



Training Course Agenda

PDA 531 Technical Report No. 54-2 and 54-4: Practical Application of Quality Risk Assessment Tools

DAY 1

8:30 Introduction to Risk Planning
Risk Terminology
QRM History

12:00 Lunch

13:00 Review of ICH Q9
Simple Data Analysis and QRM Tools

- Data Analysis
- Flow Charts

16:00 End of Day 1

DAY 2

8:30 Simple Data Analysis and QRM Tools

- Cause/Effect Diagram

Simple QRM Tools: Classroom Exercises

- Process Mapping
- Cause and Effect

12:00 Lunch

13:00 Complex QRM Tools

- RRF
- FTA
- FMEA

16:00 End of Day 2

DAY 3

8:30 Complex QRM Tools: Classroom Exercises

- RRF
- FTA
- FMEA
- PHA
- HAACP

12:00 Lunch

13:00 Complex QRM Tools: Classroom Exercises

- RRF
- FTA
- FMEA
- PHA
- HAACP

16:00 End of Training Course