

Event Agenda

Practical Application of Quality Risk Assessment Tools Training Course (PDA 531)

| 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 |
| 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 |

| Complex QRM Tools: Classroom Exercises |
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| • RRF |
| • FTA |
| • FMEA |
| • PHA |
| • HAACP |
| Lunch |
| Complex QRM Tools: Classroom Exercises |
| • RRF |
| • FTA |
| • FMEA |
| • PHA |
| • HAACP |
| End of Event |
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