PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA

TRAINING ON ASSESSMENT OF COMMON SUBMISSION DOSSIER TEMPLATE (CSDT)

for General Medical Devices and IVDs

ABOUT THE TRAINING

This module provides participants with a comprehensive understanding of the Common Submission Dossier Template (CSDT) requirements for both General Medical Devices (GMD) and In Vitro Diagnostic Medical Devices (IVD).

The training covers key documentation elements, conformity assessment against the Essential Principles of Safety and Performance (EPSP), and technical evidence requirements for regulatory submissions.

Through practical exercises and case studies, participants will enhance their skills in preparing, reviewing, and evaluating CSDT submissions from both regulatory and industry perspectives, applicable to different categories of medical devices.

TRAINING OUTCOME

Upon completion of this training, participants will be able to:

- Understand the structure and content requirements of the Common Submission Dossier Template (CSDT) for both General Medical Devices (GMD) and In Vitro Diagnostic Medical Devices (IVD) under Act 737 and Medical Device Regulations 2012.
- Apply the principles and requirements to prepare, compile, review, and assess CSDT dossiers in alignment with Malaysian regulatory requirements and ASEAN AMDD provisions.
- Develop practical skills in mapping technical evidence against the Essential Principles of Safety and Performance (EPSP), reviewing verification and validation data, assessing clinical and performance evaluation evidence, and evaluating risk management documentation to support regulatory compliance and successful CSDT submissions.
- Identify potential compliance gaps in regulatory submissions, including labelling, Quality Management System (QMS) requirements, and supporting documentation, from both regulator and industry perspectives.
- Strengthen regulatory consistency and harmonisation by aligning CSDT assessment and submission practices with international frameworks, including IMDRF STED and ASEAN CSDT.

TRAINING DETAILS

DATE	:	7 July 2026 (Tuesday)
TIME	:	8:30 am – 4:30 pm
VENUE	:	Seminar Room, Level G, Medical Device Authority (MDA), Cyberjaya

EARLY REGISTRATION RECOMMENDED

TRAINING FEE:
RM 1000/ PARTICIPANT

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

TIME	TOPIC / ACTIVITY
08:30 AM - 09:00 AM	Registration & Welcome Briefing
09:00 AM - 09:45 AM	**Session 1:** Structure of CSDT for GMD and IVDs
09:45 AM - 10:00 AM	Morning Refreshment Break
10:00 AM - 11:00 AM	**Session 2:** Essential Principal & Pre-Clinical (GMD)
11:00 AM - 12:00 PM	**Session 3:** Essential Principal & Pre-Clinical (IVD)
12:00 PM - 01:00 PM	**Session 4:** Clinical Evidence for GMD & IVD
01:00 PM - 02:00 PM	Lunch Break
02:00 PM - 03:30 PM	**Session 5:** Labelling
03:30 PM - 03:45 PM	Afternoon Refreshment Break
03:30 PM - 04:30 PM	Case Studies & Hands-On Exercises (GMD & IVD)
04:30 PM	End Session

SCAN TO REGISTER

Register Before: 30th June 2026