Medical Device AUTHORITY MALAYSIA

PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA

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THE TRAINING OF
ISO 14971:2019
RISK MANAGEMENT
FOR MEDICAL DEVICES

ABOUT THE TRAINING

Every medical device produced shall be safe to be used and effective. There is no compromise in ensuring every lives is protected when they are exposed to medical devices.

The ISO 14971 standard is developed to outline a systematic approach on how to identify, manage, and control risk of medical devices from the point of conception and design to the disposal of the medical devices.

LEARNING OBJECTIVES

This course aims to help delegates to understand the ISO 14971:2019 standard and the course content outlined is to provide delegates with:

- Examples of risks related to medical devices and its consequences
- Practical knowledge in analysing, estimating, evaluating, and controlling risk related to medical devices throughout its life cycle

COURSE BENEFITS

Upon completion of this training, delegates will:

1. Be able to apply ISO 14971 in their respective medical device risk management activities
2. Have better understanding on different tools used in risk management (i.e Failure Mode and Effects Analysis – FMEA, Preliminary Hazard Analysis – PHA, Hazard Analysis Critical Control Points – HACCP)

WHO SHOULD ATTEND

This programme is particularly useful to those responsible for medical device risk management especially the management team, designers, product and process responsible personnel, and supply chain personnel.

TRAINING DETAILS

DATE
13 August 2026 (Thursday)

TIME
8:30 am – 5:00 pm

VENUE
Medical Device Authority (MDA), Cyberjaya

EARLY REGISTRATION RECOMMENDED TRAINING FEE:

RM 1000 /participant

(Fee Included: Comprehensive Training, E-certificate, Training materials and Meals)

REGISTER NOW!

SCAN QR CODE

REGISTRATION OPEN UNTIL 31 JULY 2026

TRAINING AGENDA

TIME	DETAILS
09.00 am – 09.15 am	Opening and introduction
09.15 am – 10.15 am	Medical device and its risk classification General requirements for risk management system
10.15 am – 10.30 am	**Morning break**
10.30 am – 12.30 pm	Risk Management Plan (with example) Risk Analysis Risk Evaluation
12.30 pm – 01.30 pm	**Lunch**
01.30 pm – 03.30 pm	Risk Control Evaluation of overall residual risk
03.30 pm – 03.45 pm	**Afternoon break**
03.45 pm – 04.45 pm	Risk management review Production and post-production activities Risk Management File (with example)
04.45 pm – 05.00 pm	Summary and End of course

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.