



**ISO13485:2016**  
**Quality Management System**  
Training Brochure



## **INTRODUCTION**

The medical device industries and their products are highly regulated. Organizations shall understand the relevant requirements to avoid legal liabilities on top of products non-conformity which may impact organization's reputation as well as business growth.

ISO 13485 is an international standard for an organization that is involved in one or more stages of the life-cycle of a medical device (i.e design and development, production, labelling or packaging) on a voluntarily or contractual basis. ISO 13485 is developed as requirements to ensure that medical device manufacturers meet customers and regulatory requirements.

This training course is aimed to provide focused interpretation of ISO 13485:2016 requirements and examples of practical implementation activities. This course also includes overview of medical devices in general and the different classification of medical devices.

## **COURSE OBJECTIVES**

This course aims to help delegates to understand and interpret the ISO 13485:2016 Standard. The consultant will also share practical examples to help delegates to understand the content better which the delegates can implement the Standard effectively.

The course content outlined is to provide delegates with:

- The understanding of what a medical device is
- Knowledge and interpretation of ISO 13485:2016 requirements
- Simple practical implementation examples

## **COURSE OUTLINES**

- The purpose of ISO13485
- Clause 1: Scope
- Clause 2: Normative References
- Clause 3: Terms and Definitions
- Clause 4: Quality Management System
- Clause 5: Management Responsibility
- Clause 6: Resource Management
- Clause 7: Product Realization
- Clause 8: Measurement, Analysis and Improvement

## **COURSE BENEFITS**

Upon completion of this training, delegates will: -

1. Have a good understanding of medical device and its classification
2. Have a good understanding and interpretation of the ISO 13485:2016 requirements
3. Be able to apply and implement ISO 13485 effectively

## **TARGET AUDIENCE**

This programme is designed for ALL functions and levels of an organization who need to gain understanding of the requirements in the standard, especially organizations that has embarked on the journey and plan to be certified with ISO 13485.

This programme is particularly useful to those managing the quality management system, process owners and internal auditors.

## **DURATION**

Two (2) full days (9.00am to 5.00pm with 1 hour lunch break in between)

## **MODE OF DELIVERY**

Remote Online Training or Classroom Training

## **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.

## **PAYMENT AND CONFIRMATION OF REGISTRATION**

### **Option 1: HRDCorp Claim under SBL-Khas Scheme**

A quotation together with course outlines and course agenda will be sent to you for HRDCorp 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@medsociety.com) the bank-in slip / remittance slip once the payment is made.

Please refer the following bank account details:

Beneficiary Name: Medsociety Sdn Bhd

Bank Account Number: 230-302-078-2

Bank: UOB Bank

Swift Code: UOVBMKYL

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.

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

### **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

Authorised training provider of AMMI

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