Introduction of AHWP

IMDRF Stakeholder Meeting
25 March 2015
Contents

• Introduction of AHWP
  – Goals
  – Strategic Framework
  – Organization structure of AHWP
  – Newly elected AHWP and AHWP TC Leaders for the term 2015-2017
  – Collaborations with IMDRF
  – Collaborations with international organizations

• Work plan of AHWP TC working groups
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)
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

Strategic Framework Elements:

- Membership expansion
- Training and capacity building
- Harmonization in Key Areas based on GHTF Principles and AHWP guidance
- Enhance AHWP’s Global Partnership

Potential Indicators of Success:

- Important Momentum built by AHWP in the Past Decade
AHWP Organization Structure

AHWP
Chair (Regulatory Authority)
Vice-chair (Regulatory Authority)
Vice-chair (Industry)

Technical Committee (TC)
TC Chair (Regulatory Authority)
TC Co-chair (Regulatory Authority)
TC Co-chair (Industry)

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

Working Groups (WGs) and Special Task Groups (STGs)
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
Special Task Group UDI & Nomenclature

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 |
Collaborations with IMDRF

Towards Future Member of IMDRF

AHWP is an affiliate organization of IMDRF since April 2012
Collaborations with International Organizations

AHWP is an affiliated organization of IMDRF.
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
Collaborations with International Organizations (Cont.)

Present (2015.03)

- ISO GS1
- IMDRF DITTA
- WHO RAPS
- PAHO
- UNITAR
- IEC
- UNDP

Near Future (2015~)

Collaborations with International Organizations
<table>
<thead>
<tr>
<th>Work Group</th>
<th>Work Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>WG 1 – Pre-market: General MD</td>
<td>- CSDT (Common Submission Dossier Template)</td>
</tr>
<tr>
<td></td>
<td>- Grouping for pre-market submission</td>
</tr>
<tr>
<td></td>
<td>- Combination products (MD) guidelines</td>
</tr>
<tr>
<td>WG 2 – Premarket: IVDD</td>
<td>- IVDD definitions and labeling</td>
</tr>
<tr>
<td></td>
<td>- Classification and conformity assessment</td>
</tr>
<tr>
<td></td>
<td>- Clinical evidence</td>
</tr>
<tr>
<td></td>
<td>- Advertising and promotion</td>
</tr>
<tr>
<td>WG 3 – Pre-market: Software as a Medical Device</td>
<td>- Development of AHWP document on MD software qualification and classification</td>
</tr>
<tr>
<td></td>
<td>- Risk Classification of MD software</td>
</tr>
<tr>
<td></td>
<td>- Development of white paper on MD software</td>
</tr>
<tr>
<td>WG 4 – Post-market</td>
<td>- Review, update and develop WG 4 guidance documents</td>
</tr>
<tr>
<td></td>
<td>- Conduct survey on post-market status</td>
</tr>
<tr>
<td>Work Group</td>
<td>Work Items</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>WG 5 – Clinical Performance and Safety</td>
<td>- Decide whether or not to adopt GCP standards</td>
</tr>
<tr>
<td></td>
<td>- Establish appropriate AHWP guidelines on clinical performance/safety</td>
</tr>
<tr>
<td>WG 6 – Quality Management System: Audit &amp; Assessment</td>
<td>- Activate audit training programs</td>
</tr>
<tr>
<td></td>
<td>- Finalize the official auditing guidance for distributors</td>
</tr>
<tr>
<td></td>
<td>- Develop auditing of SMEs</td>
</tr>
<tr>
<td>WG 7 – Quality Management System: Operation &amp; Implementation</td>
<td>- Practical adoption of WG 7 guidance documents</td>
</tr>
<tr>
<td></td>
<td>- Promote voice of AHWP in the development of ISO standards and IMDRF guidance documents</td>
</tr>
<tr>
<td></td>
<td>- Develop feedback mechanism to the work of WG 7</td>
</tr>
<tr>
<td>WG 8 – Standards</td>
<td>- Develop guidance documents on roles and application of standards</td>
</tr>
<tr>
<td></td>
<td>- Awareness presentation on GHTF-SGI-n044 and pilot standard</td>
</tr>
</tbody>
</table>
### Highlight of Work Plans of AHWP TC WGs (Cont.) for the term 2015-2017

<table>
<thead>
<tr>
<th>Work Group</th>
<th>Work Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>WG 9 – Training</td>
<td>- Develop gap analysis and training plans to fit economies’ needs</td>
</tr>
<tr>
<td></td>
<td>- Develop trainer team locally in each economy</td>
</tr>
<tr>
<td>STG – Special Task Group on UDI &amp; Nomenclature</td>
<td>- Promote and monitor the development of nomenclature</td>
</tr>
<tr>
<td></td>
<td>- Promote and monitor the development of UDI</td>
</tr>
</tbody>
</table>
Thank You