Work Plans for GHWP Work Groups

1 WG3,5 Clinical evidence and clinical evaluation requirements for software as a medical device Good Reliance Practices for Mb, IVD, and SaMD throughout the life cycle Al-related review guidance development Guidance on Safety & Performance Checklist WG2 AHWP/WG2-F001:2018- Labelling for In Vitro Diagnostic Medical Devices Al/ML based SaMD change submission requirement—Comparison of requirements from key jurisdictions Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representative; Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives; Medical Device Adverse Event (AP) Report Form; Guidance for control of sterile and implantable medical device Revise Guidance for Auditing Supplier to Medical Device Manufacturers (to replace GHWP/WG6/P003:2023) – focus on setting up procedure & implementation of supplier audit Revise Comparison study of new ISO13485 vs. QMS requirements in GHWP member economies (extend to cover implementation and upper regulations) (GHWP TCWG7/D001:2023) Comparison study of new ISO13485 vs. QMS requirements in GHWP member economies (GHWP TCWG7/D002:2022) Guidance both Medical Device Organizations - Product Localization for Manufacturing and Importation (WG7/NWIP: 2023) Guidance for Remote Inspection (WG7/NWIP: 2023) Guidance for Remote Inspection (WG7/NWIP: 2023) Guidance for Quality Agreement of Medical Devices Contract Manufacturing Guidance on the Validation of Processes for Production. Whitepaper on Role of Standards in Demonstration of Safety and Performance Guidelines on development of GHWP Documents - Part 2: Structure and drafting UDI – Data Elements Creation and Placement of UDI	No.	WG	Work Plan	Status
## Al-related review guidance development Guidance on Safety & Performance Checklist ### AHMP/WG2-F001:2018- Labelling for In Vitro Diagnostic Medical Devices ### AHMP/WG2-F001:2018- Labelling for In Vitro Diagnostic Medical Devices ### Al-related Fewiew Guidance on Safety & Performance Checklist ### AHMP/WG2-F001:2018- Labelling for In Vitro Diagnostic Medical Devices ### Al-related Fewiew Guidance for In Vitro Diagnostic Medical Devices ### Al-related Fewiew Guidance for Aldrerse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representatives; ### Medical Device Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives; ### Medical Device Adverse Event (AE) Report Form; ### Guidance for control of sterile and implantable medical device ### Revise Guidance for Auditing Supplier to Medical Device Manufacturers (to replace GHWP/WG6/P003:2023) – focus on settling up procedure & implementation of supplier audit ### Revise Guidance for Auditing Supplier to Medical Device Manufacturers (to replace GHWP/WG6/P003:2023) – focus on settling up procedure & implementation of supplier audit ### Revise Guidance for Auditing Supplier to Medical Device Manufacturers (to replace GHWP/WG6/P003:2023) – focus on settling up procedure & implementation and upper regulations) #### WG6 ### GUID HOWER TOWG7/D001:2023) Comparison study of new ISO13485 vs. QMS requirements in GHWP member economies #### GUID HOWER TOWG7/D001:2023) Guidance Document for Medical Device Organizations - Product Localization for Manufacturing and Importation #### WG6 #### GUID HOWER TOWG7/D001:2023) Guidance for Quality Agreement of Medical Devices Contract Manufacturing ### Guidance on the Validation of Processes for Production. #### WG7/MWIP: 2023) Guidance for Processes for Production. #### WG7/MWIP: 2023) Guidance for Processes for Production. #### WG7/MWIP: 2023) Guidance for Processes for Production. ##### WG7/MWIP	1	WG3,5	Clinical evidence and clinical evaluation requirements for software as a medical device	
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