Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

GHWP Updates

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WWW.CMDE.ORG.CN

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• Brief Introduction of GHWP

Vision
To Achieve International Harmonization of Medical Device Regulations through Collaborative Efforts of Regulators and the Industry.

Mission
To Strategically Accelerate Medical Device Regulatory Convergence through Promotion of an Efficient and Effective Regulatory Model for Medical Devices.

Organization strcture

- **GHWP**
  - Chair (Regulatory Authority)
  - Vice-Chair (Regulatory Authority)
  - Vice-Chair (Industry)
- **Capacity Building**
- **Secretariat Team**
- **GHWP Administration Services Limited (ASL)**
- **Technical Committee (TC)**
  - TC Chair (Regulatory Authority)
  - TC Co-Chair (Regulatory Authority)
  - TC Co-Chair (Industry)
- **Advisory Panel to TC**
- **Working Groups (WG1-WG9)**

Goals
To develop and recommend approaches for the global convergence and harmonization of medical device regulations.
To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements.
To promote capacity building in members and to foster strategic membership expansion.
To work in collaboration with related international organizations such as IMDRF, WHO, ISO, IEC,APEC, OECD.

- # GHWP Member in the World

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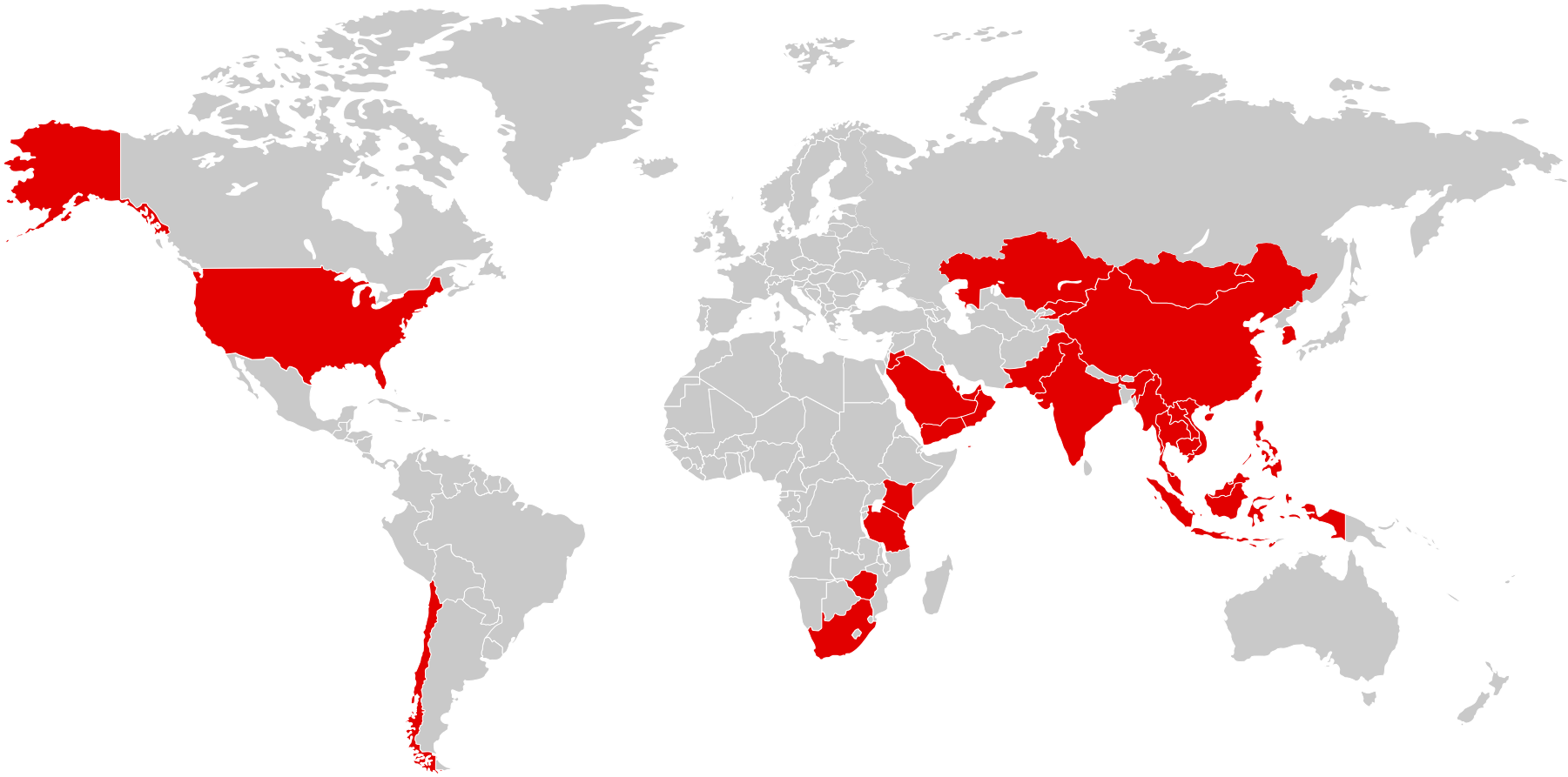

32 GHWP member countries or regions

GHWP member covered 56.82% population in the world

• GHWP&IMDRF

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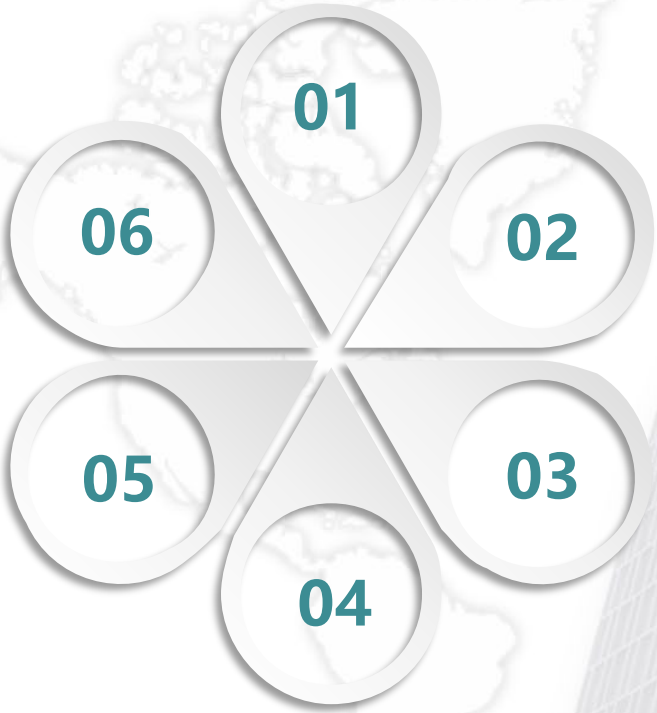
As an Asian regional organization with linkage to GHTF (IMDRF later) (1998-2000)

GHWP is consist of the medical device regulatory authorities and the medical device industry

Guidance documents are formed by work groups



Strong collaborations with each other

Established in 1990s

Focus on harmonize medical device regulations

• GHWP UPDATES

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GHWP Towards Medical Device Harmonization

25th Annual Meeting & 25th TC Meeting (30th Nov & 1st Dec 2021)

Official Rebranding of AHWP into GHWP(1st Dec 2021)

GHWP & APACMed Regulation Transformation(26th-27th May 2022)

New Proposal to be finalized

- GHWP Strategic Framework Towards 2026 Strategic Objectives
- GHWP New Organization to be discussed

New Guidance Documents

- Clinical Evidence for IVD Medical Devices - Clinical Performance Studies for In Vitro Diagnostic Medical Devices (by WG2 & WG5)
- Regulatory Mechanism for Medical Devices Including In Vitro Diagnostic Medical Devices and Software as Medical Devices During A Public Health Emergency (by WG1, WG2 & WG3)
- Replacement Reagent and Instrument Family Policy (by WG2)

Guidance Documents with IMDRF

In the near five years 10 guidance documents were issued, of which the four guidance documents were related to IMDRF Work Group documents.

- GHWP TC

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Work Group 5 (WG5) –
Clinical Evidence for Performance and Safety

Work Group 4 (WG4) –
Post-market

Work Group 6 (WG6) –
Quality Management System:
Audit & Assessment

Work Group 3 (WG3) -Pre-market:
Software as a Medical Device

Work Group 7 (WG7) –
Quality Management System:
Operation & Implementation

Work Group 2 (WG2) –
Pre-market: IVDD

Work Group 8 (WG8) –
Standards

Work Group 1 (WG1) –
Pre-Market Submission and CSDT

Work Group 9 (WG9) –
UDI & Nomenclature

The 4-Step Procedure for Endorsement

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GHWP Final Documents
(including Guidance Documents)

Step 4

FINAL

- Documents accepted, approved and/or passed resolutions
- Available at GHWP web as GHWP official documents

Step 3

PROPOSED FINAL

- Documents prepared for approvals and/or resolutions at annual meeting
- Post on GHWP website + circulations

Step 2

PROPOSED

- Documents discussed in GHWP and/or TC Meetings
- Post on GHWP website + circulations → Call for Comments

Step 1

DRAFT

- Initiated by Chairs of Committees / WGs / STGs / Secretariat
- For discussion within group members*

(*Administrative requirement as reminded by GHWP Chair to submit NWIP Form to GHWP Leadership and/or TC Leadership for endorsement)

• GHWP TC UPDATES

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	Name	Description	Latest achievements
WG1	Pre-Market Submission and CSDT	1.Guidelines for use of electronic labels and electronic instructions for use (IFU) as the compliance supplementation of labels (in collaboration with WG2 and WG3); 2. The definition of patient customized products and applicable pre-marketing ; 3. Guidelines for changes to a registered medical device (in collaboration with WG2).	Regulatory Mechanism for Medical Devices Including In Vitro Diagnostic Medical Devices and Software as Medical Devices During A Public Health Emergency(1 Dec 2021)
WG2	Pre-market: IVDD	1. Label and registration change requirements of IVD regents and registration requirements of a series of IVD reagent products applicable to the same instrument. 2. Related activities of international harmonization and standards organization within its scope of responsibility.	Replacement Reagent and Instrument Family Policy(1 Dec 2021) Clinical Evidence for IVD Medical Devices clinical Performance Studies for In Vitro Di-agnostic Medical Devices(1 Dec 2021)
WG3	Pre-market: Software as a Medical Device	The requirements for application dossiers of independent software registration, the requirements for software cybersecurity, and the review and approval management of medical device software.	Regulatory Mechanism For Medical Devices Including In Vitro Diagnostic Medical Devices and Software as Medical Devices During a Public Health Emergency(1 Dec 2021)
WG4	Post-market	Continuous updating and maintenance of the Post-marketing Resource Center	Post Market Resource Centre (Feb 2021)

• GHWP TC UPDATES

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	Name	Description	Latest achievements
WG5	Clinical Evidence for Performance and Safety	Continuously monitoring the progress of clinical requirements of the International Organization for Standardization (including related work items of IMDRF, ISO 14155 and ISO 20916), and continuing to conduct situation analysis on the work contents of WG5	Clinical Evidence for IVD Medical Devices- Clinical Performance Studies for In Vitro Diagnostic Medical Devices.(1 Dec 2021)
WG6	Quality Management System: Audit & Assessment	The effective implementation of the assessment of QMS in AHWP members	Online training session: Co Chair Vincent Lam conducted remote audit technique (4 Feb 2021)
WG7	Quality Management System: Operation & Implementation	1. Making a comparison of similarities and differences between the related requirements of local QMS of each GHWP member in the ISO 13485; 2. Drafting guidelines related to QMS in the localization process of enterprises and importers.	QMS consideration for manufacturers and importers for localization
WG8	Standards	The transformation and adoption of ISO 16142-1:2016 and ISO 16142-2:2017.	Virtual Training: Medical Device Process Validation: The Need for a State of Art and Holistic Risk Based Approach (22 April 2021)
WG9	UDI & Nomenclature	The main work of WG9 includes formulating UDI rules of GHWP on the basis of global harmonization, and obtaining an understanding of the UDI awareness among members .	Seminar: UDI Regulation and Implementation Seminar (28th July 2021)

• GHWP TC in progress

- Guidelines to be adopted and implemented at the 26th annual meeting

WG 1, WG2 and WG3

- Guidelines for the Categorization of Changes to a Registered Medical Devices.（Newly revised）

WG8

- Medical Gas System – Recognized Essential Principles of Safety and Performance – Standards for Demonstrating Compliance.

WG9

- GHWP UDI Rules.

The other WGs

- e-IFU, change management , SaMD, etc.

• GHWP in progress

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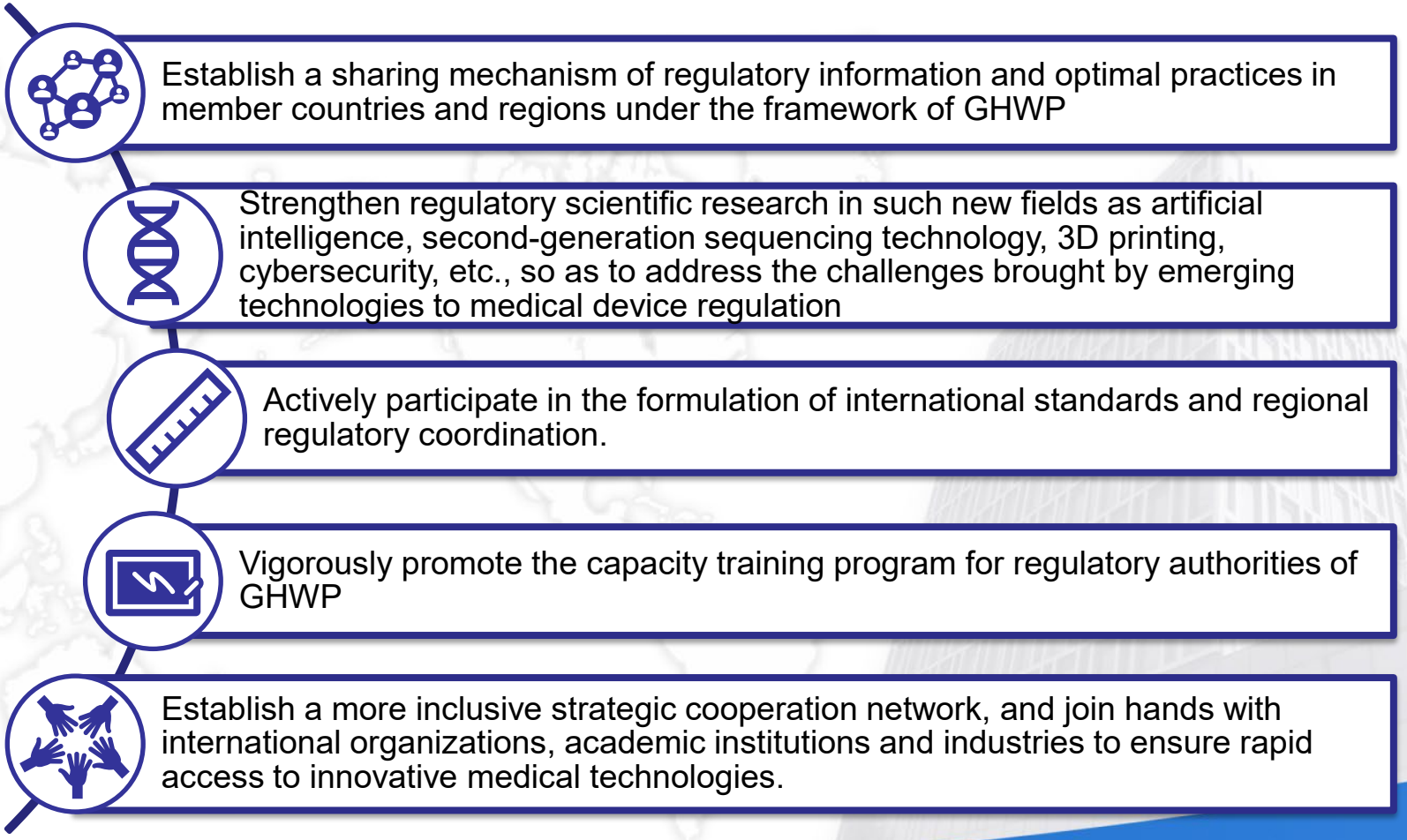
- Several considerations to deepen the global harmonization work



- **GHWP in progress**

Upcoming 26th GHWP Annual Meeting and GHWP TC Meeting

- Will be held in the Kingdom of Saudi Arabia for 4 days in mid-February 2023. **(**Subject to further web-announcement)

• GHWP in progress

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26th GHWP Annual Meeting and GHWP TC Meeting

Achievement

New members
New guidance documents

A

Election

GHWP
GHWP TC
Work Groups

B

Influence

International Org
Region and Country
International Conference

C

• GHWP &China

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2000

AHWP

AHWP determined its official work rules and the composition of members.

2007

Chengdu,China

China held the AHWP Annual Meeting for the first time.

2009-2011

China

China served as the rotating chairmanship of AHWP. During this period,the number of AHWP members increased to 22.

2021

AHWP/GHWP

Official rebranding of AHWP into GHWP means transforming from Asia Focus initiatives to Global Presence of 32 members.

2023-2026

China

NMPA shall make further efforts to support the work of GHWP and GHWP TC so as to promote and contribute Chinese wisdom.

Thank you

Please visit our website www.ghwp.info

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