



TENTATIVE PROGRAMME
SEMINAR WITH MEDICAL DEVICE INDUSTRY 2018
*(ENHANCING QUALITY OF SUBMISSIONS AND FACILITATING COMPLIANCE
WITH THE MEDICAL DEVICE ACT)*
DATE : 18TH, 19TH, & 20TH APRIL 2018
VENUE : HOTEL MARRIOTT, PUTRAJAYA

DAY 1 (18TH APRIL 2018)

TIME	PROGRAMME
8.30-9.00 am	Registration Breakfast
9.00-9.30 am	<i>Opening Speech</i> Zamane Abdul Rahman Chief Executive MDA
9.30-10.30 am	<i>New Policy and Regulatory Requirement on Medical Device Medical Device Regulations 2018</i> Ir. Sasikala A/P Thangavelu
10.30-11.00 am	Coffee break
11.00-1.00 pm	<i>Establishment Licensing Renewal</i> Muhd Radhuan Bin Abdul Halim
1.00-2.30 pm	Lunch
2.30-3.30 pm	<i>Contract Manufacturers : Licensing, Registration and CFS Application</i> Salbiah Bt Yaakop
3.30-4.00 pm	Coffee break
4.00-5.00 pm	<i>Labelling for Medical Devices : A Walkthrough</i> Salbiah Bt Yaakop
5.00 pm	End of Event



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DAY 2 (19TH APRIL 2018)

TIME	PROGRAMME
8.30-9.00 am	Registration and Breakfast
9.00-10.30 am	<i>Registration on Medical Devices : Update and Issues</i> Mariamah A/P Krishnasamy
10.30-11.00 am	Coffee break
11.00-12.00 pm	<i>Requirement of Combination Products</i> Nurul Hidayah Bt A.Azmi
12.00-1.00 pm	<i>Guidance Document on Change Notification</i> Maryam Nazeera Bt Suhaimi
1.00-2.30 pm	Lunch
2.30-3.30 pm	<i>PMSV Regulatory Requirement</i> Mohd Zul Hirsham Bin Junaidi
3.30-4.00 pm	Coffee break
4.00-5.00 pm	<i>Enforcement of Medical Device Act</i> Idamazura Binti Idris
5.00 pm	End of event

DAY 3 (20TH APRIL 2018)

TIME	PROGRAMME
8.30-9.00 am	Registration and Breakfast
9.00-10.30 am	Notification of Medical Devices for Clinical Investigation/Performance Evaluation Aidahwaty Ariffin @ M.Olaybal
10.30-11.00 am	Coffee break
11.00-12.30 pm	Notification of Medical Devices for the Purpose of Clinical Research Nashirah Bt Naimi
12.30-2.15 pm	Lunch
2.15-3.00 pm	Notification of Medical Devices for the Purpose of Special Access Dery Akmal Bin Abdul Rahman
3.00-3.15 pm	Coffee break
3.15-4.00 pm	Notification of Medical Devices for the Purpose of Custom Made Dery Akmal Bin Abdul Rahman
4.00-5.00 pm	Notification of Medical Devices for the Purpose of Demonstration for Marketing and Education Nur Maizura Bt Zarmani
5.00 pm	End of event

*Tentatif jadual tertakluk kepada perubahan