GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

GHWP TC 2025

Contents

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

- TC Top Priorities
- Guidance Development Direction
- Guidance Development Status
- Guidance Adoption Assessment
- TC Training Programs

TC Top Priorities

✓ Accelerate Guidance Development

- Quarterly meetings between TCLT & WG LT.
- Working Groups (WGs) confirm new work item proposals, guidance development plan and timelines.
- Establish guidance review rules with TC advisors.

Person-in-charge: Li Jun, Miang ,Vera

✓ Enhance TC Capacity Building

- Develop TC training plan and conduct trainings with CB.
- All training invitations/slides/videos should be posted on GHWP website.
- Support trainings of GHWP Academy, especially propose the trainings of GHWP Guidance.

Person-in-charge: Adelheid, Vera

✓ Guidance Adoption Assessment

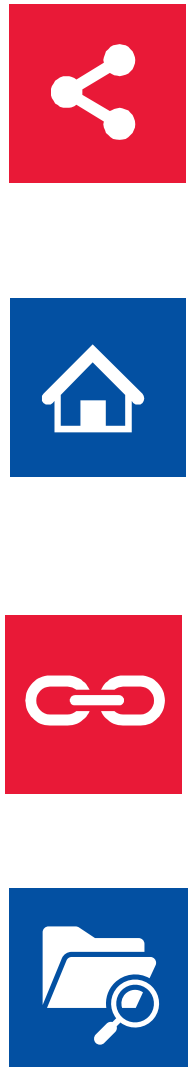
- Continue the assessment within GHWP member countries/regions.
- Solicit the potential guidance from WGs for assessment.

Person-in-charge: Li Jun, Vera, Yasha, Victoria

✓ Guidance Clean-up

- WGs conduct to clean up the guidance

Person-in-charge: Miang, Adelheid



✓ Improve TC WG Advisors Engagement

- Establish Guidance Review Procedure and Rules for TC Advisors.
- Improve TC advisor engagement in **all GHWP TC events.**

Person-in-charge: Mohammed, Miang, Adelheid

✓ TC Leaders Meeting

- Develop the meeting agenda and topics for TCLT meeting in Egypt in June.
- Invite all WG Chairs and Cochairs to join the meeting and update the work progress and guidance development status.

Person-in-charge: Miang, Victoria

✓ GHWP & TC Annual Meeting

- Finalize and review the guidance for endorsement in Annual Meeting.
- Invite WG leaders and members to join annual meeting.

Person-in-charge: all

Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Guidance Development

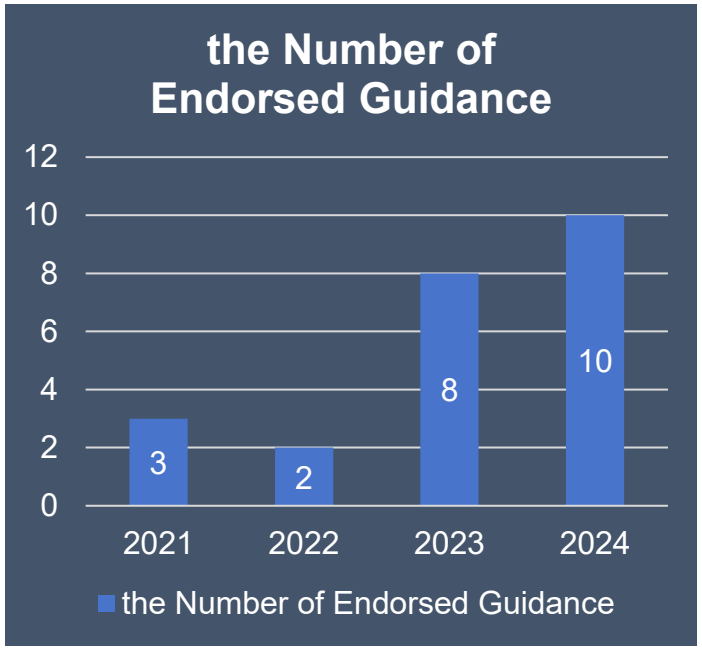
Guidance Development Direction

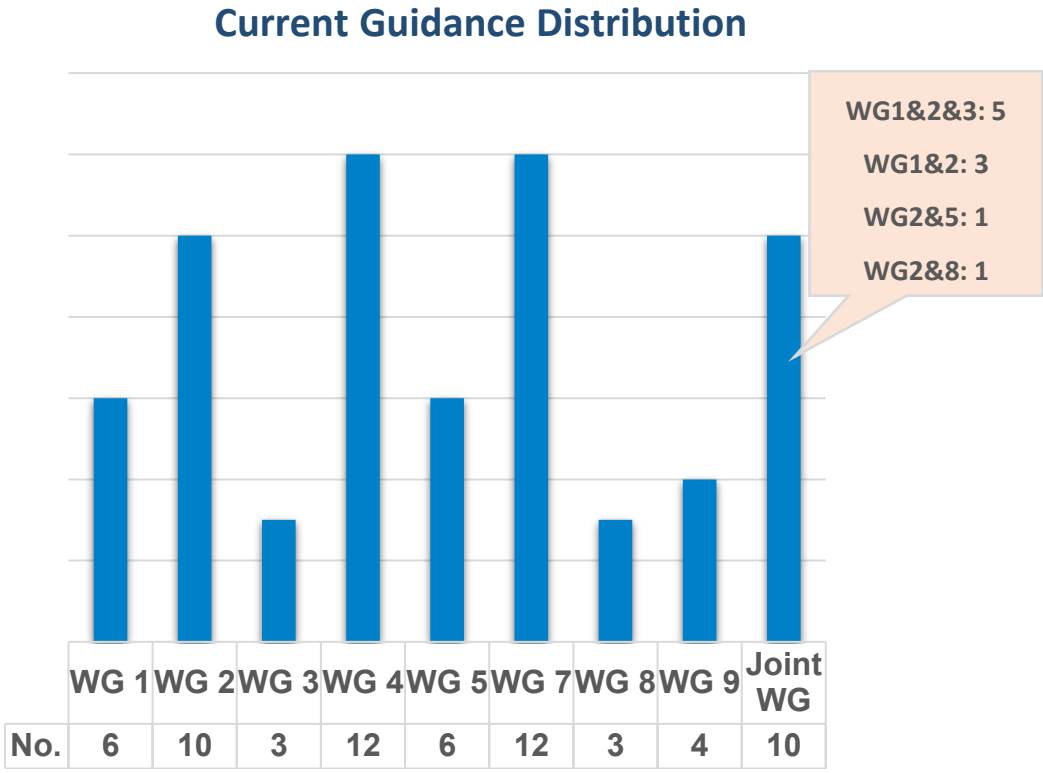
Guidance Development Status

8
To be Endorsed in 2025

66
Current Guidance

22
Drafting Guidance





Guidance to be Endorsed in 2025 Annual Meeting

No.	WG	Guidance to be Endorsed
1	1,2,3	Guidance on Determining of Lead Authority and Communication Process for Combination Products (WG1 lead)
2	3	Guidance on pre-market requirement for artificial intelligence/machine learning based computer-aided detection (CADe) and computer-aided diagnosis (CADx) software as a medical device
3	4	Playbook for Design and Implementation of Active Post-Market Surveillance System
4		Definition and Classification of Field Corrective Actions, including Field Safety Corrective Actions, Recalls and Non-Safety related Field Corrective Actions
5	7	Guidance for Remote Inspections of Medical Device Manufacturers
6		Guidance for Control of Sterilized and Implantable Medical Device
7		White Paper on Overview of Quality Management System Requirements and Implementation in GHWP member country or region
8	9	UDI Application Guidance Considerations for Manufacture to Facilitate an Effective UDI Implementation

Posted on GHWP Website for Public Consultation

Drafting Guidance

No.	WG	Guidance Document
1	1,2,3	Guidance for Additional Considerations to Support Pre-market Conformity Assessment of AI-based SaMD for Image Analysis in Digital Pathology
2	5,3	Guidance for SaMD clinical evidence and clinical evaluation (WG5 lead)
3	8,7	Guidance on the Validation of Processes for Production (WG8 lead)
4	1	White Paper on the Comparative Study for Lifetime of Active Medical Devices Program Application (NWIP)
5	2	Labelling for In Vitro Diagnostic Medical Devices
6	3	Guidance Document on Qualification of Medical Device Software
7		Guidance document on Risk Categorization of Software as a Medical Device
8		The terms and definitions of digital therapeutics medical devices
9		AI/ML based SaMD change submission requirement – Comparison of requirements from key jurisdictions
10	4	Medical Device Post-Marketing Surveillance (MD-PMS): Transition from Passive to Active
11	8	White paper on Role of Standards in the Regulation of Medical Devices
12	9	Medical Device Nomenclature Insights of International Common Medical Device Nomenclature Systems
13	CERP	Guidelines on Quality Management System for Technical Evaluation (NWIP)
14		General Procedure of Common Evaluation Reliance Practice (NWIP)

Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Guidance Adoption Assessment

Guidance Adoption Assessment (1st Round in 2024)

Feedback from 4 member countries/regions: Cuba, Hong Kong, Thailand, China

WG	Document No.	Description	**China**	**Hongkong**	**Cuba**	**Thailand**
1,2,3	GHWP/WG1-WG2-WG3/F002:2023	Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)	Not Implement	Not Applicable	Partially Adopted	Not Applicable
1,2,3	GHWP/WG2-WG1-WG3/F001:2023	Categorisation of Changes to a Registered Medical Device	Partially Adopted	Not Applicable	Fully Adopted	Not Applicable
1,2,3	GHWP/WG2-WG1-WG3/F001:2021	Regulatory Mechanism for Medical Devices Including In Vitro Diagnostic Medical Devices and Software as Medical Devices During A Public Health Emergency	Fully Adopted	Not Applicable	Fully Adopted	Not Applicable
2	GHWP/WG2/F001:2023	Guidance for Additional Considerations to support Conformity Assessment of In vitro Companion Diagnostic Medical Device	Fully Adopted	Not Applicable	Not Implement	Not Applicable
7	GHWP/WG7/F003:2023	Guidance for Audit Supplier to Medical Device Manufacturers	Fully Adopted	Not Applicable	Fully Adopted	Not Applicable
7	GHWP/WG7/F004:2023	Guidance Document on the Risk-Based Approach to Quality Management System Aspects: ISO13485:2016	Fully Adopted	Not Applicable	Fully Adopted	Fully Adopted
9	GHWP/WG9/F001:2023	UDI Rules	Fully Adopted	Not Applicable	Not Implement	Not Applicable

Guidance Adoption Assessment (2nd Round in 2025)

11 Guidance Documents Selected for Assessment

Selection criteria for guidance: GHWP original guidance; Implemented within 5 years

Consultation Scope and Period: GHWP Member countries/regions & WG Chairs; Deadline: August 30

WG	Doc. No.	Guidance
1,2,3	GHWP/WG1-WG2-WG3/F002:2023	Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)
1,2,3	GHWP/WG2-WG1-WG3/F001:2024	Change Management to Registered Medical Devices
1,2,3	GHWP/WG2-WG1-WG3/F001:2023	Categorisation of Changes to a Registered Medical Device
1,2,3	GHWP/WG2-WG1-WG3/F001:2021	Regulatory Mechanism for Medical Devices Including In Vitro Diagnostic Medical Devices and Software as Medical Devices During A Public Health Emergency
2	GHWP/WG2/F001:2023	Guidance for Additional Considerations to support Conformity Assessment of In vitro Companion Diagnostic Medical Device
7	GHWP/WG7/F002:2024	Guidance Document for Medical Device Organizations-Product Localisation for Manufacturing and Importation
7	GHWP/WG7/F003:2023	Guidance for Audit Supplier to Medical Device Manufacturers
7	GHWP/WG7/F004:2023	Guidance Document on the Risk-Based Approach to Quality Management System Aspects: ISO13485:2016
9	GHWP/WG9/F001:2023	UDI Rules
8	GHWP/WG8/F001:2023	Medical Gas System- Essential Principals of Safety and Performance
9	GHWP/WG9/F001:2024	Creation and Placement of Unique Device Identifier

Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Training Programs

TC Training Programs in 2025

GHWP Academy

- 3rd Guangzhou Training
- 4th Chongqing Training

In-Country Training

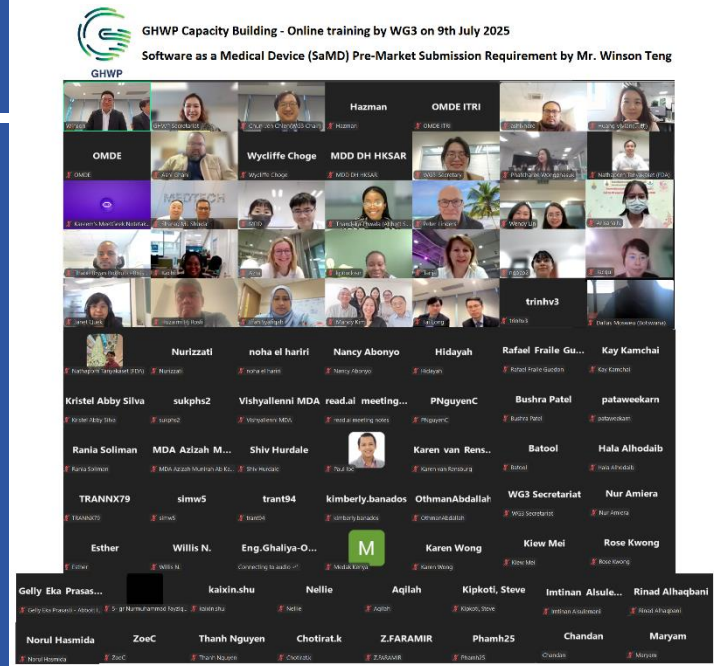
- Nov. 13, Oman

CB Training at GHWP Annual meetings & TC meetings

- June, Egypt
- Dec. Thailand

TC Online Training

- every month
- Online training



TC Training Programs

2024 Completed Trainings:

10

May	**WG7**	Overview of QMS in Japan
June	**WG9**	GHWP UDI Rule
June	**WG7**	Guidance on Risk Based Approach to QMS aspects ISO13485:2016
June	**WG1**	e-IFU and e-labelling
July	**WG5**	Systematic review and meta - analysis on the performance reports
Oct.	**WG7**	A Guide to Understanding Best Practices in Audit Life Cycle Management
Oct.	**WG3**	Guidance Document on Qualification of Medical device Software
Nov.	**WG4**	Introduce the Adverse Event Terminology (AET) system across different jurisdictions
Nov.	**WG8**	Medical Gas System (MGS) – Essential Principles of Safety and Performance (EPSP) – Standards for Demonstrating Compliance
Dec.	**WG7**	Comparison study of ISO 13485 vs. QMS requirements in GHWP member countries or regions

2025 Completed & Ongoing Trainings:

13

Aug.	**WG1**	Change Management to Registered Medical Devices
Jan.	**WG2**	GHWP Guideline Reagent Replacement and Instrument Family Policy
July	**WG3**	White Paper: Software as a Medical Device (SaMD) Pre-Market Submission Requirement – Comparison of requirement from Key jurisdictions
Nov.	**WG4**	Post-Market Control Strategies for End-of-Life Products
May	**WG7**	Digital Application in Quality Management System
June	**WG7**	Medical Device Cybersecurity
Oct.	**WG7**	Sharing of QMS Requirement and Practice in Chinese Taipei
May	**WG9**	Creation and Placement of UDI
Nov.	**WG9**	UDI Data Elements
TBC	**WG5**	Post Market Clinical Studies-Post-market surveillance
TBC	**WG7**	TBC
TBC	**WG8**	Role of Standards
TBC	**CERP**	TBC

TC together

- Oriented to members' needs
- Oriented to regulatory and industrial needs
- Oriented to cutting-edge innovation

- Develop high-quality guidance
- Continuously Enhance Capacity Building by Diverse Trainings
- Invite regulators & experts from GHWP member countries/regions to join TC and WGs

- Fully exert GHWP's unique strengths (joint efforts by regulators and industry) and initiative of members
- Enhance GHWP competitiveness and influence


thank you
danke
謝謝
ngiyabonga
рахмат
teşekkür ederim
спасибо
gracias
tapadh leat
dank je
bedankt
dziękuję
obrigado
go raibh maith agat
merci
sukriya
kop khun krap
terima kasih
dakujem
arigatô
grazie
takk
taiku
mauruuru
hvala
sagolun
mochchakkeram
Баярлалаа
faafetai lava
kiitos
dankie
dhanyavad
köszönöm
enkosi
gracie
sobodi
dėkuji
mèsi
didi madloba
najis tuke
kam sah hamnida
rahmat
ありがとう
tanemirt
rahmet
diolch
dhanyavadagalu
shukriya
мерси
merci
ευχαριστώ
감사합니다
xièxie
তোমাকে ধন্যবাদ
chnorakaloulioun
gratias ago
gracies
sulpáy
djiere dieuf
tau
дякую
mamnun
chokrane
murakoze
obrigada
asante
manana
хвала
tenki
matondo
misaotra
blagodaram
vinaka
спасибі
akun
dankon
aciū
paldies
grazzi
mahalo
barka
welalin
tack
spas
mersi
kia ora