PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA

MDA CORE
CENTRE OF EXCELLENCE

THE TRAINING OF
FUNDAMENTAL UNDERSTANDING OF MEDICAL DEVICES & IVDS

TRAINING DETAILS

28 JANUARY 2025 (WEDNESDAY)

8:45 am - 5:00 pm

Seminar Room, Level G, Medical Device Authority (MDA), Cyberjaya, Selangor

CORE FOCUS

- Definition of medical devices under Act 737 & MDR 2012
- Risk-based classification in accordance with MDR 2012 and the ASEAN Medical Device Directive (AMDD)
- Intended purpose as the primary determinant
- Medical vs non-medical vs combination products
- Rehabilitation, physiotherapy & speech therapy devices based on MDA/GD/0061
- Application of Malaysian & ASEAN regulatory guidance

EXPECTED OUTCOMES

- Understand and interpret the regulatory definition of medical devices and IVDs under the Malaysian Medical Device Act 2012 (Act 737)
- Differentiate accurately between medical devices, non-medical products, and combination products based on intended purpose and regulatory criteria
- Apply risk-based classification principles in accordance with Malaysian and ASEAN regulatory guidance
- Determine and justify the manufacturer's intended purpose, including interpretation of IFU, labelling, and promotional claims
- Assess borderline products and identify common misclassification pitfalls encountered by the industry
- Correctly classify rehabilitation, physiotherapy, and speech therapy devices in line with applicable MDA guidance
- Demonstrate practical competency in regulatory classification through hands-on case studies and scenario-based exercises

TRAINING FEES
RM 1,000
PER PARTICIPANT

Register Now !

BEFORE : **20 JANUARY 2026**

or Register Here

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

PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA

MDA CORE
CENTRE OF EXCELLENCE

Target Audience

- **Industry Regulatory**
- **Technical Personnel**

Training Agenda

Time	Session
08.45 AM – 09.15 AM	Registration and Opening
09.15 AM – 10:15AM	Definition of a Medical Device (Act 737 & Global Context)
10.15 AM – 10.30 AM	Morning Break
10.30 AM - 11.45 AM	Risk-Based Classification, Medical, Non-Medical, and Combination Products
11:45 AM - 12:45 PM	Intended Purpose, Claims & Regulatory Impact
12.45 PM - 02:00 PM	Lunch Break
02:00 PM - 03:00 PM	Application of Malaysian & ASEAN Regulatory Guidance
03:00 PM - 03:15 PM	Tea Break
03:15 PM - 04:15 PM	Classification of Rehabilitation, Physiotherapy, and Speech Therapy Devices
04:15 PM - 04:50 PM	Case Studies and Hands-On Exercises
04:50 PM - 05: 00 PM	Wrap-Up & Closing