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

Medsociate
Medsociate Sdn Bhd

Industry Expert Training Series * HRDF SBL Scheme Claimable

ISO13485 : 2016 Internal Auditing

Course Brochure

INTRODUCTION

Medical Device manufacturing is a regulated industry with stringent requirements to control processes aimed at ensuring safety & effectiveness of medical devices. Such good manufacturing practices are met through the implementation of ISO 13485. The new ISO 13485:2016 extends the scope to the entire medical device supply chain, greater emphasising risk management with increased focus on the organisations ability to meet applicable customer and regulatory requirement.

The need for self-assessment is specified and achieved through internal auditing of the ISO 13485 Quality Management System which aids regulatory compliance as well as identifies opportunities for improvement. This course is designed to give participants the knowledge and skills needed to undertake an unbiased and constructive ISO 13485 Quality Management System audit in line with the generic guidelines laid down in ISO 19011. Participants will learn the skills and techniques of a process audit and how to communicate the findings so as to increase the effectiveness of the organisation's management system

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 to the new standard. Participants will learn how to apply these principles to produce effective internal audits of medical device manufacturing firms and supply chain.

COURSE OUTLINE

The course covers tutorials, discussions, case study and facilitated activities on the following:

1. Overview of Internal Auditing
2. The requirements of ISO 13485:2016
3. Differences between ISO 13485:2016 and ISO 13485:2003 – terms, definitions, audit principles & approach
4. The role of Risk Management in ensuring a well-structured and adequate QMS
5. Pre-Audit Preparation
6. Conducting the Audit
7. Reporting the Audit
8. Follow-up after the Audit
9. The interrelationships between ISO 13485:2016 and the selected medical device regulations – EU, Malaysia, ASEAN Medical Device Directive.
10. Role of the Medical Devices Single Audit Program (MDSAP).
11. Transition timelines and strategies

BENEFITS

Upon completion of the training, participants will be able to:

- ✓ perform ISO 13485 auditing with the skills and methodology acquired
- ✓ apply the process-based approach in auditing
- ✓ have a clear understanding of the ISO 13485:2016 standard and what auditors look for
- ✓ understand conformity and compliance that need to be demonstrated
- ✓ conduct assessment on conformity & compliance of audited ISO 13485 QMS
- ✓ plan, manage & maintain a compliant ISO 13485 QMS
- ✓ confirm as to whether existing organisational practices and documentation are adequate or require changes and enhancements to meet the requirements of the standard and the ever changing regulatory environment.

TARGET AUDIENCE

This course is designed for company staff with audit responsibility for the organisation's ISO 13485 Quality System or will be undertaking Internal Quality Audits. It is suitable for all functions and levels tasked:

- ✓ to carry out internal audits on manufacturing activities and medical device supply chain
- ✓ to organise the audit program for their ISO 13485 or integrated management system
- ✓ to train or guide other internal auditors.

PRE-REQUISITE

Prior knowledge of ISO 13485 is recommended.

COURSE DURATION

Two (2) full days

TRAINER'S PROFILE

Tony is the Director of Continuing Medtech Education of Medsociate Sdn Bhd (an approved trainer provider under Malaysian Human Resources Development Fund as well as Authorized Training Provider and Secretariat for the Association of Malaysian Medical Industries). He is also 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 FEES/ PAYMENT AND REGISTRATION DETAILS

Course fees, payment and registration details will be provided once the course is open for registration. For details, visit www.ammi.com.my.

CONTACT

For enquiries, please email to secretariat@ammi.com.my.
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