Medical Device Authority
MInistry of Health Malaysia

OVERVIEW ON MEDICAL DEVICE REGISTRATION PROCESS

TRAINING DETAILS

Wednesday, 28 August, 2024

At 08:00 am until 05:00 pm

Putrajaya/ Cyberjaya
(To be Confirmed)

Training Fee

RM1000

Per Pax

REGISTER NOW!

Overview

This training will provide an overview of Malaysia's medical device registration process. It is recommended for new establishments, conformity assessment bodies, and stakeholders who want to gain essential information on medical device regulatory requirements for a successful registration process.

It covers a basic understanding of the medical device registration, change notification, and labeling requirements outlined by the Medical Device Act 2012 (Act 737), Medical Device Regulation 2012, and related guidance documents. Additionally, this training will cover medical device life cycle development and clinical evidence topics.

CLOSING DATE: 9 AUGUST 2024

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

Contact us at:

Trainingpackage@mda.gov.my

Medical Device Authority - MDA | Medical_Device_Authority | Medical Device Authority - MDA

https://www.mda.gov.my/

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TRAINING OUTLINE

08:30 AM – 08:55 AM :

Registration

08:55 AM – 09:00 AM :

Briefing

09:00AM – 09:45 AM :

Medical Device Life Development: From Prototype to Regulatory Approval

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09:45 AM – 11:15 AM :

Overview Medical Device Registration Process

11:15 AM – 11:30 AM :

Short Break

11:30 AM – 12:15 PM :

Change Notification requirement

12.15 PM – 01.00 PM :

Labelling

01:00 PM – 02:00 PM :

Lunch Break

02:00 PM – 05:00 PM :

Clinical Evidence

****This Program Outline is Subject to Change**