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

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Authorised Training Provider

Industry Expert Training Series * HRDF SBL Scheme Claimable

Intermediate Level

Risk Management for Medical Devices (EN ISO14971:2019)

Training Brochure

HRDF CLAIMABLE

RISK MANAGEMENT FOR MEDICAL DEVICES (EN ISO14971:2019) - Intermediate

INTRODUCTION

ISO 14971 is an ISO standard for the application of risk management to medical devices. ISO 14971:2019 was released mid-December, and the EN version was released on December 18, 2019 to replace the ISO 14971:2007 and EN ISO 14971:2012 respectively.

Main highlighted of the updates is as follows:

- The key concepts and core approach to risk management was maintained
- Clarification was added around the following:
  - ✓ Production and post-production information
  - ✓ Clinical benefits and risk-benefit analysis
  - ✓ Update the guidance in the annexes
  - ✓ Revise ISO/TR 24971- The Technical Report that provides guidance on the application of ISO 14971

- Informative Annexes would primarily reside in ISO TR 24971 because it is easier to update a Technical Report than it is a standard. A new Clause was added: Clause 2 on Normative References. As a result, all Clauses past Clause 1 are incremented by 1.
- While the Technical Report complements the standard, it is important to note that the information in ISO TR 24971:2019 serves only as a guidance, and not requirements. As well, the first 3 annexes in ISO 14971:2019 act as guidance, and not requirements. The ISO/TR 24971:20XX has not been released yet.

COURSE OBJECTIVE

This training aims to provide participants with a clear understanding and insight into the new EN ISO 14971:2019 requirements. The training takes a look at what the major changes in 2019 updates/revision and also covers some of the commonly used risk management tools such as FMEA, FTA etc.

COURSE OUTLINE

Session 1 & 2 (2 half-day):

- EN ISO 14971:2019 Requirements
  - ➢ Clause 1 Scope
  - ➢ Clause 2 Normative Reference
  - ➢ Clause 3 Terms and Definitions
  - ➢ Clause 4 General Requirements for Risk Management System
  - ➢ Clause 4.1 Risk Mgt Process
  - ➢ Clause 4.2 Management Responsibilities

- Clause 4.3 Competence of Personnel
- Clause 4.4 Risk Management Plan
- Clause 4.5 Risk Management File
- Clause 5 Risk Analysis
- Clause 6 Risk Evaluation
- Clause 7 Risk Control

Session 3 & 4 (2 half-day)

- EN ISO 14971:2019 Requirements (continue)
  - Clause 8 Evaluation of Overall Residue Risk
  - Clause 9 Risk Management Review
  - Clause 10 Production and Post-Production Activities
- Review on EN ISO 14971:2012 Annex Z on Potential New Annex in EN ISO 14971:20XX
- ALARP Concept
- Summary
- Extra Information

TARGET AUDIENCE

Professionals from quality assurance, regulatory affairs, research and development, process improvement, manufacturing and others who involve and wish to understand how to apply and develop proper risk management documentation for product and process of medical device industry.

PRE-REQUISITES

Basic understanding of the ISO 13485:2016 and use of risk management tools such as FMEA is an added advantage. Previous knowledge of ISO 14971:2007 or EN ISO 14971:2012 is not required.

DURATION

4 half-day course running from 8.30am to 12.30pm **or** 1.30pm to 5.30pm.

MODE OF TRAINING

Online

TRAINER'S PROFILE

Harry Wong has over 19 years' of professional work experience in Quality Assurance of medical device, Ceramic Former and Metal Stamping for Electrical, Electronics and Automotive industries. He currently holds the position of Associate Director, Global Complaint and Risk Management, Global Quality Assurance in one of the global leaders in protection solutions. As the subject matter expert of risk management, he provides advice, direction and training for Risk Management personnel across global sites and facilities; ensuring their risk management process complies with all necessary regulatory standards including QSR (FDA), MDD and ISO requirements. He is responsible for developing the global harmonized risk management SOP and tools which are implemented in the global organization facilities and sites.

Harry Wong is also an ASQ Certified Quality Engineer and Lead Auditor for ISO 9001 and ISO 13485 and has extensive involvement in mock audits for global sites preparing for CCC, ANVISA, SEI and FDA.

PAYMENT AND CONFIRMATION OF REGISTRATION

Option 1 : Direct Bank-in or via E-Banking upon receipt of Invoice

An invoice will be sent to you within 3 working days upon your registration. Please note that any Early Bird Discounts (for registration within validity period) will be reflected in the invoice. Please email us (admin@medsociate.com) the bank-in slip / remittance slip once the payment is made.

Please refer the following bank account details:
Beneficiary Name: Medsociate Sdn Bhd
Bank Account Number: 230-302-078-2
Bank: UOB Bank
Swift Code: UOVBMYKL

For Government Sector - A Local Order (LO) or letter of approval to participate must be submitted before your registration can be confirmed.

Option 2 : Direct Online Payment

You may choose to make credit card payment via Paypal. An invoice with payment link will be sent to your email address separately when you choose this option.

CANCELLATION / REFUND POLICY

The organisers, AMMI/ Medsociate Sdn Bhd reserves the right to cancel or postpone any training or event but with due notice to the registered participants / company(s). Any payment made will be refunded in full if the cancellation is made by AMMI/ Medsociate Sdn Bhd. No shows and cancellations made by participants/ companies within the specified period will incur the specified costs as per below schedule.

Prior to Training Date	Cancellation Charges
30 days or more	No charges
15-29 days	25% of training course fee
8 - 14 days	50% of training course fee
0 - 7 days	100% of training course fee

SUBSTITUTION

Replacement of participant is allowed at no additional cost if you are unable to attend. Please inform us of the replacement in writing at least 3 working days before the training date.

CONTACT

For enquiries, please email to Medsociate Sdn Bhd
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