The Training of
ISO 13485:2016
Quality Management System Requirements for Medical Devices

DATE
14 July 2026 (Tuesday)

TIME
8:30 am – 5:00 pm

VENUE
Medical Device Authority (MDA), Cyberjaya

ABOUT THE TRAINING

ISO 13485 is an international standard that defines quality management system requirements for organizations involved in any stage of the medical device lifecycle, such as design, production, labeling, or packaging. It is applied on a voluntary or contractual basis to ensure compliance with customer and regulatory requirements.

This training course focuses on interpreting and understanding the requirements of ISO 13485:2016.

LEARNING OBJECTIVES

This course aims to help delegates to understand the ISO 13485:2016 Standard requirements. 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 of ISO 13485:2016 requirements

COURSE BENEFITS

Upon completion of this training, delegates will:

1. Have a good understanding of the ISO 13485:2016 requirements
2. Be able to apply and implement ISO 13485 effectively

WHO SHALL ATTEND THIS COURSE

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 learners learning the ISO 13485 for the very first time, quality assurance personnel, and regulatory affairs personnel.

SCAN TO REGISTER

or visit our registration link:
https://forms.gle/J3ghFpUhBrmLK4Cs6

For enquiries, please contact:
training.mda@mda.gov.my | 03-8230 0300

EARLY REGISTRATION RECOMMENDED TRAINING FEE:

RM 1000 / participant

FEE INCLUDED:

- Comprehensive Training
- E-certificate
- Training materials
- Meals

Upon submission of your registration, an invoice for payment, along with the payment method details, will be issued within 2–3 working days.

This program is claimable under the SBL Scheme. Please refer here for the SBL Scheme terms and conditions.

TRAINING TENTATIVE

TIME	DETAILS
09.00 am – 09.15 am	Opening and introduction
09.15 am – 10.15 am	Introduction to Medical Device Clause 1: Scope Clause 2: Normative References Clause 3: Terms and Definitions
10.15 am – 10.30 am	Morning break
10.30 am – 12.30 pm	Clause 4: Quality Management System Clause 5: Management Responsibility Clause 6: Resource Management
12.30 pm – 01.30 pm	Lunch
01.30 pm – 03.30 pm	Clause 7: Product Realization
03.30 pm – 03.45 pm	Afternoon break
03.45 pm – 04.45 pm	Clause 8: Measurement, Analysis and Improvement
04.45 pm – 05.00 pm	Summary and End of Course