Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

GHWP TC Status Report

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Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

- GHWP TC Overview
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Overview of the TC WGs

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

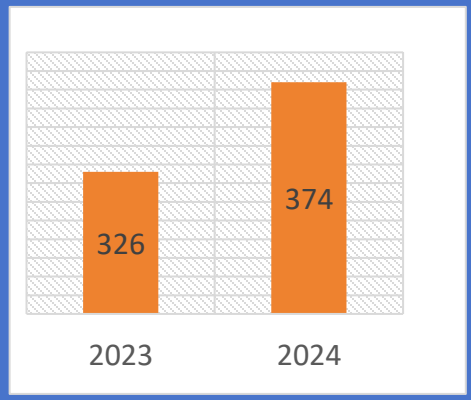
WG: 8
STG: 1
Members: 374

- TC Acting Chair (SFDA)
  - TC Cochair (NMPA)
  - TC Cochair (J&J)
  - TC Advisor
  - TC Secretariat

Working Groups & STG

WG1: Premarket	Member: 50 (Reg-11, Ind-39) Country/Region: 13
WG2: Premarket IVDD	Member: 47 (Reg-21, Ind-26) Country/Region: 18
WG3: Premarket SaMD	Member: 52 (Reg-14, Ind-38) Country/Region: 12
WG4: Post Market	Member: 38 (Reg-21, Ind-17) Country/Region: 8
WG5: Clinical Evidence	Member: 20 (Reg-9, Ind-11) Country/Region: 9
WG7: Quality Management System	Member: 53 (Reg-9, Ind-43) Country/Region: 11
WG8: Standards	Member: 31 (Reg-11, Ind-20) Country/Region: 10
WG9: UDI & Nomenclature	Member: 33 (Reg-10, Ind-23) Country/Region: 7
STG: MDCERP	Member: 50 (Reg-15, Ind-35) Country/Region: 8

TC Bearers & Members: 360



GHWP Effective Guidance

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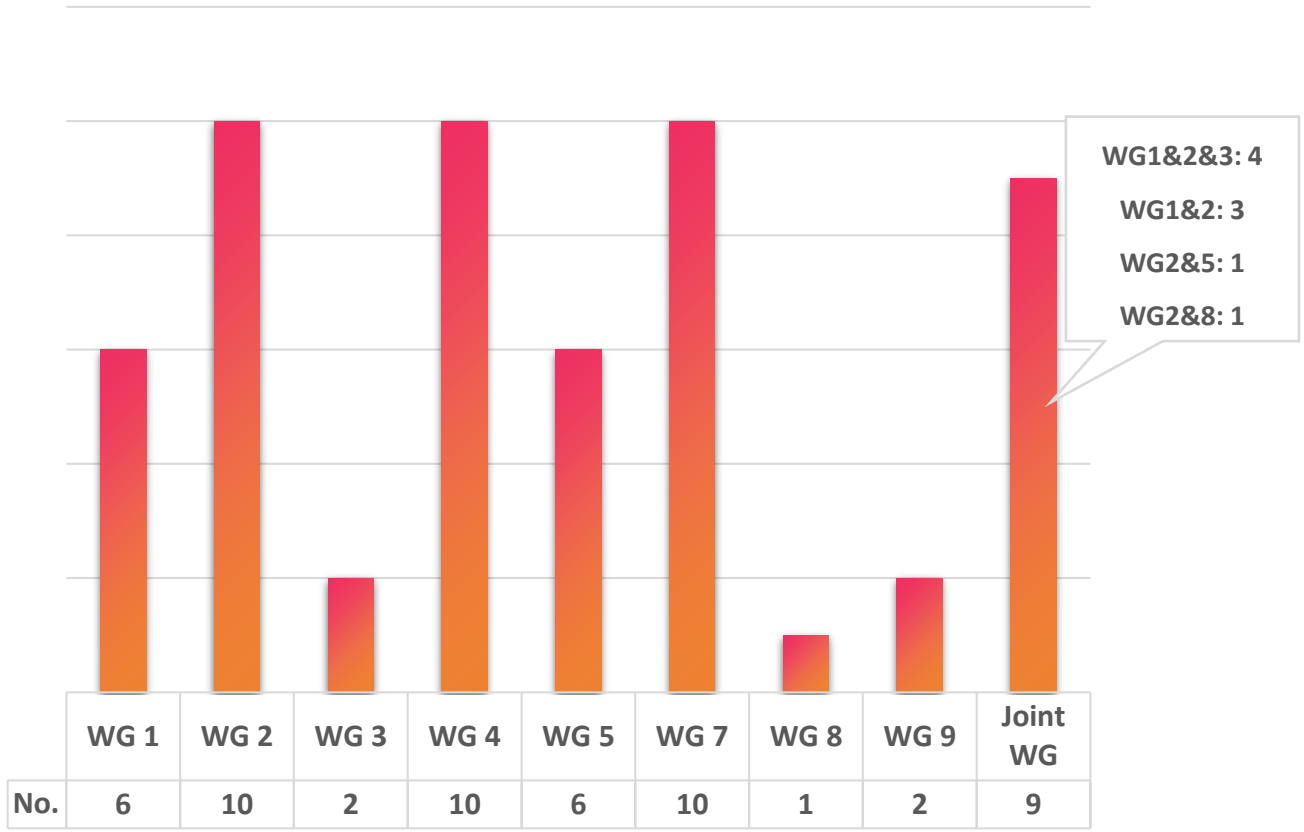
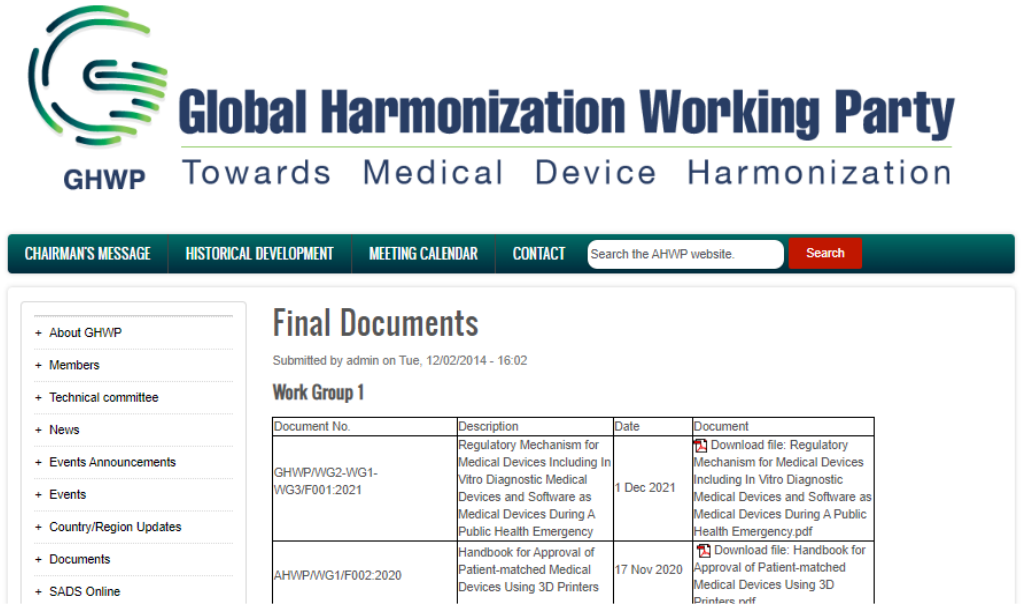
GHWP Effective Guidance: 56



	WG 1	WG 2	WG 3	WG 4	WG 5	WG 7	WG 8	WG 9	Joint WG
No.	6	10	2	10	6	10	1	2	9



For further reference:
http://www.ghwp.info/index.php/node/263

Guidance to be Endorsed in 28th GHWP Annal Meeting

No.	WG	New Working Item	New/Revise
1	WG1,2,3	GHWP/WG2-WG1-WG3/PD001:2024 Change Management to Registered Medical Devices (Led by WG2)	New
2	WG3	GHWP/WG3/PD001:2024 Software as a Medical Device (SaMD) Pre-Market Submission Requirement–Comparison of requirement from Key jurisdictions	New
3	WG4	GHWP/WG4/PD001:2024 Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives	Revise
4		GHWP/WG4/PD002:2024 Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representative	Revise
5	WG7	GHWP/WG7/PD001:2024 Comparison study of ISO13485 vs. QMS requirements in GHWP member country/region（White Paper）	Revise
6		GHWP/WG7/PD002:2024 Guidance Document for Medical Device Organizations - Product Localization for Manufacturing and Importation	New
7	WG8	GHWP/GL/WG8-SEC/P001/2024 Guidelines on development of GHWP Documents - Part 1: Procedure for development	New
8		GHWP/GL/WG8-SEC/P002/2024 Guidelines on development of GHWP Documents - Part 2: Structure and drafting	New
9	WG9	GHWP/WG9/PD001:2024 Creation and Placement of UDI	New
10		GHWP/WG9/PD002:2024 UDI – Data Elements	New

Guidance in Development

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No.	WG	Guidance Document	New/Revise
1	1,2,3	Guidance on Regulatory Practices for Combination Products (WG1 lead)	New
2	5,3	Guidance for SaMD clinical evidence and clinical evaluation (WG5 lead)	New
3	8,7	Guidance on the Validation of Processes for Production (WG8 lead)	New
4	1	Development Guidance for Active Medical Device Reliability Evaluation Program	New
5	2	Labelling for In Vitro Diagnostic Medical Devices	Revise
6	3	Guidance Document on Qualification of Medical Device Software	Revise
7		Guidance document on Risk Categorization of Software as a Medical Device	Revise
8		The terms and definitions of digital therapeutics medical devices	New
9		AI/ML based SaMD change submission requirement – Comparison of requirements from key jurisdictions	New
10	4	Medical Device Adverse Event (AE) Report Form	Revise
11		Medical Device Post-Marketing Surveillance (MD-PMS): Transition from Passive to Active	New
12	7	Guidance for Remote Inspection to Medical Device Manufacture	New
13		Guidance for Quality Agreement of Medical Devices Contract Manufacturing	New
14		Guidance for Control of Sterilized and Implantable Medical Device	New
15		Comparison study of ISO13485 vs. QMS requirements in GHWP member countries or regions	Revise
16	8	Whitepaper on Role of Standards in the Regulation of Medical Devices	New
17	9	UDI Application	New
18		White Paper of Nomenclature	New

TC Capacity Building in 2024

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

- Focus on GHWP current effective guidance;
- GHWP country/region members will be targeted audience.
- If guidance are being drafted, the training should be carried out once documents are endorsed;

No.	Date	WG	Topic	Type	Speaker
1	May	WG7	Overview of QMS in Japan	Online	Mr. Hideki Asai (GHWP Advisor)
2	June	WG9	GHWP UDI Rule	Online	Mr. Yi Li (NMPA), Mr. Azzam (SFDA), Experts from industry
3	June	WG7	Guidance on Risk Based Approach to QMS aspects:ISO13485:2016	Online	Mr. Ee Bin Liew (WG7 Cochair)
4	June	WG1	e-IFU and e-labelling	Online	Mr. Sharad Shukla (WG1 member, J&J Medtech)
5	July	WG5	Systematic review and meta - analysis on the performance reports	Online	Dr. NURNEQMAN NASHREQ BIN KOSNI (MDA)
6	October	WG7	A Guide to Understanding Best Practices in Audit Life Cycle Management	Online	Ms. Hailey Chu (BSI-Regulatory Lead)
7	October	WG3	Guidance Document on Qualification of Medical device Software	Online	Dr. Sheng-Hui Liao
8	November	WG4	Introduce the Adverse Event Terminology (AET) system across different jurisdictions	Online	Expert from NMPA, SFDA and PMDA
9	November	WG8	Medical Gas System (MGS) – Essential Principles of Safety and Performance (EPSP) – Standards for Demonstrating Compliance	Physical- 2nd GHWP training in Guangzhou, China	Ir Khairi Mohd Daud (WG 8 co-opted member)
10	December	WG7	Comparison study of ISO 13485 vs. QMS requirements in GHWP member countries or regions	Online	Annie Yin, WG7 Secretary, Vice President, Roche Diagnostics

Thank you


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