AHWP Updates

Ali Al Dalaan, MBA-IT,PRA,QMS-LA

Vice Executive President, Medical Devices Sector

SFDA, Kingdom of Saudi Arabia

AHWP Chair

August 2020

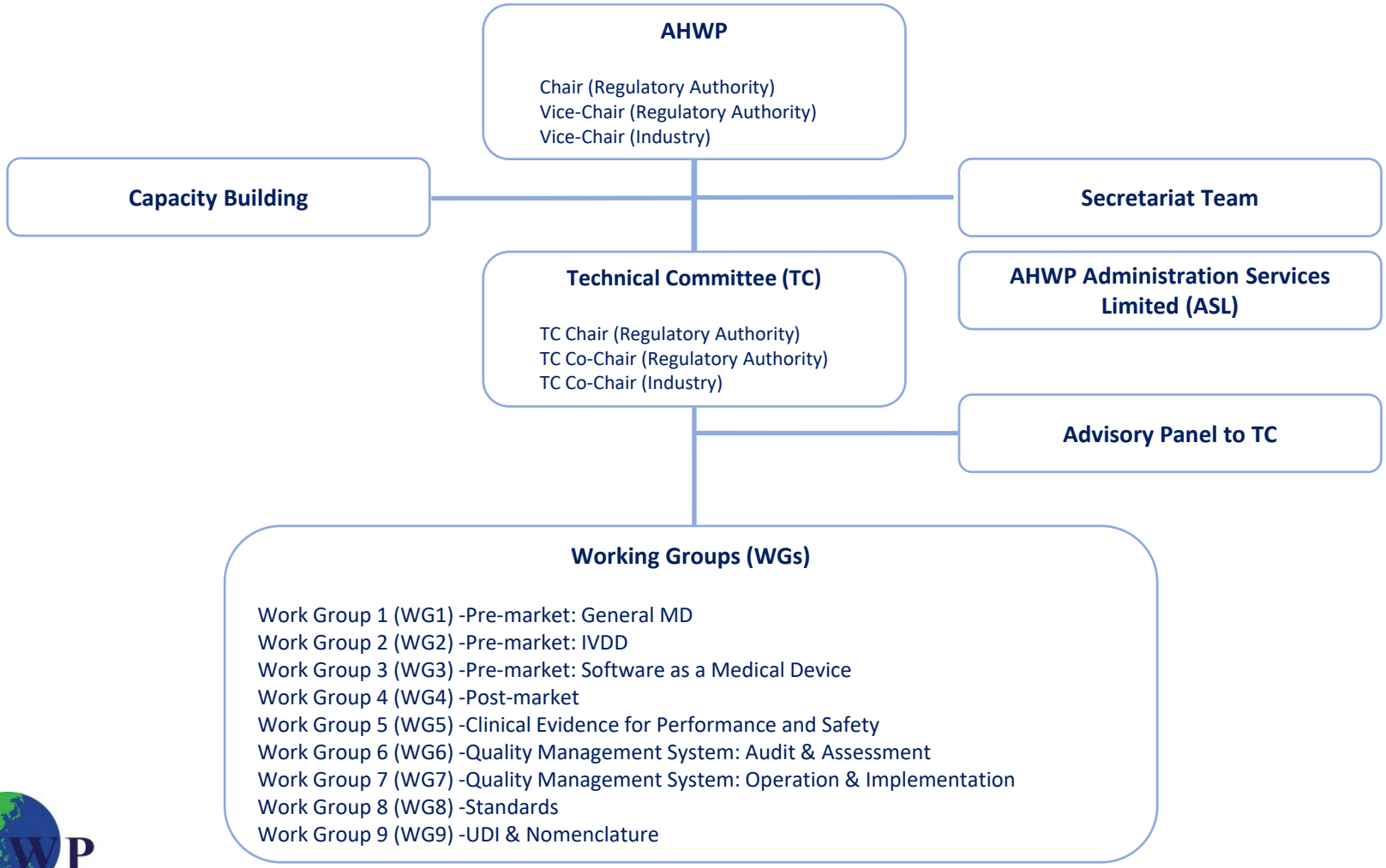
ASIAN HARMONIZATION WORKING PARTY

Asian Harmonization Working Party

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**

AHWP Organization Structure



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Introduction of AHWP

ASIAN HARMONIZATION WORKING PARTY

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.

AHWP Goals

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.

AHWP Members
from 31 Countries / Regions

Brunei Darussalam	Kazakhstan	Pakistan	Sultanate of Oman
Cambodia	Kingdom of Bahrain	People's Republic of China	Tanzania
Chile	Kingdom of Saudi Arabia	Philippines	Thailand
Chinese Taipei	Kyrgyz Republic	Republic of Kenya	United Arab Emirates
Hong Kong SAR, China	Laos PDR	Republic of Korea	Vietnam
India	Malaysia	Singapore	Yemen
Indonesia	Mongolia	South Africa	Zimbabwe
Jordan	Myanmar	State of Kuwait	

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(as of March 2020)

AHWP Office Bearers (Term 2018-2020)

ASIAN HARMONIZATION WORKING PARTY

AHWP Main Committee	
Chair	**Mr. Ali M. AL-DALAAN** Vice Executive President, Medical Device Sector, Saudi Food and Drug Authority, **Kingdom of Saudi Arabia**
Vice Chair (Regulatory Authority)	**Mr. GAO Guobiao** Deputy Director General, Medical Device Registration Dept., National Medical Products Administration, **People's Republic of China**
Vice Chair (Industry)	**Ms. Quan TRAN** Head of Regulatory & Government Affairs and Quality Assurance Asia Pacific, Invisalign Singapore Pte Ltd., **Singapore**

AHWP Technical Committee	
Chair	**Ir. Sasikala Devi THANGAVELU** Director, Policy, Code, & Standard Division, Medical Device Authority, Ministry of Health, **Malaysia**
Co-Chair (Regulatory Authority)	**Dr. Jeong-Rim LEE** Director, Cardiovascular Devices Division, Ministry of Food and Drug Safety (MFDS), **Republic of Korea**
Co-Chair (Industry)	**Mr. Alfred KWEK** Director, Public Affairs, Edwards Lifesciences Asia Pte. Ltd., **Lao PDR**

AHWP 2019
SULTANATE OF OMAN

ASIAN HARMONIZATION
WORKING PARTY

AHWP Annual Meeting 2019

11-14 Nov 2019

Hotel Grand Millennium Muscat

Muscat, Sultanate of Oman

ORGANIZING COMMITTEE MEMBERS

Ali M. Al Dalaan
AHWP Chair

Dr.Mohammed Al Rubaie
Director General,
Directorate General of Pharmaceutical Affairs and Drug Control (DGPA&DC),
Ministry of Health, Oman

Eng.Faiza Al Zadjali
Director of Medical Devices Control Department - DGPA&DC
Ministry of Health, Oman

Gao Guobiao
AHWP Vice Chair

Sasikala Devi Thangavelu
AHWP TC Chair

Jeong-Rim Lee
AHWP TC Chair

Tran Quan
AHWP Vice Chair

Alfred Kwek
AHWP TC Vice Chair

Bryan So
AHWP Secretariat

Carol Yan
AHWP TC Secretariat

Jack Wong
AHWP TC Secretariat

Miang Tanakasemsub
AHWP TC Secretariat

Fajer Alkusair
AHWP Secretary

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Major Outcome of AHWP Oman Meeting 2019

- Resolved the Amendment 6 to House Rules
- Endorsed AHWP, APACMed, Deloitte: White paper on Competency Framework for Medical Technology Regulators
- Endorsed the Guidance Documents prepared by WG
  - ✓WG1,2,3: Categorisation of Changes to a Registered Medical Device
  - ✓WG1,2,3: Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)
  - ✓WG9: Challenges & Recommendations for the Implementation of a Globally Coordinated UDI system
- Endorsed the admission of a New Member: Kyrgyz Republic
- Endorsed the admission of a New Liaison Member: GMDN Agency
- Initiated the process on AHWP change of name to GHWP

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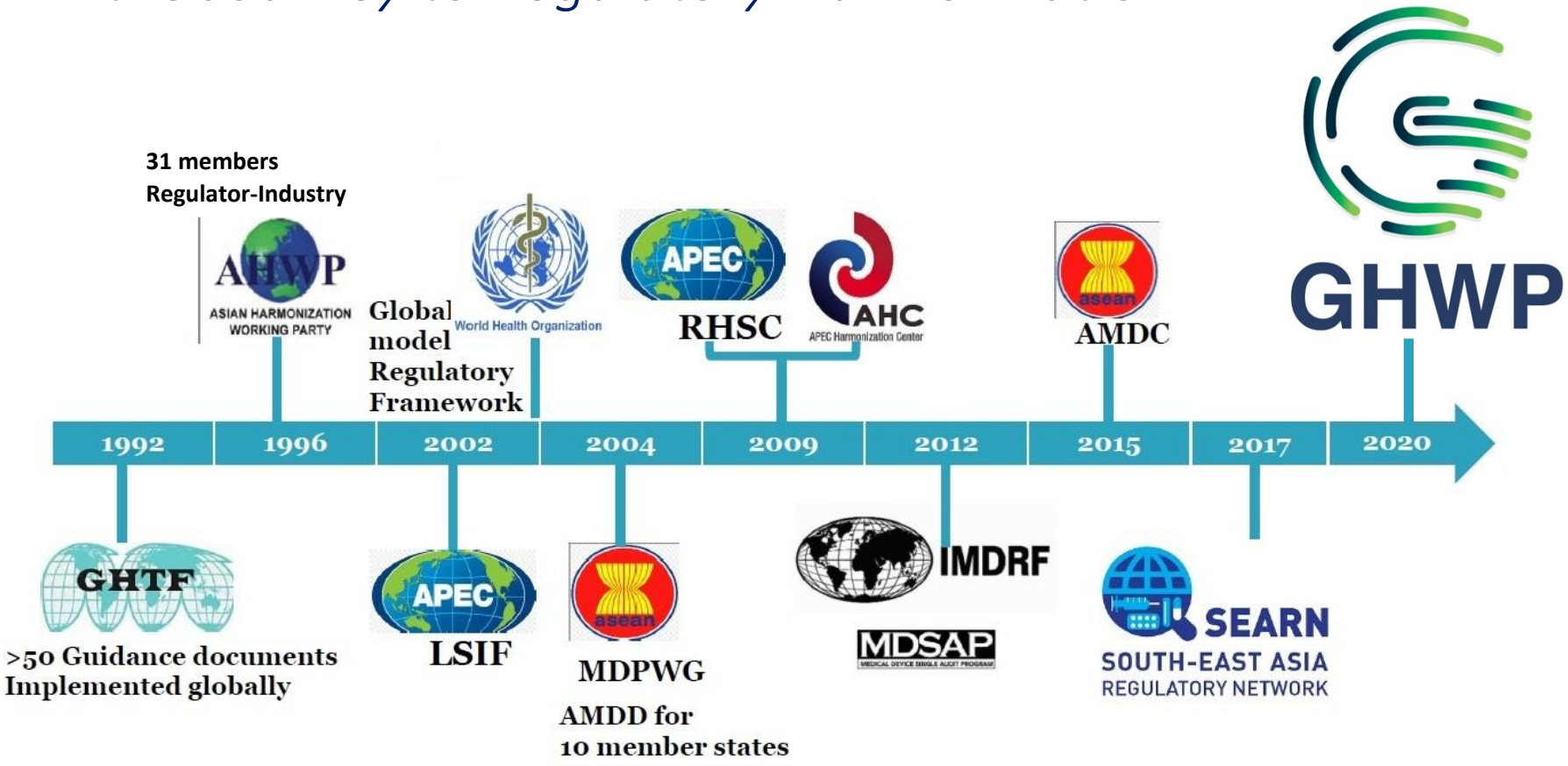
AHWP Changes into GHWP

- in the Journey to Regulatory Harmonization



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New Name, Logo and Website

GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

ghwp.info

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Rationales of the Change

Global Harmonization Working Party
GHWP
Towards Medical Device Harmonization

- Better reflect the vision and representation of the Working Party with members from Asia, Africa, Middle East and South America

- Open up membership to medical device regulatory authorities and industries worldwide

- Extend efforts in medical device regulatory harmonization from the original focus in Asia into a global prospective

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Meanings of the New Name

Global Harmonization Working Party (GHWP)

- **"Global":**

  Global collaboration in medical devices regulation

- **"Harmonization Working Party":**

  Continuity of work and commitment on the convergence of medical device regulations

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Meanings of the New Logo

Harmonization and Convergence in Medical Devices Regulation

Step forward to Global Collaboration in Medical Devices regulation

The Impact of the organization

GHWP Global Harmonization Working Party
Towards Medical Device Harmonization

AHWP ASIAN HARMONIZATION WORKING PARTY

Meanings of the New Logo

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ASIAN HARMONIZATION WORKING PARTY

Timeline for the Change of Name into GHWP

- PRESS RELEASE "Pre-announcement on AHWP Change of Name to GHWP" issued and web-posted on 30th March 2020

- OPEN LETTER "AHWP transformation into GHWP with Unchanged Position on Regulatory Authorities-Industry-Partnership" issued and web-posted on 29th June 2020

- New name & logo to be formally announced and endorsed in the coming Annual Meeting

- More information also available at ahwp.info / ghwp.info

ASIAN HARMONIZATION WORKING PARTY

GHWP Global Harmonization Working Party
Towards Medical Device Harmonization

ASIAN HARMONIZATION WORKING PARTY

AHWP 2020 Annual Meeting in China

(details to be announced on web)

List of Emergency Use Authorization (EUA) of AHWP Member Country/Region

AHWP Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CHAIRMAN'S MESSAGE | HISTORICAL DEVELOPMENT | MEETING CALENDAR | CONTACT | Search the AHWP website. | Search

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+ Events
+ Country Updates
+ Documents
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+ Secretariat
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List of Emergency Use Authorization (EUA) of AHWP Member Country/Region

Submitted by admin on Thu, 04/09/2020 - 05:45

Members	EUA Information
Chinese Taipei	List of COVID-19 related EUA on Manufacturing/Import of Medical Device http://www.fda.gov.tw/ENG/site.aspx?sid=11194
Kingdom of Saudi Arabia	List of SFDA Emergency Use Authorization (EUA) and Medical Devices Marketing Authorization for COVID-19 IVD Test Kits https://www.sfda.gov.sa/en/medicaldevices/Authorized/Documents/EAUdevices.pdf Saudi FDA Regulatory requirements for Emergency Use Authorization (EUA) for IVDD and Personal Protective Equipment (PPE) during the outbreak of COVID-19 https://www.sfda.gov.sa/en/medicaldevices/regulations/Documents/SFDA-Efforts-COVID19.pdf New Update https://www.sfda.gov.sa/en/medicaldevices/regulations/Documents/SFDA-International-EffortsEN.pdf
People's Republic of China	1. NMPA gives emergency approvals to COVID-19 test kits http://english.nmpa.gov.cn/2020-03/27/c_465663.htm?from=singlemessage&isappinstalled=0 2. Regulatory Requirements and Standards for Coronavirus Reagent Test Kits and Protective Equipment in China http://english.nmpa.gov.cn/2020-03/30/c_467202.htm
Republic of Korea	List of COVID-19 Diagnosic Kits Authorized for Use under Emergency Use Authorizations https://www.mfds.go.kr/eng/brd/m_52/view.do?seq=74424&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1
Singapore	Guidance on expedited approval of COVID-19 Diagnostic Tests - Provisional Authorisation HSA's Regulatory Position on Respiratory Devices: Supply for Management of COVID-19 patients Guidance on 3D Printing of Essential Medical Devices and Accessories for Use in COVID-19 Situation

www.ahwp.info

Online Meetings during COVID-19

- TC Leaders Meeting 18th March 2020
- TC Leaders Meeting 21st May 2020
- Secretariat Meeting 26th June 2020
- TC Work Groups Progress Meeting 9th Jul 2020
- Secretariat Meeting 18th Aug 2020
- AHWPTC Meeting in Oct 2020 (to be confirmed)

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Key Events

- Annual Meeting
- TC Leaders Meeting
- Capacity Building Program
- Trainings and Workshops

AHWP TC Leaders Meeting in Riyadh, Saudi Arabia, 2019

24th AHWP Annual Meeting in Muscat, Oman, 2019

AHWP TC Meetings

Annual AHWP TC Meetings

2015 AHWP TC Meeting
Nov 5th 2015 in Bangkok, Thailand

2016 AHWP TC Meeting
Nov 24th 2016 in Cebu, Philippines

2017 AHWP TC Meeting
Dec 7th 2017 in Delhi, India

AHWP TC Leaders Meetings

TC Leaders Meeting
Mar 19-20th 2015 in Singapore

TC Leaders Meeting
April 27-29th 2016 in Seoul, Korea

TC Leaders Meeting
March 2-3rd 2017
in Hong Kong, China

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AHWP Global Partnership

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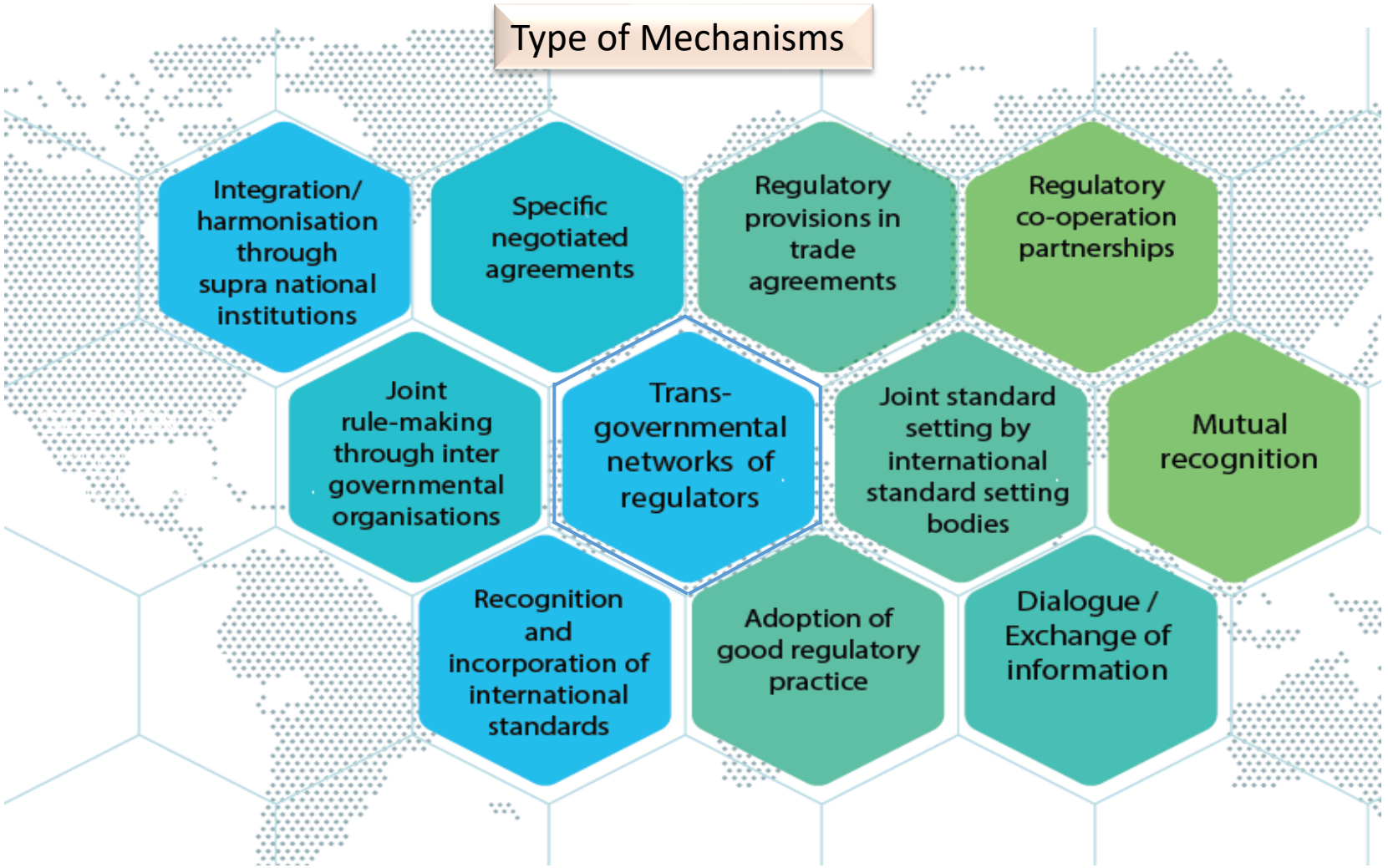
AHWP Activities with Liaisons

International Regulatory Cooperation



* Courtesy: AHWP
* IRC: Policy Brief (OECD, 2018), Regulatory Policy Outlook (OECD, 2015)
* International Regulatory Co-operation: Addressing Global Challenges (OECD, 2013)

AHWP Capacity Building

Workshops: Nov 15' Thailand; Nov 16' Philippines; Dec 17' India

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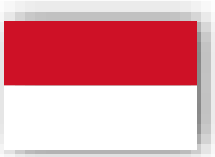
In-country Trainings



Indonesia

- July 28-29th, 2016
- 50 Indonesia regulators
- 20 experts from industry
- Topics: AHWP's essential principles of safety and performance and clinical studies

Vietnam

- Aug 25-26th, 2016
- 50 Vietnam regulators
- Topics: classification of medical devices & IVDs, pre-market approval, post-market surveillance

Malaysia

- Aug 10th, 2017
- 200 international regulators, experts and industry
- Topics: software, information technology, post-market considerations

Kazakhstan

- Oct 23-24nd, 2017
- 25 regulators and experts from testing lab
- Topics: CSDT for pre-market registration submit-ssion, Risk classifyca- tion, Good distribution practice; QMS audit of manufacturing sites

In-country Trainings

Development & Implementation of AHWP Guidelines

AHWP WG Achievements:

Guideline documents were endorsed
- 3 in 2017
- 5 in 2018
- 3 in 2019 + White paper

2019 endorsements:

- "White paper on Competency Framework for Medical Technology Regulators" By AHWP, APACMed, Deloitte
- "Categorization of Changes to a Registered Medical Device"
- "Principals of Regulatory Requirements for Electronic Instructions for Use(eIFU)"
- "Challenges and Recommendations for the Implementation of a Globally Coordinated UDI system"

ASIAN HARMONIZATION WORKING PARTY

AHWP TC Strategic Plan

Collaborating Activities	•Harmonization in key areas based on IMDRF Principles and AHWP Guidance
Working Group Tasks	•Development of AHWP Guidance •Pre- and post-market control, UDI •QMS, Clinical evidence, Standards
Capacity Building Projects	•In-country trainings •Implementation of Guidance •Regulatory Competency Handbook

ASIAN HARMONIZATION WORKING PARTY

WG Plans for 2018 - 2020 (1)

WG	Tasks	Timeline	Progress in 2020
WG1	• E-labeling/e-IFU guideline (collaboration with WG2 & WG3) • •3D printing handbook update • Change management for medical device registration guideline (collaboration with WG2 & WG3)	Endorsed 2019 TBD Q4, 2019	➢ on-going investigation of existing guidelines of personalized medical devices from other regulatory authorities, including IMDRF guidance. ➢ In-progress of development of Guidance document on critical or major changes
WG2	• E-labeling/e-IFU guideline (collaboration with WG1 and WG3 •Change management for medical device registration guideline (collaboration with WG1 & WG3) • Guidance document for approval of reagent for instrument family • Clinical Evidence for IVD-Clinical Performance Studies for IVD •Contribution to WHO Technical Specification Documents	Endorsed 2019 Q4, 2019 Q4, 2020 Q4, 2020 2018-2020	➢ Target endorsement in 2020 ➢ Target endorsement in 2020 ➢ Continue working with WHO IVD PQ team to maintain WHO technical documents
WG3	• White paper on pre-market initial submission format for SaMD • E-labeling/e-IFU guideline (collaboration with WG2 & WG3) • White paper on cybersecurity for SaMD • Change management for medical device registration guideline • Guidance document on Cyber Security for SaMD • Guidance document for pre-market submission format for SaMD (draft) •White Paper/Guidance on Artificial Intelligence(AI)	Q4, 2018 Endorsed Q1, 2019 Q4, 2019 TBD Q3, 2020 TBD	➢ Pending for finalization and endorsement ➢ Final draft under review ➢ In-progress, collaborating with WG1 ➢ Final draft under review ➢ First draft under review ➢ Project team in recruting

WG Plans for 2018 - 2020 (2)

WG	Tasks	Timeline	
WG4	• Updating the post-market resource centre • Gap analysis on the implementation of AHWP guidance among AHWP members • Participation in the development works of ISO TC210/WG6 •Report on post-market support in relation to COVID-19 •Study on post-market trend in medical devices with AI and cybersecurity	Oct. 2020 Dec. 2020 Dec. 2020 Nov. 2020 Feb. 2021	➢ Ongoing ➢ Ongoing ➢ Ongoing ➢ New item ➢ New item
WG5	• Annual review SWOT analysis of WG5 framework • Guidance document on general principles of clinical investigation audit & inspection for medical devices • Training: WG5 & AHWP members • Survey: country regulations/guidelines and implementation	Q4, 2018 Q4, 2018 Q4, 2018 Q4, 2019	Ongoing progress
WG6	• Guidance document on understanding the roles of IMDRF documents concerning auditing (draft) • Guidance document on the current best practice in determination of regulatory audit duration (draft)	Q4, 2018 Q2, 2019	Ongoing progress
WG7	• Comparison study of new ISO13485 vs QMS requirements in each country • QMS consideration for manufacturers and importers for localization	Q2, 2020 Q4, 2020	Ongoing progress
WG8	• Guidance document on code of practice for good engineering maintenance management of medical devices • Collecting a list of standards used for medical device regulatory purposes that are recognized by AHWP member countries • Continue working relationship with ISO TC210, etc	Q4 2020? TBD	➢ Continue seeking comments on the drafted guidance ➢ Ongoing, need more members to join ➢ Ongoing
WG9	• AHWP UDI report • AHWP UDI rule-White Paper, target endorsement at 2020 annual meeting	TBD Q4 2020	➢ Ongoing ➢ On track

AHWP TC - Strategic Framework Towards 2020

ASIAN HARMONIZATION WORKING PARTY

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, Q2, 2018 (TBD)
- TC Tele-conference, Q3, 2018
- TC Annual Meeting, Oct 2018, Malaysia

3-year Work Plan

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

Capacity Building Program

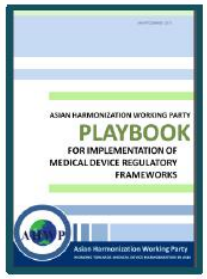
- In-country Trainings
- Implementation of Guidelines
- Regulatory Competency Handbook

ASIAN HARMONIZATION WORKING PARTY

Enhancing Regulatory Agencies and Industries

Our Capacity Building Journey

2014 - 2017	2018 - 2019



KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

Ministry of Health & Family Welfare

MINISTRY OF HEALTH OF THE REPUBLIC OF KAZAKHSTAN

Food and Drug Administration

FDA Food and Drug Administration PHILIPPINES

Medical Device Authority Ministry of Health Malaysia

Competency Framework for Medical Technology Regulators

Food and Drug Administration

Thailand in-country regulator training – 35 participants

White Paper

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

Webinar

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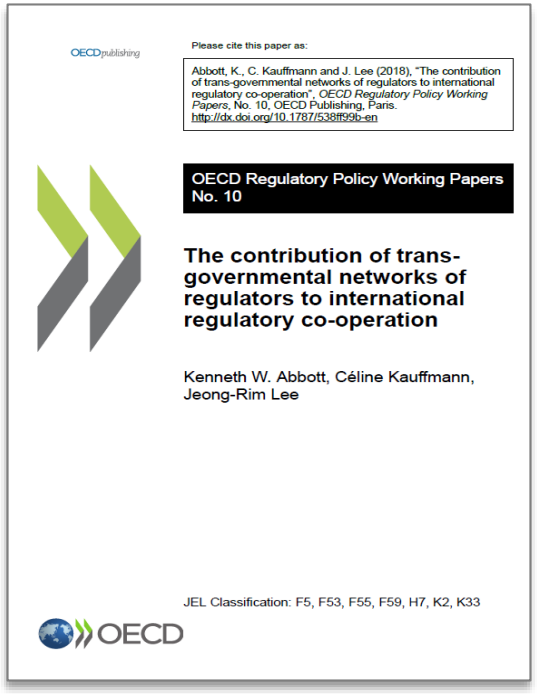
Collaboration with the OECD

Title: 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 drafting the 2nd OECD Report (2017 - 2018)
- Published as an OECD report (September, 2018)

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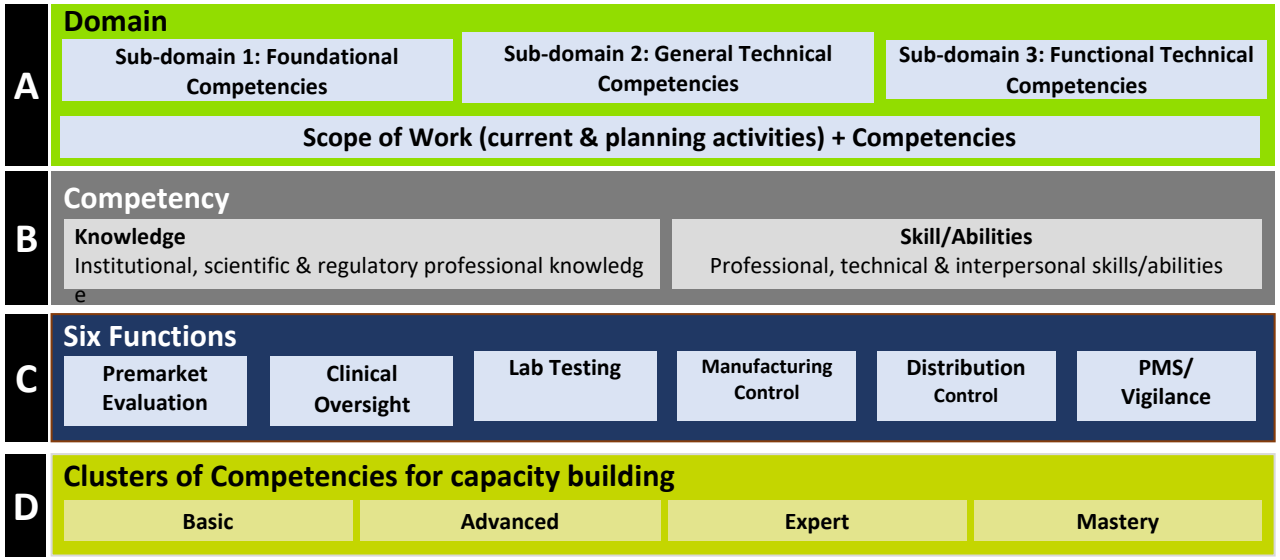
Competency Handbook for Medtech Regulators

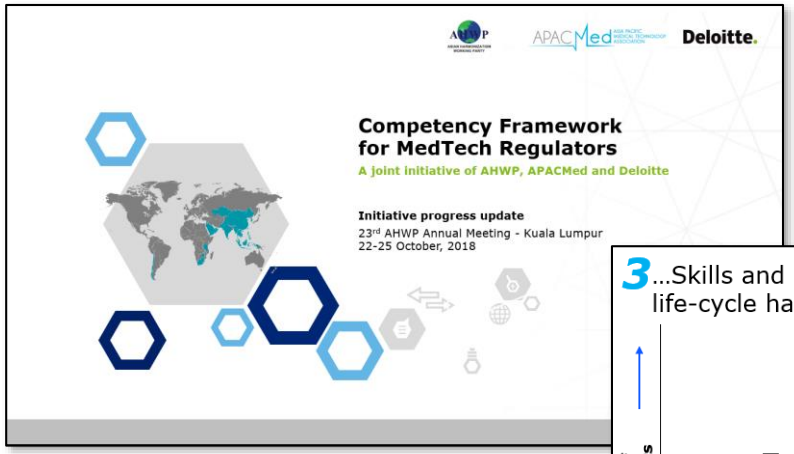
PROJECT SCOPE:

- AHWP survey for regulators among its 31 member countries and regions
- APACMed launching similar survey among companies to assess satisfaction & expectation

High-Level Competency Framework for MedTech Regulators



Collaboration in Capacity Building: Joint AHWP-APACMed-Deloitte project



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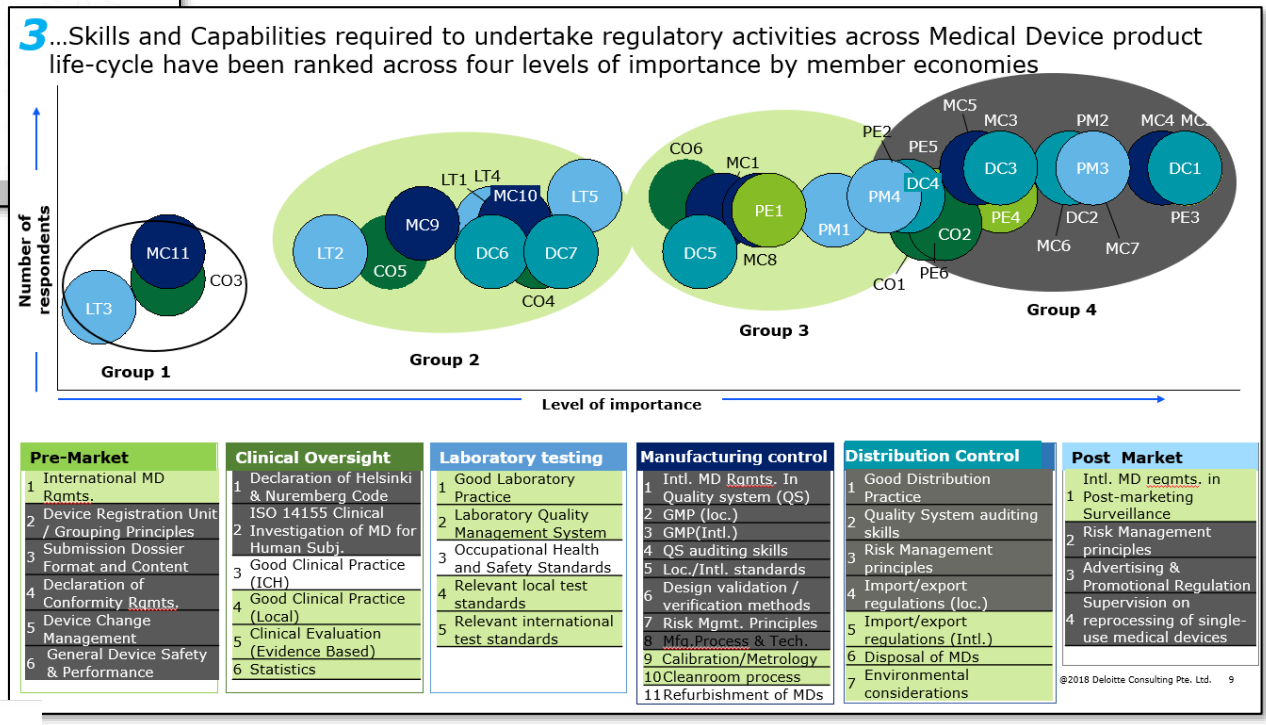

"Competency Framework for Asia Pacific MedTech Regulatory Professionals"

Deloitte. APACMed ASIA PACIFIC MEDICAL TECHNOLOGY ASSOCIATION

* Courtesy: APACMed

Q&A