Introduction of AHWP

IMDRF Stakeholder Meeting

25 March 2015

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- Introduction of AHWP
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- Work plan of AHWP TC working groups

ASIAN HARMONIZATION WORKING PARTY

Asian Harmonization Working Party (AHWP)

Working Towards Medical Device Harmonization in Asia

Established as a **non-profit** organization formed in 1996-97.

Its goals are to **study and recommend ways to harmonize medical device regulations** in the Asian and other regions for **establishing harmonized requirements, procedures and standards.**

The Working Party is a group of experts from the medical device **regulatory authorities** and the medical device **industry**.

24 Member Economies (as of Jan 2015)

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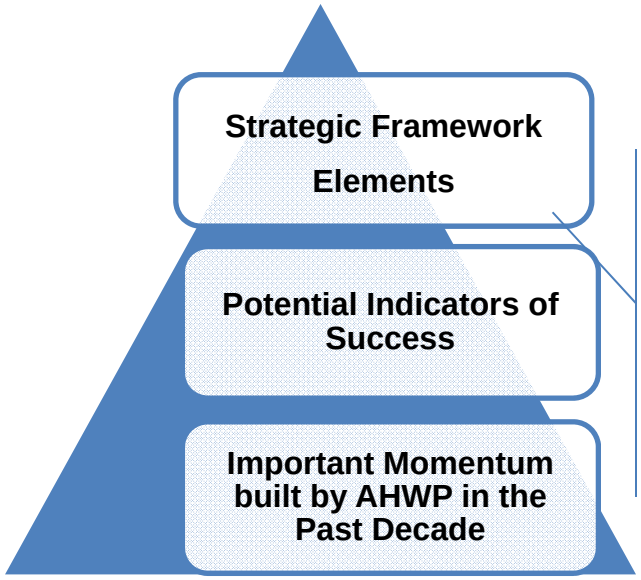
AHWP Strategic Framework towards 2020

The foreseeable Harmonization Horizon

- **AHWP Strategic Framework towards 2020 – The Foreseeable Harmonization Horizon**
- Adopted in the 18th AHWP Annual Meeting in Malaysia 2013



① Membership expansion
② Training and capacity building
③ Harmonization in Key Areas based on GHTF Principles and AHWP guidance
④ Enhance AHWP's Global Partnership

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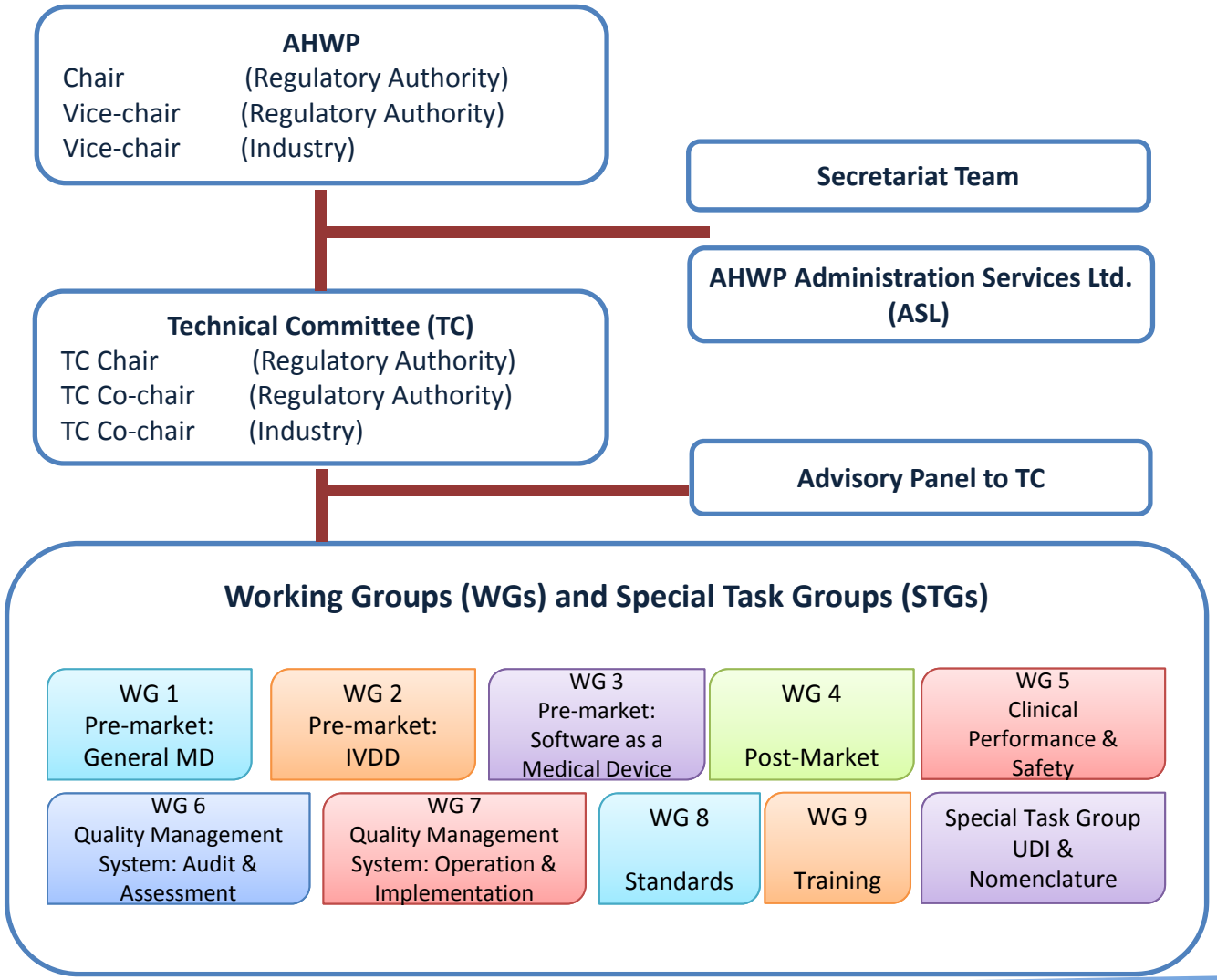
AHWP Organization Structure



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http://www.ahwp.info

AHWP and AHWP TC Leaders

for the term 2015-2017

AHWP Chair	Dr. Hee-Kyo Jeong Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety(MFDS), Republic of Korea
AHWP Vice-chair (Regulatory Authority)	Mr. Zamane Abdul Rahman Chief Executive, Medical Device Authority, Ministry of Health, Malaysia
AHWP Vice-chair (Industry)	Ms. Quan TRAN Vice President, Regulatory Affairs and Quality Assurance, APAC and Greater China, GE Healthcare Pte Ltd, Singapore
AHWP TC Chair	Mr. Ali M. Al-Dalaan Executive Director, Saudi Food and Drug Authority, Kingdom of Saudi Arabia
AHWP TC Co-chair (Regulatory Authority)	Dr. Jeong-Rim Lee Director, Cardiovascular Devices Division, Ministry of Food and Drug Safety (MFDS), Republic of Korea
AHWP TC Co-chair (Industry)	Mr. Alfred Kwek Regional Director, Government Affairs/HME, Samsung Electronics, Singapore

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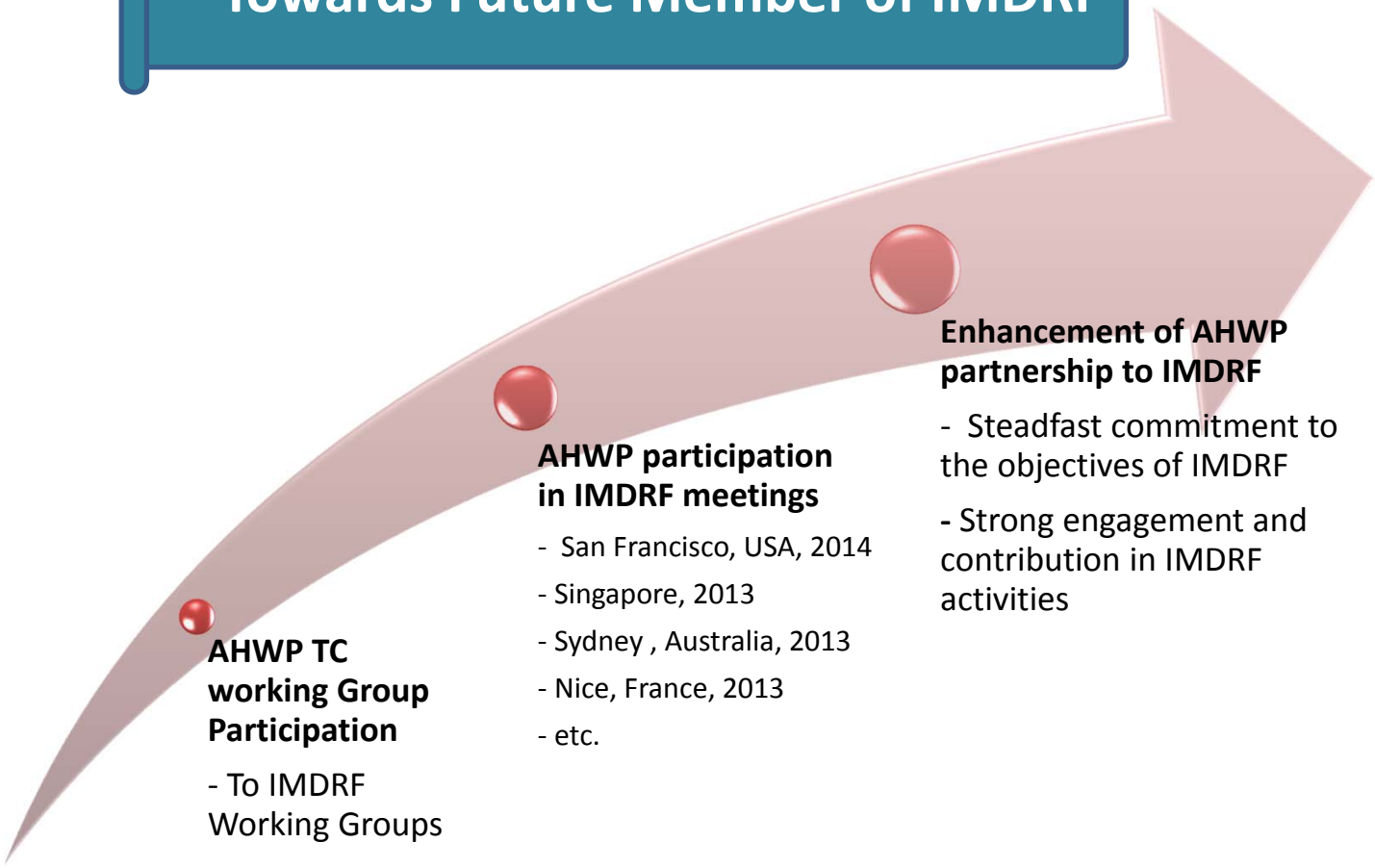
Collaborations with IMDRF

Towards Future Member of IMDRF



AHWP TC working Group Participation

- To IMDRF Working Groups

AHWP participation in IMDRF meetings

- San Francisco, USA, 2014
- Singapore, 2013
- Sydney , Australia, 2013
- Nice, France, 2013
- etc.

Enhancement of AHWP partnership to IMDRF

- Steadfast commitment to the objectives of IMDRF
- Strong engagement and contribution in IMDRF activities

AHWP is an affiliate organization of IMDRF since April 2012

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Collaborations with International Organizations

IMDRF International Medical Device Regulators Forum

AHWP is an affiliated organization of IMDRF.

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Collaborations with International Organizations (Cont.)

- Collaborations at TC Working Group level, e.g.:
  - ISO 13485/TC210 *(QMS)* – WG7: QMS - Audit & Assessment
  - ISO 14155/TC194 *(Clinical investigation)* – WG6: QMS - Operation & Implementation
  - Participation of nomenclature work at GMDN, IMDRF and WHO – STG: UDI & Nomenclature
  - PAHWP-LSHTM Joint Conference on IVDD on Sep 16, 2013 – WG2: Premarket - IVDD
- Organization of Joint conference/training workshops at AHWP annual meeting, e.g. (during the past 3 years):
  - AHC-AHWP Joint Workshop, Chinese Taipei, 2012
  - 1st AHWP-RAPS Joint Conference, Malaysia, 2013
  - AHC-AHWP Joint Workshop, Seoul, 2014
  - GS1 lunch Training Workshop, Seoul, 2014
- AHWP Liaison member: DITTA, GS1
- AHWP is an Affiliate Organization to IMDRF
- Leadership's report at WHO meetings

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Collaborations with International Organizations (Cont.)

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Highlight of Work Plans of AHWP TC WGs

for the term 2015-2017

Work Group	Work Items
WG 1 – Pre-market: General MD	- CSDT (Common Submission Dossier Template) - Grouping for pre-market submission - Combination products (MD) guidelines
WG 2 – Premarket: IVDD	- IVDD definitions and labeling - Classification and conformity assessment - Clinical evidence - Advertising and promotion
WG 3 – Pre-market: Software as a Medical Device	- Development of AHWP document on MD software qualification and classification - Risk Classification of MD software - Development of white paper on MD software
WG 4 – Post-market	- Review, update and develop WG 4 guidance documents - Conduct survey on post-market status

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

for the term 2015-2017

Work Group	Work Items
WG 5 – Clinical Performance and Safety	- Decide whether or not to adopt GCP standards - Establish appropriate AHWP guidelines on clinical performance/safety
WG 6 – Quality Management System: Audit & Assessment	- Activate audit training programs - Finalize the official auditing guidance for distributors - Develop auditing of SMEs
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 - Develop feedback mechanism to the work of WG 7
WG 8 – Standards	- Develop guidance documents on roles and application of standards - Awareness presentation on GHTF-SGI-n044 and pilot standard

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

for the term 2015-2017

Work Group	Work Items
WG 9 – Training	- Develop gap analysis and training plans to fit economies' needs - Develop trainer team locally in each economy
STG – Special Task Group on UDI & Nomenclature	- Promote and monitor the development of nomenclature - Promote and monitor the development of UDI

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Thank You

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