**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