Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

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

GHWP TC

- 7 meetings were held
- Update on WGs Progress
- Work Plan
- AOM

WG 1 – PRE-MARKET SUBMISSION & CSDT

- 1. (Joint Wok) Document development of Artificial Intelligence

  Status: On-going
- 2. (Joint Work-lead) Revise guidance document 'Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU):2019'

  Status: on-going
- 3.(Joint Work-lead) Revisit a GHWP Document "Categorisation of Changes to a RegisteredMedical Device, AHWP/WG2-WG1-WG3/F001:2019" –

  Status: For endorsement

WG 2 – PRE-MARKET IVDD

- 1. Survey report on Good Reliance Practice across GHWP member countries

  -Status: 1st version of g introduction video and the survey plans
- 2.(Joint Work) Revisit a GHWP Document "Categorisation of Changes to a Registered Medical Device, AHWP/WG2-WG1-WG3/F001:2019"

  -Status: For endorsement
- 3.(Joint Work) GHWP guidance document on Clinical Evaluation for IVD related IVD related to Covid 19 PCR testing devices

  Status: Kick-off meeting – (2022/06/17)
- 4.(Joint Work) Revisit a GHWP Document "Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU), AHWP/WG1-WG2-WG3/F002:2019"

  - Status: Provided the core member list from WG2 to WG1
- 5.Participation in IMDRF New Working Group on "Clinical evidence for IVD medical devices"

  - Status: Kick-off meeting (2022/02/22)

GHWP TC & WGs PROGRESS REPORT SUMMARY

WG 3 – PRE-MARKET: SOFTWARE AS A MD

1. White paper on pre market initial submission format for SaMD

   Status: On-going

2. Guidance document on Cyber Security for SaMD

   Status: On-going

3. Guidance document for premarket submission format for SaMD (draft)

   Status: On-going

WG 4 – POST- MARKET

1. Updating the Post-market Resource Centre

   Status: On-going

2. Gap analysis on the implementation of GHWP guidance among GHWP members

   Status: Only 6 returns were received.

3. Participation in the development works of ISO TC210/ WG6

   Status: Suggest to remove this work item due to publication of ISO/TR 20416:2020

4. Report on post-market support in relation to COVID 19

   Status: Study write-up is being compiled.

5. Study on post-market trend in medical devices with AL and cycbersecurity

   Status: Write-up is being prepared based on the limited information in hand and still on-going.

WG 5 – CLINICAL EVIDENCE FOR PERFORMANCE & SAFETY

1. Regular review of Global clinical regulatory updates

   Status: WG5 review new and changing regulation related to global clinical regulatory environment.

2. GHWP guidance document on Clinical Evaluation for IVD related IVD related to Covid 19 PCR testing devices.

   Status: WG 5 & WG 2 structure the guidance document.

3. Gap analysis between IMDRF and GHWP Guidance
   - Clinical Evidence for Medical Device – Key Definitions and Concepts, Clinical Evaluation and Clinical investigation

   Status: Draft guidance for WG 5 review

4. Training for WG 5 and GHWP members on ISO 14155:2020 and ISO 20916: 2019

   Status: WG5 will organize a workshop during GHWP annual meeting.

GHWP TC & WGs PROGRESS REPORT SUMMARY

WG 6 – QMS: AUDIT & ASSESSMENT

- A guide to understanding best practices in audit life cycle management.
  Status: In proof reading stage
- 2.A guide to understanding presently available audit duration determination systems.
  Status: In proof reading stage
- 3.A guidance for NB auditing suppliers to medical device manufacturers.
  Status: In proof reading stage
- 4.Co-Chair Vincent will conduct online training session on remote audit technique.
  Status: Training completed as planned.

WG 7 – QMS: OPERATION & IMPLEMENTATION

- 1. Comparison study of new ISO13485 vs QMS requirements 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: ISO13485:2016
  -Status: On-going

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
- 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 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.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
  Status: NWIP submitted on 25 Nov 2022

WG 9 – UDI & NOMENCLETURE

- 1. Work Item Update: UDI report
  Status: GHWP UDI Rule White Paper – On-going
- 2.Work Item Update: Nomenclature
  Status: On-going
- 3.Work Item Update: Collaboration
  Status: On-going
- 4.GHWP UDI Webinar
  Status: On-going
- 5.WG 9 Team Virtual Meeting
  Status: On-going
- WG 9 Working Item Introduction/Training (Virtual)
  Status: 20 December 2022

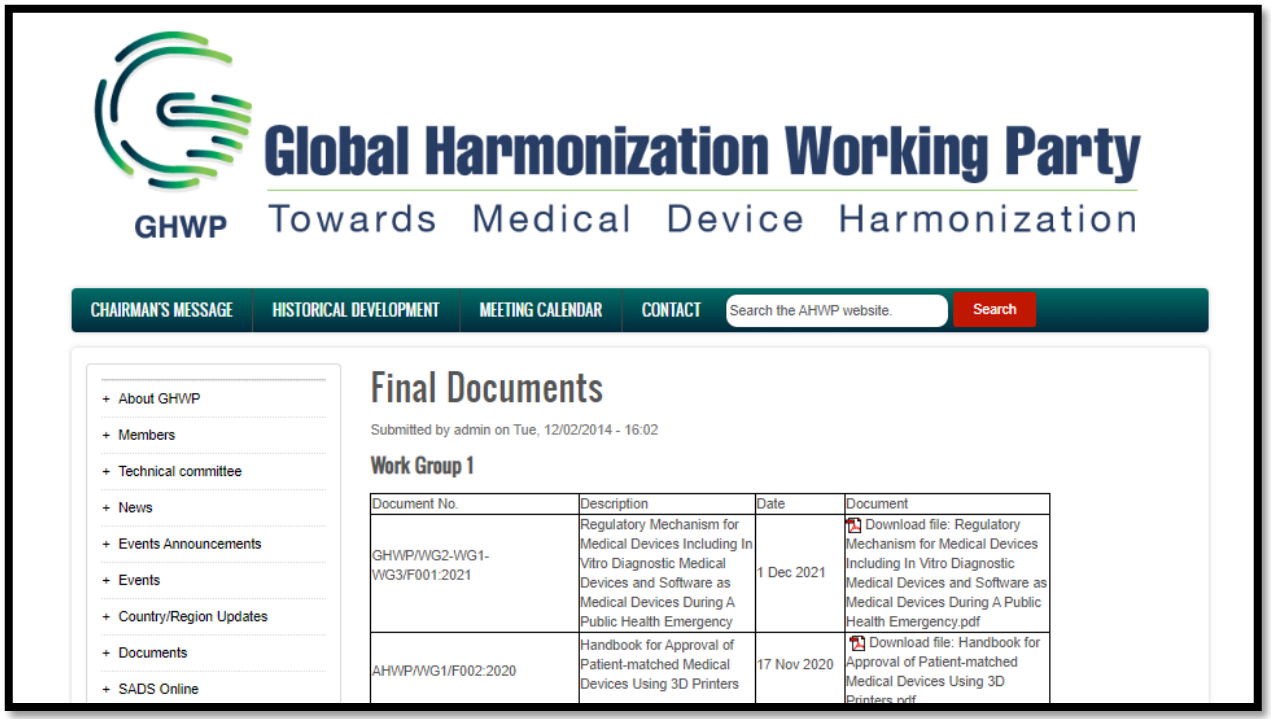
GHWP – Published Guidance Documents (77)

Under WGs

- 53 Documents

Under Secretariat, CB, Others

- 24 Documents



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

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

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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

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

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

