LIMITED SEATS
APPLY NOW

Medical Device AUTHORITY MALAYSIA

HANDS-ON WORKSHOP

EFFICIENT WAY TO PREPARE FOR MDA DOCUMENTATION SUBMISSIONS

The workshop is mindfully curated to assist the industry in effectively preparing documents required by the authority for better submission and fewer errors. This workshop also gives guidance on how to use the online systems created by MDA such as Medical Device Centralised Online Application System (MeDC@St) and Medical Device Centralized Reporting System (MeDCReSt). This workshop is beneficial to establishments, the medical device industry, and especially new start-up companies in the successful application of establishment licenses, product certificates, and reporting.

26-29 SEPTEMBER 2022

Meranti Room, Level 6, MDA, Cyberjaya

Register Now :

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

Registration Form

trainingpackage@mda.gov.my

MODULE 1 (26 SEPTEMBER 2022) LICENSING

NEW APPLICATION, RENEWAL, AMENDMENT, SURRENDER, CHANGE OF OWNERSHIP

MODULE 2 (27 SEPTEMBER 2022) REGISTRATION

CLASSIFICATION, COMBINATION, VERIFICATION & FULL CONFIRMITY, RE-REGISTRATION, CHANGE NOTIFICATION

MODULE 3 (28 SEPTEMBER 2022) POST-MARKET

INTRO TO MEDCREST, MEDCREST MODULE: MANDATORY PROBLEM REPORTING, FIELD CORRECTIVE ACTION, RECALL, APPLICATION, COA, LABELLING

MODULE 4 (29 SEPTEMBER 2022) INDUSTRY FACILITATION

CFS & MC: EXPORT ONLY MANUFACTURER, NOTIFICATION: EXPORT ONLY, SPECIAL ACCESS, CUSTOM-MADE, CLINICAL RESEARCH USE, DEMO FOR MARKETING, EDUCATION

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Medical Device AUTHORITY MALAYSIA

MODULE 1: LICENSING

CURATED FOR MEDICAL DEVICE ESTABLISHMENTS

Module 1 of this Workshop is aimed to provide guidance and step-by-step assistance for establishments to apply for establishment licence, renewal of establishment licence, change ownership of the application, and hands-on Medc@st online application system.

MODULE 1 AGENDA

TIME	TOPIC
8.30 – 8.55 am	**Participant Registration**
8.55 – 9.00 am	**Program Briefing**
9.00 - 9.30 am	**New Application of Establishment License**
9.30 - 10.45 am	**New Application of Establishment License (Hands-On MeDC@St)**
10.45 - 11.00 am	**Short Break**
11.00 - 11.45 am	**Renewal of Establishment License**
11.45 - 1.00 pm	**Renewal of Establishment License (Hands-On MeDC@St)**
1.00 - 2.00 pm	**Lunch Break**
2.00 - 2.15 pm	**Amendment Major and Minor of Establishment License**
2.15 - 3.00 pm	**Amendment Major and Minor of Establishment License (Hands-On MeDC@St)**
3.00 - 3.15 pm	**Short Break**
3.15 - 3.30 pm	**Surrender of Establishment License**
3.30 - 4.15 pm	**Surrender of Establishment License (Hands-On MeDC@St)**
4.15 - 4.30 pm	**Change of Ownership Application**
4.30 - 5.00 pm	**Change of Ownership Application (Hands-On MeDC@St)**
5.00 pm	**End of workshop**

e-Cert Provided

RM1,300

CLICK OR SCAN TO REGISTER

CLOSE ON SEPTEMBER 19, 2022!

DATE: 26 SEPTEMBER 2022
TIME: 9 AM–5 PM

Fees
RM1,300
Per Pax & Per Module

LIMITED SEATS APPLY NOW

Medical Device AUTHORITY MALAYSIA

MODULE 2: REGISTRATION

CURATED FOR MEDICAL DEVICE PRODUCTS

Module 2 of this Workshop is aimed to provide guidance and step-by-step assistance for medical device representatives to do a product classification, combination product registration, medical device registration process, and hands-on Medc@st online application system.

MODULE 2 AGENDA

TIME	TOPIC
8.30 – 8.55 am	**Participant Registration**
8.55 – 9.00 am	**Program Briefing**
9.00 - 9.45 am	**Product classification**
9.45 - 10.15 am	**Combination product**
10.15 - 10.30 am	**Short Break**
10.30 - 11.45 pm	**Medical Device Registration Process (Verification Process & Full Conformity)** • **Classifying** • **Grouping**
11.45 - 1.00 pm	**Medical Device Registration Process (Verification Process & Full Conformity)** • **Conformity Assessment (QMS, PMS, Technical Documentation, DoC)**
1.00 - 2.00 pm	**Lunch Break**
2.00 - 3.30 pm	**Re-registration of Medical Device**
3.30 - 3.45 pm	**Short Break**
3.45 - 5.00 pm	**Update on Change Notification**
5.00 pm	**End of workshop**

RM1,300

e-Cert Provided

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TIME: 9 AM–5 PM

Fees
RM1,300
Per Pax & Per Module

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Medical Device AUTHORITY MALAYSIA

MODULE 3: POST-MARKET

CURATED FOR MEDICAL DEVICE ESTABLISHMENTS

Module 3 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.

MODULE 3 AGENDA

TIME	TOPIC
8.55 – 9.00 am	**Program Briefing**
9.00 - 10.15 am	**Introduction to MeDCReSt**
10.15 - 10.30 am	**Short Break**
10.30 - 11.30 pm	**MeDCReSt Module: Mandatory Problem Reporting**
11.30 - 12.15 pm	**MeDCReSt Module: Field Corrective Action (FCA)**
12.15 - 1.00 pm	**MeDCReSt Module: Recall**
1.00 - 2.00 pm	**Lunch Break**
2.00 - 2.30 pm	**Application on Advertisement**
2.30- 3.30 pm	**Code of Advertisement**
3.30 - 3.45 pm	**Short Break**
3.45 - 5.00 pm	**Labelling**
5.00 pm	**End of workshop**

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CLOSE ON SEPTEMBER 19, 2022!

DATE: 28 SEPTEMBER 2022
TIME: 9 AM–5 PM

Fees
RM1,300
Per Pax & Per Module

LIMITED SEATS
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Medical Device AUTHORITY MALAYSIA

MODULE 4: INDUSTRY FACILITATION

CURATED FOR MEDICAL DEVICE REPRESENTATIVE

Module 4 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

MODULE 4 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**

RM1,300

e-Cert Provided

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CLOSE ON SEPTEMBER 19, 2022!

Fees
RM1,300
Per Pax & Per Module

DATE: 29 SEPTEMBER 2022
TIME: 9 AM–4.45 PM