Medical Device AUTHORITY MALAYSIA

In-Depth Training on
General Medical Devices

14 May 2025

08:30 am - 05:30 pm

Medical Device Authority, Cyberjaya

Training Fee
RM 1,000
Per Pax

Training Overview

This comprehensive training session is designed to provide participants, comprising new establishments, conformity assessment bodies, and stakeholders, with an in-depth understanding of the essential topics related to general medical devices under the Medical Device Act 2012 (Act 737) and the Medical Device Regulations 2012.

It will focus on risk classification, device grouping, the Common Submission Dossier Template (CSDT), Essential Principles of Safety and Performance (EPSP), clinical evidence requirements, and specific considerations for Software as a Medical Device (SaMD), particularly those incorporating AI/ML technologies. Through interactive case studies, quizzes, and practical examples, participants will gain a hands-on understanding of how to meet regulatory requirements for medical device registration in Malaysia.

Register Here!

Registration Close: 5 MAY 2025
Upon acceptance of the registration, an invoice (for payment purposes) together with details of the payment methods will be issued within 24 hours)

Targeted Group

- Regulatory Affairs Teams
- Conformity Assessment Bodies (CABs)
- Clinical Affairs Professionals
- Stakeholders involved in the regulatory compliance process for medical devices

Training Outline

Training 3: In-Depth Training on General Medical Device Requirements

08:30 AM - 09:00 AM	**Registration & Briefing**
09:00 AM - 09:30 AM	Risk Classification for General Medical Device
09:30 AM - 10:00 AM	Grouping for General Medical Device
10:00 AM - 10:30 AM	CSDT & EPSP for General Medical Device
10:30 AM - 11:00 AM	**Short Break**
11:00 AM - 12:30 PM	Addressing Clinical Evidence Requirements for General Medical Device
12:30 PM - 02:00PM	**Lunch Break**
02:00 PM - 03:00 PM	Case studies: Breakup session
03:00 PM - 04:00 PM	Quiz
04:00 PM	**End of Program**

** This training Outline is Subject to Change