Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

REPORT HIGHLIGHTS

Ali Aldalaan. MBA

Chair, AHWP Technical Committee
Executive Director SFDA Medical Devices

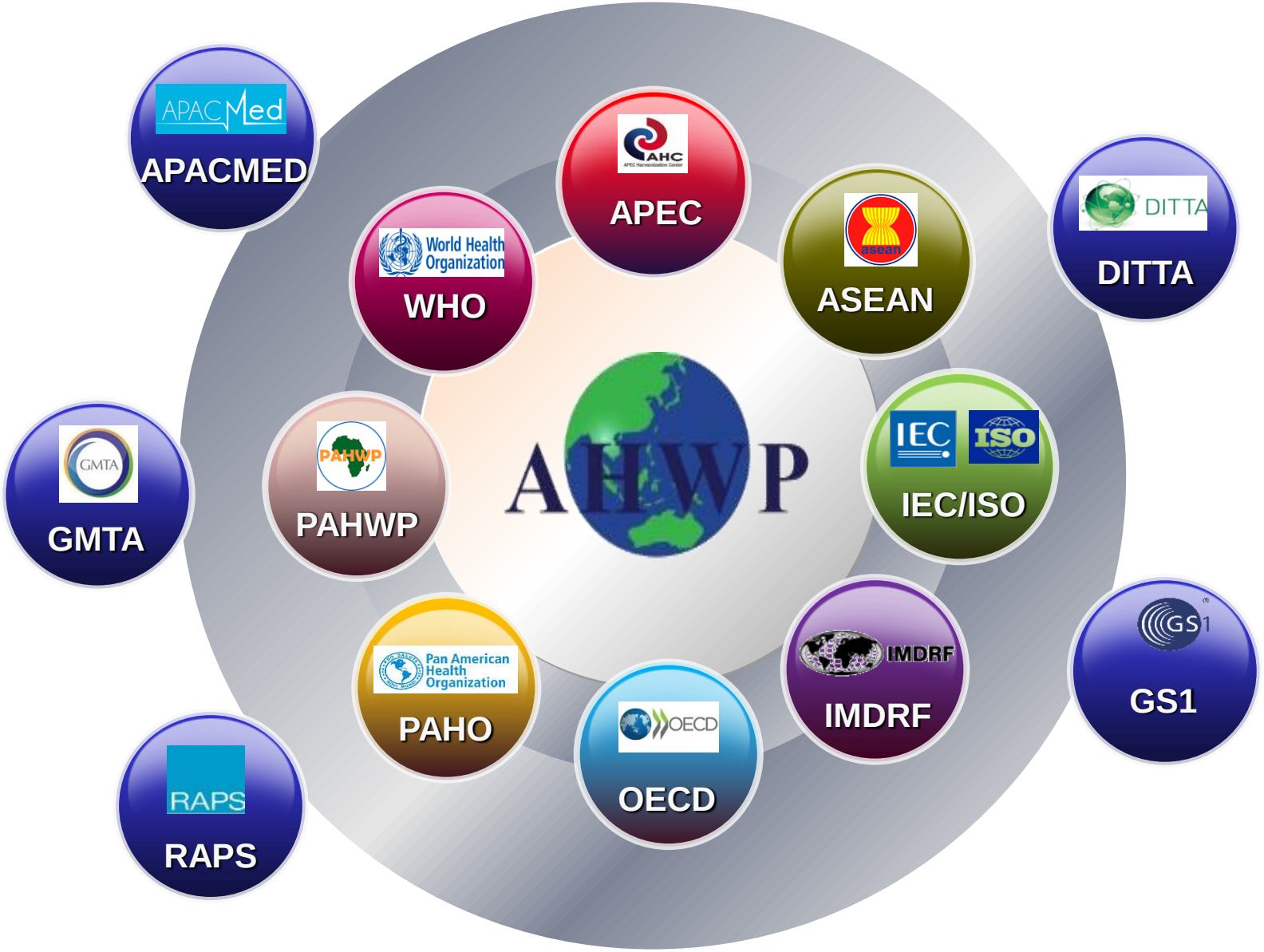
The 21st AHWP and 20th AHWP Technical Committee (TC) Meeting annual meting.
21- 25th -29th , 2016 . Cebu ,Philippine

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

TC TEAM

TC Office Bearers	Positions
Chair **Co-Chair** **Co-Chair** **Secretary**	Mr Ali M Al-Dalaan Dr Jeong-Rim Lee Mr Alfred Kwek Mr Jack Wong Ms Chadaporn Tanakasemsub (Miang)
Work Groups	**Positions**
WG1: Pre-market	Chair - Mr. Essam Mohammed Al Mohandis Co-Chair – Ms. Kate Hyeong Joo Kim
WG2: Pre-market - IVDD	Chair - Mr. Wen-Wei TSAI Co-Chair – Ir. Albert POON
WG3: Pre-market - Software as a Medical Device	Chair - Dr. Rama SETHURAMAN Co-Chair - Mr Tony Yip
WG4: Post-market Scope includes post-market aspect of WG 1-3 device categories	Chair - Ms. Jennifer MAK Co-Chair – Ms Kitty Mao
WG5: Clinical Evidence for performance & safety	Chair - Ms. Yuwadee PATANAWONG Co-Chair - Ms. Sumati Randeo
WG6: Quality Management Systems: Audit & assessment	Chair - Mr. Abdullah AL RASHEED Co-Chair - Ms. Shirley SUM
WG7: Quality Management Systems: Operation & implementation	Chair - Ms. Aidahwaty M.Olaybal Co-Chair - Mr. Ee Bin Liew
WG8: Standards	Chair - Ms. Maria Cecilia MATIENZO Co-Chair – Mr Tony Low
STC (UDI & Nomenclature)	Chair - Mr. LI Jun Co-Chair – Ms Carol Yan

Collaborating International Organizations & International Associations of Industry


APACMED
APEC
ASEAN
DITTA
WHO
GMTA
PAHWP
AHWP
IEC/ISO
IMDRF
GS1
PAHO
OECD
RAPS

TC CO-OPERATION WITH INTERNATIONAL ORGANIZATIONS:

- ISO TC 210 Nov 15-20 ,2015 review ISO 13485-2016 FD and handbook Seattle,USA AHWP TC was participated.
- 9th MDRIF Meeting March 7 – 11, 2016 Brasilia, Brazil.TC Co-Chair presented AHWP TC report.
- Asia Pacific Health Care Summit 2016, April 7-8 ,2016 Singapore TC Chair was a speak .
- WHO Inter-Country Meeting on Designing & Implementing Regulatory Program For MD, April 11-14, 2016 Hosted by SFDA. Riyadh, KSA . Joanna presented AHWP TC (Playbook)

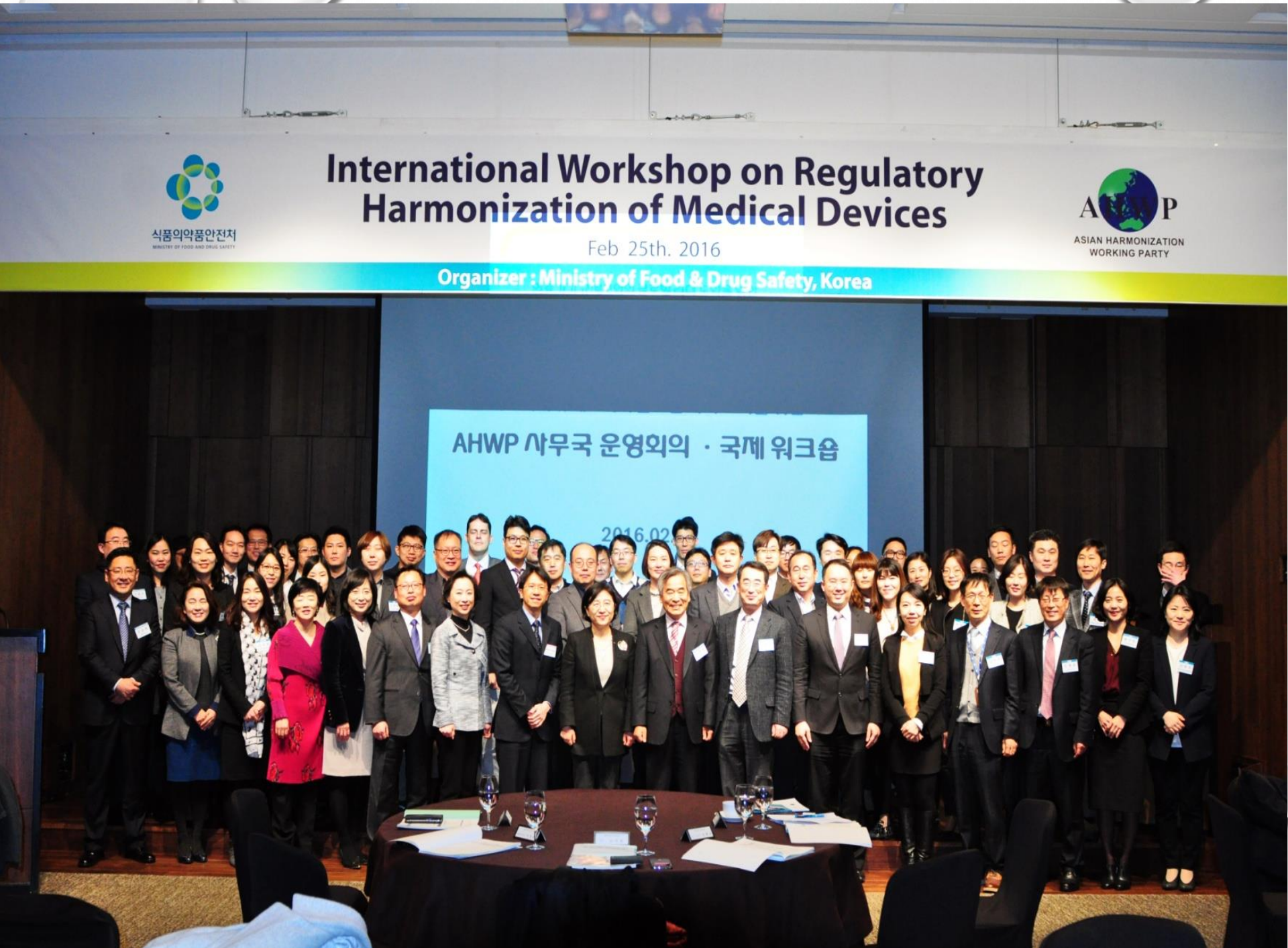
TC Co-operation with International Organizations:

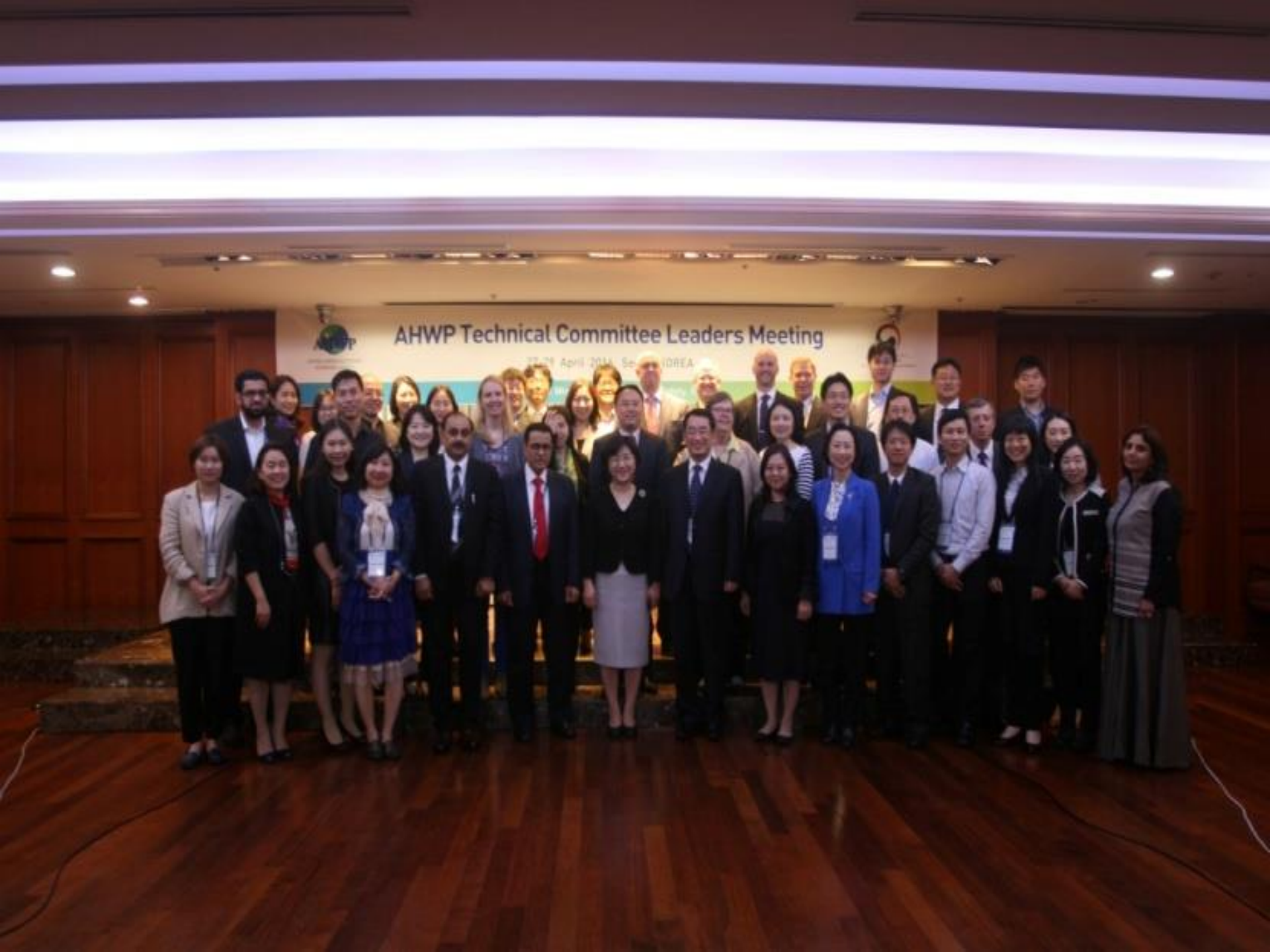
- OECD Meeting of International Organizations & Regulatory Policy Committee, April 11-15, 2016, Paris, France. TC Co-Chair presented AHWP.
- APEC RHSC Workshop of Medical Device Vigilance .Sept 5, 2016, Seoul, Korea.WG4 Chair

- 10th IMDFR Meeting, Sept 13 – 15, 2016, Florianopolis, Brazil.
  TC Co-Chair presented TC activities.
- RAPS Regulatory Convergence, Sept 17-20, 2016, San Jose, USA.
  TC Chair was a speaker.

TC Meeting and activities

- International Workshop on Regulatory Harmonization of Medical Devices, Feb 2016, Korea
- AHWP TC Leaders Meeting, April 2016, Korea. 27-28 April 2016, Seoul, Korea
- AHWP Regulators Forum 29 APRIL 2016 ,Seoul, Korea
- The 2nd International Medical Device Communication Forum, June 2016, Korea
- Manage and organize AHWP annual meeting activities


식품의약품안전처
MINISTRY OF FOOD AND DRUG SAFETY
International Workshop on Regulatory Harmonization of Medical Devices
Feb 25th. 2016
AHWP
ASIAN HARMONIZATION WORKING PARTY
Organizer : Ministry of Food & Drug Safety, Korea
AHWP 사무국 운영회의 · 국제 워크숍
2016.02


AHWP Technical Committee Leaders Meeting

Summary of Future Plan and Developed Guidance Documents:

WG 1

- **Guidance on regulatory practices for Combination products (Target completion Nov 2016)**
- **Guidance for minor change reporting (target completion Nov 2016)**
- **E-labeling as an alternate method for compliance to labeling requirement (target completion date 2017)**

WG2

- **Guidance Document for Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device' (target endorsement Non 2016)**
- **Guidance Document for Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Devices (target endorsement Nov 2016)**
- **Guidance Document for Conformity Assessment for IVDs (target endorsement Nov 2016)**
- **Guidance Document for Classification of IVDs (target endorsement Nov 2016)**
- **Guidance Document for In Vitro Companion Diagnostic Devices (target endorsement Nov 2017)**

WG3

- **Risk Categorisation of SaMD (For endorsement Nov 2016)**
- **White paper on Pre-market Submission requirements for SaMD (Q4 2016 first draft)**

WG4

- **Review and update the existing WG4 guidance documents on Adverse Events (AE) Reporting .**
- **Develop guidelines on Adverse Events (AE) reporting for PCI devices (target endorsement Q4 2016)**
- **Review and update the existing WG4 guidance documents on SADS**
- **Develop Post-market Resource Centre**

WG5

- Global Clinical Regulatory updates & collaboration with International standards bodies like ISO 14155 with regards to developing new guidance documents. Following were shared and accomplished in 2016
  - ISO 14155 TC Gap Analysis with ICH GCP and ISO 13485:2016
  - Updates on APAC New Regulations
  - Updates on IMDRF WG on software clinical evaluation

WG 5 has arranged training workshop on Clinical Evaluation in Annual AHWP meeting Nov 22nd 2016 in Cebu, Philippines which will cover guidance documents training.

➢WG5

- DRAFT GUIDANCE DOCUMENT ON "GENERAL PRINCIPLES OF CLINICAL INVESTIGATION AUDIT & INSPECTION" PREPARED IN SUPPORT WITH ISO 14155 TECHNICAL COMMITTEE. THE DRAFT GUIDANCE UNDER REVIEW BY WG 5 MEMBERS TARGET ENDORSEMENT Q4 2017 .

➢WG 5 MEMBERS REVIEWED AND SUPPORTED ADOPTION AND ENDORSEMENT OF FOLLOWING GHTF GUIDANCE DOCUMENTS IN 2017:

- CLINICAL INVESTIGATIONS
- POST - MARKET CLINICAL FOLLOW UP STUDIES

WG6

- SUBMIT THE IMDRF DOCUMENTS (N3, N4, N11, N22) FOR COMMENTS AS DRAFT PROPOSED DOCUMENTS FOR AHWP (TARGET ENDORSEMENT NOV 2017)
- ALIGNING WG6 DOCUMENTS WITH WG7 DOCUMENTS

WG7

- COMPLETE SURVEY FOR GUIDANCE DOCUMENT ADOPTION
- UPDATE GUIDANCE ON MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM - REQUIREMENTS FOR DISTRIBUTORS

WG8

- **Create List of Recognised Standards used in AHWP member economies Phase 1 Revised Draft December 2016. Phase 2 Q3 2017 – Draft.**

Playbook Training

- **Systematic Coverage of AHWP Playbook Chapter Topics**
- **E.g. Steps to Legislation Development, Manpower Planning, etc**
- **Key Features: In-Country (Indonesia and Vietnam) + Hands-on Case studies**
- **21/22 Nov: PB topics + Cybersecurity, Product Liability, IT requirements**
- **Value add to Emerging Economies implementation regulations**

STG - UDI and Nomenclature

- **Understand status of UDI development in IMDRF**
- **International collaboration to learn implementation challenges**
- **STG provide regional support to Member Economies**
- **Country specific pilot and research – feasibility study for selected product types in 2017**

TC WG Work Items
- Proposed work items for endorsement

WG1 Document on "Guidance on Regulatory Practices for Combination Products"

WG1 Document on " Guidance for Minor Change Reporting"

WG2

- **Guidance Document for Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'**

- **Guidance Document for Classification of IVDs**

- **Guidance Document for IVD Common Template for a Submission Dossier.**

- **Guidance Document for Conformity Assessment for IVDs.**

WG3

- **RISK CATEGORISATION OF SAMD (FOR ENDORSEMENT NOV 2016)**

- WG4 DOCUMENT ON "GUIDELINES FOR ADVERSE EVENT REPORTING OF PERCUTANEOUS CORONARY INTERVENTION (PCI) DEVICES1 FOR THE MEDICAL DEVICE MANUFACTURER OR ITS AUTHORIZED REPRESENTATIVE“
- WG7 GUIDANCE DOCUMENT – QUALITY MANAGEMENT SYSTEMS REQUIREMENTS FOR DISTRIBUTORS / IMPORTERS / AUTHORIZED REPRESENTATIVES (REVISION)

Thank You