MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia

REGULATORY TRAINING
POST-MARKET REQUIREMENTS

16 JULY 2024
WEDNESDAY | 8:30 AM - 5:30 PM
MDA HQ / CYBERJAYA/PUTRAJAYA
(TO BE CONFIRMED)

Training fee
RM 1000
Per pax

OBJECTIVES

To provide explanations and disclosures regarding to post-market responsibilities based on Act 737 and the Medical Devices (Duties and Obligations of Establishments) Regulations 2019 to ensure the implementation is according to MDA's expectations and complies with the outlined legal requirements.

OVERVIEW

MDA Regulatory Training on Post-Market Requirements is a 1-day course that helps you to have a better view and understanding of the requirements of post-market duties and obligations as stipulated in the Medical Device Act (Act 737) and Medical Device Regulation Act 2012 to enable the effective implementation of post-market systems in the medical device industry.

Our speaker will share information on the requirements of post-market surveillance and vigilance and provide expert advice for manufacturers, medical device professionals, and interested individuals throughout the course.

In this training, you will learn the concept on collecting and analyzing the post market data, identifying the reportable incident and reporting steps, and applying the root cause analysis to determine the corrective and preventive actions including implementation of field corrective actions (FCA) and conducting a recall as well as how to integrate those elements in the quality management system (QMS).

TARGET AUDIENCES

- **Establishment (especially manufacturer and AR)**
- **Medical device professionals involved in the maintenance of medical devices, post-market surveillance, complaint handling, incident reporting, and regulatory compliance**
- **Regulatory affairs managers**
- **Quality managers**
- **Clinical/Medical Professionals**
- **Interested individuals**

Contact Us:

Should you have any queries, please contact us through email at:
trainingpackage@mda.gov.my

Scan the QR Code to register

Closing Date: 1 July 2024

Upon acceptance of the registration, an invoice (for payment purposes) together with details of the payment methods will be issued accordingly

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PROGRAM OUTLINE

08.30 AM – 08.55 AM : Registration

08.55 AM – 09.10 AM : Briefing

09.10 AM – 10.00 AM : **Overview of Post-Market Framework**

10.00 AM – 11.00 AM : **Management of Post-Market Data & Feedback**

11.00 AM – 01.00 PM : **Management of Incident**

01.00 PM – 02.15 PM : Lunch Break

02.15 PM – 03.15 PM : **Corrective & Preventive Action (CAPA)**

03.15 PM – 03.30 PM : Tea Break

03.30 PM – 04.15 PM : **Recall: Management of Recall Strategy**

04.15 PM – 05.15 PM : **Roles of MDA**

05.15 PM : End of Session

****This Program Outline are Subject to Change**

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