ASIAN HARMONIZATION WORKING PARTY

GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

AHWP/GHWP

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

Vice Executive President, Medical Devices Sector

SFDA, Kingdom of Saudi Arabia

AHWP/GHWP Chair

Aug 2021

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Global Harmonization Working Party

Towards Medical Device Harmonization

AHWP/GHWP Updates

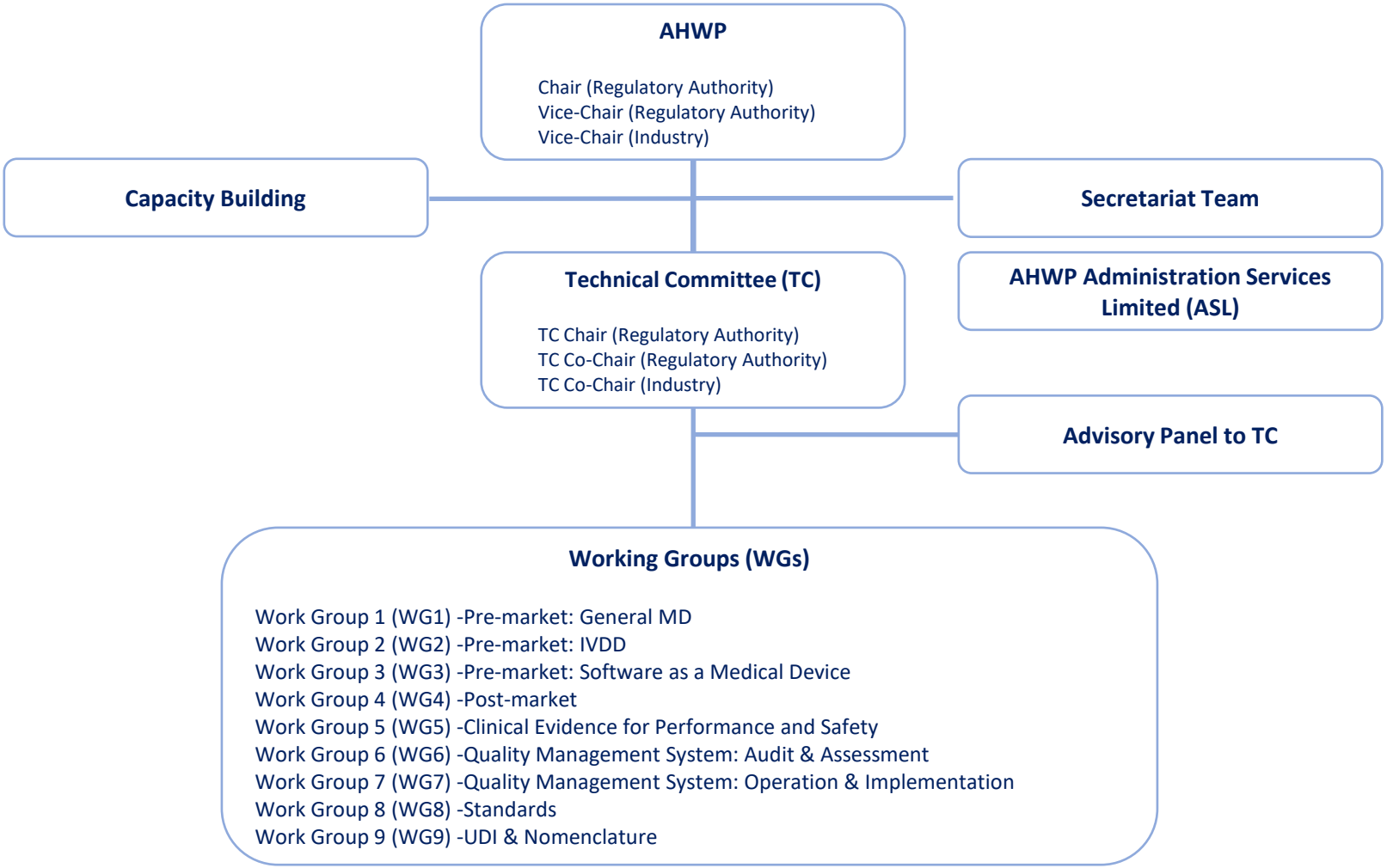
ASIAN HARMONIZATION WORKING PARTY

GHWP Global Harmonization Working Party
Towards Medical Device Harmonization

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



ASIAN HARMONIZATION WORKING PARTY

GHWP Global Harmonization Working Party
Towards Medical Device Harmonization

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	

(as of Mar 2021)

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ASIAN HARMONIZATION WORKING PARTY

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Global Harmonization Working Party

Towards Medical Device Harmonization

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 Office Bearers (Term 2018-2020)

[Term of Office Bearers extended until next election in physical annual meeting, targeting 2022]

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**

ASIAN HARMONIZATION WORKING PARTY

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

- **Upcoming AHWP/GHWP 25th Annual Meeting** will be held **Online in two half-days in 2021,** virtually hosted by SFDA:

  Day One : 30th Nov 2021 (TUE)

  Day Two : 1st Dec 2021 (WED)

  Time : 1200 to 1530 (KSA Time)

SFDA
الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

- Please pre-registrate to our online Annual Meeting via our official website: www.ahwp.info/www.ghwp.info

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Towards Medical Device Harmonization

- Face-to-Face Annual Meeting with Elections to be held in 2022 in China, to be hosted by NMPA

国家药品监督管理局
National Medical Products Administration

- More details will soon be available on official web of AHWP/GHWP www.ahwp.info/www.ghwp.info

ASIAN HARMONIZATION WORKING PARTY

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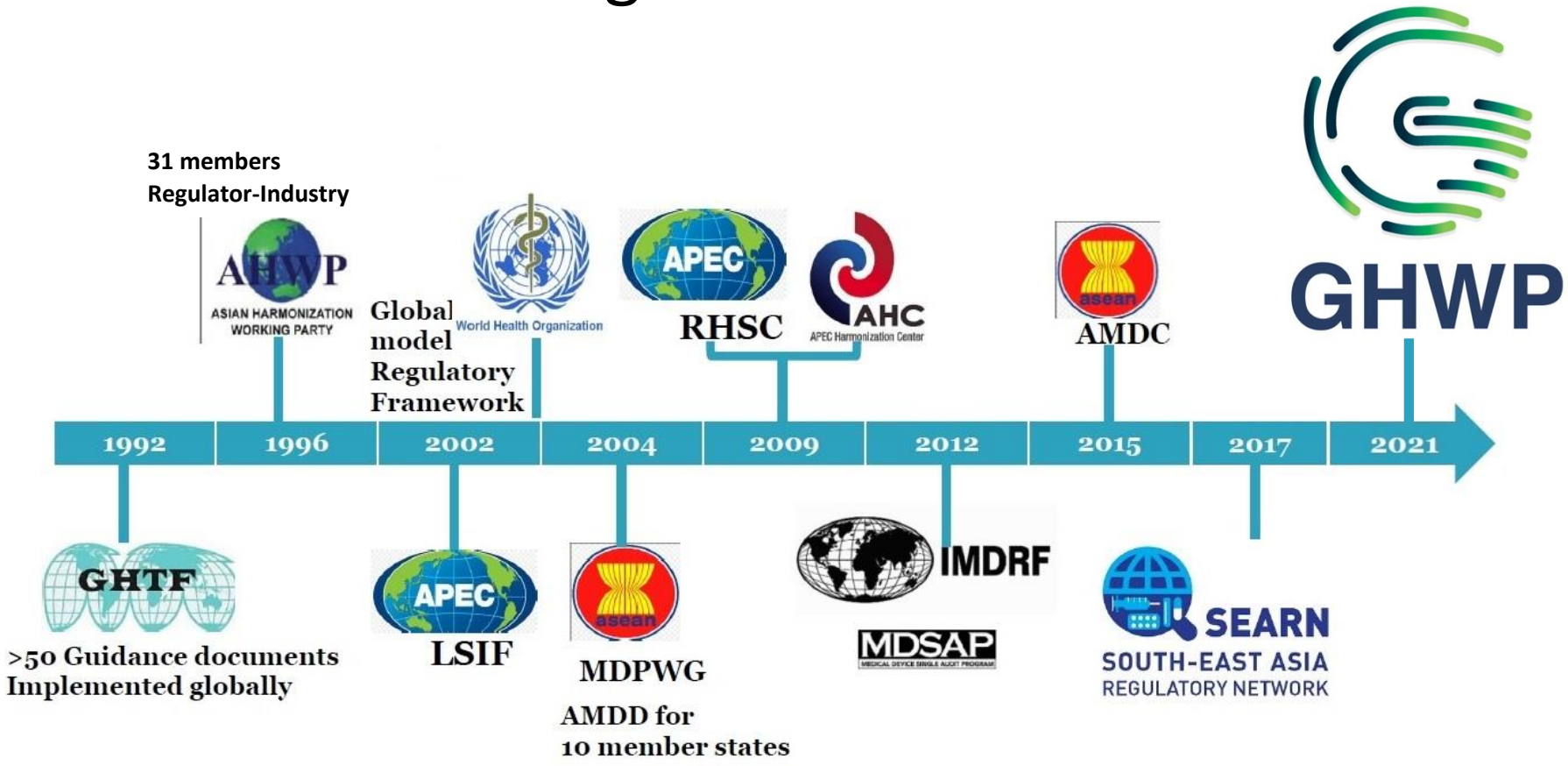
Global Harmonization Working Party

Towards Medical Device Harmonization

AHWP Rebranding into GHWP

- in the Journey to Regulatory Harmonization

AHWP Rebranding into GHWP



New Name, Logo and Website

GHWP Global Harmonization Working Party
Towards Medical Device Harmonization

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 and New Logo

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

GHWP Global Harmonization Working Party
Towards Medical Device Harmonization

AHWP ASIAN HARMONIZATION WORKING PARTY

GHWP Global Harmonization Working Party
Towards Medical Device Harmonization

Meanings of the New Logo

Timeline for the Change of Name into GHWP

30th March 2020

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

29th June 2020

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

Next Physical Annual Meeting

(target 2022, subject to further web-announcement)

New name & logo to be formally announced and endorsed

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

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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+ Events
+ Country Updates
+ Documents
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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

Workshop on Capacity Building For Regulatory Authorities in AHWP/GHWP by end Sep 2021

- To collect inputs on Phase II whitepaper and curriculum on Capacity Building
- To formulate Phase II curriculum for regulatory authority
- In partnership with APACMed & supported by Company Sponsors

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Workshop on Emergency Use Authorization (EUA) by Oct 2021 (tentatively)

- To share EUA experience by members of AHWP/GHWP
- To discuss key EUA elements with contributions from both Regulatory Authorities and Industries
- Sharing of new EUA guidance by WG1 & WG2 on MDD and IVDD Pre-market requirements

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Global Harmonization Working Party

Towards Medical Device Harmonization

AHWP/GHWP
TC and WG Plans

ASIAN HARMONIZATION WORKING PARTY

GHWP Global Harmonization Working Party
Towards Medical Device Harmonization

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)

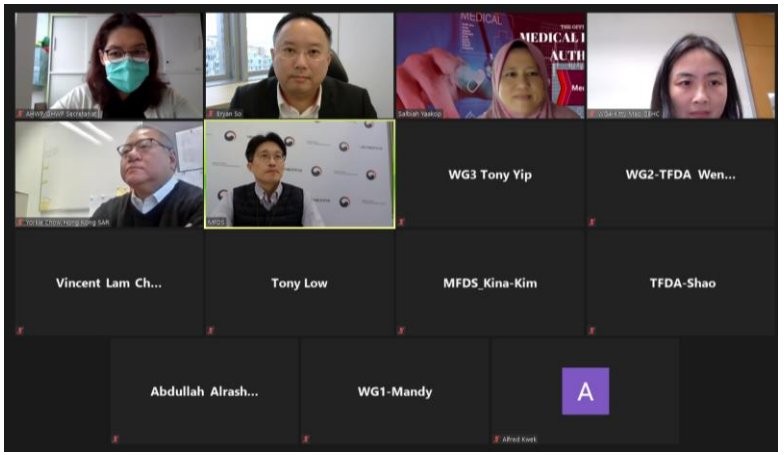
WG	Work Plan	Timeline
Joint Work by WG 1, 2 & 3	New guidance on artificial intelligence	Ongoing
	Change management for medical device registration guideline	Ongoing
	E labeling/e IFU guideline	Ongoing
	Emergency Regulatory Mechanism for Medical Devices including In Vitro Diagnostic Medical Devices and Software as Medical Devices during a Public Health Crisis	Q4, 2022
WG1	(Joint Wok) Document development of Artificial Intelligence	Ongoing
	(Joint Work-lead) Revise guidance document 'Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU):2019'	TBD (2021~2022)
	(Joint Work-lead) Develop the training module/document to guide change management per significance	TBD (2021~2022)
WG2	(Joint Work-lead) Emergency Regulatory Mechanism for Medical Devices including In Vitro Diagnostic Medical Devices and Software as Medical Devices during a Public Health Crisis	Q4, 2022
	Replacement Reagent and Instrument Family Policy	Q4, 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 (To be updated)	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 (To be updated)	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 (To be updated)	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 (To be updated)	Comparison study of new ISO13485 vs QMS requirements in each country	Q3, 2021
	QMS consideration for manufacturers and importers for localization	Q4, 2021
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. <u>Current status:</u> 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	
	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	On-going
	AHWP UDI Webinar	Week of July 19
	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
  - Meeting on 21st Jun 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

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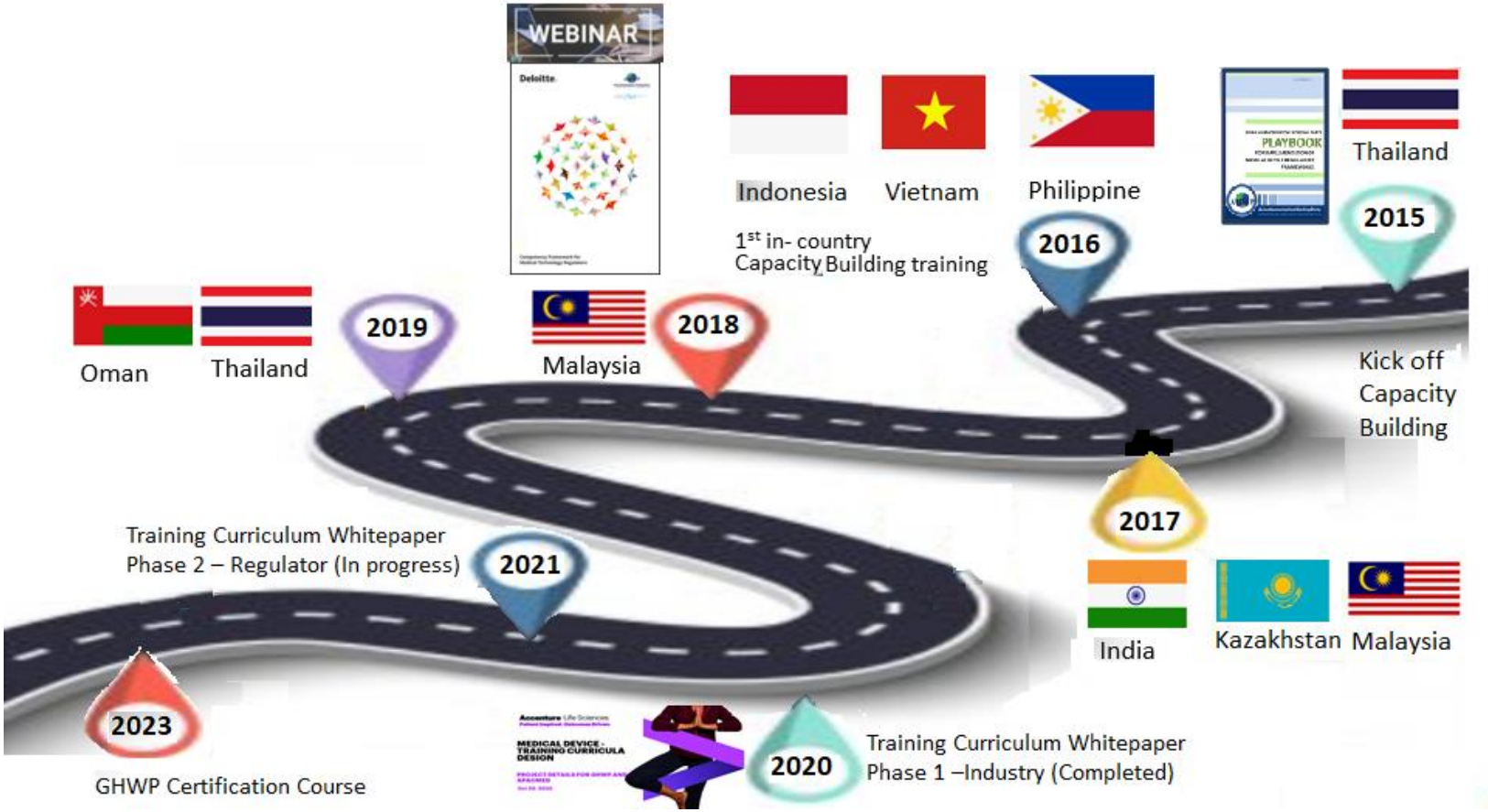
Towards Medical Device Harmonization

AHWP/GHWP
Capacity Building Journey

AHWP/GHWP Capacity Building Program 2015 and Beyond



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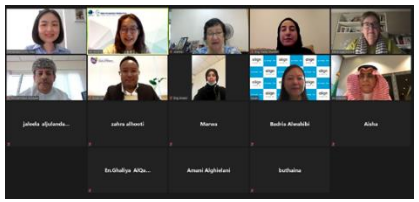
AHWP/GHWP Capacity Building Trainings

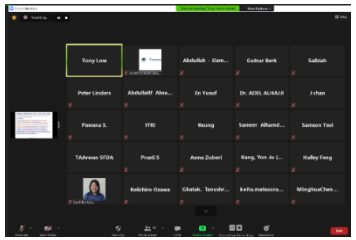
30 Nov – 3 Dec 2020
Oman Virtual Training



4 Feb 2021
Awareness Training on Remote Auditing

22 Mar 2021
Webinar on IAF CertSearch

22 Apr 2021
WG Training on Process Validation



29 Jun 2021
Medical Device Regulation in Australia – 2021 and Beyond

28 Jul 2021
UDI Regulation and Implementation Seminar

Sep 2021
Capacity Building Workshop Training Curriculum for Regulatory

Recent Activities

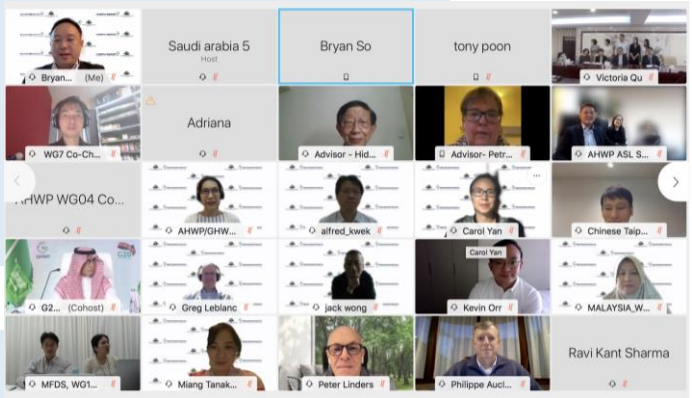
- Capacity Building
  - Oman Virtual Training
  - Awareness Training on Remote Auditing
  - Webinar on IAF CertSearch
  - Work Group Training on Process Validation
  - Medical Device Regulation in Australia – 2021 and Beyond
  - UDI regulation and implementation seminar

- TC WG Chairs Meetings
- Secretariat Meetings
- OC Meetings for Annual Meeting

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, 15th Mar, 27th Apr and 29th Jun
- TC WGs Progress Meeting 3rd Feb and 21st Jun
- Capacity Building Training 4th Feb, 22nd Mar, 22nd Apr and 29th Jun

AHWP History since 1996

- achieving its visions towards harmonization and convergence
- with inclusive partnership of Regulators and Industry

AHWP

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AHWP History

TC meeting

1st	2001	Sept	Kualarunpur Malaysia
2nd	2002	Dec	Bangkok Thailand
3rd	2004	April	Taipei Chinese Taipei
4th	2005	Nov	Genting, Malaysia
5th	2006	Sept	Seoul, Korea
6th	2007	April	Hong Kong China
7th	2007	Oct	Chengdu, China
8th	2008	Nov	New Delhi, India
9th	2009	Nov	Hong Kong China
10th	2010	May	Singapore
11th	2010	Sept	Taiwan

Chair

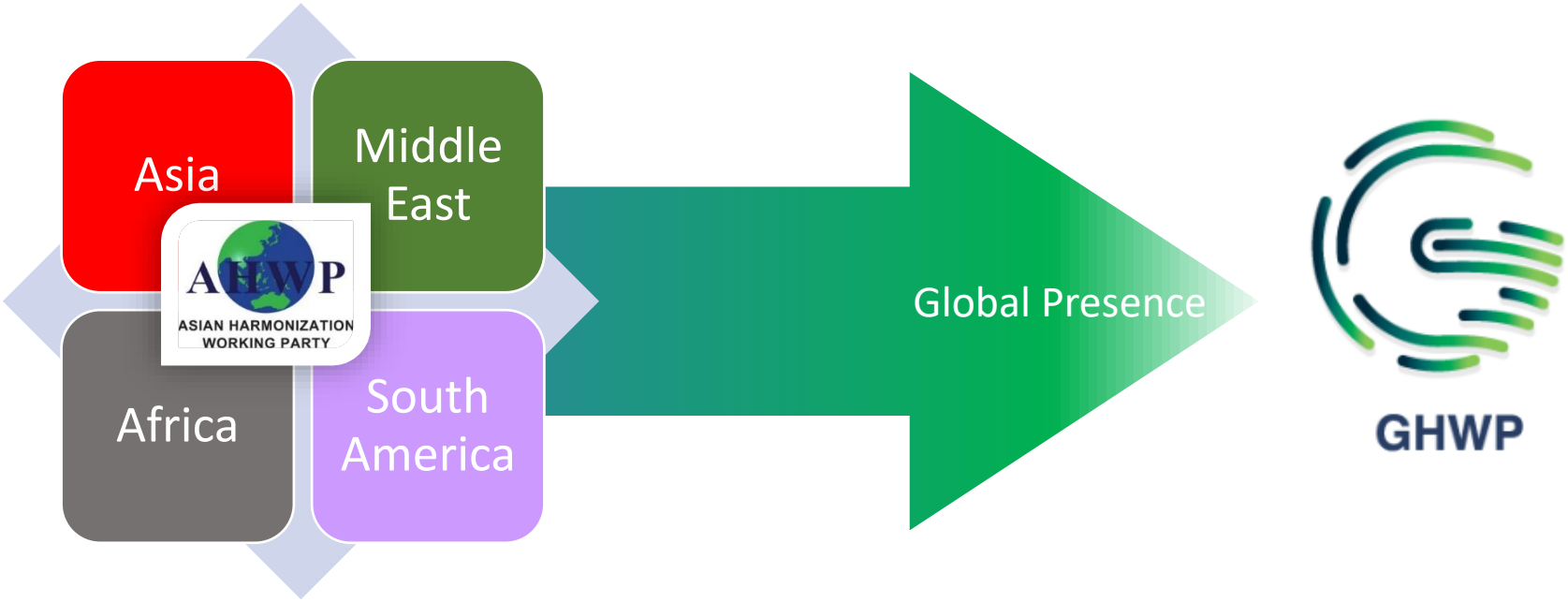
1999-2005 Dr C.Tan
2005 -2008 Dr Pillay
2009- 2012 Dr Wang Boating

General Meeting

1st – 3rd	1996 -1997		
4th	1998	Sydney	Australia
5th	1999	June	Bethesda,Maryland USA
6th	2000	Sept	Ottawa Canada
7th	2000	Mar	Singapore
8th	2001	Sept	KualaLumpur, Malaysia
9th	2002	May	Singapore
10th	2005	Nov	Genting, Malaysia
11th	2006	Sept	Seoul, Korea
12th	2007	Oct	Chengdu, China
13th	2008	Nov	New Delhi, India
14th	2009	Nov	Hong Kong
15th	2010	Nov	Saudi Arabia

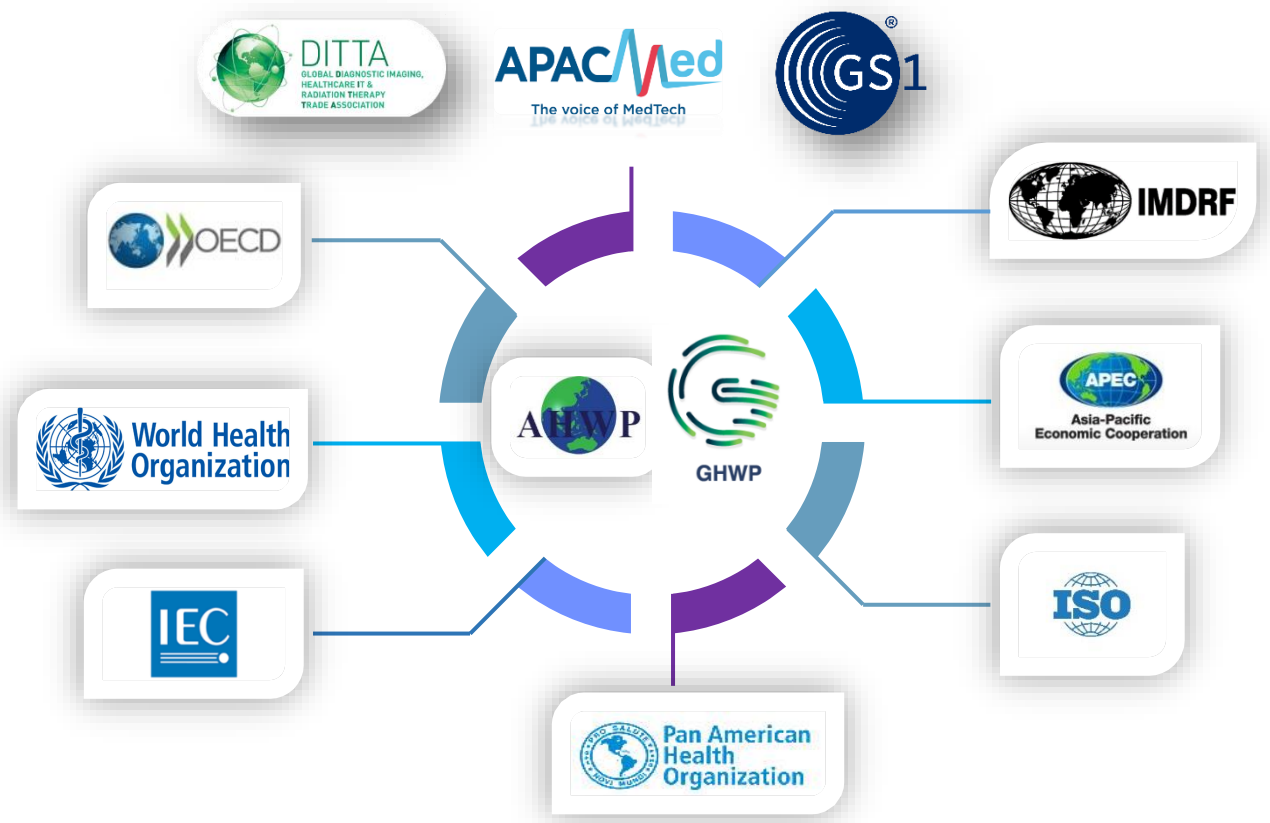
From Asia Focus to Global Presence

- transforming from Asia Focus initiatives to Global Presence of 31 members
- re-banding into Global Harmonization Working Party (GHWP)
- unchanged inclusive partnership of Regulators and Industry



Strong Collaborations with International Org

- strong collaborations with international organizations such as WHO, IMDRF, ISO ,APEC and OECD and global and regional liaison members of DITTA, APACMed and GS1



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Towards Medical Device Harmonization

AHWP/GHWP actively participated in the global initiatives in medical device convergence, with recent activities included:

- AHWP/GHWP was invited to nominate experts for joining the new Joint Advisory Group 5 (JAG5) under the leadership of IEC TC 62 and ISO/TC 210

- AHWP/GHWP has also participated in the IEC TC62 under Category A Liaison

Please visit our website

www.ahwp.info / www.ghwp.info

Global Harmonization Working Party

Towards Medical Device Harmonization

- Stay tuned for new activities and updates
- Check out our guidance documents and give us comments
- Welcome your joining to AHWP/GHWP

Thank You !!

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