Global Harmonization Working Party

GHWP

Towards Medical Device Harmonization

GHWP Updates

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Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

The Global Harmonization Working Party was **formed in 1996-97** by a group of committed regulatory affairs professionals working towards greater harmonization of medical device regulations

The Party, formerly known as Asian Harmonization Working Party, was **rebranded to Global Harmonization Working Party (GHWP) in 2021**

At present there are 33 member countries/regions in GHWP, where **regulatory authority and industry representatives have equal voting rights** in GHWP annual meetings

GHWP Members from 33 Countries/Regions & 6 Liaison Partners

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

GHWP Liaison Members (Liaison Partners)
Asia Pacific Medical Technology Association (**APACMed**)
Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association (**DITTA**)
Global Medical Device Nomenclature Agency (**GMDN Agency**)
Global Medical Technology Alliance (**GMTA**)
GS1
Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (**IACRC**)

GHWP Chair and Leadership 2023-2025

Dr. Xu Jinghe
GHWP Chair
Deputy Commissioner
NMPA, China

Ms. EunHee Cho
GHWP Vice-chair (Industry)
RA Director, Abbott Medical, Korea

Dr. Abdullatif S. Al Watban
GHWP TC Chair
Executive Director, Medical Devices Evaluation
Medical Devices Sector, SFDA, Saudi Arabia

Ms. Jun Li
GHWP TC Co-chair (Regulatory Authority)
Deputy Director General
Department of Medical Device Regulation
NMPA, China

Ms. Miang Tanakasemsub
GHWP TC Co-chair (Industry)
Head of Regulatory Affairs, Asia Pacific
Johnson & Johnson Vision, Thailand

GHWP Organization Structure

New

GHWP
Chair (Regulatory Authority)
Vice-Chair (Regulatory Authority)
Vice-Chair (Industry)

Strategic Advisory Board (SAB)

Capacity Building

Secretariat Office
(in Hong Kong SAR, China)

GHWP Academy
(to be established)

New

GHWP Technical Committee (TC)
TC Chair (Regulatory Authority)
TC Co-Chair (Regulatory Authority)
TC Co-Chair (Industry)

GHWP Administration Services Ltd (ASL)
(in Hong Kong SAR, China)

Advisory Panel to TC

Working Groups (WGs)
WG1 - Pre-market: General MD
WG2 - Pre-market: IVDD
WG3 - Pre-market: Software as a Medical Device
WG4 - Post-market
WG5 - Clinical Evidence for Performance & Safety
WG7 - Quality Management System*
WG8 - Standards
WG9 - UDI & Nomenclature

** WG 6 combined into WG 7*

GHWP Strategic Advisory Board (SAB)

- To bring knowledge and experience to support in **high-level planning and steering on the development of GHWP**, and the promotion of GHWP's mission, vision, and goals

- To **provide advice, recommendation, insights and intelligence for the strategic positioning and development of GHWP**

- The role of SAB should be **differentiated from GHWPTC Advisory Panel**, which offers technical/professional advice towards meeting the goals of GHWP

- **Experts from regulatory authorities of GHWP member countries or regions** with robust medical device regulatory systems, or other **international or regional organizations** as SAB Members, including the participation of **experts from industry** on need basis

- **Number of members in the SAB shall not exceed ten (10),** preferably from different continents

Full text available under GHWP House Rules 20

GHWP Strategic Advisory Board (SAB) – Cont.

- **"GHWP Procedure for Strategic Advisory Board Establishment and Operation"** with more details on the operations of the SAB was released in July 2023, and available on GHWP website

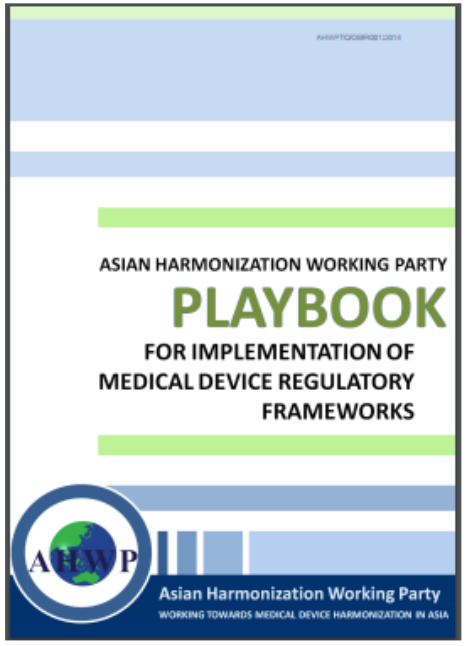
- **Roundtable Meeting shall generally be held by video conference**, or as a side event at the GHWP TC meeting

- SAB Member(s) will be awarded with a letter of appointment by GHWP Chair at the first GHWP Annual Meeting following their appointment

- Appointment to the SAB is **on a voluntary basis**

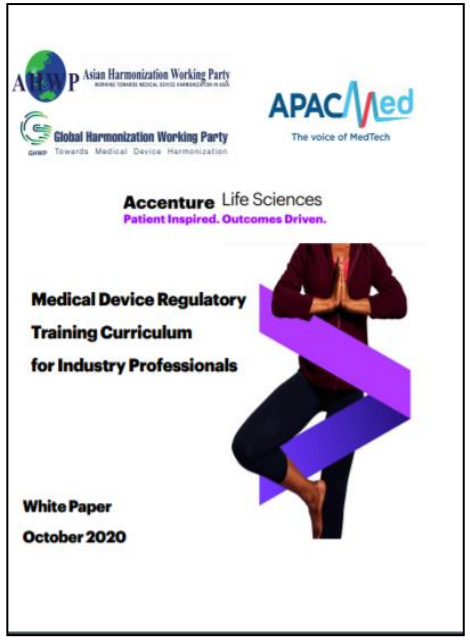
Full text available at GHWP website: http://www.ghwp.info/index.php/node/884

GHWP from Playbook to Academy

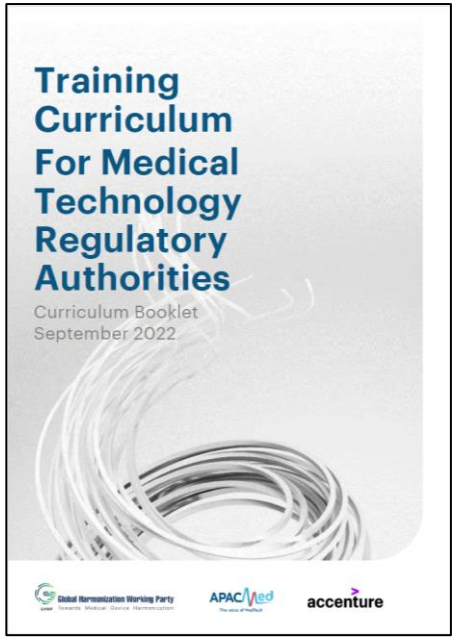


Playbook for implementation of medical device regulatory frameworks

Competency framework for medical technology regulators



Medical Device Regulatory training Curriculum for Industry Professionals



Training Curriculum for Medical Technology Regulatory Authorities

GHWP Academy

GHWP Capacity Building Online Training System

2014 - 2017	2018 - 2019	2020-2021	2022-2023	2023-2026

GHWP Academy

Purpose

- To facilitate the implementation of the *Global Harmonization Working Party Strategic Framework towards 2026*, and fulfill GHWP's mission, vision and goals, GHWP Leadership decides **to establish the GHWP Academy in its member countries and regions** for
  - **carrying out training, research and knowledge exchange** in the field of medical devices
  - **enhancing medical device regulatory capability** of its member countries and regions
  - promoting global medical device regulations toward **convergence, harmonization and reliance**

Full text available at GHWP website - http://www.ghwp.info/node/888

GHWP Academy

Mode of Training

- GHWP Academy **mainly focuses on on-site trainings**, while online trainings are also encouraged to benefit a wider range of participants

Call for Comments

- "Measures for the Building of GHWP Academy" on GHWP website on 13th Sep 2023
- Deadline for submission of comment **by 28th Sep 2023**

Application for GHWP Academy

- Deadline for submission of application form & full proposal will be on **23rd Oct 2023**

Full text available at GHWP website - http://www.ghwp.info/node/888

GHWP 27th Annual Meeting & Technical Committee Meeting

27th to 30th November 2023

Shanghai International Convention Center, Shanghai, China

Welcome to Join Us !!

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THANK YOU / QUESTIONS

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