Summary on Guidance Documents

WG	No. of endorsments	Document No.	Description	Date	Status			
					Need to revise	Revised by	Keep	Abolished by
1 & 2	3	AHWP/WG1-WG2/F001: 2017	Regulation and treatment of e-IFU and e-Label of Medical Devices-Review of International Practice	2017-12-31	N	Keep current	Y	2024
		AHWP/WG2-WG1/F001:2016	Definition of the Terms "Medical Device" and "In Vitro Diagnostic (IVD) Medical Device"	2016-11-26	Y	2023	Y	N
		AHWP/WG2_WG1/F001:2015	Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'	2015-11-06	N	Keep current	Y	2024
2 & 5	1	GHWP/WG2-WG5/F001:2021	Clinical Evidence for IVD Medical Devices - Clinical Performance Studies for In Vitro Diagnostic Medical Devices	2021-12-01	N	Keep current	Y	N
2 & 8	1	AHWP/WG2-WG8/F002:2014	Role of Standards in the Assessment of Medical Devices	2014-11-21	Y	2023	Y	N
1, 2 & 3	4	GHWP/WG2-WG1-WG3/F001:2023	Categorisation of Changes to a Registered Medical Device	2023-02-16	Y	2023	Y	N
		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	2021-12-01	N	Keep current	Y	N
		AHWP/WG2-WG1-WG3/F001:2019	Categorisation of Changes to a Registered Medical Device	2019-12-03	N	Keep current	Y	N
		AHWP/WG1-WG2-WG3/F002:2019	Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)	2019-12-02	Y	2023	Y	N
1	6	AHWP/WG1/F002:2020	Handbook for Approval of Patient-matched Medical Devices Using 3D Printers	2020-11-17	Y	2024	Y	N
		AHWP/WG1/F001:2020	Guidance for Minor Change Reporting	2020-11-17	N	Keep current	Y	N
		AHWP/WG1/F001:2016	Guidance on Regulatory Practices for Combination Products	2016-11-26	Y	2024	Y	N
		AHWP/WG1/F001:2015	Guidance for Preparation of a Common Submission Dossier Template Dossier for Genera Medical Device	2015-11-06	Y	2025	Y	N
		AHWP/WG1/F002:2015	White Paper on Regulation of Combination Products - A review of International Practice	2015-11-06	N	Keep current	Y	N
		AHWP/WG1/F001:2014	White Paper on Medical Device -Software Qualification and Classification White Paper	2014-11-21	Y	2024	Y	N
2	10	GHWP/WG2 /F001:2021	Replacement Reagent and Instrument Family Policy	2021-12-01	N	Keep current	Y	N
		AHWP/WG2/F001:2018	Labelling for In Vitro Diagnostic Medical Devices	2018-10-25	Y	2024	Y	N
		AHWP/WG2/F001:2017	Guidance for Additional Considerations to support Conformity Assessment of Companion In vitro Diagnostic Medical Devices	2017-09-04	Y	2023	Y	N
		AHWP/WG2/F001:2016	Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	2016-11-26	Y	2024	Y	N
		AHWP/WG2/F002:2016	Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices	2016-11-26	N	Keep current	Y	N
		AHWP/WG2/F003:2016	Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices	2016-11-26	Y	2026	Y	N
		AHWP/WG2/F001:2014	Comparison between CSDT and STED IVDDs	2014-11-21	N	Keep current	Y	2024
		AHWP/WG1a/F004:2013 (now restructured to WG2)	Comparison between the GHTF Summary Technical Documentation (STED) formats for Medical Devices and In Vitro Diagnostic Medical Devices and the Common Submission Dossier Template (CSDT) format	2013-12-06	N	Keep current	Y	2024
		AHWP/WG1a/F002:2013 (now restructured to WG2)	Essential Principles of Safety and Performance of IVD Medical Devices	2013-12-06	Y	2025	Y	N
		AHWP/WG1a/F001:2013 (now restructured to WG2)	GHWP Regulatory Framework for IVD Medical Devices	2013-12-06	Y	2025	Y	N
3	2	AHWP/WG3/F001:2016	Guidance document on Risk Categorisation of Software as a Medical Device	2016-11-26	Y	2024	Y	N
		AHWP/WG3/F001:2015	Guidance Document on Medical Device Software - Qualification and Classification	2015-11-06	Y	2023	Y	N
4	10	AHWP/WG4/F001:2016	Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representative	2016-11-26	Y	2024	Y	N
		AHWP/WG4/F002:2016	Post Market Resource Center	2016-11-26	Y	2023	Y	N
		AHWP/WG4/F003:2016	GHWP Safety Alert Dissemination System (SADS)	2016-11-26	N	Keep current	Y	2025
		AHWP/WG4/F001:2015	Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives	2015-11-06	Y	2024	Y	N
		AHWP/WG4/F001:2014	Adverse Event Reporting Timelines Guidance for Medical Device Manufacturer and its Authorised Representative	2014-11-21	N	Keep current	Y	N
		AHWP/WG2/F001:2013 (now restructured to WG4)	Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative	2013-12-06	N	Keep current	Y	N
		AHWP/WG2/F002:2012 (now restructured to WG4)	Definition and Classification of Field Corrective Actions, including Field Safety Corrective Actions, Recalls and Non Safety related Field Corrective Actions	2012-11-20	Y	2025	Y	N
		AHWP/WG2/F001:2012 (now restructured to WG4)	Medical Device Adverse Event (AE) Report Form	2012-11-20	Y	2024	Y	N
		AHWP/WG2/SADS/002 (now restructured to WG4)	Safety Alert Dissemination System: Safety Alert Dissemination	2008-01-23	N	Keep current	Y	2025
		AHWP/WG2/SADS/001 (now restructured to WG4)	Framework for GHWP Safety Alert Dissemination System (SADS)	2008-01-23	N	Keep current	Y	2025
5	6	AHWP/WG5/F002:2017	Post Market Clinical Follow-Up Studies	2017-12-06	Y	2024	Y	N
		AHWP/WG5/F001:2017	Clinical Investigation	2017-12-06	Y	2023	Y	N
		AHWP/WG5/F001:2015	Clinical Evaluation	2015-11-06	Y	2023	Y	N
		AHWP/WG5/F002:2015	Clinical Evidence for Medical Device - Key Definitions and Concepts	2015-11-06	Y	2023	Y	N
		AHWP/WG5/F003:2015	Clinical Evidence for IVD Medical Device - Key Definitions and Concepts	2015-11-06	Y	2024	Y	N
		AHWP/WG5/F004:2015	Clinical Evidence for IVD Medical Devices- Scientific Validity Determination and Performance Evaluation	2015-11-06	Y	2024	Y	N
6	7	AHWP/WG6/F001:2016	MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization	2016-11-26	N	Keep current	Y	2025
		AHWP/WG6/F002:2016	MDSAP: Overview of Auditing Organization Assessment and Recognition Decision Related Processes	2016-11-26	N	Keep current	Y	2025
		AHWP/WG6/F003:2016	Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition	2016-11-26	N	Keep current	Y	2025
		AHWP/WG6/F004:2016	Competence and Training Requirements for Auditing Organizations	2016-11-26	N	Keep current	Y	2025
		AHWP/WG6/F001:2015	Distributor Auditing Checklist	2015-11-06	N	Keep current	Y	N
		AHWP/WG6/F002:2015	Guidance on Regulatory Auditing of Quality Management System of Medical Device Distributions: Auditing Strategies	2015-11-06	N	Keep current	Y	N
		AHWP/WG6/F003:2015	Regulatory Audit Report Guidance Document	2015-11-06	N	Keep current	Y	2025
7	3	AHWP/WG7/F001:2016	Quality Management System-Medical Devices Requirements for Distributors, Importers and Authorized Representatives	2016-11-26	N	Keep current	Y	N
		AHWP/WG7/F001:2014	Guidance on Medical Device Quality Management System - Requirements for Distributors	2014-11-21	N	Keep current	Y	N
		AHWP/WG3/F001:2013 (now restructured to WG7)	Quality management system – Medical devices – Nonconformity Grading System for Regulatory Purposes and Information Ex-change	2013-12-06	N	Keep current	Y	2025
8	1	GHWP/WG8/F001:2023	Medical Gas System – Essential Principles of Safety and Performance – Standards for Demonstrating Compliance	2023-02-16	N	Keep current	Y	N
9	2	AHWP/WG9/F001:2019	AHWP UDI White Paper	2019-12-14	N	Keep current	Y	N
		AHWP/STG/F001:2015	Guidance for Medical Device Naming Rule	2015-11-18	N	Keep current	Y	N
Secretariat	18	GHWP/SECRETARIAT/F001:2023	Amendment 8 to the Global Harmonization Working Party House Rules	2023-02-16	N	Keep current	Y	N
		GHWP/SECRETARIAT/F001:2021	Amendment 8 to the Global Harmonization	2021-12-01	N	Keep current	Y	N
		GHWP/SECRETARIAT/F002:2021	Amendment 7 to the Global Harmonization	2021-12-01	N	Keep current	Y	N
		AHWP/SECRETARIAT/F002:2019	Amendment 6 to the Global Harmonization Working Party House Rules	2019-11-22	N	Keep current	Y	N
		AHWP/SECRETARIAT/F001:2019	Amendment 7 to the Asian Harmonization Working Party (GHWP) & AHWP Technical Committee (GHWPTC) Terms of Reference (TOR)	2019-11-22	N	Keep current	Y	N
		AHWP/SECRETARIAT/F002:2017	Amendment 5 to the Asian Harmonization Working Party House Rules	2017-12-06	N	Keep current	Y	N
		AHWP/SECRETARIAT/F001:2017	Amendment 6 to the Global Harmonization Working Party (GHWP) & GHWP Technical Committee (GHWPTC) Terms of Reference (TOR)	2017-11-20	N	Keep current	Y	N
		AHWP/SECRETARIAT/F001:2016	GHWP Vision & Mission	2016-11-26	N	Keep current	Y	2025
		AHWP/SECRETARIAT/F002:2016	Working Group Technical Document Endorsement Mechanism	2016-11-26	N	Keep current	Y	N
		AHWP/SECRETARIAT/F003:2016	Working Group Technical Document Endorsement Mechanism	2016-11-26	N	Keep current	Y	N
		AHWP/SECRETARIAT/F004:2016	Official Observer	2016-11-26	N	Keep current	Y	N
		AHWP/Secretariat//F001:2014	Amendment 3 to the Global Harmonization Working Party House Rules	2014-11-21	N	Keep current	Y	N
		AHWP/SECRETARIAT/F002:2013	Amendment 2 to the Global Harmonization Working Party House Rules	2013-12-06	N	Keep current	Y	N
		AHWP/SECRETARIAT/F001:2013	Amendment 1 to the GUIDANCE for Member Economy Hosting the Meetings of GHWP or its Technical Committees	2013-12-06	N	Keep current	Y	N
		AHWP/SECRETARIAT/F002:2012	Amendment 1 to the Global Harmonization Working Party House Rules	2012-11-20	N	Keep current	Y	N
		AHWP/SECRETARIAT/F001:2012	Amendment 2 to the Global Harmonization Working Party (GHWP) & Global Harmonization Working Party Technical Committee (GHWPTC) Terms of Reference	2012-11-20	N	Keep current	Y	N
		AHWP/SECRETARIAT/001	The Global Harmonization Working Party House Rules	2010-11-30	N	Keep current	Y	N
		AHWP/SECRETARIAT/002	Amendment 1 to the Global Harmonization Working Party (GHWP) & Global Harmonization Working Party Technical Committee (GHWPTC) Terms of Reference	2010-11-30	N	Keep current	Y	N
apacity Buildi	2		Training Curriculum For Medical Technology Regulatory Authorities	2023-02-16	N	Keep current	Y	N
		AHWP/AHWP-APACMED-DELOITTE/F001:2019	White paper on Competency Framework for Medical Technology Regulators	2019-11-22	N	Keep current	Y	N
Others	7	GHWP/OB/F001:2023	Global Harmonization Working Party Strategic Framework towards 2026	2023-02-16	N	Keep current	Y	N
		AHWP/OB/F001:2013	Asian Harmonization Working Party Strategic Framework Towards 2020 - "The Foreseeable Harmonization Horizon"	2013-12-06	N	Keep current	Y	N
		AHWP/STG(LE)/001A	Asian Harmonization Working Party (AHWP) & Asian Harmonization Working Party Technical Committee (AHWPTC)	2010-11-30	N	Keep current	Y	N
		AHWP/STG(LE)/002	Memorandum and Articles of Association of AHWP ASL	2010-06-07	N	Keep current	Y	N
		AHWP/TC/LEADERSHIP/001	Requirements of Medical Device Nomenclature System for the Asian Harmonization Working Party	2010-03-02	N	Keep current	Y	N
		AHWP/STG(LE)/001	Asian Harmonization Working Party (GHWP) & Asian Harmonization Working Party Technical Committee (AHWPTC) Terms of Reference	2009-11-06	N	Keep current	Y	N