Update on AHWP Work

September 2016
Expansion of AHWP Member Economies

- 26 member economies as of September 2016
- 4 new member applications from Africa and Middle-East
AHWP’s Global Partnership

Collaborating International Organizations & International Associations of Industry
Ongoing Participation in IMDRF MC Meetings and Working Groups

Towards Regulatory Convergence

Adverse Event Terminology

RPS

MDSAP, etc.
AHWP Meetings & Activities

**AHWP Meetings**
- AHWP TC Leaders Meeting, April 2016, Korea
- International Workshop on Regulatory Harmonization of Medical Devices, Feb 2016, Korea
- The 2\textsuperscript{nd} International Medical Device Communication Forum, June 2016, Korea

**Co-operation with International Organizations**
- Asia Pacific Health Care Summit, April 2016, Singapore
- WHO Inter-Country Meeting on Designing & Implementing Regulatory Program for Medical Device, April 2016, Saudi Arabia
- OECD Meeting of International Organizations & Regulatory Policy Committee, April 2016, France
Collaboration with OECD

Co-operative Work with OECD Regulatory Policy Committee

- Draft: OECD Report of International Regulatory Co-operation
- Presentation: AHWP Experiences in Regulatory Harmonization
- Case Study: International Regulatory Co-operation in Medical Device Field
Regulatory Harmonization

Lists of Working Documents for Regulatory Framework in 2016

**WG1**
- Qualification of Combination Products and Technical Requirements for Pre-market Submission
- Good Review Practice
- Approval of Medical Devices Manufactured using 3D Printers
- Minor Change Reporting

**WG2**
- Conformity Assessment for IVD

**WG3**
- Medical Device Software - Qualification and Classification

**WG4**
- Adverse Events Reporting Details for Specific Devices
- Guidance Documents on Safety Alert Dissemination System

**WG7**
- Medical Device Quality Management System - Requirements for Distributors
**AHWP Capacity Building Project(1)**

**Objectives**

- Provide guidance to AHWP member economies to develop medical device regulatory framework
- Promote better understanding of international best practices towards regulatory harmonization

**CBP based on the AHWP Playbook**

- **Legislative Controls**
- **Manpower & Resources**
- **Implementation – Phased in Approach**
- **Post-Market Considerations**
- **Pre-Market Essential Principles**
- **Clinical Studies & Evaluation**

Bring it together with international collaboration & partnership

Reduce the administrative costs of re-inventing the medical device regulatory framework
AHWP Capacity Building Project

2015

Initial kick-off
AHWP Annual Meeting
Nov 2 – 3
Thailand

2016

1st In-country Training
July 28- 29
Indonesia

2nd In-country Training
August 25 – 26
Vietnam

2017

Phase II
• Build Curricula
• Develop Competency Assessment Tools

Workshop
AHWP Annual Meeting
Nov 21 – 22
Philippines
1\textsuperscript{st} In-Country Capacity Building Training
- Bandung, Indonesia, July 28 – 29, 2016
- 50 Indonesia Ministry of Health officers
- 20 experts from industry and academia
- AHWP’s CSDT, Essential principles of safety and performance, Clinical studies

2\textsuperscript{nd} In-Country Capacity Building Training
- 50 Vietnam Ministry of Health officers, experts from industry and academia
- Classification of medical devices & IVD, Pre-market approval, Post-market surveillance
Upcoming AHWP Annual Meeting

- Date: Nov 21-25, 2016
- Venue: Radisson Blu Hotel, Cebu, Philippines
- Program:
  - AHWP Annual Meeting, Working Group Meetings
  - Capacity Building Workshops
  - Reports from Collaborating International Organizations, etc.
- Registration Website: http://pamdrap.org/AHWP2016
Thank you !