



## Agenda

### I. The Standard

- Introduction to Auditing
- 0:15 Presentation: Guide to Internal Auditing 13485
- 0:15 Review Document: ISO 13485:2003
- 0:30 Exercise: Is it a Requirement?
- 2:00 Presentation: Requirements of ISO 13485:2003
- 0:45 Exercise: Find the Requirement
- 0:15 Questions

### II. The Audit

- 0:30 Scheduling the Audit
- 0:30 Planning the Audit
- 0:45 Opening Meeting
- 0:45 Audit 4.2 Documentation
- 0:45 Audit 5.0 Management Responsibility
- 0:45 Audit 7.2 Customer-Related processes
- 0:45 Audit 7.4 Purchasing
- 0:45 Audit 8.5 Corrective Action
- 0:30 Auditors Document Findings
- 0:30 Final Audit Report
- 0:30 Closing Meeting
- 0:30 Creating the Audit File