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

Medsociate
Authorised Training Provider

Industry Expert Training Series * HRDCorp SBL-Khas Scheme Claimable

Intermediate Level

EU Medical Device Regulations (EU MDR 2017/745)

Training Brochure

REGISTERED HRD CORP TRAINING PROVIDER

EU Medical Device Regulations (EU MDR 2017/745) – Intermediate Level

INTRODUCTION

The EU Medical Device Regulation (MDR) 2017/745 was published on 5th May 2017, and it has replaced the EU Medical Device Directive (MDD 93/42/EEC) and the EU Active Implantable Medical Device Directive (AIMDD 90/385/EEC). It came into force on the 25th May 2017, and all the related and relevant manufacturers have three years transition period to comply with the EU MDR. However, the European Parliament has adopted and supported the European Commission's proposal to postpone the effective compliance and application of the EU MDR to 26th May 2021 due to the Covid-19 outbreak.

The 175-pages document outlined regulatory requirements to the economic operators (a manufacturer, an authorized representative, an importer and/or a distributor) as well as the notified bodies. The EU MDR also outlined the Rules (with added Rules compared to the previous EU Medical Device Directive) for medical device classification purposes.

The EU MDR compliance is important and mandatory for all existing economic operators that involved in marketing medical devices in the EU market as well as all economic operators who wish to expand their medical device distribution into the EU market.

COURSE OBJECTIVES

This course aims to give delegates in-depth knowledge regarding the EU Medical Device Regulation and the course content outlined is to provide delegates with information on:

- The structure of the EU Medical Device Regulation
- Who shall comply with the EU Medical Device Regulation
- The Rules and Classifications of the medical devices
- The Technical Documentation (Annex II and III of the EU MDR)
- Clinical Investigation and Evaluation
- Conformity assessment procedures

COURSE OUTLINE

Day 1

Opening and introduction

1. Background of the EU Medical Device Regulation and its Structure
2. The role and responsibilities of the economic operators
3. Person Responsible for Regulatory Compliance
4. Medical device Rules and Classifications
5. Risk Management and Technical Documentation

EU Medical Device Regulations (EU MDR 2017/745) – Intermediate Level

Day 2

Day 1 Recap

5. Risk Management and Technical Documentation (Continue)
6. Clinical Investigation and Evaluation
7. Conformity assessment procedures
8. Course summary

COURSE BENEFITS

Upon completion of this training, delegates will have the knowledge on: -

1. The purpose and structure of the EU MDR
2. Who should be the appointed the Person Responsible for Regulatory Compliance
3. Added Rules in the EU MDR for medical devices classifications
4. The requirements on Risk Management Process and Technical Documentation
5. The requirements on Clinical Investigation and Evaluation
6. The different assessment route in accordance to Article 52 – Conformity assessment procedures

DURATION

2 full-day course running from 8.30am to 5.30pm.

MODE OF TRAINING

Online Training

TARGET AUDIENCE

This program is very useful to delegates who handles EU MDR compliance and actively involved in EU MDR compliance planning and execution. However, this program is not restricted only to Quality and Regulatory Affairs personnel, personnel from other functions such as Design and Production will be benefited from this program as well.

TRAINER'S PROFILE

Kenny Chong is the General Manager at Quintas Consulting Sdn Bhd where his role also includes maintaining top quality training, consultancy and coaching service for Medical Device & other regulated industries.

He has been involved in the Medical Device Industry for the past 14 years, working with Straits Orthopaedics, Symmetry Medical, Neville-Clarke as well as BSI Services. In this time,

his experience throughout the entire product lifecycle and all 3 medical device regulatory stages has enabled him to gain qualification on all medical device technology scopes.

He is a trained CQI & IRCA Lead Auditor of ISO 9001:2015, ISO 14001:2015, OHSAS 18001:2007 as well as ISO13485:2016. He has also attended and passed training on Conformity Assessment Procedures on Quality Management System & Post Market Surveillance by the Medical Device Authority, Malaysia.

PAYMENT AND CONFIRMATION OF REGISTRATION

Option 1: HRDF Claim under SBL-Khas Scheme

A quotation together with course outlines and course agenda will be sent to you for HRDF grant application upon confirmation of the training. Please send us the grant application number for our record upon submission.

Option 2: Self-paying

2a) Direct Bank-in or via E-Banking

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.

2b) 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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