Medical Device Authority Malaysia

HANDS-ON WORKSHOP

LIMITED SEATS APPLY NOW

EFFICIENT WAY TO PREPARE FOR MDA DOCUMENTATION SUBMISSIONS

A face-to-face platform for medical device establishments, medical device industry representatives, conformity assessment bodies, and stakeholders to have an in-depth understanding of the regulatory requirements by the Medical Device Authority (MDA) based on Act 737, Medical Device Regulation 2012, Medical Device Regulation 2019 and Medical Device (Exemption) Order 2016. This workshop is beneficial to establishments, the medical device industry, especially to new start-up companies.

MODULE 1 (27 JULY 2022) POST-MARKET

COMPLAINT HANDLING
MANDATORY PROBLEM REPORTING
FIELD CORRECTIVE ACTION (FCA)
RECALL
ADVERTISEMENT
LABELLING

MODULE 2 (28 JULY 2022) INDUSTRY FACILITATION

CFS/ MC
NOTIFICATION (EXPORT ONLY, SPECIAL ACCESS, CUSTOM-MADE, CLINICAL RESEARCH, DEMO FOR MARKETING, EDUCATION)

VENUE:
BILIK MERANTI, LEVEL 6, MDA, CYBERJAYA

Workshop Secretariat

03-8230 0240 / 0355 / 0211 / 0395 / 0343

trainingpackage@mda.gov.my

Module 1: Post-Market

Medical Device AUTHORITY MALAYSIA

LIMITED SEATS APPLY NOW

Curated for Medical Device Establishments

Module 1 of this Workshop is aimed to provide guidance and step-by-step assistance for establishments to do complaint handling, mandatory problem reporting, field corrective action and medical device recall, labeling of medical device, understanding code of advertisement, and also hands-on apply for advertisement.

e-Cert Provided

MODULE 1 AGENDA

TIME	TOPIC
8.55 – 9.00 am	Program Briefing
9.00 - 10.30 am	Overview of Post Market Surveillance & Vigilance (PMSV) • Complaint handling • Mandatory Problem Reporting
10.30 - 10.45 am	Short Break
10.45 - 1.00 pm	Overview of Post Market Surveillance & Vigilance (PMSV) • Field Corrective Action (FCA) • Recall
1.00 - 2.00 pm	Lunch Break
2.00 - 3.00 pm	Code of Advertisement
3.00 - 3.15 pm	Short Break
3.15 - 3.45 pm	Application on Advertisement
3.45 - 5.00 pm	Labelling
5.00 pm	End of workshop

CLOSE ON JULY 21, 2022!

Fees RM1,300 Per Pax

27 JULY 2022
9.00 AM - 5.00 PM

CLICK OR SCAN TO REGISTER

Module 2: Industry Facilitation

LIMITED SEATS APPLY NOW

Curated for Medical Device Representative

Module 2 of this Workshop is aimed to provide guidance and step-by-step assistance for medical device representatives to apply for CFS/MC, Notification for Export Only, Notification for Demonstration, Marketing & Education, Clinical Research Use, Custom-made, and also Notification for Special Access

e-Cert Provided

MODULE 2 AGENDA

TIME	TOPIC
8.55 – 9.00 am	Program Briefing
9.00 - 10.30 am	Certificate Free Sale (CFS) & Manufacturing Certificate (MC) – Export Only Manufacturer or OEM Manufacturer
10.30 - 10.45 am	Short Break
10.45 - 11.45 pm	Notification for Export Only
11.45 - 12.45 pm	Notification for Special Access Medical Device
12.45 - 2.00 pm	Lunch Break
2.00 - 2.45 pm	Notification for Custom-Made Medical Device
2.45 - 3.30 pm	Notification for Clinical Research Use
3.30 - 3.45 pm	Short Break
3.45 - 4.15 pm	Notification for Demonstration for Marketing
4.15 - 4.45 pm	Notification for Education
4.45 pm	End of workshop

CLOSE ON JULY 21, 2022!

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28 JULY 2022
9.00 AM - 5.00 PM

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