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)

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

- Advisory Panel to TC

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

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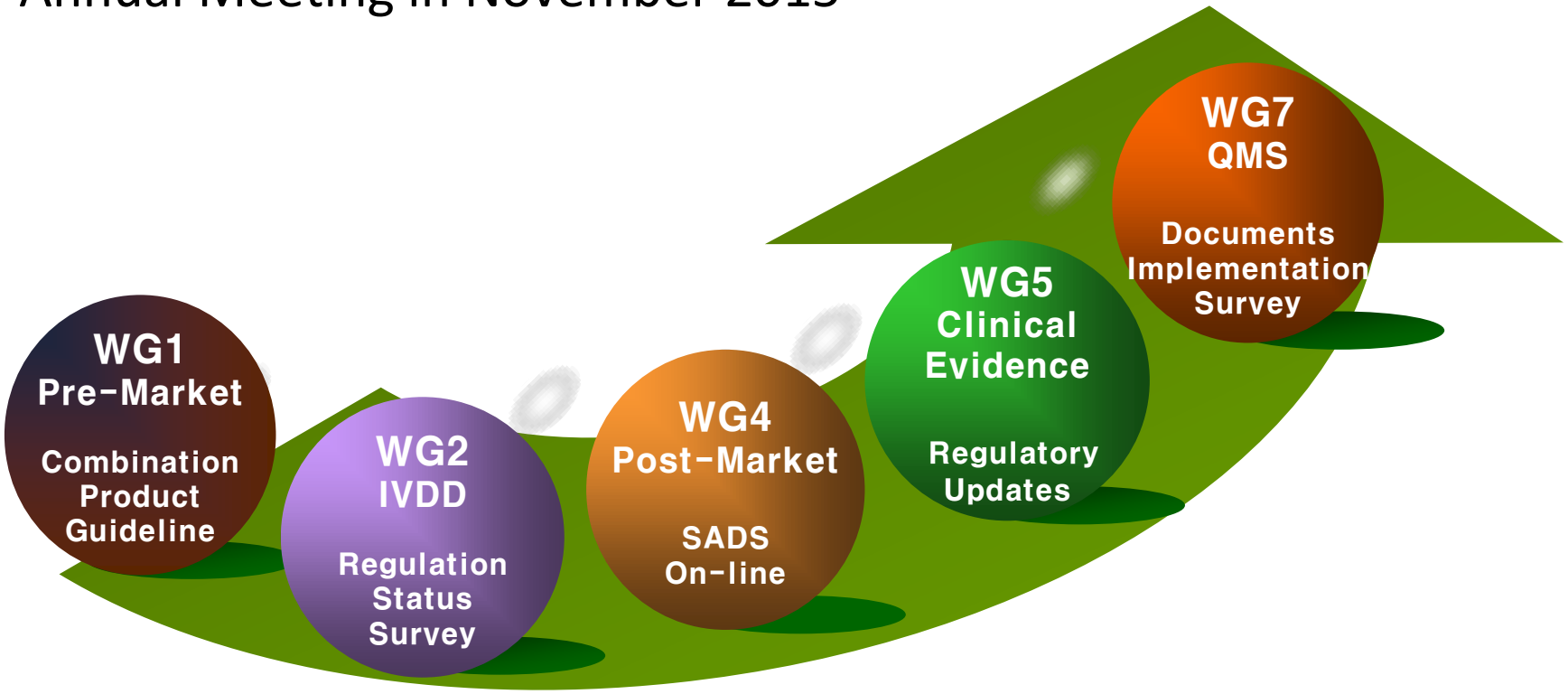
Development and Implementation of AHWP Guidelines

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



AHWP Working Group Activities

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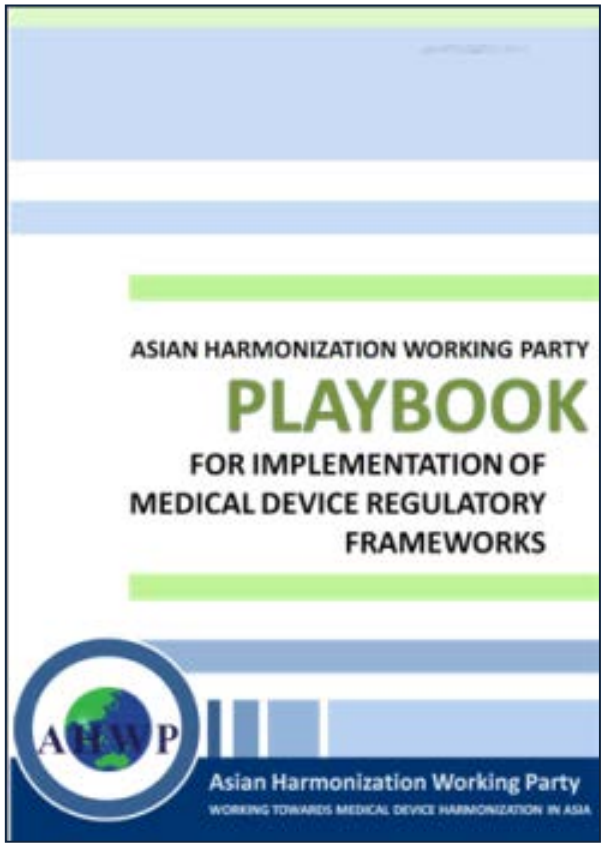
AHWP Training & Capacity Building



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

AHWP Member Economy

- Training & Capacity Building
- Regulatory Harmonization on Regulations

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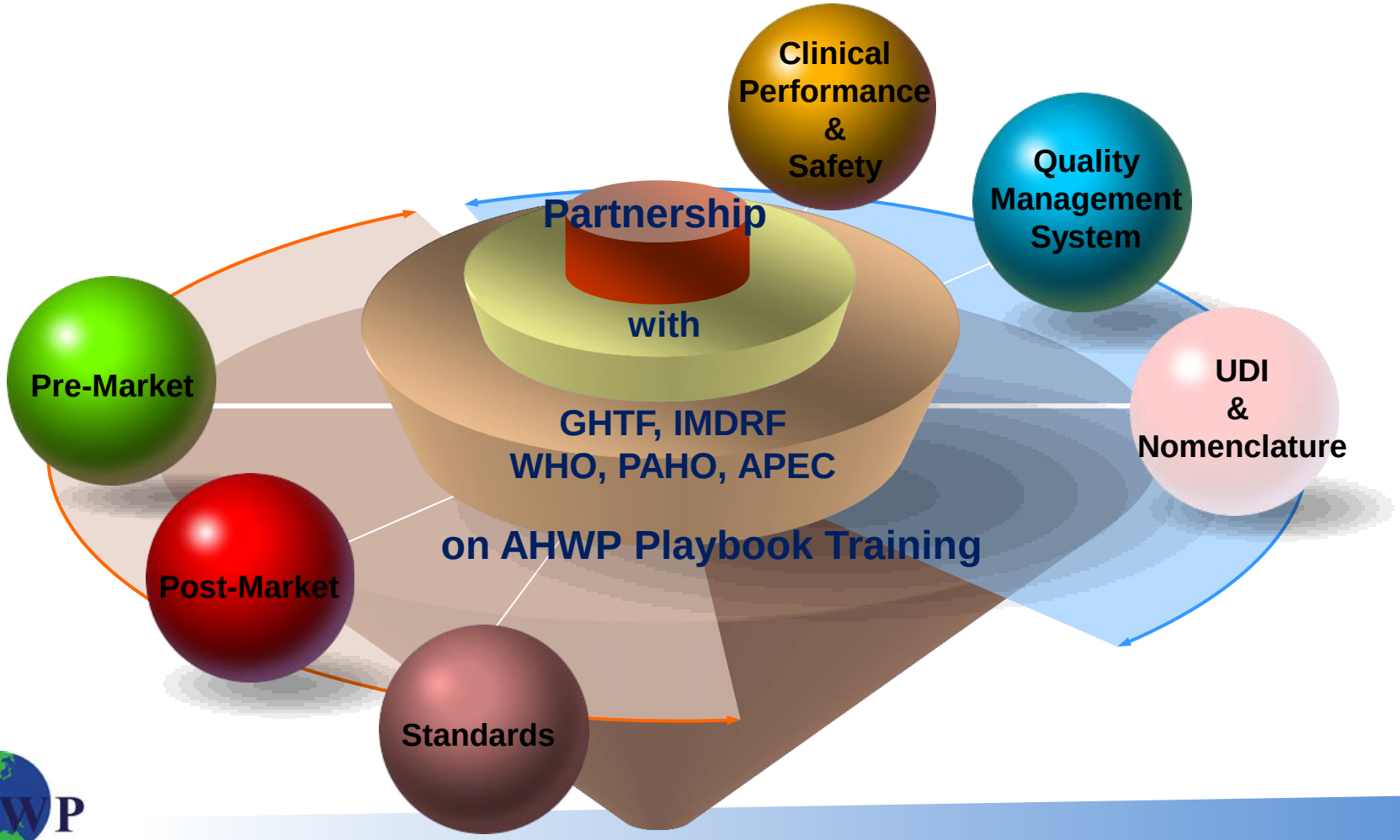
Global Partnership

- Adopting AHWP Guidelines in collaboration with Global Partners



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Highlight of Work Plans of AHWP TC WGs

Work Group	Work Items
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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Highlight of Work Plans of AHWP TC WGs (Cont.)

Work Group	Work Items
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

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Highlight of Work Plans of AHWP TC WGs (Cont.)

Work Group	Work Items
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

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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

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Upcoming AHWP Meeting in 2015

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

	Agenda
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

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Thank You

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