



Event Agenda

Environmental Monitoring Training Certificate Program (PDA 102.3)

DAY 1

8:30 **Welcome and Introductions**

9:00 History and Introduction to Basic Microbiology

9:30 Introduction to Environmental Monitoring and Risk

10:15 **Break**

10:30 Cleanroom Walkthrough Practical Activity

11:00 ISO Classifications, Importance of Cleanrooms, and ISO 5 Areas

11:30 Cleaning and Disinfection

12:00 **Lunch**

13:00 Cleaning and Disinfection Practical Activity

13:30 Federal Laws, Regulatory Requirements, and Expectations

14:15 Sample Site Selection and Frequency

14:45 **Break**

15:00 Sample Site Selection Practical Activity

15:30 Preparation and Quality Control of Microbiology Media

16:00 **End of Day 1**

DAY 2

8:30 EM Media & Incubation Schemes

9:00 EM Applications

9:45 EM Applications Air Monitoring Practical Activity

10:30 **Break**

10:45 Surface Sampling

11:15 Surface Sampling Practical Activity

12:00 **Lunch**

13:00 Water Systems and Sampling

13:30 Rapid Microbiological Test Methods

13:45 Environmental Monitoring During Sterility Testing



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14:00	Facility Monitoring
14:15	Environmental Monitoring Practical Activity
14:45	Break
15:00	Gowning and Personnel Monitoring
15:30	Gowning and Personnel Monitoring Practical Activity
16:00	End of Day 2

DAY 3

8:30	Alert and Action Levels, Data Collection, and Data
9:00	Identification of Microorganisms
9:30	Data Management
10:00	Break
10:15	Trending and Analysis
10:45	Trending Analysis Practical Activity
11:15	Investigations and Deviations
12:00	Lunch
13:00	Investigation Practical Activity
13:45	FDA/Regulatory Enforcement
14:15	Open Discussion on Recent 483s and Warning Letters
14:45	Break
15:00	Q&A
16:00	End of Event