



Event Agenda

Analysis of Environmental Monitoring Data Training Course (PDA 612.1)

DAY 1

9:00 Welcome/Introductions

Environmental Monitoring (EM) Data Management Definition, Process Risks
-Considerations of manual analysis vs. automated

Industry Requirements and Guidelines

Meaningful Data Analysis Models – Routine, Non-Routine

Data Analysis for Excursions, Investigations, Root Cause

12:00 End of Day 1

DAY 2

9:00 Welcome Back/Recap

Overview of Data Integrity Guidelines (FDA, MHRA, EMA, PICS)

ALCOA+ Principles and Reasoning
-cGMP Requirements, Data Integrity (21 CFR parts 211, 212)

Conducting Data Integrity Risk Assessment for EM Data Tracking and Trending

Routine Audit Trail Review/Non-Routine, Incident-Based Audit Trail Review Techniques

12:00 End of Event