Medical Device AUTHORITY MALAYSIA

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MEDICAL DEVICE WEBINAR 2021

POLICY UPDATES AND NEW MEDICAL DEVICE REGULATIONS UNDER ACT 737: ADVERTISEMENT, POST MARKET REQUIREMENTS AND MEDICAL DEVICE RE-REGISTRATION

10 JUNE, 2021

INVITED SPEAKERS

Encik Ahmad Shariff Hambali
Chief Executive of MDA

Updates on Medical Device Act, Regulations and Circular Letters

Puan Salbiah Yaakop

The Medical Device (Advertising) Regulations 2019 P.U. (A) 317

Puan Idamazura Idris

Application for Approval of Medical Device Advertisement

Puan Suhaida Rasul

Updates on Medical Device Re-Registration

Puan Mariammah Krishnasamy

Implementing the New Medical Device Regulations on "Duties and Obligations Of Establishments", P.U.(A) 318 on the 1st of July. What's Next?

Encik Mohd Zul Hirsham Junaidi

Medical Device Regulations of Duties and Obligations of Establishments: Walkthrough with MDA (MPR, Complaint Handling)

Puan Norshafina Sahinin

Medical Device Regulations of and Duties and Obligations of Establishments: (FCA & FSN, Medical Device Recall)

Encik Ikhwan Hafiz Zainuddin

OVERVIEW

MDA-CORE is pleased to announce its webinar for year 2021 entitled "Policy Updates And New Medical Device Regulations Under Act 737: Advertisement, Post Market Requirements And Medical Device Re-Registration". It will be a one-day program, to be held on 10 June, 2021.

This event is targeted to all medical device stakeholders especially establishments, medical device industry representatives, healthcare organisations and conformity assessment bodies. This webinar will also provide a platform for fruitful and meaningful discussions, and sharing of information on new regulatory developments for medical device.

MDA-CORE sincerely extends an invitation to you to participate in this upcoming webinar.

OBJECTIVE

The objectives of this webinar are to disseminate information on the latest developments and requirements on:

- Medical Device (Duties and Obligation of Establishment) Regulations 2019;
- Medical Device (Advertising) Regulations 2019;
- Re-registration of Medical Device upon expiry

Medical Device Authority Malaysia

JUNE 2021

TARGET AUDIENCE

This webinar will benefit all relevant stakeholders who are involved with medical device including:

- Manufacturers, authorized representatives, importers, and distributors;
- Conformity Assessment Bodies (CABs);
- Medical device industry representatives;
- Healthcare organisations; and
- Interested individuals.

TENTATIVE AGENDA

8:30 – 8:55 am	Registration
8:55 – 9:00 am	Briefing
9:00 – 9:15 am	Opening Address by Chief Executive of MDA
9:15 – 9:45 am	Updates on Medical Device Act, Regulations and Circular Letters
9:45 - 11:00 am	The Medical Device (Advertising) Regulations 2019 P.U. (A) 317
11:00 - 11:20 am	Application for Approval of Medical Device Advertisement
11:20 – 11:30 am	Short Break
11:30 – 12:30 pm	Updates on Medical Device Re-Registration
12:30 - 1:30 pm	Implementing the New Medical Device Regulations on "Duties and Obligations Of Establishments", P.U.(A) 318 on the 1st of July. What's Next?
1:30 - 2.15 pm	Lunch Break
2:15 - 3.30 pm	Medical Device Regulations of and Duties and Obligations of Establishments: Walkthrough with MDA (MPR, Complaint Handling)
3:30 - 4.45 pm	Medical Device Regulations of and Duties and Obligations of Establishments: (FCA & FSN, Medical Device Recall)
4.45 pm - 5.00pm	Wrap Up and Adjournment

REGISTRATION

Training fee for per participant: RM 700

Limited to 200 participants ONLY.

Registration of participants will be on a first-come-first-served basis. Upon payment confirmation, MDA will provide a link to join the training program.

Kindly complete the provided Registration Form (Please Scan QR Code) or click HERE

CONTACT US

For questions regarding the webinar please contact the Training Secretariat:

via email to events@mdb.gov.my or you may contact

Ms Shamala 03 8230 0223 or Mdm Maryam 03 8230 0355 or Mdm Rasidah 03 8230 0211 or Ms Nurhakimah 03 8230 0391