AMMI
ASSOCIATION OF MALAYSIAN MEDICAL INDUSTRIES
PERSATUAN INDUSTRI PERUBATAN MALAYSIA
Medtech Malaysia

Medsociate
Medsociate Sdn Bhd

Industry Expert Training Series * HRDF SBL Scheme Claimable

Transition to ISO13485 : 2016 Quality Management System

Course Brochure

INTRODUCTION

The new ISO 13485:2016 extends the scope to the entire medical device supply chain, introduction of the Risk Based Approach to QMS processes, with new as well as expansion of existing requirements and an increased focus on the organisations ability to meet applicable customer and regulatory requirement.

This course introduces the concepts needed to understand, develop/upgrade, and deploy a quality management system as outlined in the medical devices quality management standard ISO 13485:2016. This course also discusses the aspects of ISO 14971, which contains key principles and guidance for risk management.

Participants will be led by an experienced tutor with over 2 decades of auditing, training and quality assurance as well as management system development experience.

Participants will engage in small group activities and lively debate, along with instructor led segments to gain the knowledge needed to effectively manage changes brought by the new standard. Participants will learn how to apply these principles to achieve and maintain medical device regulatory compliance.

COURSE OUTLINE/ OBJECTIVES

1. Understand Quality Management Terminology & Definitions (including revisions), Concepts and Guidelines.
2. Understand differences in objective evidence between 13485:2003 and ISO 13485:2016 to be demonstrated.
3. Interpret All Clauses of ISO 13485:2016 to accurately address your comapany's Role in the Medical Device Supply Chain.
4. Understand what is meant as Risk Based Approach, how it differs from Risk Management and how to evident its incorporation in to your ISO 13485:2016 based Quality Management System.
5. Learn World Class Practices to ensure Effective Implement of each Clause of ISO 13485:2016.
6. Understand requirements for Transition from 13485:2003 and ISO 13485:2016 - Timelines and Strategies.
7. Learn how to Prepare for an Audit and to Maintain ISO 13485:2016 Certification.
8. Understand relationship of ISO 13485:2016 and its roles in compliance to medical device regulations –Malaysia, ASEAN Medical Device Directive and the soon to be significantly amended EU regulations.

TARGET AUDIENCE

- Those involved in the Design, Production, Subcontract Manufacturing, Importation, Distribution, Installation, Servicing or appointed as Authorized Representatives in the Medical Device sector.
- Anyone tasked with development of a QMS or conversion from ISO 13485:2003.
- Management representatives.
- Implementation team members.
- Auditors (Internal or External /Supply Chain).
- Quality Managers.
- Regulatory Affairs personnel.

PRE-REQUISITES

This is an introductory course designed for individuals with little or no previous knowledge of implementing a quality management system. This course is intended for both those familiar with ISO 13485:2003 as well as to those new to Quality Management Systems (QMS) / Good Manufacturing Practices (GMP). Basic knowledge of Medical Devices Regulations and Management Systems would be beneficial, but not necessary.

DURATION

Two (2) full days

TRAINER'S PROFILE

Tony Low is the Malaysian Representative to the Asian Harmonization Working Party (AHWP) and co-Chair on the Workgroup for Standards as well as being on the task force for the development on the guidance document on ISO 13485:2016. Tony has been involved in Conformity Assessment for the past 26 years, working with renowned CAB's such as SGS, Bureau Veritas (BV), Underwriters Laboratories (UL), British Standards Institution (BSI), DQS and TÜV. In this time, his experience throughout the entire product lifecycle and all 3 medical device regulatory stages has enabled him to gain qualifications on all medical device technology scopes.

He is a qualified Notified Body auditor (EU Medical Device Directives – CE Marking) as well as a management systems auditor for Medical (ISO 13485, GDPMD / GDPMDS), Quality, Health, Safety, Environmental and Social Accountability. His involvement in academia has seen him serving in a lecturer's role at the Singapore Institute of Manufacturing Technology's (SIMtech) Graduate Diploma in MedTech Manufacturing as well as the Medtech Talent and Employment Programme (a joint programme under the Northern Corridor Implementation Authority (NCIA) and the Association of Malaysian Medical Industries (AMMI)).

COURSE REGISTRATION DETAILS

Course fees, payment details and online registration log-in will be provided once the course is open for registration.

CONTACT

For enquiries, please email to secretariat@ammi.com.my
c/o Medsociate Sdn Bhd
(HRDF Approved Training Provider - Registration No. 4195)
(AMMI Authorized Training Provider and Secretariat)
Tel: +6010 4040 662 Fax: +603 2178 4347