The Road to Regulatory Harmonization
AHWP Update

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Vice Executive President, Medical Devices Sector
AHWP Chair
AHWP Goals

AHWP goals are to study and recommend ways to harmonize medical device regulations in the Asia and other continents and to work in coordination with the International Medical Device Regulators Forum (IMDRF), APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards.
AHWP 2018-2020 Term

AHWP
Chair Saudi FDA – Ali Al-Dalaan
Vice-Chair China NMPA – Gao Guo Biao
Vice-Chair Tran Quan

Secretariat Team

AHWP ASL

Technical Committee
Chair Malaysia MDA, Sasikala Devi Thangavelu
Co-Chair South Korea MFDS - Dr Jeong Rim Lee
Co-Chair Alfred Kwek

Advisory Panel to TC

Working Groups
Current AHWP Membership

AHWP Member Country or Region: 31 (22 Years)

- Brunei Darussalam
- Cambodia
- Chile
- Chinese Taipei
- Hong Kong SAR, China
- India
- Indonesia
- Jordan
- Kazakhstan
- Kingdom of Bahrain

- Kingdom of Saudi Arabia
- Kyrgyz Republic
- Republic of Korea
- Laos
- Malaysia
- Mongolia
- Myanmar
- Pakistan
- People's Republic of China
- Philippines
- Republic of Kenya

- Singapore
- South Africa
- State of Kuwait
- Sultanate of Oman
- Tanzania
- Thailand
- United Arab Emirates
- Vietnam
- Yemen
- Zimbabwe

Asia, Middle East, Africa, S. America
23rd AHWP Annual Meeting
October 22-25, 2018, Kuala Lumpur, Malaysia

- Participation of global organizations (IMDRF, WHO, APEC, OECD, etc)
- Joint workshop plans with liaisons
- Strategy for Improvement of Regulatory Capacity, Enforcement and Co-operation
Ahwp Technical Committee
Short-term & long-term Plans update
- Guideline topics and development plans by each WGs
- Development of Competency Handbook by AHWP TC
- In-country training plans
AHWP - Strategic Framework Towards 2020

Key Elements:
- Training and Capacity Building
- Develop AHWP Competency hand book
- Harmonization in Key Areas based on IMDRF Principles and AHWP Guidance

Collaborating Activities
- TC Tele-conference, Jan 2018
- TC Leaders Meeting, May 2018, Beijing
- TC Tele-conference, Q3, 2018
- TC Annual Meeting, Oct 2018, Malaysia
- TC Leaders Meeting, April 2019 Riyadh

3-year Work Plan
- Development of AHWP Guidelines
- Pre- and post-market control, UDI
- QMS, Clinical evidence, Standards

Capacity Building Program
- In-country Trainings
- Implementation of Guidelines
- Regulatory Competency Handbook
DEVELOPMENT & IMPLEMENTATION OF AHWP GUIDANCE

AHWP WG Achievements and Updates:
Guidance documents were endorsed

- 12 in 2015
- 15 in 2016
- 3 in 2017
- 5 in 2018
- 7-8 in 2019

➢ WG1 in collaborating with WG2 and WG3
➢ Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)
➢ Target endorsement at the 2019 Annual Meeting

➢ WG2 in collaboration with WG1 and WG3
➢ Change Management Document (ongoing)

➢ WG3
➢ Guidance for Pre-Market Submission Format for SaMD
➢ Guidance for Review and Approval on Medical Device Software
➢ Guidance document on Cyber Security for SaMD
➢ Drafting phase

➢ WG4
➢ Post-Market

➢ WG5
➢ Clinical Evidence

➢ WG6
➢ Post-Market SW

➢ WG7
➢ QMS

➢ WG8
➢ Standard

➢ WG9
➢ Nomenclature & UDI

➢ AHWP UDI Whitepaper by WG9
➢ Target endorsement at 2019 Annual meeting

➢ WG10
➢ Training

➢ WG8
➢ Guidance on Code of practice for good engineering maintenance management of medical devices, deliberation is still in progress

➢ WG6
1. An overview document which will allow the Regulatory authority to view the relevant or applicable IMDRF documents which serve to complete the audit cycle.
2. A guidance document intended as overview document for audit duration calculation.
   Target endorsement at 2019 Annual meeting
Continuous Efforts for Global Harmonization

APEC LSIF RHSC/ Medical Device Vigilance
- Join the Project ‘Roadmap to Promote Convergence’ and training workshops

IMDRF WG/ UDI & Standards
- Join the International Workshop on UDI, Feb 2018, Brussels
- Participated IMDRF meeting in March, Shanghai, September Beijing

IMDRF WG/ Personalized Medical Devices
- Attended IMDRF face to face meeting for Personalized Medical Devices
  * Personalized Medical Devices definitions N49 is approved by MC
  * Now working on another documents for Personalized Medical Devices conformity pathways

IMDRF WG/ Principles of IVD Medical Devices Classification
- Working on revision of GHTF / SG1 / N045: 2008 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
- Provided AHWP experience and comments on IVD Classification
- Attend IMDRF IVD WG F2F meeting in Aug, Moscow, Russia

IEC/ISO Works
- Attending TC meetings: ISO TC210

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Collaboration with the OECD

The Contribution of Trans-Governmental Networks of Regulators to International Regulatory Co-operation

A Case Study of the AHWP on Medical Devices

1. Overview
- History
- Intended objectives of regulatory co-operation
- Landscape of regulatory actors
- Collaboration with other IOs

2. Governance & Operational Modalities
- AHWP Membership
- Structure and governance
- Institutional setup
- The range of AHWP instruments
- Implementation mechanism (CBP)
- Quality mechanism of instruments

3. Assessment
- Benefits
- Challenges

Participation in publishing the OECD Report (2018)
Enhancing Regulatory Agencies and Industries
Our Capacity Building Journey

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<td>Competency Framework for Medical Technology Regulators</td>
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<td>Thailand in-country regulator training – 35 participants</td>
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**White Paper**

1. Approach to Develop the Competency Framework
2. Survey Findings
3. Introducing Framework
4. Guidelines on Use of Framework

**Webinar**
AHWP Capacity Building Projects

3 Capacity Building Workshops & 4 In-country Trainings (2015-2017)

- CB Workshops: Thailand Nov’15; Philippines Nov’16; India Dec’17
- In-country Trainings: Indonesia ’16; Vietnam ’16; Malaysia ’17; Kazakhstan ’17
- Topics: CSDT for pre-market registration submission, Risk classification, Good distribution practice, QMS audit, SW, Information technology, Post-market considerations

Launch Competency Framework for MedTech Regulators

A joint initiative of AHWP, APACMed and Deloitte
AHWP – TC Strategic Plan 2019-2020

GOAL 1
To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and other continents.

GOAL 2
To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements.

GOAL 3
To promote capacity building in member economies and to foster strategic membership expansion.

GOAL 4
To work in collaboration with related international organizations such as International Medical Device Regulators Forum (IMDRF), WHO, ISO, IEC.
VISION

MISSION

GOAL 1
- Develop framework for medical device regulations based on GHTF or WHO
- Identify harmonization elements
- Identify element of regulatory control

GOAL 2
- Identify Policy to regulate premarket, placement & post market
- Regulatory Documents Act, Regulation, Order, guidance documents, guideline, SOP, Standard Implementation by phases: Voluntary, transition, Mandatory
- Programs on convergence and harmonization of medical device regulations in Asia and other continents
- Consultation program
- Annual worksyop
- Regulatory Updates
- Attachment Programs
- Regulatory Visit

GOAL 3
- Identify Priority Working Area (PWA) & experts
- Identification of Priority Working Area (PWA)
- Competency Program
- Attachment programs
- Identify Trainers
- Training Programs
- Regulatory Visit

GOAL 4
- Identify Competency Gaps and needs among members
- IMDRF
- WHO
- ISO
- PAHO
- APEC-LSIF
The 24\textsuperscript{rd} AHWP Annual Meeting & The 23\textsuperscript{rd} AHWP TC Meeting

Sultanate of Oman, Muscat
November 11\textsuperscript{th} – 14\textsuperscript{th}, 2019

AHWP Capacity building Workshop,
Technical Committee Workshop
Joint Sessions with liaison members,
Technical Committee meeting
AHWP Annual meeting
Thank you