# ISO 13485 Medical Devices Quality Management System

**Course Outline**

**1) MD-QMS Introduction and Process Approach**

- Purpose and benefits of MD-QMS-Requirements for Regulatory Purposes including understanding of the basic MD-QMS principles
- Terms, Fundamentals and Principles
- Process Approach with PDCA
- Mandatory documents for regulatory purposes
- Difference between compliance and conformance
- Relationship between IMDRF and GHTF
- Principles of IMDRF
- MDR European Union Regulations

**2) Auditing Principle**

- Auditing objectives
- Types of audits
- Audit life cycle
- Terms and Definition
- Principle of Auditing
- Annex A – Guidance of Auditors

**3) Role and Responsibilities of Auditor**

- Audit Programme objectives
- The auditees responsibilities
- The lead auditors' responsibilities
- Auditors qualification and certifications

**4) Planning an Audit**

- Pre-Audit planning
- Reviewing documentation
- Developing an audit plan
- Preparing checklists or working documents
- Communication factors

**5) Conducting an Audit**

- Opening meeting
- Collecting objective/audit evidence
- Effective interviewing techniques
- Identifying and recording nonconformities
- Preparing for the closing meeting

**6) Reporting Audit Results**

- Conducting the closing meeting
- Preparing the audit report
- Distributing the audit report

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**7) Corrective Actions**

- Corrective action responsibilities
- Follow up scheduling
- Monitoring corrective action

**8) ISO 13485:2016 Registration**

- The registration processes
- Surveillance audits

**9) Exercises / Role Play (50% of course time)**

**10) Written Examination**

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