

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

*Syllabus, Rev.2*

## Day 1 - MD-QMS Introduction and Process Approach

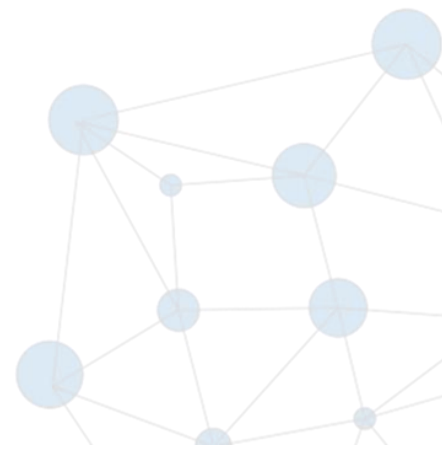
Module	Topics
<b>Session Kick-Off</b>	<ul style="list-style-type: none"> <li>• Introductions</li> <li>• Course objectives and expectations</li> </ul>
<b>MD-QMS Introduction and Process Approach</b>	<ul style="list-style-type: none"> <li>• Purpose and benefits of MD-QMS-Requirements for Regulatory Purposes including understanding of the basic MD-QMS principles Terms, Fundamentals and Principles</li> <li>• Process Approach with PDCA</li> <li>• Mandatory documents for regulatory purposes</li> <li>• Difference between compliance and conformance</li> <li>• Relationship between IMDRF and GHTF</li> <li>• Principles of IMDRF</li> <li>• MDR European Union Regulations</li> <li>• MD-QMS Requirements (Clause 1 to 8)</li> </ul>
<b>Auditing Basics and ISO 19011:2018</b>	<ul style="list-style-type: none"> <li>• Audit Process</li> <li>• Audit objectives</li> <li>• Types of audits</li> <li>• Audit life cycle</li> <li>• Terms and Definition</li> <li>• Principle of Auditing</li> <li>• Audit resources</li> </ul>
<b>Role and Responsibilities</b>	<ul style="list-style-type: none"> <li>• The auditees responsibilities</li> <li>• The lead auditors' responsibilities</li> <li>• Auditors' qualification and certifications</li> </ul>
<b>ISO 19011 'Conducting an audit' activities</b>	<ul style="list-style-type: none"> <li>• Audit methods</li> <li>• Stage 1 &amp; 2 audit</li> <li>• Audit plan</li> <li>• Audit evidence and findings</li> <li>• Initiating the audit</li> <li>• Identifying risks and opportunities related to the audit</li> </ul>
<b>Preparing Audit Activities Planning an Audit</b>	<ul style="list-style-type: none"> <li>• Managing Audit Plan</li> <li>• Pre-Audit planning</li> <li>• Audit Plan objectives, scopes &amp; criteria's</li> <li>• Reviewing documentation</li> <li>• Developing an audit plan</li> <li>• Preparing checklists or working documents</li> <li>• Communication factors</li> <li>• </li> </ul>

## Day 2 - Conducting Audit Activities

Module	Topics
<b>Conducting Audit Activities</b>	<ul style="list-style-type: none"> <li>• Processes &amp; context</li> <li>• Assigning work to audit team</li> <li>• Work Documents</li> <li>• QMS documentation, Document review - Process Approach</li> <li>• Evaluating and recording audit findings and nonconformities</li> <li>• Auditing: Planning to meet requirements</li> </ul>
<b>Conducting Audit Activities</b>	<ul style="list-style-type: none"> <li>• Opening meeting - What to cover &amp; Tips</li> <li>• Communicating During Audit</li> <li>• Communication - Difficult Situations</li> </ul>
<b>Conducting Audit Activities</b>	<ul style="list-style-type: none"> <li>• Collecting and verifying information - Sampling</li> <li>• Reviewing Documented Information</li> <li>• Note Taking</li> <li>• Site Tour- Collect Evidence Through Observations</li> </ul>
<b>Conducting Audit Activities</b>	<ul style="list-style-type: none"> <li>• Collecting and verifying information – Interviewing</li> <li>• Effective communication – Communication Skills</li> <li>• Interviewing Techniques</li> <li>• Interview Mistakes</li> </ul>
<b>Supplier Audit</b>	<ul style="list-style-type: none"> <li>• Supplier Qualification</li> <li>• Supplier Audit</li> <li>• Critical Supplier Processes</li> <li>• What to Audit? Risk Based approach</li> <li>• Supplier Auditor Responsibilities</li> </ul>

## Day 3 - Audit Conclusions and Closure

Module	Topics
<b>Determining audit conclusions</b>	<ul style="list-style-type: none"> <li>• Generating audit findings</li> <li>• Nonconformity Types</li> <li>• Non-conformities Grading (GHTF Grading &amp; MDSAP Grading)</li> <li>• Evaluating and recording audit findings and non-conformities</li> <li>• Comment or OFI (opportunity for improvement)</li> </ul>
<b>Audit Findings</b>	<ul style="list-style-type: none"> <li>• Finalize Audit Findings</li> <li>• Determining audit conclusions</li> <li>• Content of Audit Conclusions</li> <li>• Recording and presenting audit results</li> <li>• Closing Meeting</li> </ul>



<b>Audit Closure</b>	<ul style="list-style-type: none"><li>• Conducting the closing meeting</li><li>• Audit report writing</li> <li>• Preparing and Distributing Audit Report</li><li>• Completing the Audit</li><li>• Follow-up and corrective action</li><li>• How To Manage an Audit as Auditee Tips &amp; Strategies</li></ul>
<b>Session Wrap-Up</b>	<ul style="list-style-type: none"><li>• Feedback</li><li>• Final Exam instructions</li></ul>
<b>Final Exam</b>	Exam <ul style="list-style-type: none"><li>• Delegates must attend the 3 days training and pass the exam to receive a Certificate of Attendance</li></ul>

*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.*

