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

Medsociate
Medsociate Sdn Bhd
(HRDF Approved Training Provider)

Industry Expert Training Series * HRDF SBL Scheme Claimable

Risk Management for Medical Devices (EN ISO 14971:2012)

Course Brochure

INTRODUCTION

The ISO 14971:2012, application of risk management to medical devices, is a framework for effective management for medical device manufacturer to address the risks associated with the use of medical devices. The requirements that it contains provide a framework within which experience, insight and judgement are applied to manage these risks. The ISO 14971 is necessary for the manufacturers to make judgments relating to the safety of a medical device, including the acceptability of risks, taking into account the generally accepted state of the art, in order to determine the probable suitability of a medical device to be placed on the market for its intended use/intended purpose.

COURSE OBJECTIVE

This training aims to provide participants with a clear understanding and insight into the ISO 14971 – application of risk management to medical devices and identify the hazards associated with medical devices and their accessories, estimate and evaluate the risks, control these risks and monitor the effectiveness of the control.

OUTLINE

1. Risk Management - Objective
2. Risk Management as established in ISO14971:2012
3. General requirements for risk management
4. Types of Risk Analysis Techniques
5. How to implement according to ISO14971:2012
6. Risk evaluation process
7. Annex D of ISO14971:2012 (Risk Concepts applied to medical devices)
8. Table ZA.1 – Correspondence between Directive 93/42/EEC and ISO14971
9. Exercise: Example of how to comply with the Directive.

SPEAKER'S PROFILE

Ms PS Gan, a Bachelor of Science in Chemistry graduate, has more than 10 years of practical and managerial experience having held local and oversea positions as Quality Management Representative in a multinational company. Her expertise covers implementation of quality management system, risk management, process validation and ISO audits.

TARGET AUDIENCE

Professionals directly involved in regulatory affairs, quality assurance, process development or manufacturing. Quality managers, quality engineers and quality technicians involved in the development and manufacturing of medical devices.

PRE-REQUISITES

Basic understanding of the Medical Devices Regulations, ISO 13485:2016 and basic understanding of Design and Development Control is preferred. Previous knowledge of ISO 14971:2007 not required.

DURATION

Two (2) full days

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 or admin@medsociate.com

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