Work Plans for GHWP Work Groups

No.	WG	Work Plan	Status
1	WG3,5	Clinical evidence and clinical evaluation requirements for software as a medical device	To be approved in 2024 TC Meeting
2	WG1	Good Reliance Practices for MD, IVD, and SaMD throughout the life cycle	
3		AI-related review guidance development	
4		Guidance on Safety & Performance Checklist	
5	WG2	AHWP/WG2-F001:2018- Labelling for In Vitro Diagnostic Medical Devices	
6	WG3	AI/ML based SaMD change submission requirement –Comparison of requirements from key jurisdictions	
7	WG4	Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representative;	
8		Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives;	
9		Medical Device Adverse Event (AE) Report Form;	
10	WG7	Guidance for control of sterile and implantable medical device	
11		Revise Guidance for Auditing Supplier to Medical Device Manufacturers (to replace GHWP/WG6/P003:2023) – focus on setting up procedure & implementation of supplier audit	
12		Revise Comparison study of new ISO13485 vs. QMS requirements in GHWP member economies (extend to cover implementation and upper regulations)	
13		(GHWP TCWG7/D001:2023) Comparison study of new ISO13485 vs. QMS requirements in GHWP member economies	
14		(GHWP TCWG7/D002:2022) Guidance Document for Medical Device Organizations - Product Localization for Manufacturing and Importation	
15		(WG7/NWIP: 2023) Guidance for Remote Inspection	
16		(WG7/NWIP: 2023) Guidance for Quality Agreement of Medical Devices Contract Manufacturing	
17	WG8	Guidance on the Validation of Processes for Production.	
18		Whitepaper on Role of Standards in Demonstration of Safety and Performance	
19		Guidelines on development of GHWP Documents - Part 1: Procedure for development	
20		Guidelines on development of GHWP Documents - Part 2: Structure and drafting	
21	WG9	UDI – Data Elements	
22		Creation and Placement of UDI	