



Training Course Agenda

PDA 612 Analysis of Environmental Monitoring Data with Respect to cGMP and Data Integrity Guidelines

DAY 1

8:30 **Welcome and Introductions**

9:00 Environmental Monitoring (EM) Data Management Definition and Process Risks
Considerations of manual analysis vs automated

10:30 **Coffee/Tea Break**

10:45 Review of industry requirements and guidelines on EM data analysis

12:00 **Lunch**

13:00 Understanding meaningful data analysis models for routine, non-routine monitoring

14:30 **Coffee/Tea Break**

14:45 Understanding data analysis for excursions, investigations and root cause

16:00 **End of Day 1**

DAY 2

8:30 **Recap Day 1**

9:00 Overview of Data Integrity Guidelines (FDA, MHRA, EMA and PICS)

10:30 **Coffee/Tea Break**

10:45 ALCOA+ principles and reasoning
cGMP requirements with respect to data integrity (21 CFR part 211, 212)

12:00 **Lunch**

13:00 Conducting a data integrity risk assessment for EM data tracking and trending

14:30 **Coffee/Tea Break**

14:45 Routine Audit Trail review and non-routine, incident-based audit trail review techniques

16:00 **End of Training Course**