Industry Expert Training Series * HRDF SBL Scheme Claimable

Post-Market Surveillance, Vigilance and Adverse Event Reporting for Medical Devices

Course Brochure

Presented by

Medsociate

Medsociate Sdn Bhd

INTRODUCTION

The medical device industry is governed by various quality system requirements and regulations of different countries. Post-Market Surveillance (PMS), Vigilance and Adverse Event Reporting are vital in ensuring Medical Device Regulatory compliance and are an essential component of ISO 13485 Quality Management System.

COURSE OBJECTIVES

This course is designed to enable you to identify proactive and reactive sources of information which are a regulatory requirement to be incorporated in post-market surveillance procedures applicable to all medical devices (including IVD's). By developing a post-market surveillance plan you can target the right sources of post-market information will ensure continued regulatory compliance and identify user requirements enabling continued product development. This course also highlights the importance of PMS as an integral part of a company's Risk Management cycle (ISO 14971) as well as the practical applications and integration into the lifecycle of a medical device.

COURSE OUTLINE

1. Understand the regulatory requirements for Post-Market Surveillance (PMS) including recalls, field advisory notices and vigilance; and how these are interpreted in ISO 13485, ISO 14971 and various GHTF/IMDRF guidance documents.
2. Identify the responsibilities for responsibilities for PMS
3. Create procedures for PMS and Vigilance
4. Identify sources of information for PMS (proactive) and Vigilance (reactive)
5. Implement cost effective and targeted post-market clinical follow-up using various tools and techniques.
6. Recognize when a complaint needs to be reported as an adverse event or incidents.

TARGET AUDIENCE

Key persons involved in defining, planning, or implementing Post-Market Surveillance, Vigilance, Adverse Event Reporting and Customer Complaint Handling activities:

- ✓ Regulatory professionals
- ✓ Quality managers
- ✓ Clinical affairs specialists
- ✓ Complaint handling specialists
- ✓ Design and development professionals
- ✓ Authorized Representatives, Importers, Distributors and Manufacturers

PRE-REQUISITE

Basic knowledge of medical devices, ISO 13485, medical device regulations would be beneficial but not essential.

DURATION

Two (2) full days

TRAINER'S PROFILE

Tony Low is the Malaysian Representative to the Asian Harmonization Working Party and co-Chair on the Workgroup for Standards. Tony has been involved in Conformity Assessment for the past 25 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 admin@medsociate.com
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