



# Event Agenda

Fundamentals of an Environmental Monitoring Program Training Course (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**