ISO 13485:2003 Auditor Training Course

24 hours

DAY 1

- History of the standard in medical devices device industry
- Scope of the 13485:2003
- Process approach
- Quality Management System Requirements
- Documentation Controls
- Management Responsibility
- Resource Management
- Design and Development Controls
- Purchasing Controls
- Production and Services Controls
- Handling, Storage, distribution and installation
- Identification and Traceability
- Control of monitoring and measuring devices
- Control of Nonconforming Product
- Analysis of data
- Improvement: Corrective and Preventive Actions (CAPA)

DAY 2

- Scope of the 19011:2002, definitions
- Audit types & roles
- Auditor responsibilities
- Personal qualities of an auditor
- Management of audit program
- Overview of audit activities
- What's audit plan? Plan preparation
- Calculation of time and resources
- What's checklist, types of checklists
- Conducting auditing activities
  - opening meeting
  - gathering evidences (sampling)
  - questioning

- observations
- taking notes
- communication
- handling difficult situations

DAY 3

- Audit Reporting
  - what is nonconformity
  - audit finding definition
  - writing of nonconformity report
  - reaching audit conclusions
  - structure of audit report
  - audit report writing and approval
  - audit report distribution, timing and retention
- If the auditee does not conform
- Closing Meeting - contribution
- Evaluating CAPA proposal
- NCRs resolution – audit follow-up
- Audit final closing
- Q & As