RED DEVELOPING AUSTRALIA'S MTP SECTOR WORKFORCE
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ISO 13485:2016 PREPARATION WORKSHOP

Day	Topics	Duration	Objectives	Case Studies & Workshops
1	**Overview of Quality Management Systems, particularly ISO 13485:2016** • Current challenges in the medical device industry • Medical device regulatory environment: FDA, TGA, EU • Introduction to ISO 13485:2016 • Sponsor and manufacturer's obligations • A risk-based model for building a compliance program • Fundamental requirements quality systems for distributors	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	**Workshop:** Prepare a list of responsibilities for both sponsor and manufacturer of medical devices
	Benefits of quality system certification and of alignment • What is a Quality System? • Building a quality culture • Key elements of ISO 13485 • Differences between ISO 9001 and ISO 13485	3 hours	Understand the benefits of a 'quality culture' and how to build one. Understand where ISO 13485 fits with other quality systems.	**Activity:** Compare and contrast compliance culture vs quality culture **Workshop:** Prepare a plan for a single 'Plan Do Check Act' cycle for a designated scenario such as responding to a customer complaint.
2	**Purpose, structure and requirements of ISO 13485:2016** **Quality Risk Management for medical devices** • A practical approach for the implementation of risk management as part of a Medical Device Quality System. • Concepts within ISO 14971– Application of Risk Management to Medical Devices. • Overview of how risk management practices are used to support quality and compliance programs in Medical Device companies.	3.5 hours	Understand the application of risk management Be able to conduct a risk assessment in accordance with the requirements.	**Workshop:** Conduct a high level design risk assessment for a designated device using a provided template.
	Purpose, structure and requirements of ISO 13485:2016 **Management Responsibility** • How personal actions guide and sustain an organisation. • How the Management System works to help an organisation fulfill its legal and ethical responsibilities in the following areas:	2 hours	Understand and develop strategies for meeting the requirements for management responsibility	**Workshop:** Devise a plan specifying the responsibilities management has in ISO 13485 including implementation strategies

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	– Planning for Quality – The role and profile of the Management Representative(s) – Internal communications – Effective management reviews			
	Purpose, structure and requirements of ISO 13485:2016 **Resource Management** • 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. • Specifically covering the ISO requirements for: – Human Resources (competence, awareness and training) – Infrastructure – Work environment	2 hours	Understand and develop strategies for meeting the requirements for resource management	**Workshop:** Critique of sample training records for compliance **Workshop:** Evaluate environmental risk factors in an industrial scenario
3	**Purpose, structure and requirements of ISO 13485:2016** **Product realization** • Planning • Customer-related processes • Design and development • Purchasing • Provision of production and services • Control of monitoring and measuring devices • Delivery of the medical device	5 hours	Be able to understand and implement the requirements for designing, developing and delivering a medical device.	**Workshop:** Prepare change control for design change using template **Case studies:** Regulatory non-compliance re. lack of (1) design documentation (2) purchasing control **Workshops:** - Assess requirements for process validation for a provided manufacturing process - Prepare an audit plan focused on instruments used in production for a provided scenario - Propose CAPA for a provided manufacturing issue
	Purpose, structure and requirements of ISO 13485:2016 **Measurement, Analysis and Improvement** • Customer feedback – Post Market Surveillance • Recalls	2 hours	Be able to understand and implement the requirements	**Workshop:** Prepare 'Points to Consider' for assessment of : • Product conformity

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	• Control of nonconforming product • Internal audits • Monitoring and measurement of processes and of product • Analysis of data • Improvement – general requirements		for measurement, analysis and improvement	• Process conformity • Quality system effectiveness
4	**Overview of application process for ISO 13485:2016** • Who needs accreditation? • Which bodies are authorised to inspect? • How do I apply for accreditation?	2 hours	Know where to go and how to approach making an application for accreditation to ISO 13485:2016	**Workshop:** Mock application process
	Development of documentation required for ISO 13485:2016 • Fundamental requirements for document and record control • Tips for content and format of procedures • The design and role of Data Collection Forms • Structure of, and relationship between quality system documents • The role of good documentation practices as part of Data Integrity • Tools for writing procedures • Requirements for Quality Manual and for Medical Device file • Archiving	3.5 hours	Learn to practically apply good writing techniques to produce high quality documents needed for ISO 13485:2016 accreditation	**Workshop:** Write a clearly expressed procedural document for a designated task (draw on SP6528 Good Writing Practices) **Workshop:** Critique a completed document – assessing for good documentation practices
	Preparation for applying for ISO 13485:2016 • Key points relating to audit readiness for each section of ISO 13485:2016 • How to perform a self-assessment • What to expect during an accreditation audit.	2 hours	Apply process of implementing a QMS that meets requirements of ISO 13485:2016 Learn to self-assess readiness for accreditation Understand requirements of an ISO 13485 auditee.	**Workshop:** Conduct self-assessment based on provided scenario **Activity:** Mock audit: Understanding evidence