



GHWP

# Global Harmonization Working Party

Towards Medical Device Harmonization

## GHWP Status Report

12<sup>th</sup> Dec 2024

**Bryan SO**

**GHWP Executive Secretary General**

Managing Director, Multi-Scale Medical Robotics Center,  
The Chinese University of Hong Kong, Hong Kong SAR, China

GHWP was established in 1996/1997, with the vision to achieve international harmonization of medical device regulatory framework among regulatory authorities, convergence of regulatory requirements, via open and trust-based efforts between regulatory authorities and the industry across the globe



**GHWP Strategic Framework  
Towards 2026**

**GHWP  
Strategic  
Objectives**



**GHWP**



Membership



Regulatory  
Convergence



Regulatory  
Science



Regulatory  
Reliance



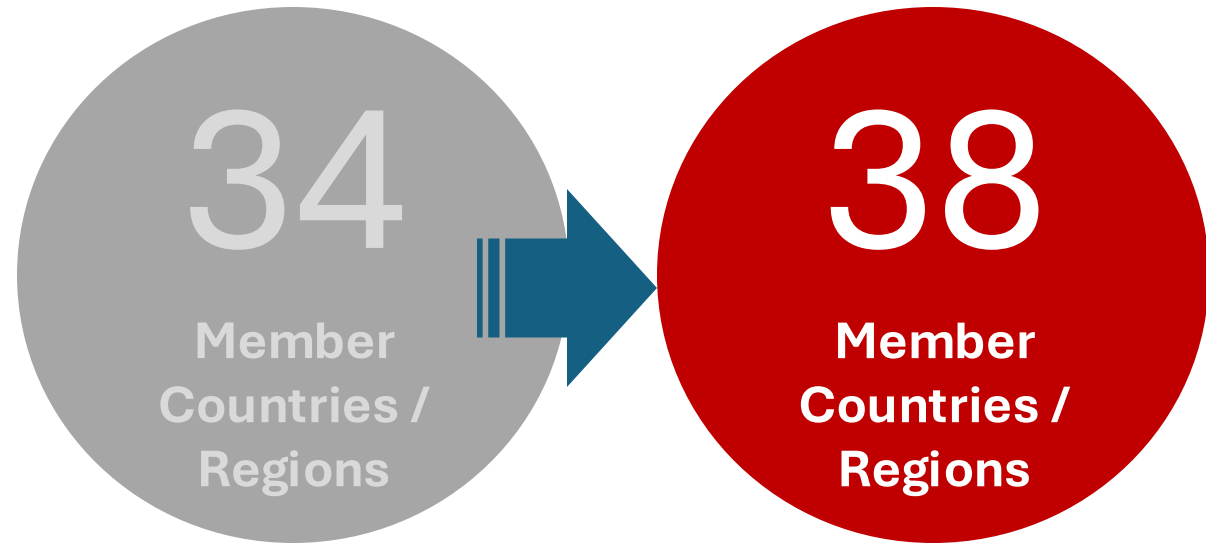
Capacity  
Building



Global  
Partnership

# 4 New Members to GHWP

- Botswana
- Ghana
- Macao SAR, China
- Uzbekistan



**Global Harmonization Working Party**

GHWP

Towards Medical Device Harmonization

# Unique Strength of GHWP



Medical Device Regulatory International Organization with **Strong Partnership** between Regulatory Authorities & Industries

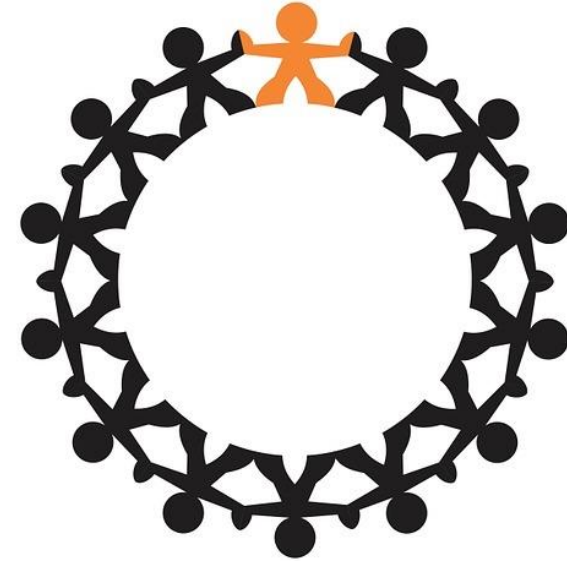


**Active Involvement of the Industries** from planning, decision-making process, towards implementation

# Unique Strength of GHWP



Regulatory Authority & Industry  
enjoy **Equal Voting Rights** on Key  
Issues in GHWP



**Chairs in GHWP are always  
Regulators** Industry serves as Vice-  
chairs/Co-chairs in GHWP Leadership,  
TC Leadership & WG/STG

Simple majority or Voting by GHWP Members

## Decision-Making in GHWP

GHWP Leadership

GHWP/TC Leadership



# Structural reform in GHWP for Better Engagement

## Management Committee

- To enlarge the participation of Member Country/Region in Leadership-level planning and implementation
- Only for in-principle approval for the formation of MC in 28<sup>th</sup> Annual Meeting
- Details in PROPOSED FINAL document will be further refined in Q1 2025, followed by public consultation



# Enhancement in GHWP for better communications and effective decision- making

## e-Voting

To accelerate decision-making by enabling e-Voting as an alternative to onsite voting

## Revamp of GHWP Website

To enhance communications and user experience

# Website - Highlights



Convergence • Harmonization • Reliance

# Website - Highlights



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[Our Work](#) [Leaderships](#) [Members](#) [What's New](#) [Events](#) [Guidance Documents](#) [Resources](#) [About](#)

## Driving Forward Global Medical Device Harmonization

[Explore More](#)



# Website - Highlights

- Vision, Mission and Goal >
- Strategic Framework** >
- Work Plan >
- House Rules
- Terms of Reference

- Level 3 Item 1
- Level 3 Item 2
- Level 3 Item 3



Easy Navigation with Drop-down Menu

## Guidance Documents

### Explore by Document Status





# Website - Highlights

## Guidance Documents



Filter by Status ▼

Search for guidance documents...

Search

Reset

Sort by: **Newest** ▼

Filter by Status:

- In Progress (55)
- NWIP (25)
- Draft (11)
- Proposed (Call for Comments) (4)
- Proposed Final (15)
- Final (128)
- Full Adoption of Guidance Documents by Other Organization (57)
- Abolished (42)

### Guidance Documents - Clinical Performance Studies for In Vitro Diagnostic Medical Devices

Publish Date: 11 Jun 2024 [Call For Comments](#)

### Quality Management System-Medical Devices Requirements for Distributors, Importers and Authorized Representatives

Comment Period: 14 Jun 2024 - 18 Jul 2024



# Website - Highlights

Home > Guidance Documents >

[Call For Comments](#)

## Clinical Evidence for IVD Medical Devices - Clinical Performance Studies for In Vitro Diagnostic Medical Devices

Publication Date: 10 Jun 2024 | Comment Period: 14 Jun 2024 - 18 Jul 2024

**Call for Comment on This Proposed Document**

Proposed Document: Regulatory requirements for Medical Devices including In Vitro Diagnostic Medical Devices and Software as Medical Devices during a public health emergency

Any comments and suggestions on the proposed document are welcome. Please send them with the template attached to the [GHWP / GHWP Secretariat \(secrestat@ghwp.info\)](mailto:GHWP@ghwp.info) by 18 Jul 2024.

[Download Comment Template](#)

### Abstract

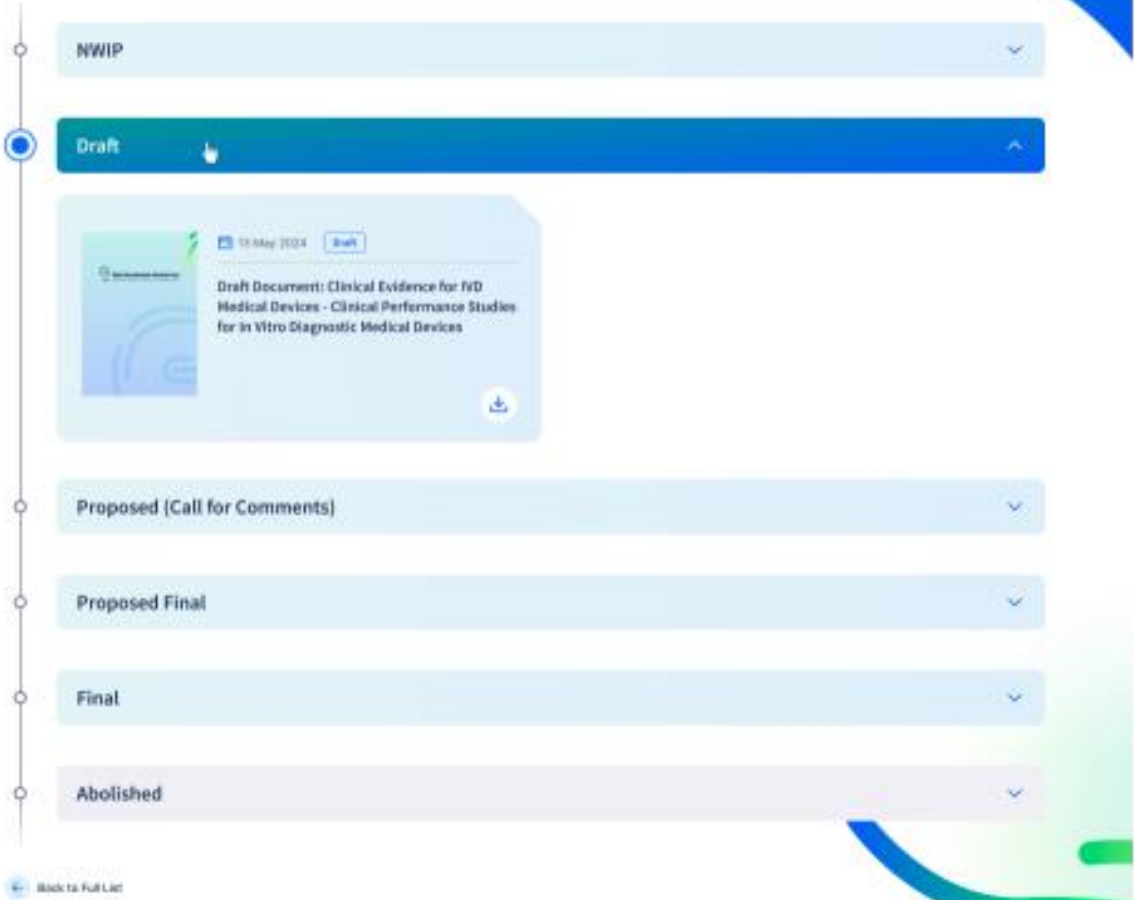
This document is produced by the Asian Harmonization Working Party, based on Global Harmonization Task Force Final Document GHTF2003/N69-2012 of GHTF Study Group 5. The document is intended to provide non-binding guidance for use in the regulatory systems of in vitro diagnostic (IVD) medical devices, and has been subject to consultation throughout its development. There are no restrictions on the reproduction, distribution, translation or use of this document. However, incorporation of this document, in part or in whole, into any other document does not convey or represent an endorsement of any kind by the Asian Harmonization Working Party.

### General Information

|                   |   |
|-------------------|---|
| Status:           | Proposed (Call for Comments)  |
| Publication Date: | 10 Jun 2024   |
| Number:           | AHAWP02-WG5-901-2023  |
| Number of Pages:  | 25  |
| Authoring Group:  | Work Group 2 - Framework IVD<br>Work Group 5 - Clinical Evidence for Performance and Safety |

[View Document](#)

## Life Cycle



Highlight of “Call for Comment” documents & Documents Life Cycle

# Website - Highlights

Home >

## Leaderships

### About GHWP Leadership

**GHWP Chair**



**Dr. Xu Jinghe**  
Deputy Commissioner, National Medical Products Administration (NMPA), China

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



**Ms. Eka Purnamasari**  
Director for Medical Devices Control, Ministry of Health, Indonesia

**GHWP Vice-Chair (Industry)**



**Ms. EunHee Cho**  
RA Director, Abbott Medical Korea, Korea

**TC Chair (Regulatory Authority)**



**Dr. Mohammed Majrashi**  
*Executive Director*  
*Surveillance and Biometric*  
*Saudi Food & Drug Authority (SFDA)*  
*Kingdom of Saudi Arabia*

**TC Co-chair (Regulatory Authority)**



**Ms. Li Jun**  
Deputy Director General, Department of Medical Device Regulation, National Medical Products Administration (NMPA), China

**TC Co-chair (Industry)**



**Ms. Miang Tanakasemsub**  
Head of Regulatory Affairs (IRA), Head of Regulatory Affairs (IRA), Asia Pacific (API), Johnson & Johnson Vision

GHWP Leaderships



# Website - Highlights

5/10



Media Handling - Video and Photo

# Website - Highlights



Responsive design for Mobiles and Tablets

# Website - Highlights

What are you looking for?

 [Search](#)

Search History

Events

Guidance Document

Leaderships

## Search Result

 [Search](#)

Total 57 Search Results

[Home](#) > [Guidance Documents](#) >

### Adoption of "The Quality Management System – **Medical Devices** – Guidance on the Control of Products and Services Obtained from Suppliers"

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[Home](#) > [Guidance Documents](#) >

### Call for Comments on the Proposed Document 'Change Management to Registered **Medical Devices**'

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[Home](#) > [Guidance Documents](#) >

### Clinical Evidence for IVD **Medical Devices** - Clinical Performance Studies for In Vitro Diagnostic Medical Devices

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Site Search feature for Documents and News & Events

# Website - Highlights

## Events

### Explore Featured Events



26 May 2024 | Events

#### Registration Is Open for the Capacity Building for Medical Device Industries Event

Explore More 

## Upcoming Events

Filter by Categories 

Search for event...

Search

Reset

## Events pages with Search function

Home > Events >

## The First GHWP Innovative Medical Device Symposium (With Final Agenda)

Apply Now

19 Apr 2024 | Symposium

#### Schedule

27 May 2024 - 1 Jun 2024  
9:30am - 6:30pm

#### Application Deadline

20 May 2024

#### Location

South China University of Technology, Panyu District, Guangzhou, the People's Republic of China

#### Fee

RMB 20,000 /USD 2,800 Per Person  
(Banking Service Fees Are Not Included)

#### Organizer

GHWP (Guangzhou) Academy  
Guangdong Institute of Advanced Biomaterials and Medical Devices

#### Target

Medical Device Researchers, Regulators, Producers  
Invited GHWP Members  
Invited Council Members of GHWP Academy

## Overview

In order to further enhance the regulatory capacity of the Global Harmonization Working Party (GHWP) member countries and regions, and to help innovative medical device products benefit people around the world, GHWP will hold the first GHWP (Guangzhou) Academy Training from May 27th to May 31st, 2024. The training theme is "Collaborative Empowerment—Innovative Medical Devices Embrace the World".

The training combines face-to-face courses, panel discussions, on-site Q&A, case sharing, practical training, and interactive communication. The May 27 morning training agenda will be streamed live online.

Visit Website 



Dr. Hisham bin Saad Aljadhey, Chief Executive Officer

## Event Detail page with Clear Information Layout for Actions

[www.ghwp.info](http://www.ghwp.info)

[www.ghwp.org](http://www.ghwp.org)

(New GHWP website under new domain name will be launched in Q1 2025)

# E-Voting System




**Global Harmonization Working Party**

Towards Medical Device Harmonization

Welcome to GHWP E-Voting  
[ Voting for the Act: Lorem ipsum dolor sita ]

Enter Your One-Time Password

I'm not a robot 

[Get One-Time Password](#) [Enter to Vote](#)

Welcome to GHWP E-Voting  
[ Voting for the Act: Lorem ipsum dolor sita ]

Enter Your One-Time Password

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[Get One-Time Password](#) [Enter to Vote](#)

countdown 56s


## About the Act: Lorem ipsum dolor sita

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[View Document](#) 

Voter Name: Chan Tai Man Country/Region: Hong Kong, China

## Donec et dictumst dignissim velit tempor quam morbi sapien?

  
Affirmative Vote

  
Dissenting Vote

  
Abstention

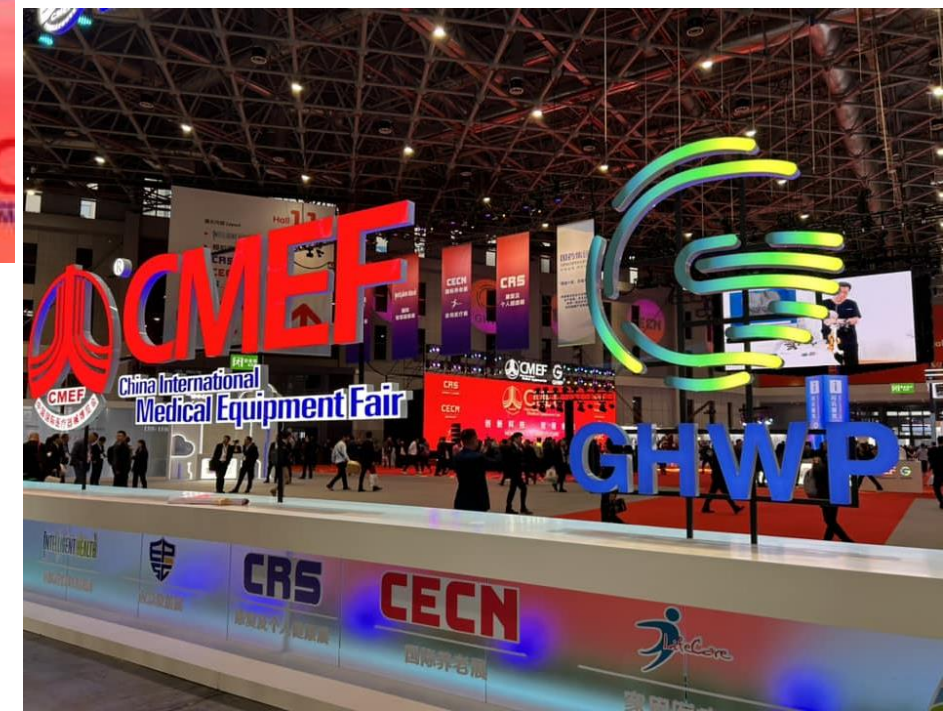
[Submit My Vote](#)

Highly Secured e-Voting system with Immutable and Anonymous Built-in Features



GHWP Thematic  
Exhibition During  
89<sup>th</sup> CMEF in  
Shanghai  
(11-14 April 2024)

Exhibition Booth with  
introductions of definitions and  
various regulatory pathways  
of innovative medical devices in  
the GHWP member countries  
and regions



# The First GHWP Innovative Medical Device Symposium on 12 April 2024 during the 89th China International Medical Equipment Fair (CMEF)



200+

experts from regulatory authorities & industries

Speakers from **China Malaysia, Japan and Korea**

innovative medical device regulatory policy, **MedTech Assessment Routes** for Novel, Innovative Medical Devices, and **regulatory reliance** and industry globalization and industry achievements



# Inauguration of the GHWP (Guangzhou) Academy and 1<sup>st</sup> Training in June 2024

创新医疗器械走向世界:首期GHWP(广州)学院培训合影  
Innovative Medical Devices Embrace the World: The 1st GHWP (Guangzhou) Academy Training



Theme: **Innovative Medical Devices Embrace the World**

**300+** medical device regulators & industry

**12** member countries and regions

**5** international org

**5** days training on 27-31 Jun 2024

## Topics:

1. GHWP Promotes Global Medical Device **Regulatory Convergence, Harmonization and Reliance**
2. **Innovative Trends** Shaping the Future of Medical Device Industry
3. A series of Training on the **Premarket Regulatory Framework** of Medical Device
4. **Onsite Training** at Innovative Medical Device Enterprises in Guangdong
5. Case sharing: **Going Global with Innovative Medical Device**



# 2nd Training of GHWP (Guangzhou) Academy in November 2024

**330+** medical device regulators & industry

**5** main training topics

**3** days training on 24-26 Nov 2024

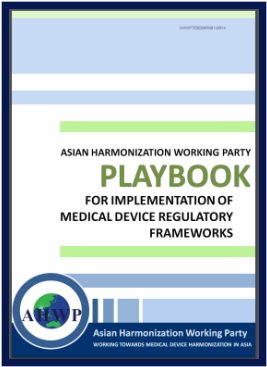
Theme: **Innovative Medical Devices Promotes Global Public Health**



## Topics:

1. GHWP Promotion of Global Medical Device Regulatory **Convergence and harmonization**
2. Regulatory Requirements and Common Issues for **Active Medical Devices**
3. Innovation and Regulatory Development in **Medical Device**
4. Innovation and Regulatory Development in **Medical Imaging and Therapeutic Equipment**
5. Innovation and Regulatory Development in **Artificial Intelligence and Digital Health**

# GHWP Capacity Building Journey



**Competency Framework for Medical Technology Regulators**



**White Paper Webinar**



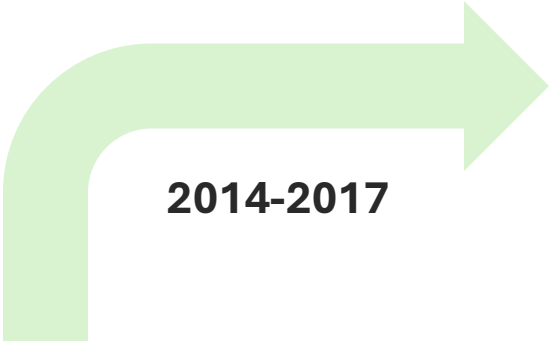
**Thailand in-country regulator training – 35 participants**

สำนักงานคณะกรรมการอาหารและยา  
Food and Drug Administration

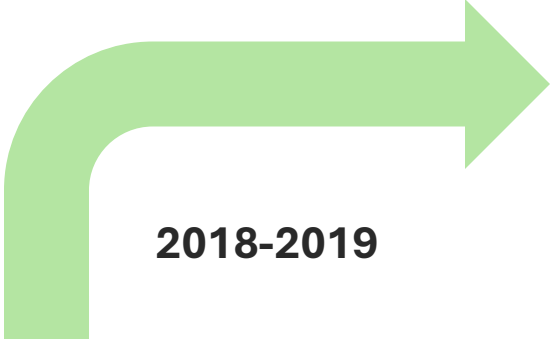
- Trainings
- Webinars
- Seminars
- Webinar curriculum whitepaper



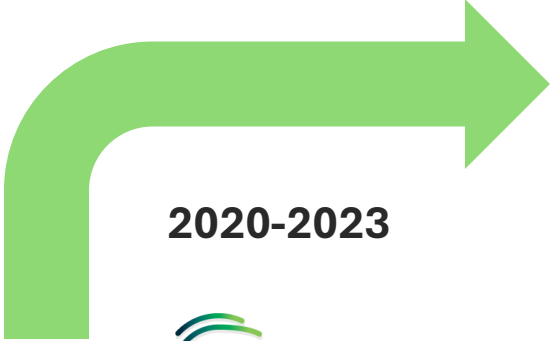
- Inauguration of GHWP (Guangzhou) Academy
- ✓ 2 training completed (total 600+ participants)
- TC WG – CB training partnership
- ✓ 10 TC WG trainings (Total 300+ participants focus on GHWP current guidelines)
- ✓ Training event recording and/or presentation to be posted on GHWP website



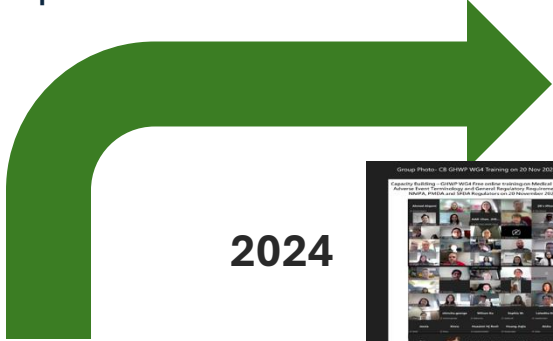
2014-2017



2018-2019



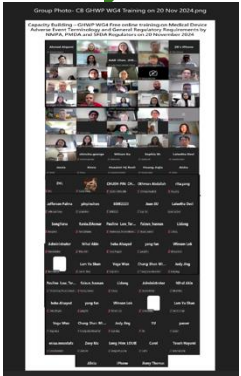
2020-2023



2024



**Global Harmonization Working Party**  
GHWP Towards Medical Device Harmonization





# GHWP Capacity Training Focus in 2025

Enhancing Training Curriculum

Leveraging GHWP (GZ) Academy to address training needs in Asia

Identifying opportunities for new GHWP Academy establishment

Delivering In-country training in Africa & Middle East

Keeping the momentum of online training

# Technical Guidance Documents in GHWP

**56** Technical Guidance Documents endorsed in GHWP

**10** new Technical Guidance Documents to be endorsed in this annual meeting

**7** Guidance Documents were selected for the survey

Questionnaires on GHWP Guidance Documents' adoption

**4** Member Countries/Regions replies: China, Cuba, Hong Kong SAR, Thailand and On-going



# Technical Committee Training in 2024

**10** TC training delivered

- 300+ participants
- 9 online plus 1 onsite
- Training focus on GHWP Guidance Documents
- Recorded training materials to be available on GHWP web



Adverse Event Terminology (AET) system across different jurisdictions

e-IFU and e-labelling

Comparison study of ISO 13485 vs. QMS requirements in GHWP member countries or regions

GHWP UDI Rule

Risk Based Approach to QMS aspects:ISO13485:2016

Best Practices in Audit Life Cycle Management

UDI in Japan

Systematic review and meta-analysis on the performance reports

Qualification of Medical device Software

Medical Gas System (MGS) – Essential Principles of Safety and Performance (EPSP) – Standards for Demonstrating Compliance

# Global Partnership

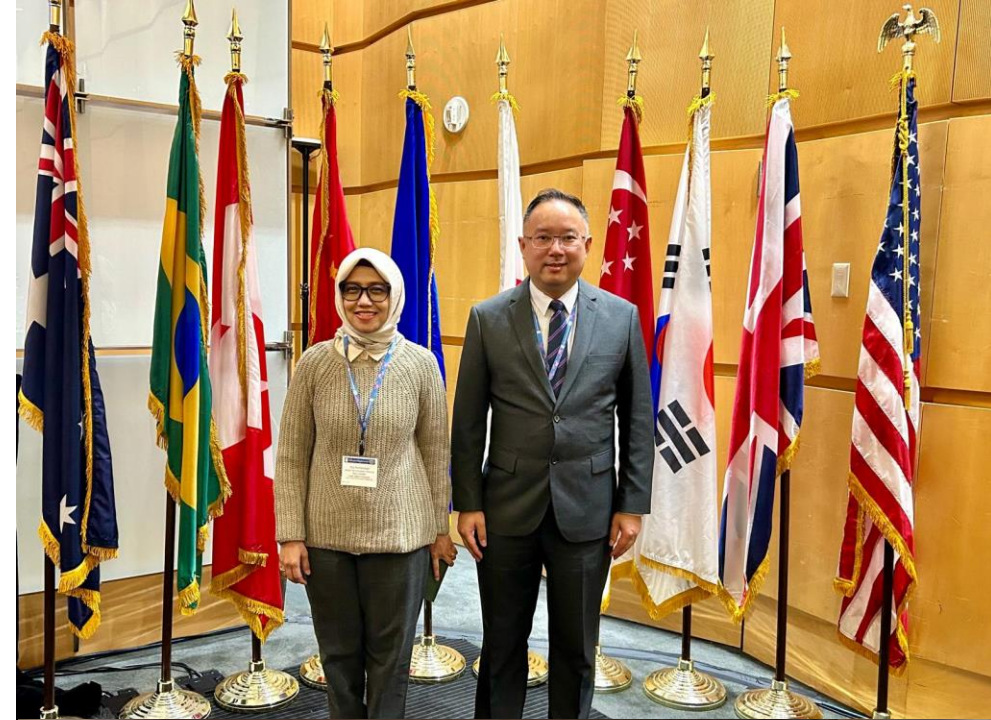


New Liaison Member :



# GHWP and IMDRF

- Online meetings between GHWP Chair with IMDRF Chair
- Regular communications between Secretariats
- GHWP participated in AI/ML, QMS WGs of IMDRF
- GHWP Leaderships attended IMDRF MC Meetings
- Presentation by GHWP in Stakeholder Session of IMDRF
- MOC in preparation





# GHWP TC Leaders Meeting in June 2025

- First GHWP meeting in Africa
- Host by Egypt EDA





- Safeguard Public Health
- Enable Innovative MedTech Accessibility
- Better Healthcare for Patients & Community

# Thank you

