# Medical Device Lead Auditors (ISO 13485:2016) Course

*Syllabus, Rev.2*

| Day 1 - MD-QMS Introduction and Process Approach | |
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| Module | Topics |
| **Session Kick-Off** | • Introductions<br>• Course objectives and expectations |
| **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<br>• Process Approach with PDCA<br>• Mandatory documents for regulatory purposes<br>• Difference between compliance and conformance<br>• Relationship between IMDRF and GHTF<br>• Principles of IMDRF<br>• MDR European Union Regulations<br>• MD-QMS Requirements (Clause 1 to 8) |
| **Auditing Basics and ISO 19011:2018** | • Audit Process<br>• Audit objectives<br>• Types of audits<br>• Audit life cycle<br>• Terms and Definition<br>• Principle of Auditing<br>• Audit resources |
| **Role and Responsibilities** | • The auditees responsibilities<br>• The lead auditors' responsibilities<br>• Auditors' qualification and certifications |
| **ISO 19011 'Conducting an audit' activities** | • Audit methods<br>• Stage 1 & 2 audit<br>• Audit plan<br>• Audit evidence and findings<br>• Initiating the audit<br>• Identifying risks and opportunities related to the audit |
| **Preparing Audit Activities**<br>**Planning an Audit** | • Managing Audit Plan<br>• Pre-Audit planning<br>• Audit Plan objectives, scopes & criteria's<br>• Reviewing documentation<br>• Developing an audit plan<br>• Preparing checklists or working documents<br>• Communication factors<br>• |

## Day 2 - Conducting Audit Activities

| Module | Topics |
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| **Conducting Audit Activities** | • Processes & context<br>• Assigning work to audit team<br>• Work Documents<br>• QMS documentation, Document review - Process Approach<br>• Evaluating and recording audit findings and nonconformities<br>• Auditing: Planning to meet requirements |
| **Conducting Audit Activities** | • Opening meeting - What to cover & Tips<br>• Communicating During Audit<br>• Communication - Difficult Situations |
| **Conducting Audit Activities** | • Collecting and verifying information - Sampling<br>• Reviewing Documented Information<br>• Note Taking<br>• Site Tour- Collect Evidence Through Observations |
| **Conducting Audit Activities** | • Collecting and verifying information – Interviewing<br>• Effective communication – Communication Skills<br>• Interviewing Techniques<br>• Interview Mistakes |
| **Supplier Audit** | • Supplier Qualification<br>• Supplier Audit<br>• Critical Supplier Processes<br>• What to Audit? Risk Based approach<br>• Supplier Auditor Responsibilities |

## Day 3 - Audit Conclusions and Closure

| Module | Topics |
|---|---|
| **Determining audit conclusions** | • Generating audit findings<br>• Nonconformity Types<br>• Non-conformities Grading (GHTF Grading & MDSAP Grading)<br>• Evaluating and recording audit findings and non-conformities<br>• Comment or OFI (opportunity for improvement) |
| **Audit Findings** | • Finalize Audit Findings<br>• Determining audit conclusions<br>• Content of Audit Conclusions<br>• Recording and presenting audit results<br>• Closing Meeting |

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| **Audit Closure** | • Conducting the closing meeting<br>• Audit report writing<br>• Preparing and Distributing Audit Report<br>• Completing the Audit<br>• Follow-up and corrective action<br>• How To Manage an Audit as Auditee Tips & Strategies |
| **Session Wrap-Up** | • Feedback<br>• Final Exam instructions |
| **Final Exam** | Exam<br>• Delegates must attend the 3 days training and pass the exam to receive a Certificate of Attendance |

*Academic hours:*

*Total of 3 days, 32 academic hours for participants that have a training certification for ISO 13485:2106.*

*If the participant has no training certification for ISO 13485, additional 16 academic hours for "Quality system" is required PRIOR to this course.*
*Total of 40 academic hours.*