



Training Course Agenda

PDA 620 Technical Report No. 88 Microbial Data Deviation Investigations in the Pharmaceutical Industry

DAY 1

8:30 Welcome, Introductions, and Icebreaker

9:00 Overview of MDDIs, Roles and Responsibilities

10:30 Break

10:45 Phases of a MDDI Investigation

12:00 Lunch

13:00 Practical Advice and Investigation Hazards

14:30 Break

14:45 Performing a Thoughtful Root Cause Analysis

16:00 End of Day 1

DAY 2

8:30 Recap Day 1

9:00 Ensuring a Strong Finish – Completing the Investigation

10:30 Break

10:45 Interactive Activity – Writing a MDDI – Phase I

12:00 Lunch

13:00 Continuation of Activity – Writing a MDDI – Phase II

14:30 Break

14:45 Investigation Presentation and Debrief

16:00 End of Training Course