

GHWPTC Status Report

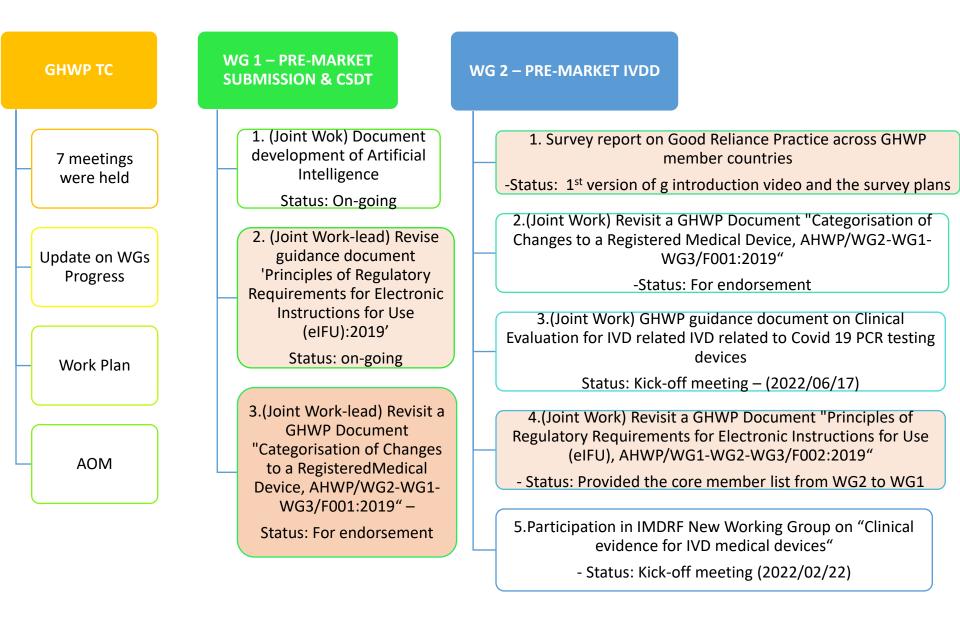
MS SALBIAH YAAKOP

GHWPTC Chair Medical Device Authority (MDA), Ministry of Health (MOH), Malaysia

GHWP TC – Office Bearers

TC Chair:	Mrs. Salbiah Yaakop Director of Policy, Industry and Internation Affaris Medical Device Authority, Ministry of Health Malaysia	Regulatory Authority
TC Co-chair:	Dr. Jeong-Rim Lee Director General Medical Device Evaluation Division Ministry of Food and Drug Safety(MFDS) Republic of Korea	Regulatory Authority
TC Co-chair:	Mr. Alfred KWEK Senior Director Edwards Lifesciences Lao PDR	Industry
Secretary:	Ms. Chadaporn (Miang) TANAKASEMSUB Head of Regulatory Affairs (RA) Asia Pacific (AP) Johnson & Johnson Vision	Industry
	Mr. Jack WONG Head of Regulatory Affairs, International RegASK	Industry
	Ms. Carol YAN Sr. consultant Founder of Yrsagacity Limited People's Republic of China	Industry
	Dr. Adelheid Schneider Head of Quality and Regulatory Affairs Asia Pacific Roche Diagnostics Asia Pacific	Industry

GHWP TC & WGs PROGRESS REPORT SUMMARY



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WG 5 – CLINICAL EVIDENCE FOR WG 4 – POST- MARKET SOFTWARE AS A MD **PERFORMANCE & SAFETY** 1. Updating the Post-market Resource Centre 1. White paper on pre 1. Regular review of Global clinical regulatory market initial updates Status: On-going submission format for Status: WG5 review new and changing regulation SaMD related to global clinical regulatory environment. 2.Gap analysis on the implementation of GHWP Status: On-going guidance among GHWP members Status: Only 6 returns were received. 2.GHWP guidance document on Clinical Evaluation for IVD related IVD related to Covid 19 PCR testing 2. Guidance document devices. 3.Participation in the development works of on Cyber Security for ISO TC210/WG6 Status: WG 5 & WG 2 structure the guidance SaMD document. Status: Suggest to remove this work item due Status: On-going to publication of ISO/TR 20416:2020 3. Gap analysis between IMDRF and GHWP Guidance 4. Report on post-market support in relation to - Clinical Evidence for Medical Device – Key 3. Guidance document COVID 19 Definitions and Concepts, Clinical Evaluation for premarket Status: Study write-up is being compiled. and Clinical investigation submission format for SaMD (draft) Status: Draft guidance for WG 5 review Status: On-going 5.Study on post-market trend in medical devices with AL and cycbersecurity 4. Training for WG 5 and GHWP members on Status: Write-up is being prepared based on ISO 14155:2020 and ISO 20916: 2019 the limited information in hand and still on-Status: WG5 will organize a workshop during going. GHWP annual meeting.

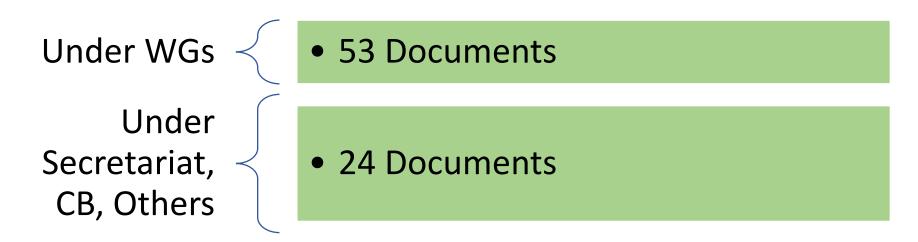
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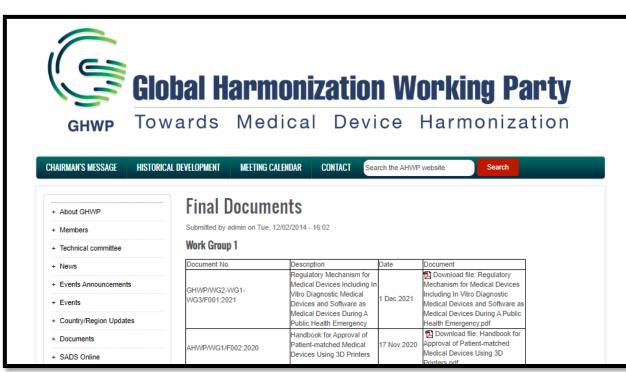
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WG 6 – QMS: AUDIT & ASSESSMENT A guide to understanding best practices in audit life cycle management. Status: In proof reading stage	WG 7 – QMS: OPERATION & IMPLEMENTATION 1. Comparison study of new ISO13485 vs QMS requirements in each country	WG 8 - STANDARDS 1. Document on Code of practice for good engineering maintenance management of medical devices: - ISO /TC210 Status: ISO TC 210 committee agreed to develop as TS	WG 9 – UDI & NOMENCLETURE 1. Work Item Update: UDI report Status: GHWP UDI Rule White Paper – On-going
2.A guide to understanding presently available audit duration determination systems. Status: In proof reading stage 3.A guidance for NB auditing suppliers to	in each country -Status: On-going 2.QMS consideration for manufacturers and importers for localization -Status: On-going 3. Guidance document on the risk based approach to quality management system aspects:	 2 .Collecting a list of standards used for medical device regulatory purposes that are recognized by GHWP member countries Status: GHWP secretariat is requested to put up the list of compiled standards in the GHWP website 3.Continue working relationship with ISO 	2.Work Item Update: Nomenclature Status: On-going 3.Work Item Update: Collaboration Status: On-going 4.GHWP UDI Webinar
4.Co-Chair Vincent will conduct online training		Tc210, etc Status:WG8/TC Chair participated in ISO/TC 210 meetings (12-16/12/2022). 4. Development of guidance on EPSP compliance for medical gas system using standards Status: For endorsement	5.WG 9 Team Virtual Meeting Status: On-going
session on remote audit technique. Status: Training completed as planned.	ISO13485:2016 -Status: On-going	 5.Proposal on development of guidance for process validation. Status: NWIP approved on 11 Oct 2022 6. Role of Standards in Demonstration of Safety and Performance 	WG 9 Working Item Introduction/Training (Virtual) Status: 20 December 2022

Status: NWIP submitted on 25 Nov 2022

GHWP – Published Guidance Documents (77)





For further reference: http://www.ghwp.inf o/index.php/node/26 3

GHWP – On-going Guidance Documents (14)

New guidance on artificial intelligence	Revision: 'Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU):2019'	Revision:"Categorisation of Changes to a Registered Medical Device, AHWP/WG2- WG1-WG3/F001:2019"	White paper on pre market initial submission format for SaMD
Guidance document on Cyber Security for SaMD	Guidance document for premarket submission format for SaMD (draft)	Guide to understanding best practices in audit life cycle management.	Guide to understanding presently available audit duration determination systems.
Guidance for NB auditing suppliers to medical device manufacturers.	Guidance document on the risk based approach to quality management system aspects: ISO13485:2016	Guidance document on Medical Gas System – Recognized Essential Principles of Safety and Performance – Standards for Demonstrating Compliance	Guidance on the Validation of Processes for Production.
	GHWP UDI Rule White Paper	New work item: Role of Standards in Demonstration of Safety and Performance	

GHWP – To be published (2)

New guidance on artificial intelligence	Revision: 'Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU):2019'	Revision:"Categorisation of Changes to a Registered Medical Device, AHWP/WG2- WG1-WG3/F001:2019"	White paper on pre market initial submission format for SaMD
Guidance document on Cyber Security for SaMD	Guidance document for premarket submission format for SaMD (draft)	Guide to understanding best practices in audit life cycle management.	Guide to understanding presently available audit duration determination systems.
Guidance for NB auditing suppliers to medical device manufacturers.	Guidance document on the risk based approach to quality management system aspects: ISO13485:2016	Guidance document on Medical Gas System – Recognized Essential Principles of Safety and Performance – Standards for Demonstrating Compliance	Guidance on the Validation of Processes for Production.
	GHWP UDI Rule White Paper	New work item: Role of Standards in Demonstration of Safety and Performance	

ACTIVITIES

GHWP – APACMed Regulatory Transformation Symposium

- Organized as a 1.5-day hybrid event in Conrad Hotel, Singapore
 - 26 May 2022

Regulatory Transformation Symposium Feature with a mix of keynote addresses, panel discussions, case study presentations and workshops

• 27 May 2022

Half Day Regulators Masterclass (Close Door)

 Representatives from WHO, IMDRF and other Regulatory Authorities from across the region participated either virtually or in person.





ACTIVITIES



ISO/TC 210 Quality management and corresponding general aspects for medical devices

- The meeting was held on 12th-16th December 2022
- Key points:
 - Preparation work on items for revision of ISO 13485:2016
 - Collaboration with IMDRF on guidance documents
 - Withdrawal of ISO 16142-1 and 16142-2
 - New work item for amendment of IS) 15223-1
 - New work item for creation of a terminology document
 - Change ISO 5137 deliverable from IS to TS tittle change and adjustment (Title: Medical device maintenance management for healthcare delivery organisations)
 - Circulation of ISO/DIS 80369-6 & ISO/DIS 80369-20
- Liaisons members: IEC, GHWP, DITTA, EUROM, IACRC, IMDRF, MedTech Europe, WFSA, WHO & GEDSA



Thank you

Please visit our website www.ghwp.info

- Stay tuned for new activities and updates
- Check out our guidance documents and give us comments
 - Welcome your joining to GHWP