

## ISO 13485:2016 PREPARATION WORKSHOP

Day	Topics	Duration	Objectives	Case Studies & Workshops
1	<b>Overview of Quality Management Systems, particularly ISO 13485:2016</b> <ul style="list-style-type: none"> <li>• Current challenges in the medical device industry</li> <li>• Medical device regulatory environment: FDA, TGA, EU</li> <li>• Introduction to ISO 13485:2016</li> <li>• Sponsor and manufacturer's obligations</li> <li>• A risk-based model for building a compliance program</li> <li>• Fundamental requirements quality systems for distributors</li> </ul>	4 hours	Describe the fundamentals of quality management systems Explain the purpose, structure and requirements of ISO 13485:2016 Describe the fundamentals of ISO 13485:2016 Understand sponsor and manufacturer obligations	<b>Workshop:</b> Prepare a list of responsibilities for both sponsor and manufacturer of medical devices
	<b>Benefits of quality system certification and of alignment</b> <ul style="list-style-type: none"> <li>• What is a Quality System?</li> <li>• Building a quality culture</li> <li>• Key elements of ISO 13485</li> <li>• Differences between ISO 9001 and ISO 13485</li> </ul>	3 hours	Understand the benefits of a 'quality culture' and how to build one. Understand where ISO 13485 fits with other quality systems.	<b>Activity:</b> Compare and contrast compliance culture vs quality culture <b>Workshop:</b> Prepare a plan for a single 'Plan Do Check Act' cycle for a designated scenario such as responding to a customer complaint.
2	<b>Purpose, structure and requirements of ISO 13485:2016 Quality Risk Management for medical devices</b> <ul style="list-style-type: none"> <li>• A practical approach for the implementation of risk management as part of a Medical Device Quality System.</li> <li>• Concepts within ISO 14971– Application of Risk Management to Medical Devices.</li> <li>• Overview of how risk management practices are used to support quality and compliance programs in Medical Device companies.</li> </ul>	3.5 hours	Understand the application of risk management Be able to conduct a risk assessment in accordance with the requirements.	<b>Workshop:</b> Conduct a high level design risk assessment for a designated device using a provided template.
	<b>Purpose, structure and requirements of ISO 13485:2016 Management Responsibility</b> <ul style="list-style-type: none"> <li>• How personal actions guide and sustain an organisation.</li> <li>• How the Management System works to help an organisation fulfill its legal and ethical responsibilities in the following areas:</li> </ul>	2 hours	Understand and develop strategies for meeting the requirements for management responsibility	<b>Workshop:</b> Devise a plan specifying the responsibilities management has in ISO 13485 including implementation strategies

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	<ul style="list-style-type: none"> <li>– Planning for Quality</li> <li>– The role and profile of the Management Representative(s)</li> <li>– Internal communications</li> <li>– Effective management reviews</li> </ul>			
	<p><b>Purpose, structure and requirements of ISO 13485:2016</b></p> <p><b>Resource Management</b></p> <ul style="list-style-type: none"> <li>• Identification and provision of resources needed to implement the quality policy and achieve its objectives, and to satisfy customer requirements, inclusive of applicable regulatory requirements.</li> <li>• Specifically covering the ISO requirements for: <ul style="list-style-type: none"> <li>– Human Resources (competence, awareness and training)</li> <li>– Infrastructure</li> <li>– Work environment</li> </ul> </li> </ul>	2 hours	Understand and develop strategies for meeting the requirements for resource management	<p><b>Workshop:</b> Critique of sample training records for compliance</p> <p><b>Workshop:</b> Evaluate environmental risk factors in an industrial scenario</p>
3	<p><b>Purpose, structure and requirements of ISO 13485:2016</b></p> <p><b>Product realization</b></p> <ul style="list-style-type: none"> <li>• Planning</li> <li>• Customer-related processes</li> <li>• Design and development</li> <li>• Purchasing</li> <li>• Provision of production and services</li> <li>• Control of monitoring and measuring devices</li> <li>• Delivery of the medical device</li> </ul>	5 hours	Be able to understand and implement the requirements for designing, developing and delivering a medical device.	<p><b>Workshop:</b> Prepare change control for design change using template</p> <p><b>Case studies:</b> Regulatory non-compliance re. lack of (1) design documentation (2) purchasing control</p> <p><b>Workshops:</b></p> <ul style="list-style-type: none"> <li>- Prepare an audit plan focused on instruments used in production for a provided scenario</li> </ul>
	<p><b>Purpose, structure and requirements of ISO 13485:2016</b></p> <p><b>Measurement, Analysis and Improvement</b></p> <ul style="list-style-type: none"> <li>• Customer feedback – Post Market Surveillance</li> <li>• Recalls</li> </ul>	2 hours	Be able to understand and implement the requirements	<p><b>Workshop:</b> Prepare 'Points to Consider' for assessment of :</p> <ul style="list-style-type: none"> <li>• Product conformity</li> </ul>

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	<ul style="list-style-type: none"> <li>Control of nonconforming product</li> <li>Internal audits</li> <li>Monitoring and measurement of processes and of product</li> <li>Analysis of data</li> <li>Improvement – general requirements</li> </ul>		for measurement, analysis and improvement	<ul style="list-style-type: none"> <li>Process conformity</li> <li>Quality system effectiveness</li> </ul> <p>Propose CAPA for a provided manufacturing issue</p>
4	<p><b>Overview of application process for ISO 13485:2016</b></p> <ul style="list-style-type: none"> <li>Who needs accreditation?</li> <li>Which bodies are authorised to inspect?</li> <li>How do I apply for accreditation?</li> </ul>	2 hours	Know where to go and how to approach making an application for accreditation to ISO 13485:2016	<b>Workshop:</b> Mock application process
	<p><b>Development of documentation required for ISO 13485:2016</b></p> <ul style="list-style-type: none"> <li>Fundamental requirements for document and record control</li> <li>Tips for content and format of procedures</li> <li>The design and role of Data Collection Forms</li> <li>Structure of, and relationship between quality system documents</li> <li>The role of good documentation practices as part of Data Integrity</li> <li>Tools for writing procedures</li> <li>Requirements for Quality Manual and for Medical Device file</li> <li>Archiving</li> </ul>	3.5 hours	Learn to practically apply good writing techniques to produce high quality documents needed for ISO 13485:2016 accreditation	<p><b>Activity:</b> The role of good documentation practices as part of data integrity</p> <p><b>Workshop:</b> Critique a completed document – assessing for good documentation practices</p>
	<p><b>Preparation for applying for ISO 13485:2016</b></p> <ul style="list-style-type: none"> <li>Key points relating to audit readiness for each section of ISO 13485:2016</li> <li>How to perform a self-assessment</li> <li>What to expect during an accreditation audit.</li> </ul>	2 hours	<p>Apply process of implementing a QMS that meets requirements of ISO 13485:2016</p> <p>Learn to self-assess readiness for accreditation</p> <p>Understand requirements of an ISO 13485 auditee.</p>	<b>Workshop:</b> Internal audit plan development