

REGISTER NOW!

LIMITED SEATS AVAILABLE!

12 OCT 2022



PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA

SEMINAR BY THE MEDICAL DEVICE AUTHORITY ON REGULATORY UPDATES OFFICIAL ANNOUNCEMENT

"Updates on Regulation, Medical Device Re-
registration, PMSV New System"



**Pn. Salbiah
bt
Yaakop**

Director of Policy,
International Affairs and
Industry Facilitation Division



**Pn. Mariammah
A/P
Krishnasamy**

Head of Registration
Branch, Pre-Market
Control Division



**En. Mohd Zul
Hirsham bin
Junaidi**

Head of Vigilance Unit,
Post-Market and
Enforcement Division

This seminar will give updates relating to the regulation, the re-registration process of medical devices and also introduce the new system launched by MDA's Post-Market and Enforcement Division, Medical Device Centralized Reporting System (MeDCReSt), that facilitate the reports from the industry and the public.

CLOSE ON OCT 15, 2022!
**Fees
RM1,500
Per Pax**

**DoubleTree by Hilton
Putrajaya Lakeside**

From 9.00 am - 5.00 pm
events@mda.gov.my
03-8230 0240 / 0355 / 0211

Registration:





Face-To-Face Seminar



DATE & LOCATION

Date	Location	Registration
31 March 2022	Cyberjaya	Closed
5 July 2022	Pulau Pinang	Closed
12 October 2022	Putrajaya	Open Now!

SEMINAR AGENDA

TIME

TOPIC

8.30 – 8.55 am

Participant Registration

8.55 – 9.00 am

Program Briefing

9.00 – 9.10 am

Opening Speech by Chief Executive of MDA

9.10 – 10.10 am

“How Does the International Medical Device Organization Influences Our National Policies? What Is MDA Up To?”

New local regulations, international medical device regulatory initiatives towards harmonization and convergence (GHWP, AMDC)

10.10 – 10.30 am

Short Break

10.30 – 12.00 pm

“My Medical Device Registration Certificates are Expiring! What Do I Do Now?”

Re-registration process of medical device

12.00 – 1.00 pm

Q&A Session 1

1.00 – 2.00 pm

Lunch Break

2.00 – 4.00 pm

“My Product Caused an Emergency, Where Do I Go?”

Newly launched reporting system (MeDCReSt), safety and performance issues on medical devices.

4.00 - 4.20 pm

Short break

4.20 – 5.00 pm

Q&A Session 2

5.00 pm

Adjournment

TARGET AUDIENCE

- Manufacturers, Authorized Representatives, Importers, and Distributors;
- Conformity Assessment Bodies (CABs);
- Medical device associations;
- Medical device industry representatives;
- Healthcare institutions or universities;
- Healthcare professionals (HCPs);
- Designated persons; and
- Interested individuals.



CONTACT US!

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