Update on AHWP Activity

IMDRF Stakeholders Forum
16 Sep 2015
Asian Harmonization Working Party (AHWP)

24 Member Economies
in Asia, Africa, Middle-East, Latin America

AHWP Organization Structure

AHWP
Chair (Hee-Kyo Jeong, MFDS)
Vice-chair (Zamane B.A. Rahman, MOH)
Vice-chair (Quan Tran, GE)

Secretariat Team
Administration Services Ltd. (ASL)
Advisory Panel to TC

Technical Committee (TC)
TC Chair (Ali M. Al-Daalan, SFDA)
TC Co-chair (Jeong-Rim Lee, MFDS)
TC Co-chair (Alfred Kwek, Samsung)

Working Groups (WGs) & Special Task Group (STG)

WG 1 Pre-market: General MD
WG 2 Pre-market: IVDD
WG 3 Pre-market: Software as a Medical Device
WG 4 Post-market
WG 5 Clinical Performance & Safety

WG 6 Quality Management System: Audit & Assessment
WG 7 Quality Management System: Operation & Implementation
WG 8 Standards
WG 9 Training
STG UDI & Nomenclature
Development and Implementation of AHWP Guidelines

- 11 Guideline Documents will be endorsed on 20th AHWP Annual Meeting in November 2015

AHWP Working Group Activities
AHWP Training & Capacity Building

- Regulatory Controls
- Legislation and Policy Framework
- Phased Implementation of Regulatory Framework

AHWP Member Economy
- Training & Capacity Building
- Regulatory Harmonization on Regulations
Global Partnership

- Adopting AHWP Guidelines in collaboration with Global Partners

- GHTF, IMDRF
- WHO, PAHO, APEC

- Pre-Market
- Post-Market
- Standards

- Clinical Performance & Safety
- Quality Management System
- UDI & Nomenclature

on AHWP Playbook Training
## Highlight of Work Plans of AHWP TC WGs

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<th>Work Group</th>
<th>Work Items</th>
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| WG 1 – Pre-market: General MD | - CSDT (Common Submission Dossier Template)  
- Endorsement of Document in 2015  
  ※ Guidance on CSDT for General Medical Device  
  ※ White Paper on summary of Combination Product Guideline |
| WG 2 – Pre-market: IVDD      | - IVDD CSDT  
- Participating in ISO TC 212/WG3  
- Survey on IVD Regulation Status and Premarket Requirements  
- Endorsement of Document in 2015  
  ※ Guidance Document on MD/IVDD Definition |
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| **WG 3 – Pre-market: Software as a Medical Device** | - Risk Classification of MD Software  
- Endorsement of Document in 2015  
※ Guidance Document on Medical Device Software – Qualification and Classification |
| **WG 4 – Post-market** | - Conduct Survey on Post-Market Status  
- Endorsement of Document in 2015  
※ Safety Alert Dissemination System(SADS)  
※ Field Safety Correction Actions(FSCAs) |
| **WG 5 – Clinical Performance and Safety** | - Endorsement of Document in 2015  
※ Guidance Document on Clinical Definition & Key Concept for MD/IVDD  
※ Guidance Document on Clinical Evaluation for MD/IVDD  
※ Guidance Document on Clinical Evidence for MD/IVDD |
## Highlight of Work Plans of AHWP TC WGs (Cont.)

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| **WG 6 – Quality Management System: Audit & Assessment** | - Activate Audit Training Programs  
- Develop Auditing of SMEs  
- Endorsement of Document in 2015  
※ Guidance Document on Regulatory Auditing for Importer and Distributor |
| **WG 7 – Quality Management System: Operation & Implementation** | - Practical Adoption of WG 7 Guidance Documents  
- Promote Voice of AHWP in the Development of ISO Standards and IMDRF Guidance Documents |
| **WG 8 – Standards**                                | - Develop Guidance Documents on Roles and Application of Standards          |
| **STG – UDI & Nomenclature**                        | - Monitor Use of Medical Device Nomenclature and Implementation of UDI       |
Future Plan

- **Collaboration with IMDRF**
  - Continuous Participation in Working Group
    - Adverse Event, MDSAP and SaMD

- **Collaboration with International Partners**
  - Training with WHO, PAHO and APEC
    - Establish Regulatory Framework using AHWP Guidelines
    - Include non-Member Economies in Africa and Latin America Region
  - Joint Workshop with DITTA, GMTA and GS1
    - Collect Idea and Suggestion about AHWP Guidelines
    - Develop New Work Items
Upcoming AHWP Meeting in 2015

- **Date:** 2 - 6 November 2015
- **Venue:** Dusit Thani Hotel, Bangkok, Thailand

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| **Day 1** | Playbook Workshop (1)  
- Tool for Regulatory Convergence- The AHWP Playbook |
| **Day 2** | Playbook Workshop (2)  
- Tool for Regulatory Convergence- The AHWP Playbook |
| **Day 3** | AHWP Workshop  
- SW validation, Clinical Evaluation, Regulatory Updates, etc |
| **Day 4** | 19th AHWP Technical Committee (TC) Meeting  
- Work Group Updates  
- Highlight of Playbook Training |
| **Day 5** | 20th AHWP Annual Meeting  
- Updates by AHWP, APAC, ASEAN, IMDRF, WHO, etc  
- Countries Updates by AHWP Member Economies  
- Resolutions for Endorsing Working Group Documents |
Thank You