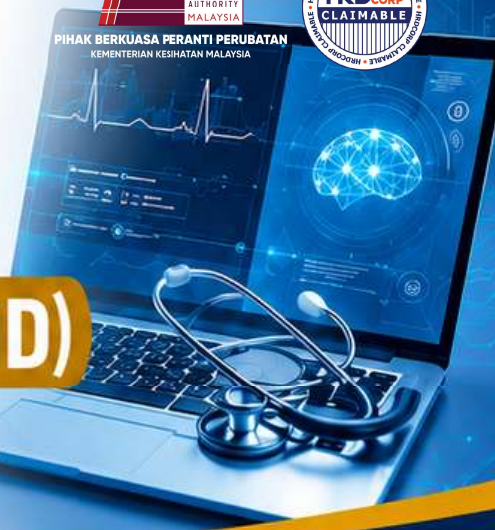
THE TRAINING OF FUNDAMENTALS OF SOFTWARE AS MEDICAL DEVICE (SaMD)

Medical Device Authority Malaysia
PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA

HRD CORP CLAIMABLE



Understanding SaMD, SiMD, and AI-Based Devices in Compliance with Act 737

TRAINING OBJECTIVES

i. To introduce participants to the definition, scope, and regulatory framework for Software as a Medical Device (SaMD), in line with Malaysia's Medical Device Act 2012 (Act 737).

ii. To provide clarity on the differences between SaMD and SiMD, with real-world examples.

iii. To explain risk classification and management, specifically for SaMD, SiMD, and AI/ML-enabled devices.

iv. To explore global regulatory practices and how they align with local requirements.

v. To cover clinical evaluation, software validation, AI applications, and post-market surveillance (PMS) in accordance with regulatory expectations under Act 737.

THIS TRAINING IS BEST SUITED FOR:

- Regulatory Affairs Personnel
- Medical Device Manufacturers and Importers
- Software Developers in Healthcare Technology
- Clinical and Technical Evaluators
- Conformity Assessment Bodies (CABs)
- Stakeholders involved in the regulatory compliance process for medical devices

TRAINING DETAILS

DATE
15 SEPTEMBER 2026 (TUESDAY)

TIME
8:30 AM – 4:00 PM

VENUE
MEDICAL DEVICE AUTHORITY (MDA), CYBERJAYA

REGISTRATION OPEN UNTIL
28 AUGUST 2026

TRAINING TENTATIVE

8:30 AM – 9:00 AM	Registration & Briefing
9:00 AM – 10:30 AM	• Fundamentals of SaMD • Differences between SaMD and SiMD • Risk Classification for SaMD, SiMD, and AI • How other countries regulate SaMD, SiMD and AI
10:30 AM – 10:45 AM	Morning Break
10:45 AM – 12:30 PM	• Artificial intelligence and machine learning medical device (Including AI and imaging medical device/equipment) • Software validation and testing • Risk assessment for SaMD and SiMD • PMS for SaMD and SiMD undertaken both by the manufacturer and other regulatory agencies.
12:30 PM – 2:00 PM	Lunch Break
2:00 PM – 4:00 PM	Clinical evaluation for software as a medical device
4:00 PM	End of Program

EARLY REGISTRATION RECOMMENDED!

TRAINING FEE
RM 1000 / PARTICIPANT

FEE INCLUDED:
COMPREHENSIVE TRAINING | E-CERTIFICATE | TRAINING MATERIALS | MEALS

SCAN TO REGISTER

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