PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA

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

Date:
24 July 2025

Time:
Start 08:30 am - 16:00 pm

Location:
Medical Device Authority, Cyberjaya

Fee

RM 1,000

Per Participant

Fundamentals of Software as a Medical Device (SaMD) - Understanding SaMD, SiMD, and AI-Based Devices in Compliance with Act 737

TRAINING OBJECTIVES

- 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).
- To provide clarity on the differences between SaMD and SiMD, with real-world examples.
- To explain risk classification and management, specifically for SaMD, SiMD, and AI/ML-enabled devices.
- To explore global regulatory practices and how they align with local requirements.
- 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

REGISTER HERE

REGISTRATION CLOSE: 10TH JULY 2025

Upon acceptance of the registration, an invoice (for payment purposes) together with details of the payment methods will be issued within 2-3 working days)

MALAYSIA MADANI

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THE TRAINING OUTLINE

Time	Topic	Details
08:30 AM - 09:00 AM	Registration & Briefing	• **Participant Registration**
09:00 AM - 10:30 AM	**Introduction to SaMD and Global Regulatory Landscape**	• Fundamentals of SaMD (definition, IMDRF guidance) • Differences between SaMD and SiMD with examples • Risk Classification for SaMD, SiMD, and AI • Overview of regulatory approaches in Malaysia and other countries • Regulatory trends in AI/ML and Good Machine Learning Practices (GMLP) • Case study discussions
10:30 AM - 10:45 AM	**Morning Break**	• **Light Refreshments and networking**
10:45 AM - 12:30 PM	**AI/ML Devices, Software Validation, Risk, and PMS**	• AI/ML in medical devices (e.g., imaging, diagnostics) • Software validation and testing (IEC 62304) • Risk assessment (ISO 14971) including cybersecurity and data bias • Post-Market Surveillance (PMS) obligations for SaMD/SiMD • Role of manufacturers and regulatory authorities in PMS and incident reporting • Case study discussions
12:30 PM - 02:00 PM	**Lunch Break**	• **Lunch**
02:00 PM - 04:00 PM	**Clinical Evaluation for SaMD**	• Evidence requirements and clinical performance evaluation • Real-world data (RWD) and clinical trials • Clinical evaluation of AI/ML-based software • Lifecycle approach to clinical validation • Case study discussions and sample clinical evaluation documentation
04:00 PM	**End of Session**	• **Summary and Q&A**

**** This training Outline is Subject to Change**

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