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## HRDF CLAIMABLE MEDICAL DEVICE REGULATORY AFFAIRS FORUM 2016

### Objectives

The objective of this forum is to facilitate open discussion among those in the medical device industry on the compliance to the Medical Device Act and its Regulations in Malaysia.

### Who Should Attend?

**Industry Players, Directors, Managers, Consultants, Officers, Regulatory Affairs**

- Regulators
- Government Departments
- Medical Device Manufacturing Companies / Exporters
- Authorized Representatives / Importers / Distributors
- Conformity Assessment Bodies (CABs)
- Healthcare Industry or Medical Professional Association
- Insurers, Investors, Bankers or other Financiers for Healthcare
- Research and Development Institutions, Legal Advisers

### SPEAKERS

#### Medical Device Authority

Mr Zamane Abd Rahman, CEO  
Mr Ahmad Shariff Hambali  
Ms Mariammah a/p Krishnasamy  
Mdm Sasikala Devi Thangavelu  
Mr Mohd Zulhirsham Junaidi

### PANEL MEMBERS

Dato' Dr Haminnuddin Hj. Abdul Hamid ,  
*Ideal Healthcare Sdn Bhd*  
Ms Ong Yean Ting, *Johnson & Johnson S/B*  
Mr Yong Tuan Heng, *Medichem S/B*  
Ms Chuah Chiew Teng, *3M Malaysia S/B*  
Ms Gan Poh Siew, *Haemonetics Malaysia S/B*

**DATE : 24 OCTOBER 2016**

**TIME : 9AM – 5PM**

**VENUE : ONE WORLD HOTEL  
BANDAR UTAMA, PETALING JAYA**

### FORUM FEES

#### Early Bird Fees (by 1 Oct 2016)

AMMI Members – RM600  
Non Members – RM800

#### Normal Fees

AMMI Members – RM700  
Non Members – RM900

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## PROGRAMME

8.30 am – 9.00 am	Registration / Welcome Refreshment
9.00 am – 9.05 am	Welcome Address by Mr Hitendra Joshi, Chairman of AMMI
9.05 am – 9.30 am	<b>Session 1 (a): New Guidelines from MDA (from January 2016) in line with supporting industry (from pre-market to post-market activities) and safeguarding public interest</b> Speaker: Mr Ahmad Shariff Hambali, MDA
9.30 am – 10.30 am	<b>Session 1 (b): Requirements of exempted medical device. Exemption order 2016 – Conformity Assessment Body (CAB) Simplify Verification Requirement</b> Speaker: Ms Mariammah A/P Krishnasamy, MDA
10.30 am – 11.00 am	Tea Break
11.00 am – 11.30 am	<b>Session 2 (a): Common deficiencies from industry in MeDC@St submission</b> Speaker: Ms Mariammah A/P Krishnasamy, MDA
11.30 am – 12.00 pm	<b>Session 2 (b): Changes Notification in MeDC@St</b> -Speaker: Mr Ahmad Shariff Hambali, MDA
12.00 pm – 12.30 pm	<b>Session 2 (c): Compliance to Medical Device Act implementation Panel Discussion</b> Moderator: Ms Gan Poh Siew, Heamonetics Malaysia Sdn Bhd Panellists: Mr Zamane Abdul Rahman, MDA Ms Ong Yean Ting, Johnson & Johnson Sdn Bhd Y.Bhg. Dato' Dr Haminnuddin Hj. Abdul Hamid , Ideal Healthcare Sdn Bhd
12.30 pm – 2.00 pm	Lunch
2.00 pm – 2.30 pm	<b>Session 3 (a): Importation Control – Medical Devices</b> Speaker: Royal Customs Department (tbc)
2.30 pm – 3.00 pm	<b>Session 3 (b): Medical Device Competency Regulatory Programme</b> Speaker: Ms Sasikala Devi Thangavelu, MDA
3.00 pm – 3.30 pm	<b>Session 4 (a): New requirements for regulating post-market activities – Draft Guidelines eg. Complaint, Adverse Event Reporting, FSCA</b> Speaker: Mr Mohd Zulhirsham Junaidi, MDA
3.30 pm – 4.00 pm	Tea Break
4.00 pm – 4.30 pm	<b>Session 4 (b): New requirements for regulating post-market activities – Draft Guidelines eg. Advertisement, Terms &amp; Conditions</b> Speaker: Mr Mohd Zulhirsham Junaidi, MDA
4.30 pm – 5.00 pm	<b>Session 4 (c): How industry meet regulatory requirement in challenges in post-market compliance Panel Discussion</b> Moderator: Ms Ong Yean Ting, Johnson & Johnson Sdn Bhd Panellists : Mr Zamane Abdul Rahman, MDA Mr Yong Tuan Heng, Medichem Sdn Bhd Ms Chuah Chiew Teng, 3M Malaysia Sdn Bhd Ms Gan Poh Siew, Haemonetics Malaysia Sdn Bhd
5.00 pm – 5.30 pm	Q&A
5.30 pm – 5.35 pm	Presentation of Memento
5.35 pm	Networking / End

## PAYMENT

Payment is required before/ on event date.

### Direct Bank-in or via E-Banking upon receipt of Invoice

Please note that any Early Bird Discounts (for registration within validity period) will be reflected in the invoice.

Please refer the following bank account details:

- Beneficiary Name: Medsociate Sdn Bhd
- Bank Account Number: 800 3930 348
- Bank: CIMB Bank
- Swift Code: CIBB MYKL

Please email us (admin@medsociate.com) the bank-in slip / remittance slip once the payment is made.

For Government Sector - A Local Order (LO) or letter of approval to participate must be presented before the training.

## SUBSTITUTION AND CANCELLATION

Substitution is allowed for a registered participant. No refund will be made for cancellation. Medsociate Sdn Bhd (AMMI Authorised Training Provider) reserves the right to cancel or postpone any training or event but with due notice to the registered participants / company(s). Any payment made will be refunded if the cancellation is made by training provider. Cancellation of attendance and refund will not be entertained as all bookings would have been reserved and confirmed.

## DISCLAIMER

The organisers are making efforts to ensure the event is an enlightening experience for all attendees. However, the organisers are not nor can be held responsible for any loss, injury or damage to any property, whatever the cause may be or for any inconvenience delegates might incur in connection with the conference. The organisers reserves the right to alter the programme without notice including the substitution, alteration or cancellation of speakers and/or topics and/or the alteration of the dates of the event should the need arise.

## CONTACT

For enquiries, please email to [secretariat@ammi.com.my](mailto:secretariat@ammi.com.my)

c/o Medsociate Sdn Bhd (HRDF Approved Training Provider - Registration No. 4195)

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