Update on AHWP Work

March 2016
Mongolia and Kazakhstan newly joined the AHWP.
AHWP consists of 26 member economies as of Nov 2015.
AHWP Annual Meeting in Bangkok (2-6 Nov 2015)

- **241 delegates**
  - 40 delegates from government authorities
  - 201 industrial delegates
- **28 countries**
  - from Africa, America, Asia-Pacific, Europe, Middle East
- **9 other international organizations’ representatives**
- **36 speakers**
- **12 endorsed AHWP guidance documents**
- **11 main themes & 6 panel discussion sessions**
- **2 new member economies**

- AHWP Playbook Workshop
- AHWP TC Workshop
- AHWP-DITTA Joint Workshop
- 19th AHWP TC Meeting
- 20th AHWP Annual Meeting
Enhance Global Partnership

- Participating International Organizations in the AHWP Annual Meeting: APEC, ASEAN, IEC, IMDRF, PAHWP, WHO, etc.

- Network with International Associations of Industry of Medical Devices: APAC Med, DITTA, GS1

Unmet Needs in AP

International Organizations

- APEC
- ASEAN
- IEC/ISO
- IMDRF
- PAHWP
- WHO etc..

Associations Industry

- APAC Med
- DITTA
- GMTA
- GS1

### New 12 AHWP Guidance Documents

- Clinical Evaluation
- Clinical Evidence for Medical Device – Key Definitions and Concepts
- Clinical Evidence for IVD Medical Device – Key Definitions and Concept
- Clinical Evidence for IVD Medical Device – Scientific Validity Determination and Performance Evaluation
- Distributor Auditing Checklist
- Regulatory Auditing of Quality Management System of Medical Device Distributions: Auditing Strategies
- Regulatory Audit Report
- Medical Device Naming Rule
Capacity Building on the Foundation of AHWP Playbook

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

www.ahwp.info
AHWP Capacity Building Project

**Phase I - On-going for the term 2015-2017**

- Kick-off workshop based on ‘AHWP Playbook’ was held in Nov 2015
- 50,000 USD was approved as seed money

**In-country Trainings:** 2 or 3 AHWP member economies annually

**Training Workshops:** AHWP Annual Meeting in 2016 & 2017

**Phase II - Planning in progress**

- Develop Handbook and Build Curricula: Target for 2017
- Develop Competency Assessment Tools: Collaborative efforts
Collaboration with IMDRF

- Continuous Participation in IMDRF MC Meetings and Working Groups
Upcoming Meetings

AHWP TC Leaders Meeting & AHWP Regulators Forum
- Date / Location: 28~29, April / Seoul, Korea
- AHWP Technical Committee Leaders Meeting
- AHWP Regulators Forum

21th AHWP Annual Meeting
- Date / Location: 5 days, November (TBD) / Philippine
- Annual Meeting of 26 Member Economies
- Technical Committee Meeting of 9 Working Groups
- Workshops for Regulatory Capacity Building
- Joint Workshops with International Organizations on Special Topics
20th AHWP Annual Meeting on Nov 2-6, 2015

Thank you!