Philippine Association of Medical Device

PAMDRAP

Regulatory Affairs Professionals

In cooperation with:

USAID FROM THE AMERICAN PEOPLE

FDA Food and Drug Administration PHILIPPINES

MEDICAL DEVICES REGULATORY HARMONIZATION WORKSHOP

CRIMSON HOTEL, MUNTINLUPA,
MANILA, The PHILIPPINES
18 - 19 June 2015

MEDICAL DEVICES REGULATORY HARMONIZATION WORKSHOP

EXPERT SPEAKER LINE UP

JENNIFER CONCEPCION	Medtronic International Ltd. SINGAPORE	- Senior Regulatory and Quality Affairs Manager, ASEAN
MICHAEL FLOOD	Locus Consulting Pty Ltd AUSTRALIA	- Principal - Alumni of Australia's TGA
ALFRED KWEK	Samsung SINGAPORE	- Director, Regulatory Affairs, South East Asia and Oceania - Alumni of Singapore's HSA
STUART PORTNOY	Medical Devices Biologic Consulting Group UNITED STATES	- Senior Consultant - Former U.S. FDA Regulator
MIANG TANAKASEMSUB	Alcon Laboratories Ltd THAILAND	- Area Head of Regulatory Affairs, Asia & Russia
SUMATI RANDEO	Abbott Laboratories INDIA & SINGAPORE	- Associate Director, Regulatory Strategy and Advocacy
ED WOO	Varian Medical Systems Pacific, Inc HONG KONG	- Director, Regulatory Affairs, APAC
MA. CECILIA MATIENZO	FDA-Center for Device Regulation, Radiation Health and Research The PHILIPPINES	- Chief , Product Licensing and Registration Division
CAROLE CAREY	C3-Carey Consultants,LCC UNITED STATES	- Independent Consultant - Alumni of US FDA

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ANTICIPATED TRAINERS ARE DETAILED ABOVE, BUT SOME NEED TO BE CONFIRMED

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DAY 1 AGENDA

8:00 **Registration**

9:00-9:30 **Welcome Remarks**
by Ms. Johanna Gulle, PAMDRAP President

Opening Remarks
by Ms. Agnette P. Peralta, Director IV, Center for Device Regulation, Radiation Health and Research Food and Drug Administration, Department of Health, the Philippines (TBC)

Introductions & Logistics
by Michael Flood

9:30 –10:40 **SESSION 1. *The Big Picture – How it all fits together***

- Elements of the product life cycle
- Relationship and relevance to the SG documents
- Roles and Responsibilities
  - Regulatory Authority (RA)
  - Manufacturers
  - Authorized Representatives
- Broad overview of the elements
  - Quality Management Systems (QMS)
  - Pre-market evaluation
  - Post-market Surveillance and Vigilance
  - Phased introduction of the framework
  - The Declaration of Conformity

10:40 – 11:00 **Coffee Break and Group Photo**

11: 00–12:15 **SESSION 2. *Definition of A Medical Device***

- What it is / What it is not?
- Combination Products
  - Devices
  - Biologics & Medicinal Products
  - Personal Protective Equipment (PPE)

12:15 –13:00 **Lunch Break**

13:00 –14:30 **SESSION 3. *Clinical Evidence***

- What is it?
- What is appropriate (linked to device classification)?
- Clinical Evidence, not necessarily Clinical Data
- The Clinical Expert Report?

14:30 –15:00 **Coffee Break**

15:00 –16:30 **SESSION 4**

Classification of Medical Devices

- Why Classify
- The Classification Rules

Labeling

- General Labeling Provisions
- Medical Devices for Processing, repacking or manufacturing principle
- Medical Devices for Processing, repacking or manufacturing
- New Update : UDI

16:30 **Panel Q & A – Speakers of the Day**

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DAY 2 AGENDA

9:00 –10:30 SESSION 1. The Common Submission Dossier Template (CSDT)

- Main sections of the CSDT
- Sample of a CSDT For Medical Device Registration
- Examples of Supporting Documents

10:30 – 11:00 Coffee Break

11: 00–12:15 SESSION 2. Good Distribution Practice

- What is it?
- Who needs it?
- Where is it applied?
- When is it needed?
- Technical aspects of GDP

12:15 – 13:00 Lunch Break

13:00 –14:30 SESSION 3.

Post-market Programs

- Importance of Post-market Surveillance
- Post market and the product life cycle
- What is post-market monitoring?
  - Reactive
  - Proactive
- Implementation plan for post-market programs
- Post-market monitoring in a global context

14:30 –15:00 Coffee Break

15:00 –16:30 SESSION 4 Implementation of the ASEAN MDD in the Philippines

16:30 -17:00 Wrap Up of Workshop

Open Q & A session
- for any topics covered in the workshop; and
- any general questions relating the ASEAN MDD and regulation of medical devices

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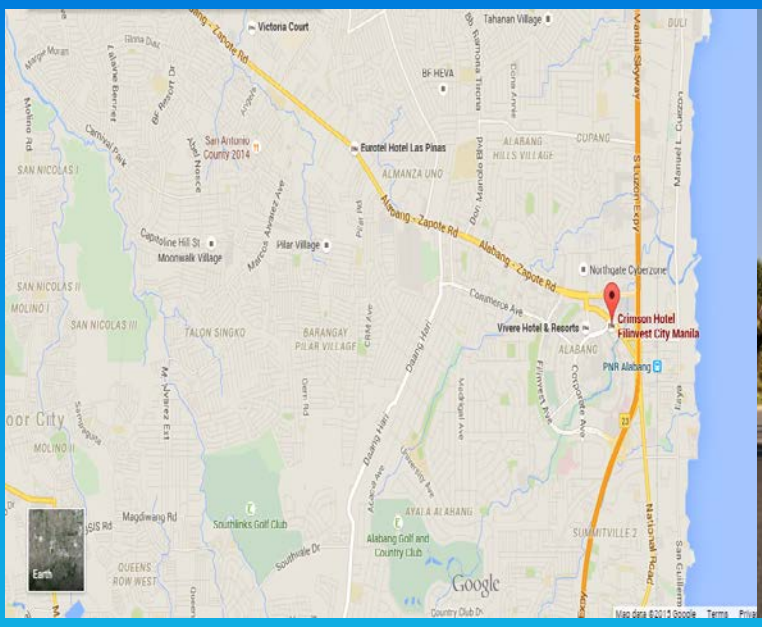
VENUE



Crimson Hotel Filinvest City
Address: Entrata Urban Complex, Filinvest City,
2609 Civic Drive, Muntinlupa, 1781
Metro Manila

For hotel accommodation please contact:
Toni Rose Tuico
Events Manager
Email:alabang.eventsmgr2@crimsonhotel.com
Tel: 63 2 8632222 loc 1203
Fax: 63 2 8632209

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REGISTRATION DETAILS

REGISTRATION FEES:

PAMDRAP Members : **Php 5,000.00**
Non-PAMDRAP : **Php 7,000.00**
Foreign Delegates : **USD 200**

Fee is for one participant and includes AM, PM snack and buffet lunch.

PAYMENT DETAILS:

Account name:
Philippine Association of Medical Device Regulatory Affairs Professionals Inc.
(Note: Please reflect full name of association)

Bank Name : **Banco De Oro**
Branch : **ADB Avenue Ortigas**
Savings Account No. : **4640-1050-21**
Swift Code : **BNORPHMM**
Address : **Ground Floor, Robinsons Equitable Tower, ADB Avenue, Ortigas Center, Pasig City, Philippines**

Bank transfer fees should be shouldered by the participant.

Please e-mail copy of filled-in registration form and deposit slip / proof of payment to **actiworkshop@pamdrap.org**

Deadline of Registration and Payment: **JUNE 11, 2015**

An acknowledgement reply will be sent to you to confirm your attendance and guaranteed slot. Kindly bring the confirmation from PAMDRAP during the event for the release of Official Receipt.

STRICTLY NO ONSITE REGISTRATION AND NO ONSITE PAYMENT

For inquiries and further information, please e-mail actiworkshop@pamdrap.org or call:

Charmaine Roson +639178218511
Julie Odarbe +639175596417

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R E G I S T R A T I O N F O R M

LAST NAME	GIVEN NAME	MIDDLE NAME

DESIGNATION/TITLE	PROFESSION/EDUCATIONAL ATTAINMENT

NAME OF COMPANY	COUNTRY

COMPANY ADDRESS

COMPANY ACTIVITY

☐ IMPORTER	☐ TRADER	☐ MANUFACTURER
☐ DISTRIBUTOR	☐ REPACKER	☐ WHOLESALER
☐ OTHERS, pls. specify		

For foreign delegates, pls. tick box for food preference:

☐ Vegetarian	☐ Halal	☐ None

SIGNATURE