ASIAN HARMONIZATION WORKING PARTY

GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

AHWP/GHWP Updates

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

Vice Executive President, Medical Devices Sector

SFDA, Kingdom of Saudi Arabia

AHWP/GHWP Chair

Mar 2021

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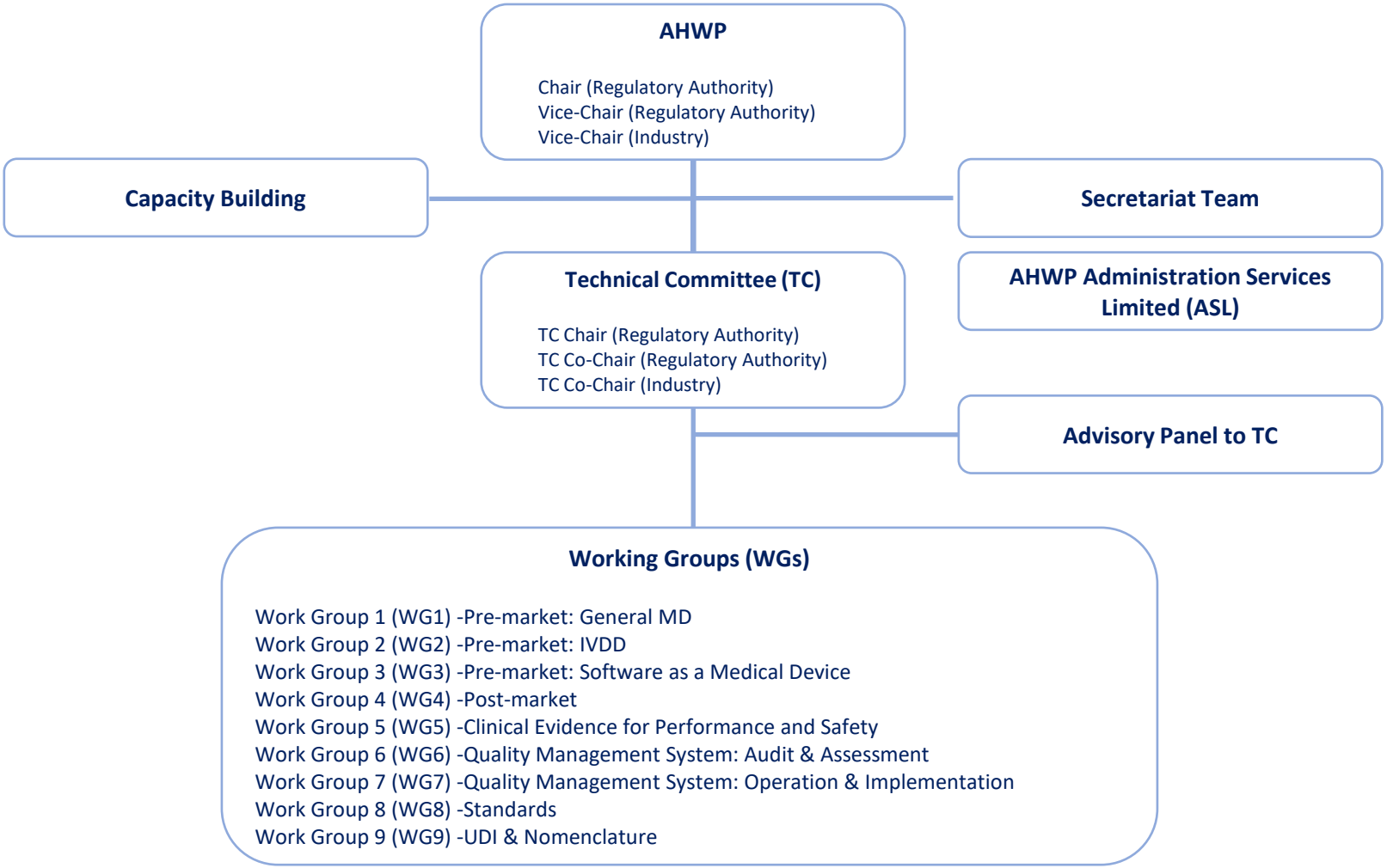
AHWP/GHWP

- Established as a **non-profit** organization **formed in 1996-97**
- Its goals are to study and recommend ways to **harmonize medical device regulations** 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/GHWP Organization Structure



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/GHWP 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 Feb 2021)

AHWP/GHWP Office Bearers (Term 2018-2020)

[Term of Office Bearers extended until next election in annual meeting, targeting Fall 2021]

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** Party Secretary, Center for Medical Device Evaluation, 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	
Acting Chair **(until next election)**	**Ms. Salbiah YAAKOP** Acting Director, Policy, Codes and Standards 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**

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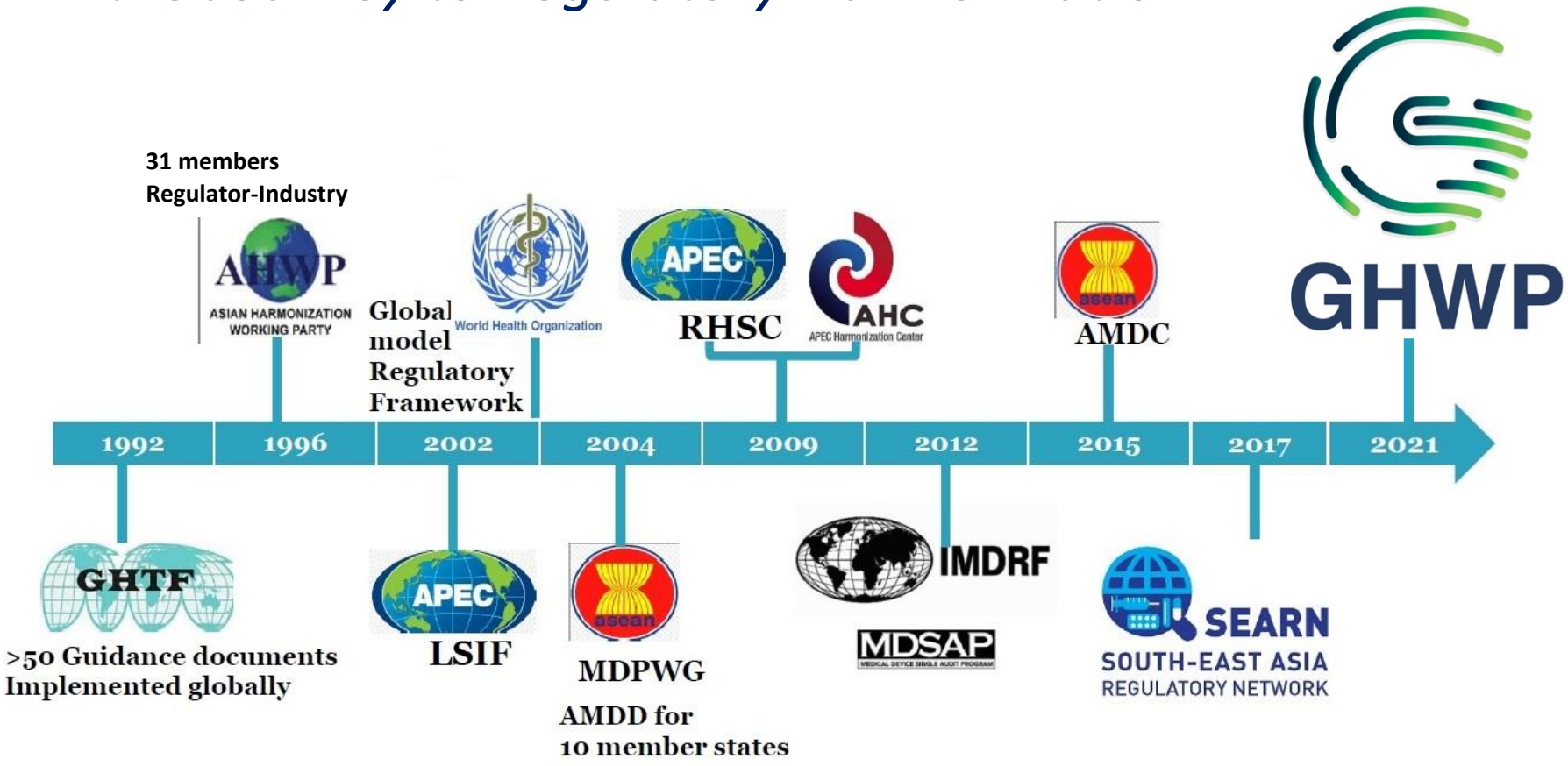
- **Annual Meeting 2020 deferred, due to COVID-19 pandemic**

- **Upcoming AHWP/GHWP Annual Meeting in China**
  (**targeting Nov/Dec 2021**, subject to further web-announcement)

AHWP Rebranding into GHWP

- in the Journey to Regulatory Harmonization



New Name, Logo and Website

ghwp.info

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

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

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

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Meanings of the New Logo

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 (target Nov/Dec 2021, subject to further web-announcement)

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

AHWP ASIAN HARMONIZATION WORKING PARTY

GHWP Global Harmonization Working Party Towards Medical Device Harmonization

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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+ Documents
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+ Web Resources
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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

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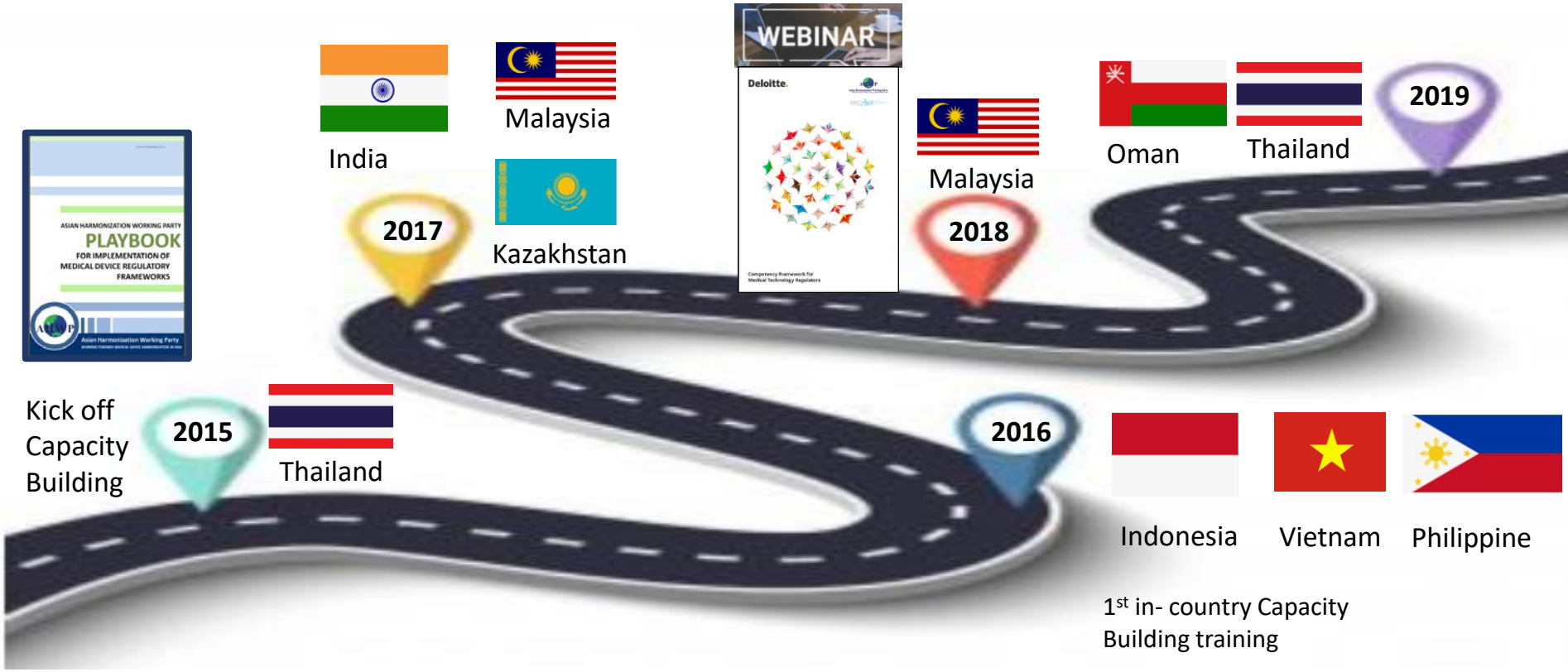
AHWP/GHWP Capacity Building Program 2015-2019



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Forging on AHWP/GHWP Capacity Building Journey

2014 - 2019

2020 - 2021

- **Training Curriculum whitepaper**
  - **Phase 1 –Industry (completed)**
  - **Phase 2 – Regulator (TBD)**

- **Virtual CB Workshop Plan**
  - **Kyrgyzstan**
  - **Laos**
  - **Oman**

2023

- **GHWP Certification Course**

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Medical Device Regulatory Training Curriculum for Industry Professionals

- White Paper Curriculum on Industry by AHWP/GHWP and APACMed
- As part of the AHWP/GHWP Capacity Building program, the draft Curriculum White Paper for Industry has been posted for public commenting on the AHWP/GHWP website
- Webinar supported by Accenture AHWP/GHWP member representatives on 30th Nov 2020, with speakers from Accenture

Medical Device Regulatory Training Curriculum for Industry Professionals

Overview & Scope

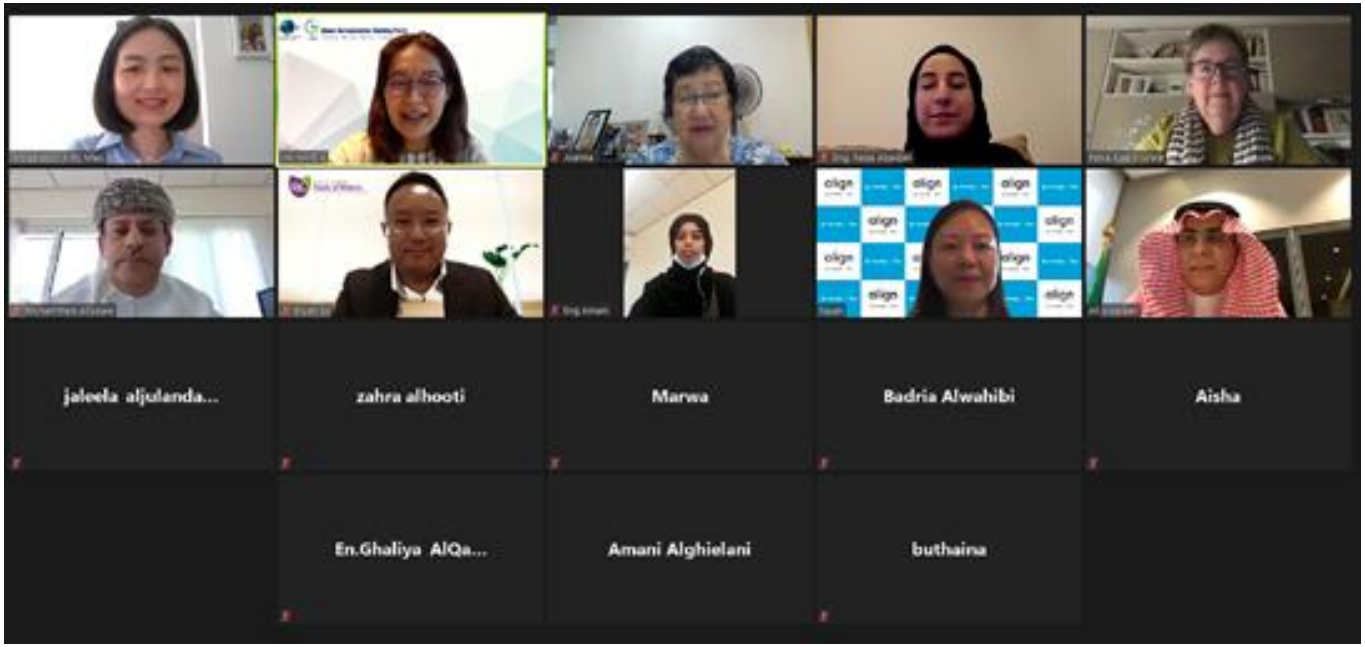
- Training curriculum is created to provide a roadmap to Medtech regulatory industry professionals across companies
- The most essential and relevant trainings and courses for MedTech Regulatory Industry Professionals have been outlined in the training curriculum

Guidelines

- Capability development leads should consider the curriculum as a roadmap and assess their current plan against the curriculum
- In case there is a module which is currently not present in their organization, they can leverage the indicative content for brief description to create trainings
- Post analysis, capability development leads should explain to their team resources the identified learning goals & its importance in a professional's career progression

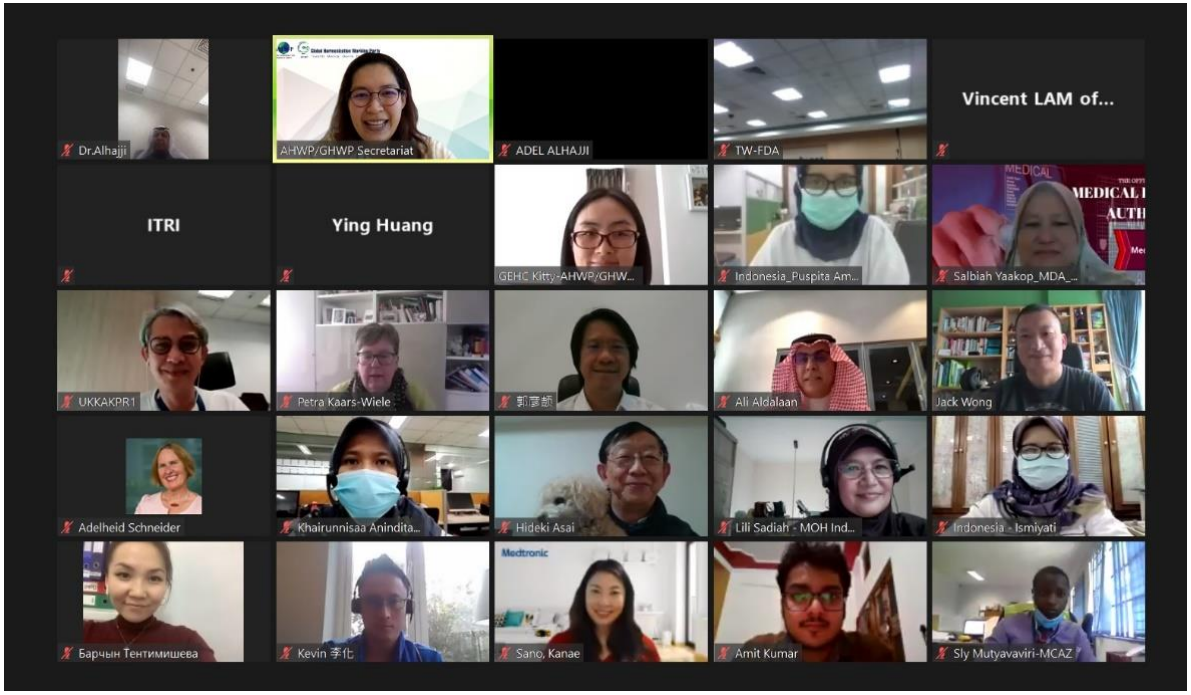
Capacity Building - Oman Virtual Training on IVD

- 4-Days Capacity Building Training (30th Nov – 3rd Dec 2020)
- Speakers: Ms. Joanna Wee and Dr. Petra Kaars-Wiele
- To share insights and revisit key elements on IVD, EU regulation and certification, submission review, interim post-market consideration, stakeholders' roles and responsibility



Capacity Building - Awareness Training on Remote Auditing

- A virtual training held on 4th Feb 2021
- Conducted by Mr. Vincent Lam, WG 6 Co-Chair, Senior Lead Auditor and Product Specialist for TÜV SÜD Product Service
- An experience sharing on the skills for planning and conduction of remote audits, and the techniques for systematic audits execution during the pandemic



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AHWP/GHWP TC Strategic Plan

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

WG Plans for 2018 - 2021 (1)

WG	WORK PLAN	TIMELINE
Joint Work by WG 1, 2 & 3	New guidance on artificial intelligence	
	Change management for medical device registration guideline	
	E labeling/e IFU guideline	
WG1	Revised 2 Final Documents 'Handbook for Approval of Patient-matched Medical Devices Using 3D Printers' and 'Guidance for Minor Change Reporting' which have been posted on the AHWP/GHWP website	Q4, 2020
WG2	Guidance on Emergency Use Authorization of SARS-CoV-2 Nucleic Acid Tests	Q3, 2022
	Replacement reagent and instrument family policy	Q3, 2021
	Clinical Evidence for IVD Medical Devices-Clinical Performance Studies for In Vitro Diagnostic Medical Devices	Q3, 2020
	Contribution to IMDRF Document Titled Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	2018-2020
	Continually work with IMDRF document updates on GHTF/SG5/N6:2012, GHTF/SG5/N7:2012 and GHTF/SG5/N8:2012	Ongoing
	Contribution to WHO Technical Specification Documents	Ongoing
WG3	White paper on pre market initial submission format for SaMD	Q2, 2021
	White paper on cybersecurity for SaMD	Q2, 2021
	Guidance document on Cyber Security for SaMD	Q4, 2021
	Guidance document for premarket submission format for SaMD (draft)	Q4, 2021
WG4	Updating the Post-market Resource Centre	Ongoing
	Gap analysis on the implementation of AHWP guidance among AHWP members	Q4, 2021
	Participation in the development works of ISO TC210/ WG6	Ongoing
	Report on post-market support in relation to COVID 19	Q4, 2021
	Study on post-market trend in medical devices with AL and cycbersecurity	Q4, 2021
WG5	Annual review SWOT analysis of WG5 framework	Q4, 2018
	Guidance document on general principles of clinical investigation audit & inspection for medical devices	Q4, 2018
	Training: WG5 & AHWP members	Q4, 2018
	Survey: country regulations/guidelines and implementation	Q4, 2019

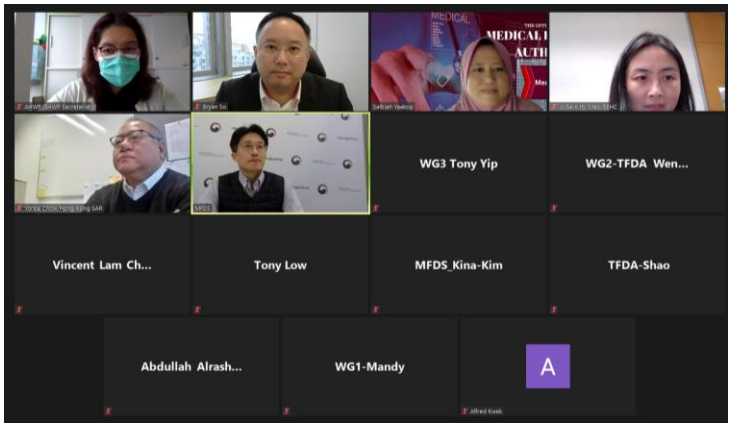
WG Plans for 2018 - 2021 (2)

WG	WORK PLAN	TIMELINE
WG6	There are 3 guides on progress and endorsement expected during the Annual meeting 2021:	
	1) A guide to understanding best practices in audit life cycle management.	
	2) A guide to understanding presently available audit duration determination systems.	
	3) A guidance for NB auditing suppliers to medical device manufacturers.	
	Co-Chair Vincent will conduct online training session on remote audit technique.	4 Feb, 2020
WG7	Comparison study of new ISO13485 vs QMS requirements in each country	Q2, 2020
	QMS consideration for manufacturers and importers for localization	Q4, 2020
WG8	Document on Code of practice for good engineering maintenance management of medical devices: endorsed, to be proposed to ISO /TC210 for development as ISO standard. Current status: New Proposal (NP 5137) on COP Good maintenance management of active medical devices has been approved and registered as new ISO project on 29 July 2020. A new WG, ISO/TC 210 WG 7 has been established on 17 Sept 2020 and Ms Salbiah Yaakop was appointed as Convenor. Member countries are encouraged to participate in the works of WG 7 through registration by their National Standards Body.	Q3, 2023
	Collecting a list of standards used for medical device regulatory purposes that are recognized by AHWP member countries -The secretariat is requested to put up the list of compiled standards in the AHWP/GHWP website for members' reference. - Member countries representatives are requested to maintain the list to ensure the lists are up to date.	Ongoing
	Continue working relationship with ISO Tc210, etc - WG8/AHWP TC Chair will be participating in the next ISO/TC 210 meetings in May 2021 and Nov 2021.	Ongoing
	Adoption of ISO 16142-2:2017 and ISO 16142-1:2016, to harmonize list of standards in demonstrating compliance with EPSP where member countries could recognize the same standards during IVD medical device evaluation by NB/CAB and regulators	Q1 2019, completed
	Proposal on development of guidance on regulatory control of medical gas - preparation of 1st draft by WG8 Chair, will be deliberated in the next WG8 meetings planned in April and June 2021.	Q4 2021
	Proposal on development of guidance on the guideline of process validation activity adaptation of International Society for Pharmaceutical Engineering (ISPE) document) for the propose of medical device validation. - preparation of 1st draft by WG8 Co-Chair - will be deliberated in WG8 meetings in June and Oct 2021.	Q4 2021
WG9	AHWP UDI report	TBD
	AHWP UDI rule White Paper,target endorsement at 2020 annual meeting	Q4, 2020

TC-Work Groups Chairs/Co-Chairs Progress Meetings

- Virtual Meeting of TC WG Chairs and Co-Chairs
  - Meeting on 17th Dec 2020
  - Meeting on 3rd Feb 2021

- Chairs and Co-Chairs of WGs discussed on:
  - Overall objectives of TC and WGs
  - WGs representation on their respective focus of regulatory convergence
  - WGs work plans, new guidance documents and progress updates
  - WG membership updates



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Key Events

- Annual Meeting
- TC Leaders Meeting
- TC Workgroup Meeting
- Secretariat Meeting
- Capacity Building Program

Recent Activities

- Capacity Building - Oman Virtual Training
- Capacity Building - Awareness Training on Remote Auditing
- Capacity Building - White Paper Webinar
- TC WG Chairs Meetings
- Secretariat Meetings

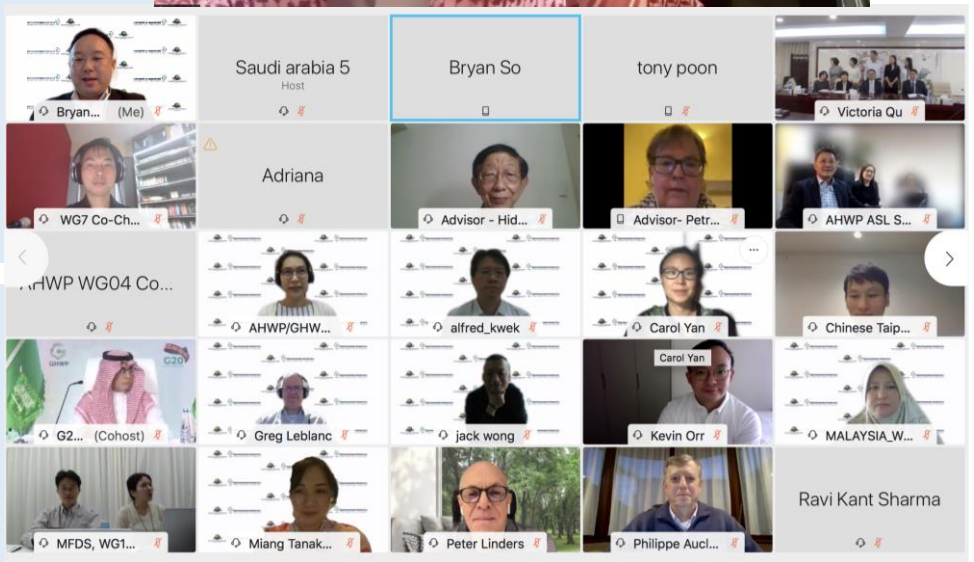
Meetings and Capacity Building go Online during COVID-19

2020

- TC Leaders Meeting 18th Mar
- TC Leaders Meeting 21st May
- Secretariat Meeting 26th Jun
- TC WGs Progress Meeting 9th Jul
- Secretariat Meeting 18th Aug
- TC Leaders Meeting 13th Oct
- Capacity Building 30th Nov - 3rd Dec
- Webinar on White Paper 30th Nov
- Secretariat Meeting 1st Dec
- TC WGs Progress Meeting 17th Dec

2021

- Secretariat Meeting 13th Jan
- TC WGs Progress Meeting 3rd Feb
- Capacity Building Training 4th Feb



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- Stay tuned for new activities and updates…

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Q&A