



Training Course Agenda

PDA 102.3 Fundamentals of an Environmental Monitoring Program

DAY 1

8:30 Introductions, Objectives, Welcome, Ground Rules

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 Training Course