

AHWP-GHWP Status Update 2020-2021

The Journey of Regulatory Harmonization

By Tran Quan

AHWP/GHWP Vice Chair/CB Lead

VP, Regulatory & Government Affairs & Quality Assurance

Align Technology, APAC

1 December 2021



24th AHWP Annual Meeting / 24th TC Meeting

November 11th – 14th, 2019, Sultanate of Oman, Muscat

Collaboration between Regulators and Industry

- Capacity Building – Fundamentals & Expanded Regulatory levels on new technologies, Digital transformation
- Cybersecurity
- UDI
- QMS



Delivering Medical Devices with Safety & Performance



Patients



AHWP Membership

AHWP Member Countries / Regions: 31 (25 Years)

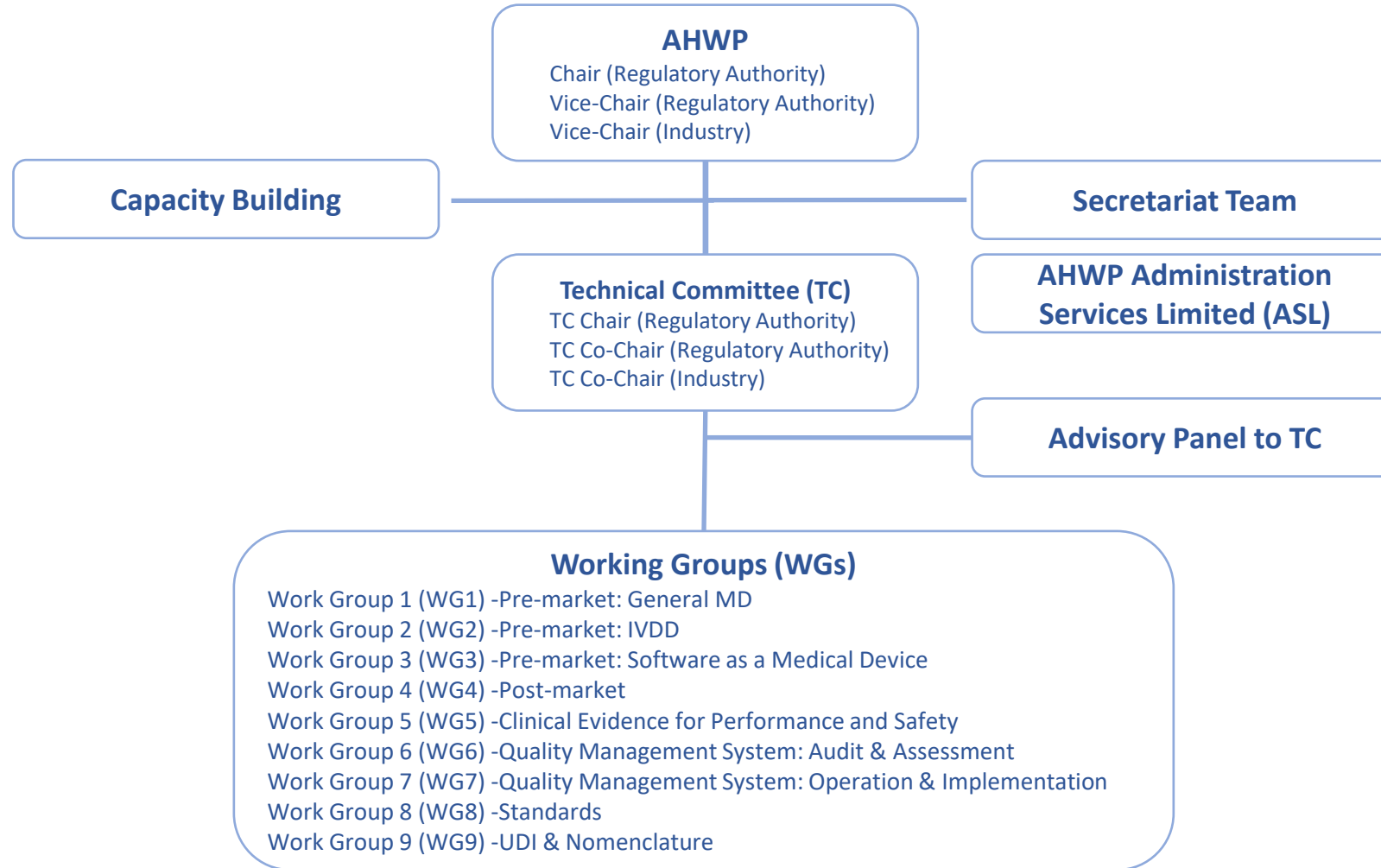
Asia, Middle East, Africa, S. America

**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**

AHWP/GHWP Organization Structure



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 VP Regulatory & Government Affairs and Quality Assurance, Align Technology Asia Pacific Lao PDR

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 General, Medical Device Evaluation Department, 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

Vision, Mission and Goal for AHWP

Vision

To achieve international harmonization and convergence of medical device regulations through collaborative efforts of regulators and the industry in Asia and beyond

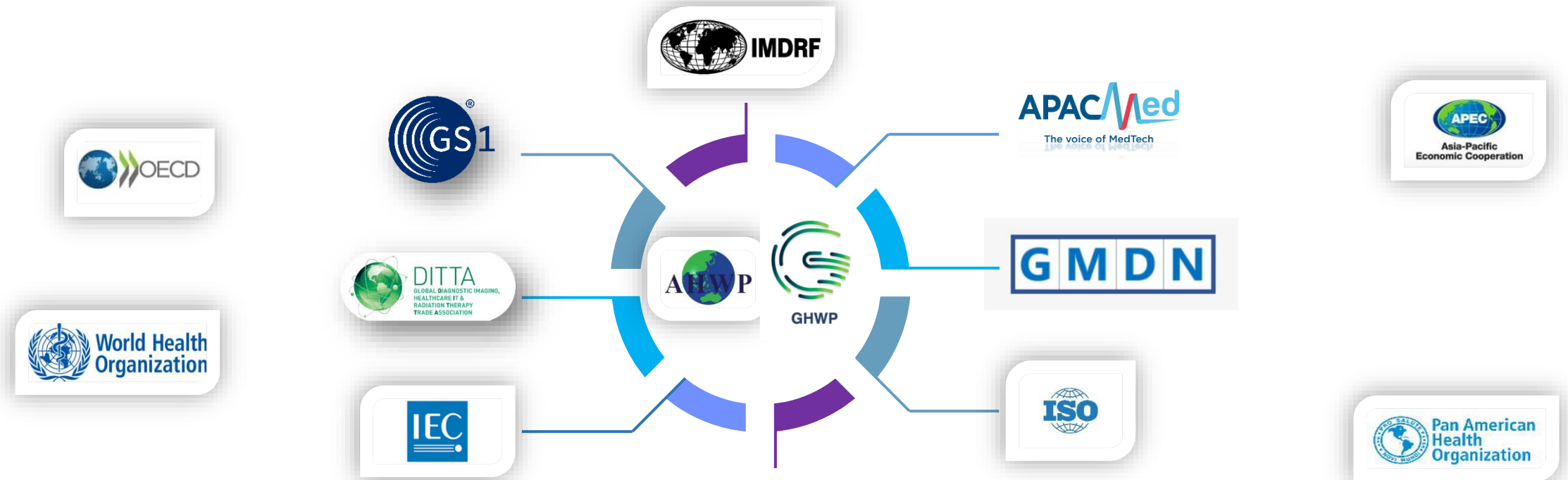
Mission

To strategically accelerate medical device regulatory convergence through promoting an efficient and effective regulatory model for medical devices

Goal

- To study, develop and recommend approach for the convergence and harmonization of medical device regulations in Asia and beyond
- To work transnationally in collaboration with IMDRF, WHO and the related international organizations
- To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements
- To promote capacity building in member economies and to foster strategic membership expansion

Strong Collaborations with International Organizations



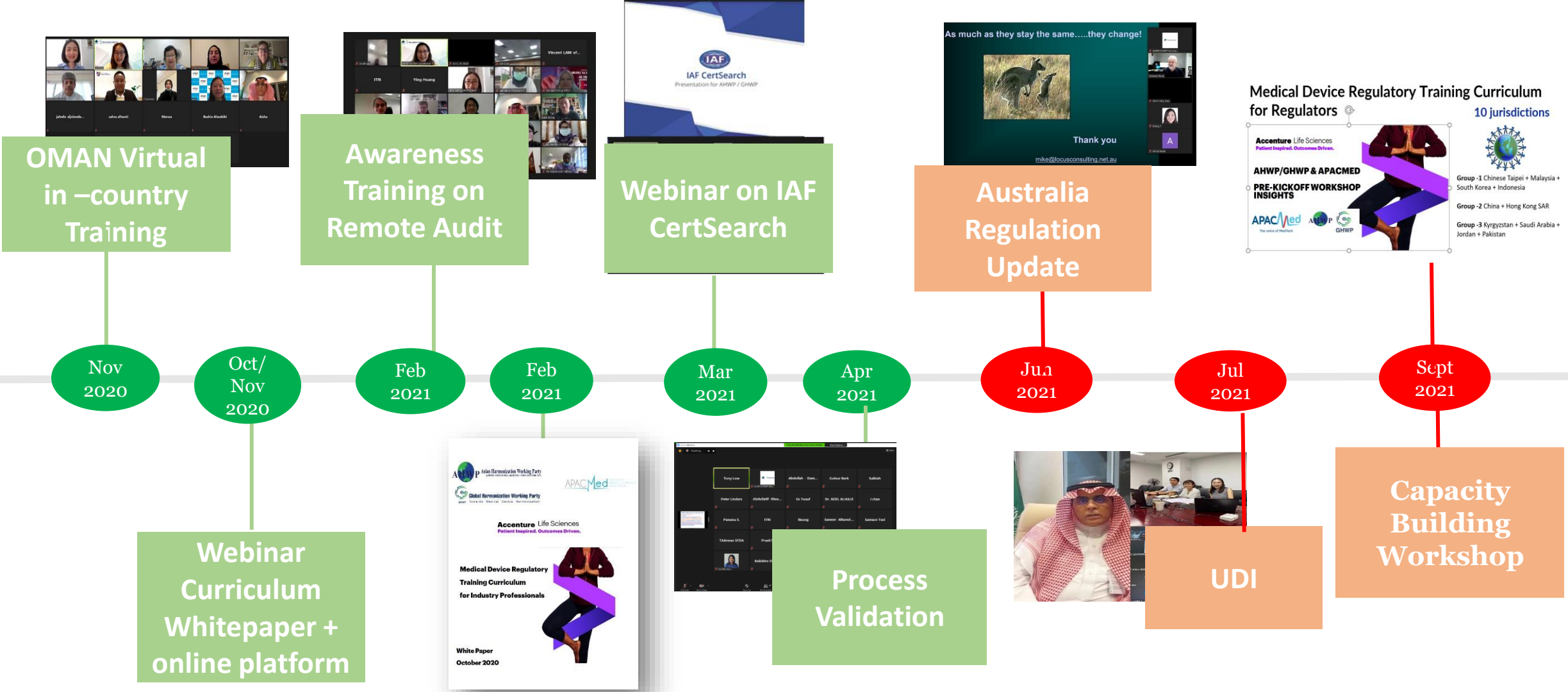
IACRC – The Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (to be admitted)

2020 AHWP/GHWP TC Leaders (Virtual) Meeting
13th October 2020, Tuesday
AGENDA

- Defer Annual Meeting 2020 due to COVID-19 pandemic

Time (KSA GMT+3)	Agenda (AHWP/GHWP TC Leaders Meeting)	Responsible Person(s)
08:00 - 08:15	Login to Virtual Meeting	All TC participants
08:15 - 08:45	Welcome and Opening	CEO SFDA
	Opening Speech by AHWP/GHWP Chair	Mr. Ali M. Al-Dalaan, AHWP/GHWP Chair
	Message by AHWP/GHWP Vice Chair	Mr. Gao Guobiao, AHWP/GHWP Vice Chair
	Group Photo (on screen photo)	All participants
08:45 - 08:50	1. Adoption of the Agenda & Roll Call	Mr. Bryan So, AHWP/GHWP Executive Secretary General
08:50 - 08:55	2. Opening address by TC Chair	Ms. Sasikala Devi Thangavelu, TC Chair
08:55 - 09:05	3. Updates on Covid-19	Ms. Sasikala Devi Thangavelu, TC Chair
09:05 - 09:15	4. Regulatory Updates & Measures in Response to COVID-19 Outbreak	Ms Adriana ELAZQUEZ BERUMEN, WHO
09:15 - 09:25	5. Updates on IMDRF	Ms Wong Woei Jiuang, IMDRF
09:25 - 11:35	6. AHWP/GHWP TC's Current Status update on new work program and Covid-19 related regulatory updates - All WG work plan and progress updates since Oman meeting - Comments and discussion on WG Program	Ms. Sasikala Devi Thangavelu, TC Chair & All TC participants
09:25 - 09:40	WG2 - WG updates and Covid-19 updates	Mr. Wen-Wei TSAI/Mr. Albert Poon
09:40 - 09:55	WG5 - WG updates and Covid-19 updates	Mr. Fikriansyah Bin Irman /Ms. Sumati Randeo
09:55 - 10:10	WG6 - WG updates, Covid-19 updates and Remote Audit	Mr. Abdullah AL RASHEED/Mr. Vincent LAM
10:10 - 10:20	BREAK	
10:20 - 10:30	WG1 – WG updates	Dr. Seil Park / Ms. Mandy Myoung Shim Kim
10:30 - 10:40	WG3 – WG updates	Mr. Abdullatif Al Watban / Mr. Tony YIP
10:40 - 10:50	WG4 – WG updates	Mr. Yorkie CHOW / Ms. Kitty MAO
10:50 - 11:00	WG7 – WG updates	Mr. WANG Ai Jun / Mr. Ee Bin Liew
11:00 - 11:10	WG8 – WG updates	Mrs. Salbiah Yaakop / Mr. Tony LOW
11:10 - 11:20	WG9 – WG updates	Ms. Jun LI / Ms. Victoria QU
11:20 - 11:35	DISCUSSION	All TC participants
11:35 - 11:45	BREAK	
11:45 - 11:55	7. AHWP/GHWP Capacity Building	Ms. Quan Tran
11:55 - 12:05	7a. AHWP/GHWP-APACMed Curriculum White Paper	Ms. Miang Tanakasemsub
12:05 - 12:20	7b. MedTech Regulatory Curriculum Training Platform	Accenture Academy
12:20 - 12:45	8a. Closed Door Meeting for AHWP/GHWP & TC Leaders - WGs activities plan - Upcoming AHWP/GHWP Annual Meetings - AOB	AHWP/GHWP Office Bearers, AHWP/GHWP TC Office Bearers, WGs Chairs & Co-chairs & Secretariat ONLY
	8b. Closed Door Meeting for TC Advisors (separate meeting link)	TC Advisors ONLY
12:45 - 13:00	9. TC Advisory Panel's Recommendations for TC works	All TC participants
13:00 - 13:10	10. Closing Remarks	Mr. Alfred Kwek, TC Co-chair

Capacity Building Events – 2020-2021



- **AHWP/GHWP 25th Annual Meeting/25th TC meeting**
2 days Online
30th Nov (Tue) and 1st Dec (Wed) 2021
1300 to 1700 KSA Time/ 1800 to 2000 Beijing/HK Time





Global Harmonization Working Party

Towards Medical Device Harmonization

AHWP Rebranding into GHWP

- the Journey of Regulatory Harmonization

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

Upcoming Online Annual Meeting

New name & logo to be formally announced and endorsed

29th June 2020

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

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



Rationales for the Change



- 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**



1996

A voluntary group of regulator and industry members from Asia



2020

AHWP transition to GHWP
The largest co-operative organization in the world

Rebrand to



1st Dec '21 **Global Harmonization Working Party (GHWP)**

31 Members
58 Guidance documents
40+ training/workshops
5000+ participants globally
6 International liaison

Thank You

