

	Training Course Agenda	
	Title: Aseptic Processing	PDA #
		100

WEEK 1

G1 – Group 1


G2 – Group 2

DAY 1

8:00	Welcome and Introductions
9:00	Types of Aseptic Processing
10:00	Coffee/Tea Break
10:15	G1: Basic Microbiology G2: Velocity Testing and Airflow Studies
12:15	Lunch
12:45	G1: EM and Pass-through SOPs G2: Velocity Testing and Airflow Studies (cont.)
14:15	G1: Velocity Testing and Airflow Studies G2: Basic Microbiology
16:15	Coffee/Tea Break
16:30	G1: Velocity Testing and Airflow Studies (cont.) G2: EM and Pass-through SOPs
18:30	End of Day 1 (optional gowning training after)

DAY 2

7:30	Optional Gowning Training
8:00	G1: Filtration G2: Water Fill
10:15	Coffee/Tea Break
10:30	G1: Water Fill G2: Filtration
12:45	Lunch
13:15	G1: Facility Cleaning and Sanitization G2: Environmental Monitoring
15:45	Coffee/Tea Break
16:00	G1: Environmental Monitoring G2: Facility Cleaning and Sanitization
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	G1: Gowning Training and Qualification G2: Aseptic Technique Qualification
12:00	Lunch
12:30	G1: Aseptic Technique Qualification G2: Gowning Training and 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	G1: Media Fill G2: Lyophilization
10:15	Coffee/Tea Break
10:30	G1: Media Fill (cont.) G2: Particle Monitoring
12:45	Lunch
13:15	Validation Overview
14:00	G1: Lyophilization G2: Media Fill
16:15	Coffee/Tea Break
16:30	G1: Particle Monitoring G2: Media Fill (cont.)
18:30	End of Day 4

DAY 5

8:00	G1: Evaluate Media Fill G2: EU/US Regulations
10:00	Break
10:15	G1: EU/US Regulations G2: Evaluate Media Fill
12:15	Training Course Evaluations
12:30	End of Training Course

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WEEK 2

G1 – Group 1


G2 – Group 2

DAY 1

8:00	Welcome Back!
8:45	Read Media Fills
10:15	Coffee/Tea Break
10:30	G1: Water Fill G2: New Process and Facility Technology
12:30	Lunch
13:15	G1: New Process and Facility Technology G2: Water Fill
15:15	Coffee/Tea Break
15:30	EM Trending and Database Technologies
17:30	End of Day 1

DAY 2

8:00	G1: Manufacturing Documentation/QC Plan G2: Moist Heat Sterilization
10:00	Coffee/Tea Break
10:15	G1: Moist Heat Sterilization G2: Manufacturing Documentation/QC Plan
12:15	Lunch
12:45	Review Autoclave Cycle
13:15	G1: Rapid Microbial Identification G2: Prep of Fill Components
15:15	Coffee/Tea Break
15:30	G1: Prep of Fill Components G2: Rapid Microbial Identification
17:30	End of Day 2

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DAY 3

8:00	G1: Product/Media Fill G2: Industry Hot Topics
10:15	Coffee/Tea Break
10:30	G1: Product/Media Fill (cont.) G2: Environmental Excursions
12:45	Lunch
13:15	G1: Industry Hot Topics G2: Product/Media Fill
15:30	Coffee/Tea Break
15:45	G1: Environmental Excursions G2: Product/Media Fill (cont.)
18:00	End of Day 3

DAY 4

8:00	G1: Isolators/Bio-Decontamination G2: Product/Media Fill
10:15	Coffee/Tea Break
10:30	G1: Endotoxin G2: Product/Media Fill (cont.)
12:45	Lunch
13:15	G1: Product/Media Fill G2: Isolators/Bio-Decontamination
15:30	Coffee/Tea Break
15:45	G1: Product/Media Fill (cont.) G2: Endotoxin
18:00	End of Day 4

DAY 5

8:00	G1: Sterility Testing G2: Liquid Particle Testing
9:15	Coffee/Tea Break
9:30	G1: Liquid Particle Testing G2: Sterility Testing
10:45	Current FDA Perspectives
12:45	Training Course Evaluations
13:00	End of Training Course