 100 Aseptic Processing

DAY 5

8:00 CCS

9:55 Break

10:05 CCS (cont.)

12:00 Wrap-Up

12:15 End of Training Course