

SEMINAR WITH MEDICAL DEVICE INDUSTRY 2018
(ENHANCING QUALITY OF SUBMISSIONS AND FACILITATING COMPLIANCE
WITH THE MEDICAL DEVICE ACT)

Greetings from the Authority.

This is to announce that the seminar are now opened for registration. The seminar will be organize from **18TH to 20TH APRIL 2018.**

Below are the details of the seminar:

DAY 1 (18TH APRIL 2018)

Date: 18 April 2018

Time: 8.30 am - 5.00 pm

Venue: Marriott Hotel, Putrajaya

Content of event on DAY 1:

- (1) To share New Policy and Regulatory Requirement on Medical Device (Medical Device Regulations 2018)
- (2) Establishment Licensing Renewal
- (3) Contract Manufacturers: Licensing, Registration and CFS Application
- (4) Labelling for Medical Devices: A Walkthrough

DAY 2 (19TH APRIL 2018)

Date: 19 April 2018

Time: 8.30 am - 5.00 pm

Venue: Marriott Hotel, Putrajaya

Content of event on DAY 2:

- (1) Registration on Medical Devices: Update and Issues
- (2) Requirement of Combination Products
- (3) Guidance Document on Change Notification
- (4) PMSV Regulatory Requirement
- (5) Enforcement of Medical Device Act

DAY 3 (20TH APRIL 2018)

Date: 20 April 2018

Time: 8.30 am - 5.00 pm

Venue: Marriott Hotel, Putrajaya

Content of event on DAY 3:

- (1) Updates on Notification of Medical Devices for Clinical Investigation/Performance Evaluation
- (2) Updates on Notification of Medical Devices for the Purpose of Clinical Research
- (3) Updates on Notification of Medical Devices for the Purpose of Special Access
- (4) Updates on Notification of Medical Devices for the Purpose of Custom Made
- (5) Updates on Notification of Medical Devices for the Purpose of Demonstration for Marketing and Education

To book a seat, please complete the REGISTRATION FORM and follow the steps for registration via email.

Seminar fee per participant: RM 742.00 (inclusive GST) per pax /day. Application for the seminar shall be made via provided Registration Form.

Steps for registration via email:

- i. Fill up the registration form
- ii. Compose a new email
- iii. Attached the registration form together with scanned bank draft
- iv. Send the email to seminar.industri@mdb.gov.my
- v. Once your email is sent and processed, you will receive a confirmation email
- vi. Please bring together the confirmation email with original bank draft during the registration day

**To download the tentative programme for day 1 to day 3. [CLICK HERE](#)
Registration Form. [CLICK HERE](#)**

**Should you have any enquiries, please do not hesitate to contact the Seminar Secretariats: Nur Azwani Binti Md Azizan (Cik.) at (03) 8230 0313 or azwani@mdb.gov.my
Fattahillah Bin Sabarudin (En.) at (03) 8230 0312 or fattahillah@mdb.gov.my**