



# MMDA NEWSLETTER

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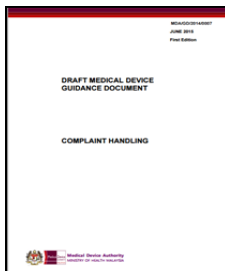
FOR CIRCULATION TO MMDA MEMBERS ONLY

Editor cum Secretary of MMDA: Ms. Ong Yean Ting

## PRESIDENT'S MESSAGE

## Medical Device Authority publishes new documents for PUBLIC COMMENT

The Medical Device Authority (MDA) has published three drafts Guidance Document for public comment. The guidances is to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.



This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

- a) Medical Device Act 2012 (Act 737);
- b) Medical Device Regulations 2012

The guidances are:-

### Field Safety Action Complaint Handling; and Distribution Record.

MMDA had collated the industry's responses and feedback to the MDA for discussion. The final guidances will be published by the MDA.

*With a blink of an eye, we have past the half-way mark of 2015. Welcome to all members to our newsletter.*

*As you are aware, on the 30th June 2015, the Medical Device Authority has announced an extension of one year for the registration of medical devices as per the Medical Device Act 737. You have played an important part in enabling MMDA's proactive approach of engaging with the authorities throughout 2014.*

*As we move into the second half of 2015, the MMDA committee members would like to take this opportunity to continue to update all its members on the latest happenings.*

*Yong Tuan Heng  
PRESIDENT*

## Our New Office

Visitor Area



Pantry



Front Area



Conference Room



## What is Happening?

20th AHWP Annual Meeting will be held at **Dusit Thani Hotel, Bangkok, Thailand** during **3 - 6 November 2015**.

This is a 4-days event, which composed of workshops, the 19th AHWP Technical Committee (TC) Meeting and the 20th AHWP Meeting. The tentative event agenda will be announced at the AHWP website soon.

**2015 APEC Business Ethics Forum**  
Sofitel Philippine Plaza | 19-20 August 2015 | Manila, Philippines

The Forum will convene senior leaders from healthcare industry associations and companies, healthcare professional organizations and patient groups, governments, and other important stakeholders from Malaysia and throughout the APEC (Asia-Pacific Economic Cooperation) region

“Change isn’t a prediction, it is happening”



## What is Changing?

These are some of the changes we can look forward to at MMDA!

### Office Relocation

Firstly, we have moved to Kelana Square.

### Why?

There is now a lot more space to conduct our activities. This includes conference room to hold training, visitor area, and also a pantry. All spaces are catered to different needs and can be used by our secretariat and any member may book the space for short term use.

# DID YOU KNOW ?

There is a Guide on Goods And Service Tax (Relief) Order 2014 & Goods And Service Tax (Relief) (Amendment) Order 2015, Item 6, First Schedule – GST Relief on Medical Equipment for Private Healthcare Facilities Registered or Licensed under the Private Healthcare Facilities and Services Act 1998 (Act 586) GST exemption order for Medical devices published by the Royal Customs of Malaysia.

### Which Medical Equipment are included in the relief order?

The list of equipment can be found in the following 2 links  
[http://gst.customs.gov.my/en/rg/SiteAssets/gst\\_order/MEDICAL%20EQUIPMENT%20LIST%20-%20Item%206%20GST%20Relief%20Order%202014.pdf](http://gst.customs.gov.my/en/rg/SiteAssets/gst_order/MEDICAL%20EQUIPMENT%20LIST%20-%20Item%206%20GST%20Relief%20Order%202014.pdf)

[http://gst.customs.gov.my/ms/rg/SiteAssets/gst\\_order/Medical%20Equipment%20list%20for%20GST%2028relief%29%20Hemodialysis%2028disposable%29.pdf](http://gst.customs.gov.my/ms/rg/SiteAssets/gst_order/Medical%20Equipment%20list%20for%20GST%2028relief%29%20Hemodialysis%2028disposable%29.pdf)

### Where can you find more information?

Please go to the official website of the Royal Malaysian Customs Department on Malaysia Goods & Services Tax:  
[http://gst.customs.gov.my/en/rg/Pages/re\\_odr.aspx](http://gst.customs.gov.my/en/rg/Pages/re_odr.aspx)