Industry Expert Training Series * HRDF SBL Scheme Claimable

CE Marking under the Medical Device Directive

Presented by

Medsociate

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INTRODUCTION

This course is designed to provide participants with the knowledge on medical device market access into the European Single Market (EEA). Internal and external auditors and management personnel responsible for quality systems for medical device manufacturers will benefit from this course. Participants will gain an overview of the requirements of the Medical Device Directive and the CE Marking approach.

Participants will be led by an experienced trainer whom, in addition to being a CE Marking auditor, has over 2 decades of assessment, training and quality assurance as well as management system development experience. Participants will lead through exercises and discussion points, including considerations in harmonizing these requirements and the IMDRF with respect to medical devices regulatory compliance

COURSE OBJECTIVES

1. Obtain an overview of the Structure of the EU Medical Devices Directive
2. Gain an understanding of EU Classification of Medical Devices
3. Obtain an overview of the European CE Marking Approach
4. Recognize the Role of Standards, Essential Requirements, and Labeling
5. Obtain an overview of Post Market Surveillance and Vigilance

TARGET AUDIENCE

- Regulatory and quality staff responsible for preparing or hosting CE Marking audits
- Organizations wishing to place their medical devices in EU and/or EFTA markets
- Those who need an understanding of the EU CE Marking approach for medical devices
- Companies preparing 'own brand' or 'private labeling' devices

PRE-REQUISITE

Participants should have experience with or basic knowledge of quality management systems for the medical device industry. Basic awareness on medical devices, quality assurance, and recognized standards (ISO 13485:2003 & ISO 14971:2007) is also recommended.

DURATION

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. He 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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