出國報告（出國類別：開會）

2024 年度全球醫療器材法規調和會(GHWP)技術委員會領袖會議報告

服務機關：衛生福利部食品藥物管理署
姓名職稱：蔡文偉科長、簡俊仁技正
派赴國家：印尼
出國期間：113 年 6 月 11-14 日
報告日期：113 年 7 月 12 日

摘要

衛生福利部食品藥物管理署（以下簡稱食藥署）派員於 113 年 6 月 11 至 14 日赴印尼峇里島參加「全球醫療器材法規調和會(Global Harmonization Working Party，簡稱 GHWP)技術委員會領袖會議」，本屆領袖會議包含對外與閉門會議，我國自民國 101 年起獲選擔任技術委員會（Technical Committee，簡稱 TC）體外診斷醫療器材上市前管理工作小組（Work Group 2（WG2）–Pre–market : IVDD）主席，並續任主席至今，並於 112 年第 26 屆年會中成功再爭取醫療器材軟體上市前管理工作小組（Work Group 3（WG3）-Pre–market：Software as a Medical Device）主席。本年度領袖會議由食藥署蔡文偉科長以 WG2 主席身份與簡俊仁技正以 WG3 主席身份出席會議，並於對外會議與閉門會議中進行報告。會議摘要如下：

一、The GHWP TC Meeting Open Door

由本屆主席介紹組織架構及現況、主要任務、已出版指引文件、國際法規調和執行、業界合作等事項，後由印尼醫療與實驗室器材協會主席 Mr. Rd. Kartono Dwidjosewojo 進行印尼醫療與實驗室器材協會簡介與分享印尼醫療器材產業現況。接續由各工作小組代表進行現況更新，其中包含小組成員及組成國更新、年度活動及工作項目進度更新。GHWP WG5 主席 Dr. Mohammed Majrashi 分享醫療器材安全性與功效性基本準則介紹與實施方法，最後由中東業界代表 Dr. Karthik G. M.分享 IMDRF 個人化醫療器材(PMDs)議題。

二、The GHWP TC Meeting Close Door

技術委員會閉門會議部分由各工作小組主席與大會討論各工作進程、新工作項目提案與預計工作規劃，及分享 GHWP 重要議題，包含 IMDRF AI/ML WG/QMS WG/ ISO TC 210 工作小組現況、Reliance Project in GHWP、GHWP 指引文件工作現況及大會規則草案分享。我國以 GHWP TC WG2 與 WG3 工作小組主席身分與會，在會上交流各小組之工作項目內容，並蒐集其他各工作小組近期成果與工作規劃，作為我國相關政策措施之參考。

藉本次會議齊聚各會員國官方與業界代表之機會，交流討論相關合作事項，說明最新工作進度，有助於倡議由我國主導之 WG2 與 WG3 之工作成果，呈現我國於醫療器材法規國際調和之努力，提升我國能見度。

關鍵詞(Keyword)：全球醫療器材法規調和會技術委員會(Global Harmonization Working Party Technical Committees, GHWP TC)、醫療器材（Medical Device)。

目次

壹、目的

本次出席 2024 年度全球醫療器材法規調和會技術委員會領袖會議之主要目的為二：

一、以 GHWP 技術委員會之體外診斷醫療器材上市前管理工作小組（WG2 – Pre–market: IVDD）主席與醫療器材軟體上市前管理工作小組（WG3 – Pre-market: Software as a Medical Device）主席之身分報告 WG2 與 WG3 今年度目前成果、新工作項目及未來工作規劃，並以 WG3 主席身份作為 GHWP 參與 IMDRF AI/ML WG 之代表，報告目前工作進度及分享結果。

二、與 GHWP 各領袖代表進行交流，取得 GHWP 大會及技術委員會規劃計畫之最新資訊。

貳、過程

一、本次出國計畫之行程概述

2024 年度全球醫療器材法規調和會技術委員會領袖會議共計 2 天，第 1 天包含 GHWP TC Meeting 對外及閉門會議，第 2 天為整日閉門會議，本署此次派員全程參與領袖會議，議程詳如附件 1。

日期	會議/活動
6/12	GHWP TC Meeting Open Door & Close Door
6/13	GHWP TC Meeting Close Door

二、關於全球醫療器材法規調和會技術委員會領袖會議之重點內容，摘要記錄如下：

(一) GHWP TC Meeting Open Door

6 月 12 日上午舉行對外會議由大會主席徐景和進行開場致詞，概略介紹組織架構及現況、主要任務與執行現況、已出版指引文件、國際法規調和執行、業界合作等事項。並由印尼醫療與實驗室器材協會主席 Mr. Rd. Kartono Dwidjosewojo 進行印尼醫療與實驗室器材協會簡介與分享印尼醫療器材產業現況，後續由各工作小組代表進行現況更新，其中包含小組成員及組成國更新、年度活動及工作項目進度更新，GHWP WG5 主席 Dr. Mohammed Majrashi 分享醫療器材安全性與功效性基本準則介紹與實施方法，最後由中東業界代表 Dr. Karthik G. M.分享 IMDRF 之個人化醫療器材(PMDs)議題。

(二) GHWP TC Meeting Close Door

6 月 12 日下午與 6 月 13 日舉行 GHWP 技術委員會閉門會議，主要討論 GHWP 工作小組工作現況、新工作項目規劃及工作小組指引文件評估結果，並分享 GHWP 重要議題，包含 IMDRF AI/ML WG/QMS WG/ ISO TC 210 工作小組現況、Reliance Project in GHWP、GHWP 指引文件評估現況與大會規則草案分享等。

GHWP 目前共有 8 個工作小組與 1 個特別任務小組，分別為 WG1 - Pre-Market Submission and CSDT、WG2 - Pre-market: IVDD、WG3 - Pre-market: Software as a Medical Device、WG4 - Post-Market、WG5 - Clinical Evidence for Performance and Safety、WG7 - Quality Management System: Operation & Implementation、WG8 – Standards、WG9 - UDI & Nomenclature、Special Task Group (STG) – Common Evaluation Reliance Practice(CERP)，我國以體外診斷醫療器材上市前管理工作小組（WG2）主席與醫療器材軟體上市前管理工作小組（WG3）主席之身分報告 WG2 與 WG3 今年度目前成果、新工作項目及未來工作規劃，並以 WG3 主席身份作為 GHWP 參與 IMDRF AI/ML WG 之代表，報告目前工作進度及分享結果(相關簡報資料詳附件 2)。

各工作小組報告摘要如下：

工作小組	成果與未來規劃
WG1	1. 預計於 2024 年與 WG2 及 WG3 共同完成 Change Management to Registered Medical Devices 指引文件。 2. 預計於 2024 年修訂 Guidance on Regulatory Practices for Combination Products。 3. 預計於 2024 年修訂 Survey questionnaire for the white paper on Good Reliance Practices。 4. 預計於 2024 年與 WG3 共同修訂 AI-related review guidance。 5. 提出 2024-2026 年新工作項目 Guidance for Active Medical Device Reliability Evaluation Program。 6. 完成既有指引文件評估。
WG2	1. 預計於 2024 年與 WG1 及 WG3 共同完成 Change Management to Registered Medical Devices 指引文件。 2. 預計於 2024 年與 WG1 及 WG3 共同完成 Guidance on regulatory practices for combination products 文件改版。 3. 提出 2024-2026 年新工作項目規劃 Guidance for Artificial Intelligence based Digital Pathology Software。 4. 未來工作規劃包含 Labelling for In Vitro Diagnostic Medical Devices、Principles of In Vitro Diagnostic (IVD) Medical Devices Classification、Essential Principles of Safety and Performance of IVD Medical Devices、GHWP Regulatory Framework for IVD Medical Devices、Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices 文件更新改版。 5. 完成既有指引文件評估，預計廢止 AHWP/WG2/F002:2016 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices。
WG3	1. 預計 2024 年完成 GHWP/WG3/WD001:2023 Guidance Document on Qualification of Medical Device Software 更新改版。 2. 進行 Guidance on pre-market requirement for artificial intelligence/machine learning based computer-aided detection（CADe）and computer-aided diagnosis（CADx）software as a medical device、Software as a Medical Device (SaMD) Pre-Market Submission Requirement - Comparison of requirement from Key jurisdictions 以及 Cyber Security for MD Pre-Market Submission Requirement - Comparison of pre-market requirements from key jurisdictions 文件工作。 3. 預計於 2024 年與 WG1 及 WG3 共同完成「Change Management to Registered Medical Devices」指引文件。 4. 執行 WG3 與 WG5 聯合工作項目 Clinical evidence and clinical evaluation

	requirements for Software as a Medical Device 指引文件。 5. 提出新工作項目修訂 AHWP/WG3/F001:2016 Guidance document on Risk categorisation of Software as a Medical Device 與 White paper- AI/ML based SaMD change submission requirement- Comparison of requirements from key jurisdictions。 6. 完成既有指引文件評估。 7. 參與 IMDRF AI/ML 工作小組。
WG4	1. 持續更新 Post-market Resources Center（PMRC）之資訊。 2. 持續修訂 Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention（PCI） devices for the Medical Device Manufacturer or its Authorized Representative、Adverse Events Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives 與 Medical Device Adverse Event（AE）Report Form。 3. 提出新工作項目 Medical Device Post-Marketing Surveillance（MD-PMS）: Transition from Passive to Active。 4. 完成既有指引文件重複性評估，並對 Adverse Events Reporting Guidance for the Medical Device Manufacturer or its Authorized Representatives 與 Medical Device Adverse Event（AE）Report Form 進行文件更新，預計於 2024 年完成該文件改版。
WG5	1. 持續進行全球臨床法規更新。 2. 與 WG3 合作完成 GHWP guidance on clinical evidence for Software as a Medical Device。 3. 進行 WG5 既有指引文件評估，預計於 2024 年 9 月完成 AHWP/WG5/F002:2017 Post Market Clinical Follow-Up Studies 、AHWP/WG5/F003:2015 Clinical Evidence for IVD Medical Device - Key Definitions and Concepts 及 IVD- Clinical performance studies using specimens from human subjects – Good Study Practice 文件更新。
WG7	1. 完成 2024 年 5 月訓練課程，主講人為 GHWP TC 顧問日本業界代表 Hideki Asai，議題為日本品質管理系統相關法規。後續預計將持續進行內部訓練，訓練時程規劃包含 2024 年 6 月份、第三季及第四季各一場。 2. 持續執行工作項目 Guidance for Remote Inspection to Medical Device Manufacturer 與 Guidance for Quality Agreement of Medical Devices Contract Manufacturing。 3. 提出新工作項目更新 Comparison study of ISO13485 vs. QMS requirements in GHWP member economies 與 Guidance for Control of Sterilized and Implantable Medical Device。 4. 參與 IMDRF QMS 工作小組。
WG8	1. 彙整 GHWP 成員國採認之醫療器材國際法規標準文件清單。

	2. 持續更新指引文件 AHWP/WG2-WG8/F002:2014 Role of Standards in Demonstration of Safety and Performance。 3. 與 WG7 合作執行 Guidance on the Validation of Processes for Production。 4. 評估 GHWP 對於 ISO 16142-1:2016 與 ISO16142-2:2017 之採認狀況。
WG9	1. 2024 年 6 月完成訓練課程，包含 GHWP UDI 規則介紹，及中國、沙烏地阿拉伯、美國及歐盟 UDI 進展及要求，與業界 UDI 實務分享。 2. 完成 AHWP UDI White Paper 與 IMDRF 文件評估，暫無須更新。 3. 執行 Creation and Placement of Unique Device Identifier 與 UDI data elements 兩份文件修訂。
STG-CERP	1. 工作規劃分為 Evaluation Standards、Evaluation Recognition 與 single Evaluation 三大方向，其中包含國際標準的採認。 2. 目前成員數為 39 位，包含 13 位監管機關代表及 26 位業界代表，來自 7 個國家，主要為中國共有 28 位。 3. 目前已完成工作包含舉辦 2 場線上會議、2 場人員訓練、建立產品範例、完成標準評估表已及建立 STG 內部規則。 4. 人員訓練規劃包含 2 場，第一場線上訓練包含 CERP 介紹及中國 NMPA 醫療器材上市前法規介紹；第二場為阿拉伯聯合大公國法規架構及中國 NMPA 醫療器材分類分級說明。

(三) GHWP TC 文件評估工作及提案採認

GHWP TC 副主席 Ms. Miang Tanakasemsub 對於工作小組指引文件評估進行完整的說明，包含目前進度、評估流程及評估結果執行方式。目前已與各工作小組完成線上討論會議，並說明若指引文件評估結果為完全相同，建議刪除該文件並採認原文件參考依據；若為部分雷同則建議更新該份文件，並於文件中新增引用文件相關宣言，此部分宣言將由 GHWP 秘書處提供；而若為 GHWP 獨有文件則可保留該文件。

GHWP TC 副主席 Li Jun 對各工作小組所提出工作項目、新工作項目提案以及 GHWP TC 工作進度進行總結說明。今年度已完成第一場 GHWP 醫療器材產業創新研討會，參與人數共計至少 200 人；工作小組年度工作項目共計 24 項，新工作項目提案中與「Good Reliance Practice Survey」相關工作項目，將聚焦於上市前管理，後續將由 STG、WG1、WG2 與 WG3 共同執行，並由 STG 主導。WG2 所提出之工作項目 Guidance for Artificial Intelligence based Digital Pathology Software，則需確認是否與 ISO TC 212 WG4 執行工作項目範圍相同，現暫撤回待確認後再次提出，建議可派員參加 ISO TC 212 WG4。WG1 與 WG4 新工作項目皆包含 Medical Device reliability evaluation program，建議可合併執行。

(四) GHWP 相關更新

1. GHWP 文件發布標準作業程序

第八工作小組(WG8)研議 GHWP 文件發布作業標準程序並進行說明，依據各階段建立個別時程規劃，包含 Proposal（NWIP）Stage、Draft Stage、Proposed Stage、Proposed Final Stage、Final Stage、Periodic Review Stage，所需時間至少為 180 天。該份 SOP 預計將於 2024 年會進行採認並正式納入「GHWP house rule」，並將有一年的寬限期。

2. GHWP 網頁改版：已於 5 月 30 日與廠商完成起始會議，預計將於 11 月 11 日完成更新並正式啟用。網站架構如下：

(1) Member countries/regions：部分國家名稱將簡化，如 Republic of Korea 將簡化為 South Korea，使搜尋更直觀。

(2) Joining GHWP：可依據不同目的選擇不同申請項目，並可直接於網頁上傳申請表。

(3) Guidance Documents：可於各文件分頁看到文件進度，包含 call for comments、abolish 等。

(4) GHWP Leadership：包含所有領袖、TC 顧問個人資料與簡歷。

(5) E-voting system：透過電子郵件登入投票，並採不記名制。新任領袖選舉仍應到場投票，故不適用。

3. 本次會議決議 2025 年全球醫療器材法規調和會技術委員會領袖會議舉辦地點在埃及，會上並撥放埃及醫療器材主管機關 Egyptian Drug Authority (EDA)介紹影片。

參、心得與建議

一、建議食藥署持續積極參與 GHWP 相關事務

GHWP 技術委員會領袖會議為各層級及工作小組間交流之重要會議，透過參與此類會議，掌握其他國家醫療器材主管機關最新資訊或政策方向，可做為研訂我國管理方針之重要參考，建議應持續參與國際醫療器材法規調和之相關事務。

二、建議持續透過 GHWP 組織平台，鏈結重要主管機關

藉由 GHWP 技術委員會領袖會議，對參與該活動之重要國家官方代表(本次如印尼衛生部)，建立關係及瞭解與醫療器材相關之重要該國管理方向，並提升我國國際能見度。

附件 1

12 Jun 2024			
08.00 - 08.30	Registration		Legian Room
	All the Leaders and guests to enter ball room		
08.30 - 09.20	Opening ceremony	MC	
5'	Preliminary report: Director General of Pharmaceuticals and Medical Devices, MoH Indonesia	Ms. Rizka Andalucia	
5'	Remarks: GHWP Chair	Mr. Xu Jinghe (NMPA China)	
5'	Remarks: Gakeslab Indonesia Chair	Mr. Kartono	
10'	Welcome remarks: Minister of Health Indonesia	Mr. Budi Gunadi*	
	Bumper opening: All the Leaders welcome to the Stage		
	Photo Session: Leaders and All Participants		
09.20 - 09.40	*Tea/coffee Break*		
09.40 - 11.00	*GHWP TC Meting (Open-door)*		
	GHWP TC Work Group Updates:		
	WG1: Pre-Market Submission and CSDT	WG1 Chair	
	WG2: Pre-Market IVDD	WG2 Chair	
	WG3: Pre-Market: Software as a Medical Device	WG3 Chair	
	WG4: Post Market	WG4 Chair	
	WG5: Clinical Evidence for Performance and Safety	WG5 Chair	
	WG7: Quality Management System	WG7 Chair	
	WG8: Standards	WG8 Chair	
	WG9: UDI & Nomenclature	WG9 Chair	
	Special Task Group - Common Evaluation Reliance Practice (CERP)	STG-CERP Chair	
11.00 - 12.00	*Open Topic related to WG:*		
	Benchmarking Regulation for Medical Devices: Essential Principle Checklist - How to Evaluate EPC	Dr. Abdullatif Watban (Saudi FDA)	
	Personalized MD: Pre-market requirement	Mr. Karthik G M, PhD. (Guardant Health)	

閉門會議

GHWP TC Closed Door Meeting Agenda (draft) Day 1- Wednesday, 12 June 2024 Attendees: GHWP LT, TC LT, TC Advisors, SAB, WG Chairs & Cochairs, Invited Observers			
Moderator: Dr. Latif, GHWP TC Chair			
ITEM	**TIME**	**TOPIC**	**SPEAKER**
1	02:00 PM - 02:10 PM	Opening Speech	**Dr. Abdullatif S. Al Watban GHWP TC Chair**
2	02:10 PM - 02:20 PM	Keynote Speech	**Dr. XU Jinghe GHWP Chair**
3	02:20 PM - 02:30 PM	Roll Call Adoption of Agenda	**All**
4	02:30 PM - 02:40 PM	Group Photo	**All**
5	**02:40 PM - 03:10 PM**	**Coffee Break**	
6	03:10 PM - 03:30 PM	WG 1 Working Progress and NWIP Q&A (5mins)	**WG1**
7	03:30 PM - 03:50 PM	WG 2 Working Progress and NWIP Q&A (5mins)	**WG2**
8	03:50 PM - 04:10 PM	WG 3 Working Progress and NWIP Q&A (5mins)	**WG3**
9	04:10 PM - 04:30 PM	WG 4 Working Progress and NWIP Q&A (5mins)	**WG4**
10	**04:30 PM - 06:00 PM**	**adjourn**	
11	**06:00 PM - 08:00 PM**	**GHWP LT & TC LT Dinner**	

GHWP TC Closed Door Meeting Agenda (draft) Day 2- Thursday, 13 June 2024 Attendees: GHWP LT, TC LT, TC Advisors, SAB, WG Chairs & Cochairs, Invited Observers			
1	09:00 AM - 09:20 AM	WG 5 Working Progress and NWIP Q&A (5mins)	**WG5**
2	09:20 AM - 09:40 AM	WG 7 Working Progress and NWIP Q&A (5mins)	**WG7**
3	09:40 AM - 10:00 AM	WG 8 Working Progress and NWIP Q&A (5mins)	**WG8**
4	**10:00 AM - 10:30 AM**	**Coffee Break**	
5	10:30 AM - 10:50 AM	WG 9 Working Progress and NWIP Q&A (5mins)	**WG9**
6	10:50 AM - 11:10 AM	STG Working Progress and NWIP Q&A (5mins)	**STG CERP**
7	11:10 AM - 11:40 AM	IMDRF AI/ML WG/QMS WG/ ISO TC 210	**GHWP Representatives in IMDRF WG/ISO TC210**
8	11:40 AM - 12:00 PM	Discussion & Input from TC Advisor	**All & TC Advisor**
9	**12:00 PM - 02:30 PM**	**Lunch Break**	

10	02:30 PM - 02:50 PM	GHWP TC Work Plan 2024 and NWIP	**Ms. Li Jun** **GHWP TC Co-Chair**
11	02:50 PM - 03:00 PM	GHWP TC Capacity Building Plan	**Ms. Quan Tran** **GHWP Capacity Building Lead** **GHWP Strategic Advisory Board**
12	03:00 PM - 03:10 PM	Member/Advisor/NWIP Application Procedure	**Mr. Bryan So** **GHWP Executive Secretary General**
13	03:10 PM - 03:20 PM	Reliance Project in GHWP	**Dr. Adelheid Schneider** **TC Secretary/WG2 Cochair**
14	**03:20 PM - 03:40 PM**	**Coffee Break**	
15	03:40 PM - 04:40 PM	Assessment Report of GHWP guidance	**Ms. Miang Tanakasemsub** **GHWP TC Co-Chair**
16	04:40 PM - 04:50 PM	Discussion on Host of 2025' TC Meeting	**Mr. Bryan So** **GHWP Executive Secretary General**
17	04:50 PM - 05:00 PM	Closing Remarks	**Ms. Eka Purnamasari** **GHWP Vice-Chair**

附件 2

Global Harmonization Working Party
Towards Medical Device Harmonization

GHWP TC Meeting
Jun 12th, 2024

WG2 – Pre-market: IVDD

Chair: Dr. Wen-Wei TSAI
Co-Chair: Dr. Adelheid Ingrid Schneider
Advisor: Ms. Shelley TANG

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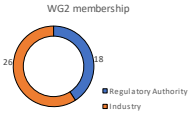
Work Progress-Membership and Activities Updates



44 members from 19 economies
- Incl. 1 advisor and 1 observer
- 1 new application in progress: Dr. Sangjin Park (Regulatory Authority, Republic of Korea)

- **Meetings in 2024**
  - WG2 kick-off meeting (online): Feb. 22
  - WG1-2-3 online meeting for "Change Management to Registered Medical Devices": Apr. 24
  - WG2 FTF meeting: Aug. 6 - 8


WG2 Kickoff Meeting (Feb. 22)

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Work Progress-Work Items Updates

	Deliverables	Timeline	Progress Update
1	Review and update GHWP/WG2/WG1-WG3/P001:2023- Change Management to Registered Medical Devices (cooperate with WG1 & WG3)	2023-2024	• Public commenting period: Oct. 13 to Nov. 20, 2023 • Revising the document in response to public feedback
2	Review and update GHWP WG1/F001:2016 Guidance on regulatory practices for combination products (cooperate with WG1 & WG3, led by WG1)	2024	• Drafting in progress
3	Guidance Documents Duplication Evaluation	2024	• Preliminary evaluation was concluded
4	Training: GHWP/WG2 /F001:2021 Replacement Reagent and Instrument Family Policy	2024 Q2/Q3	• Preparation in progress

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New Working Item Proposals (NWIP

Guidance for Artificial Intelligence based Digital Pathology Software

- WG1, WG2, and WG3 joint work item, primarily led by WG2
- Purpose: Developing an international common guidance for AI-based digital pathology software to reduce the time required for pathologists to interpret results and to improve the accuracy and reproducibility of diagnosis.
- Timeline: 2024-2025

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WG2 Future Work Plan

	Deliverables	Timeline (Tentative)
Development of GHWP Document *This is a tentative work plan for WG2. The specific work items for each year will depend on the outcomes of the kickoff meeting for that year.	Review and update GHWP/WG2/F001:2018 Labelling for In Vitro Diagnostic Medical Devices	2025
	Review and update GHWP/WG2/F001:2016 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	TBD
	Regulatory Practices on "OTC" Labelled Products and Laboratory Developed Products / Requirements and specifications focus on developed and produced in vitro diagnostic medical devices	TBD
	Grouping of IVD for Product Registration	TBD
	Review and update GHWP/WG1a/F002:2013 Essential Principles of Safety and Performance of IVD Medical Devices	TBD
	Review and update GHWP/WG1a/F001:2013 GHWP Regulatory Framework for IVD Medical Devices	TBD
	Review and update GHWP/WG2/F003:2016 Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices	TBD

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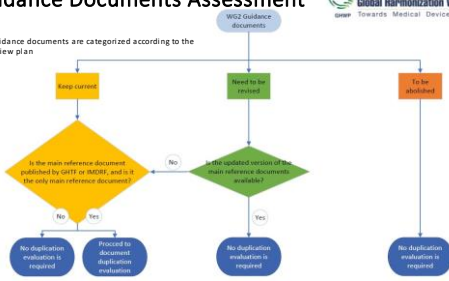
Guidance Documents Assessment

*The guidance documents are categorized according to the 2023 review plan



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Guidance Documents Assessment

19 documents in total. Plan to keep 4, revise 6, abolish 8, and 1 to be reviewed primarily by WG8.

	Document	Reference	Note
1	AHWP/WG1/WG2/F001: 2017 Regulation and treatment of eIFU and e-Label of Medical Devices Review of International Practice		• The guidance will ~~be~~ abolished by 2024.
2	AHWP/WG2/WG1/F001:2016 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'	GHTF/SG1/N071:2012 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'	• There is a difference in the definition of IVD medical devices between the GHWP and GHTF guidance documents. Additionally, the GHWP guidance document includes annex I consisting examples. • Keep current
3	AHWP/WG2_WG1/F001:2015 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'		• The guidance has been updated to "AHWP/WG2 WG1/F001:2016" and is scheduled to ~~be~~ abolished by 2024.
4	GHWP/WG2WGS/F001:2021 Clinical Evidence for IVD Medical Devices- Clinical Performance Studies for In Vitro Diagnostic Medical Devices	GHTF/SG5/N8: 2012 Clinical Evidence for IVD Medical Devices-Clinical Performance Studies for In Vitro Diagnostic Medical Devices	• The guidance document has been amended by adding more examples and introducing new a section 11.0. • Keep current

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Guidance Documents Assessment

	Document	Reference	Note
5	AHWP/WG2WG8/F002:2014 Role of Standards in the Assessment of Medical Devices	GHTF/SG1/N044:2008 Role of Standards in the Assessment of Medical Devices	• The guidance document is included in the review plan for WG8 for the year 2023.
6	GHWP/WG2WG1-WG3/F001:2023Categorisation of Changes to a Registered Medical Device	Not from IMDRF/GHTF	• The document has been revised to the proposed guidance document titled "Change Management Registered Medical Devices." It is currently undergoing the endorsement process. • Revising in Progress
7	GHWP/WG2WG1-WG3/F001:2021 Regulatory Mechanism for Medical Devices Including In Vitro Diagnostic Medical Devices and Software as Medical Devices During A Public Health Emergency	No global guidance on emergency regulatory mechanisms yet exists at the time the guidance w published	• Keep current
8	AHWP/WG2WG1-WG3/F001:2019Categorisation of Changes to a Registered Medical Device		• The guidance has been updated in 2023, and this version is suggested ~~abolition~~.

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Guidance Documents Assessment

	Document	Reference	Note
9	AHWP/WG1/WG2-WG3/F002:2019 Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)		• The guidance has been updated in 2023, and this version is suggested ~~abolition~~.
10	GHWP/WG2 /F001:2021 Replacement Reagent and Instrument Family Policy	Not from IMDRF/GHTF	• Keep current
11	AHWP/WG2/F001:2018 Labelling for In Vitro Diagnostic Medical Devices	GHTF/SG1/N70: 2011 Label and Instructions for Use Medical Devices	• New reference document: ISO 18113-2:2022 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) Part 1: Terms, definitions, and general requirements • To be Revised
12	AHWP/WG2/F001:2017 Guidance for Additional Considerations to support Conformity Assessment of Companion In vitro Diagnostic Medical Devices	Not from IMDRF/GHTF	• The guidance has been updated in 2023, and this version is suggested ~~abolition~~.

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Guidance Documents Assessment

	Document	New Reference	Note
13	AHWP/WG2/F001:2016 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	GHTF/SG1/N045: 2008 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	• Updated reference document: IMDRF/IVD WG/N64FINAL:2021 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification • To be Revised
14	AHWP/WG2/F002:2016 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices	GHTF/SG1/N046: 2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices	• The guidance shares similarities with GHTF/SG1/N06:2008, with some modifications to the wording. • To be ~~abolished~~
15	AHWP/WG2/F003:2016 Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices	GHTF/SG1/N063:2011 Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices	• This document and the GHTF guidance share a similar structure but differ in content. The GHWP document incorporates insights from its experts. • To be Revised
16	AHWP/WG2/F001:2014 Comparison between CSDT and STED IVDDs		• The guidance will ~~be~~ abolished by 2024.

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Guidance Documents Assessment

Global Harmonization Working Party
Towards Medical Device Harmonization

	Document	Reference	Note
17	**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**		• The guidance will be abolished by 2024.
18	**AHWP/WG1a/F002:2013 Essential Principles of Safety and Performance of IVD Medical Devices**	GHTF/SG1/N68:2012 Essential Principles o Safety and Performance of Medical Devic	• Updated reference document: IMDRF/GRRP WG/N47 FINAL:2024 (Edition 2) Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices • To be Revised
19	**AHWP/WG1a/F001:2013 GHWP Regulatory Framework for IVD Medical Devices**	1. GHTF/SG1/N29:2005 Information Document Concerning the Definition of th Term 'Medical Device'. 2. GHTF/SG1/N45:2007 Principles of In Vit Diagnostic Medical Devices Classificatio 3. GHTF/SG1/N46:2007 Principles of Conformity Assessment for In Vitro Diagnostic Medical Devices. 4. GHTF/SG1/N41:2005 Essential Principle Safety and Performance of Medical Devic	• Updated reference documents: 1. IMDRF/GRRP WG/N47 FINAL:2024 (Edition 2) Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices 2.IMDRF/IVD WG/N64FINAL:2021 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification • To be Revised

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Guidance Documents Selection

Global Harmonization Working Party
Towards Medical Device Harmonization

The following are the current effective guidance documents proposed to the TC for considering assessing the adoption status by Member Countries/regions:

	Document	Note
1	**AHWP/WG2WG1/F001:2016 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'**	• The definitions of MD and IVD are fundamental to the regulatory framework. • Still up-to-date.
2	**AHWP/WG2/F001:2018 Labelling for In Vitro Diagnostic Medical Devices**	• "Labelling" for IVDs is a fundamental and universal issue that applies to all IVDs. • The guidance is planned to be revised in 2025.

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Global Harmonization Working Party
Towards Medical Device Harmonization

Thank you for your attention!

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Global Harmonization Working Party
Towards Medical Device Harmonization

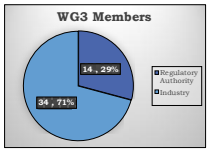
GHWP TC and WG Leaders Meeting
June 12 to 13, 2024

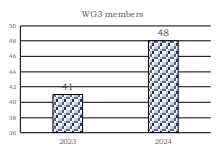
WG3 – Pre-market: SaMD

Chair: Mr. Chun-Jen Chien
Co-Chair: Mr. Tony YIP

Work Progress
WG members status

48 members from 11 economies, including Chinese Taipei, Hong Kong SAR, India, Indonesia, Japan, Kingdom of Saudi Arabia, Netherlands, People's Republic of China, Republic of Korea, Singapore, Sultanate of Oman





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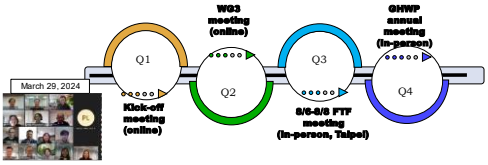
WG3 Work Plan for 2024

Work Item	Deliverables	Timeline
Activity	1. WG3 kick-off meeting (online): March 2. WG3 Q2 meeting (online): June 3. WG3 FTF meeting (With WG1&2): August 4. Annual meeting: TBD	2024



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Work Progress
Developing progress of endorsed working items

	Work Item	Deliverables	Time line	Progress update
1	Development of GHWP Document	New Guidance (new proposal item) Guidance on premarket requirement for artificial intelligence/machine learning based computer-aided detection (CADe) and computer-aided diagnosis (CADx) software as a medical device	2023-2025	Step 1. Consolidating Comments for Document Revision
		Review and update GHWP/WG3/WD001:2023 Guidance Document on Qualification of Medical Device Software	2023-2024	Step 2. Documents discussed in GHWP TC
		White Paper • Software as a Medical Device (SaMD) Pre-Market Submission Requirement Comparison of requirement from key jurisdictions • Cyber Security for MD Pre-Market Submission Requirement – Comparison of pre-market requirements from key jurisdictions	2023-2025	Step 1. Consolidating Comments for Document Revision

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Work Progress
Developing progress of endorsed working items

	Work Item	Deliverables	Timeline	Progress update
2	Development of GHWP Document	Joint Guidance GHWP/WG2-WG1-WG3/P001:2023 Change Management to Registered Medical Devices	2023-2024	Led by WG2 Consolidating Public Comments for Document Revision
		Joint Guidance Clinical evidence and clinical evaluation requirements for Software as a Medical Device (collaborate with WG5)	2023-2025	Led by WG5 Under discussion

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New Working Item Proposals (NWIP)

	Work Item	Deliverables	Timeline
1	Development of GHWP Document	Review and update AHWP/WG3/F001:2016- Guidance document on Risk Categorisation of Software as a Medical Device	2024-2025
		White paper (New proposal item) AI/ML based SaMD change submission requirement - Comparison of requirements from key jurisdictions	2024-2025

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Guidance Document Assessment

Document No.	Description	Date	IMDRF documents cited in this article	*Discrepancy to the IMDRF documents cited in this article	Suggestion
AHWP/WG3/F001:2016	Guidance document on Risk Categorisation of Software as a Medical Device	2016-11-26	IMDRF/ SaMD WG/N10FINAL:2013: Software as a Medical Device (SaMD): Key Definitions IMDRF/ SaMD WG/N12FINAL:2014: "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations	98% ~40%	revise
AHWP/WG3/F001:2015	Guidance Document on Medical Device Software - Qualification and Classification	2015-11-06	IMDRF/ SaMD WG/N10FINAL:2013: Software as a Medical Device (SaMD): Key Definitions IMDRF/ SaMD WG/N12FINAL:2014: "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations	95% ~70%	revise

* The tool for comparing similarity to the IMDRF documents : https://ethics.moe.edu.tw/news/detail/287/

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Guidance Documents Selection

Document No.	Description	Date	Note
AHWP/WG3/F001:2016	Guidance document on Risk Categorisation of Software as a Medical Device	2016-11-26	to be revised Suggest not to be used for adoption assessment
AHWP/WG3/F001:2015	Guidance Document on Medical Device Software - Qualification and Classification	2015-11-06	to be revised Suggest not to be used for adoption assessment

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Thank you for your attention!

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Global Harmonization Working Party
Towards Medical Device Harmonization

IMDRF AI/ML WG Update

WG3 Chair: Mr. ChunJen Chien

Global Harmonization Working Party
Towards Medical Device Harmonization

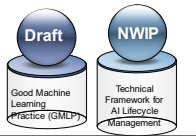
IMDRF AI/ML WG

Working Group Chair(s)


Russell Pearson
MHRA, UK


Matthew Diamond
FDA, USA

Participants



https://www.imdrf.org/working-groups/artificial-intelligence-machine-learning-enabled

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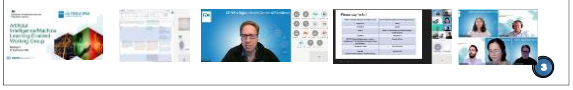
Global Harmonization Working Party
Towards Medical Device Harmonization

IMDRF AI/ML Meetings

AI/ML WG two -day meeting in the US

Aimed at refining the draft document of GMLP

Sep.13, 2023
Oct. 11, 2023
Nov. 8, 2023
Dec. 6, 2023
Jan. 17, 2024
Feb. 7, 2024
Mar. 13-14, 2024
May 8, 2024



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Global Harmonization Working Party
Towards Medical Device Harmonization

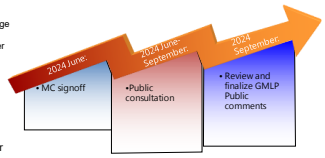
GMLP Project

Focus areas

- Needs of Generative AI/ Large Language Models (LLMs)
- Alignment with and referencing of other IMDRF documents

Future work

- An in-depth exploration of GMLP for Pre-determined Change Control Plans



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Global Harmonization Working Party
Towards Medical Device Harmonization

Draft: Good machine learning practice for medical device development: Guiding principles

Draft

Good machine learning practice for medical device development: Guiding principles

Artificial Intelligence/Machine Learning-enabled Working Group

Contents

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Global Harmonization Working Party
Towards Medical Device Harmonization

10 Guiding principles

1.The device's intended use/ intended purpose is well understood, and multi -disciplinary expertise is leveraged throughout the total product life cycle

2.Good software engineering, medical device design, and security practices are implemented

3.Clinical study participants and datasets are representative of the intended patient population

4.Training datasets are independent of test sets

5.Selected reference standards are fit -for-purpose

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Global Harmonization Working Party
Towards Medical Device Harmonization

10 Guiding principles

6.Model choice and design are tailored to the available data and the intended use/ intended purpose of the device

7.Performance is assessed with a focus on the human -AI team in the intended use environment

8.Testing demonstrates device performance during clinically relevant conditions

9. Users are provided clear, essential information

10. Deployed models are monitored for performance and re -training risks are managed

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Global Harmonization Working Party
Towards Medical Device Harmonization

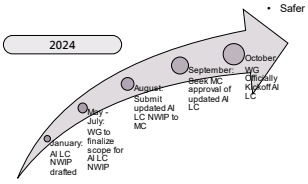
AI Lifecycle Management Project

Focus

- Recommendations for new/different approaches for AI medical software

Issues Addressed

- Best practice divergence in an emerging field
- Product safety
- Safer movement of products



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Global Harmonization Working Party
Towards Medical Device Harmonization

Suggestions

- Collaborate with the Medical Device related organization brings benefit to GHWP.
  - Acquire the latest progress/prospect from other jurisdiction/organization
  - As WG3 initiates the development of AI/CADe/CADx) guidance, it is recommended that GHWP continue to participate in IMDRF AI/ML meetings to keep abreast of IMDRF's progress and promote the harmonization of regulations/guidance.

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Global Harmonization Working Party
Towards Medical Device Harmonization

Thank you for your attention!

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