出國報告（出國類別：開會）

全球醫療器材法規調和會(GHWP)
第 26 屆年會系列會議

服務機關：衛生福利部食品藥物管理署
姓名職稱：杜培文組長、蔡文偉科長、
簡俊仁技正

派赴國家：沙烏地阿拉伯
出國期間：**112** 年 **2** 月 **13-18** 日
報告日期：**112** 年 **4** 月 **15** 日

摘要

衛生福利部食品藥物管理署派員於 112 年 2 月 13 日至 18 日赴沙烏地阿拉伯參加「第 26 屆全球醫療器材法規調和會(GHWP)年會系列會議」，會議摘要如下：

一、The 26th GHWP Technical Committee (GHWP TC) Meeting

於 TC Meeting 時，我國代表以 GHWP TC WG2 工作小組主席身分，在會上發表該小組之工作進度及未來規劃，成果豐碩備受肯定。另並蒐集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。

二、The 26th GHWP Annual Meeting

由澳洲、歐盟、日本及沙烏地阿拉伯等國之主管機關代表，說明其醫材法規管理架構或更新近況。本次會議適逢大會主席及 TC 領袖層級選舉年，結果由中國擔任 2023-2025 年 GHWP 大會主席，我國代表亦成功爭取 WG2 及 WG3 主席之連任與新任；會上亦宣布第 27 屆 GHWP 系列會議將在中國上海舉辦。

三、工作小組會議

藉本次年會系列會議已齊聚各國官方與業界代表之機會，於當地共召開 1 場工作小組會議(WG1-WG2-WG3 聯合會議)，討論相關合作事項，說明最新工作進度，有助於我國主導 WG2 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。

此次年會系列會議大會通過 1 份我國主導之指引文件，受採認為 GHWP 國際指引，並蒐集各國與各組織之最新醫材管理規範，與各國代表交流，有利於我國國際合作與發展。

關鍵詞（Keyword）：全球醫療器材法規調和會（GHWP）、醫療器材（Medical Device）。

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壹、目的

全球醫療器材法規調和會(Global Harmonization Working Party, GHWP)前身為亞洲醫療器材法規調和會(Asian Harmonization Working Party, AHWP)成立於 1999 年並於 2020 年更名為 GHWP，為一醫療器材法規調和化之自願性組織，會員國涵蓋的地理區域，超越創始之初的東亞地區，已擴及到中亞、美洲、中東、以及非洲等地區。目前會員國包括汶萊、柬埔寨、智利、香港、印度、印尼、約旦、肯亞、哈薩克斯坦、巴林、沙烏地阿拉伯、寮國、馬來西亞、蒙古、緬甸、巴基斯坦、中國、菲律賓、南韓、新加坡、南非、科威特、阿曼、坦尚尼亞、泰國、阿拉伯聯合大公國、美國、越南、葉門、辛巴威、吉爾吉斯共和國、我國以及今年新加入之會員日本，共 33 個會員組成。GHWP 各會員國代表，分別來自各國衛生主管機關、醫療器材製造業者，且有數個國際組織為 GHWP 官方聯繫交流成員(Liaison Member)，合作制定與修訂醫療器材相關國際指引或參考文件，舉辦相關法規訓練活動，共同致力於推動醫療器材法規調和之目標。

GHWP 於 112 年 2 月 13 至 16 日在沙烏地阿拉伯利雅德舉行第 26 屆年會系列會議，為與 GHWP 會員國之產官代表進行交流，食品藥物管理署由醫療器材及化粧品組杜培文組長(擔任 GHWP 我國官方第一代表)率同蔡文偉科長(現 GHWP 技術委員會之體外診斷醫療器材上市前管理工作小組主席)及簡俊仁技正等一行 3 人，共同出席會議，以取得年會期間研討醫材管理國際重要議題之最新資訊，參與 GHWP 重要決策之研商，並於會上報告說明我國主導體外診斷醫療器材上市前管理工作小組之業務進度及未來規劃。此外，藉本次會議已齊聚各國官方與業界代表之機會，於當地召開 WG1-WG2-WG3 工作小組之聯合會議，積極貢獻於醫材法規國際調和。

貳、過程

一、本次出國計畫之行程概述

本屆 GHWP 年會系列會議，包括 1 天的第 26 屆 GHWP TC Meeting 及 1 天的第 26 屆 GHWP Annual Meeting，共計 2 天，本署在 GHWP TC Meeting 及 GHWP Annual Meeting 皆有參與，議程詳如附件 1。

日期	會議/活動
2/15	第 26 屆 GHWP TC Meeting
2/16	第 26 屆 GHWP Annual Meeting

另外，除 GHWP 年會系列會議議程外，我國食藥署蔡文偉科長擔任 GHWP TC 體外診斷醫療器材上市前管理工作小組(WG2 - Pre-market: IVDD)主席，藉此會議邀集 GHWP TC 各工作小組成員與相關專家之機會，特於 2/15 下午 GHWP TC Meeting 會議後，於當地召開 WG1(Pre-Market Submission and CSDT)-WG2-WG3(Pre-market: Software as a Medical Device)聯合工作會議，針對合作研擬指引工作，進行內容討論與分工。本次 WG1-WG2-WG3 聯合工作會議，由 WG2 主席蔡文偉科長宣布規劃於 2023 年 7 月或 8 月在台灣舉行實體會議並邀請 WG1 和 WG3 參加會議， WG2 將在確定會議日期後向所有與會者發出正式邀請；對於修訂 GHWP/WG1-WG2-WG3/F002:2019 Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)之聯合工作項目，此項工作進展並由來自 3 個工作組的 12 名核心成員來執行相關工作，目標是在 2023 年底完成修訂。WG3 副主席業界代表 Mr. Tony YIP 說明人工智慧相關文件工作將配合國際醫療器材法規管理論壇(International Medical Device Regulators Forum, IMDRF)國際組織之文件進度繼續展開；對於 GHWP/WG2-WG1-WG3/F001:2019 Categorisation of Changes to a Registered Medical Device and GHWP/WG1/F001:2020 Guidance for Minor Change Reporting 之融合工作項目將在今年展開並預計在台灣舉辦之實體會議進一步討論；有關 Conformity Assessment of AI-based Digital Pathology Software 指引之工作項目，WG1 主席 Dr. Park 簡短介紹該提案內容，我國代表 WG2 主席表示擬在之後工作會議上進行進一步討論；另有關 Survey on Good Reliance Practices among GHWP member countries 工作項目，WG2 成員 Dr. Adelheid SCHNEIDER 說明更新該工作項目進度，本次會議參加者來自 10 個國家，共有 19 位。

有關前述會議出席名單，詳如下表。

1	Seil PARK	WG1 Chair
2	Mandy (Myoung Shim) KIM	WG1 Co-Chair
3	Wen-Wei TSAI	WG2 Chair
4	Tony YIP	WG3 Co-Chair
5	Fajer K. ALKUSAIR	WG1 Member (Regulator Authority)

6	Faiza ALZADJALI	WG1 Member (Regulator Authority)
7	Kenneth CAVANAUGH	WG1 Member (Regulator Authority)
8	Victoria QU	WG1 Member (Industry)
9	Ed WOO	WG1 Member (Industry)
10	Asok KUMAR	WG1 Member (Industry)
11	Anna PARK	WG1 Secretary
12	Paulyne WAIRIMU	WG2 Member (Regulatory Authority)
13	Cristina SANDJAJA	WG2 Member (Industry)
14	Pauline LAW	WG2 Member (Industry)
15	Jacqueline MONTERIO	WG2 Member (Industry)
16	Adelheid SCHNEIDER	WG2 Member (Industry)
17	Yin-ting FANN	WG2 Member (Industry)
18	Chun Jen CHIEN	WG3 Member (Regulator Authority)
19	Yasha HUANG	WG3 Member (Industry)

二、關於 GHWP 年會系列會議之重點內容，摘要記錄如下：

2 月 15 日上午舉行 TC Leaders Meeting 之閉門會議，主要討論 GHWP 未來發展策略及活化會員參與度，共識為須多發展各類文件並與國際組織如 ISO、IMDRF 等機構合作與調和，另亦鼓勵各所屬會員多發言並參與活動。接著進行第 26 屆 GHWP 技術委員會會議(TC Meeting)，GHWP TC 轄下原設有 9 個工作小組(Work Group，WG)，經本次大會後將 WG6 併入 WG7，因此 GHWP WG 最新狀態為 8 個工作小組，分別為：

(1)WG1 - Pre-Market Submission and CSDT、

(2)WG2 - Pre-market: IVDD、

(3)WG3 - Pre-market: Software as a Medical Device、

(4)WG4 - Post-Market、

(5)WG5 - Clinical Evidence for Performance and Safety、

(6)WG7 - Quality Management System: Operation & Implementation、

(7)WG8 - Standards、

(8)WG9 - UDI & Nomenclature，

以上各工作小組負責研究醫療器材各階段重要議題，並推動醫療器材法規調和化。我國食藥署蔡文偉科長為現任 WG2 主席，於本次會議簡報說明 WG2 本任期工作規劃與各項工作進度狀況(附件 2)。WG2 工作小組之產出豐盛，以跨工作小組合作方式，產出「Categorisation of Changes to a Registered Medical Device」，並已於隔日 GHWP 年會上獲大會採認，有關 GHWP TC 各工作小組於本次會議更新之成果及未來規劃，彙整重點如下表：

工作小組	成果與未來規劃
WG1	1. 通過採認 WG1、WG2、WG3 共同提出的「Categorisation of Changes to a Registered Medical Device」指引文件。 2. 完成修訂 Handbook for Approval of Patient matched Medical Devices Using 3D Printers。 3. 完成修訂 Guidance for Minor Change。 4. 與 WG1、WG2、WG3 共同修訂 Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)中。
WG2	1. 通過採認 WG1、WG2、WG3 共同提出的「Categorisation of Changes to a Registered Medical Device」指引文件。 2. 與 WG1、WG2、WG3 共同修訂 Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)中。 3. 規劃評估是否訂定 Good Reliance Practices for MD, IVD and SaMD across the life cycle 指引，並調查 GHWP 成員之 Good Reliance Practice 情況。 4. 規劃更新 GHWP/WG2/F001:2017 Guidance for Additional Considerations to support Conformity Assessment of Companion In vitro Diagnostic Medical Devices。 5. 與 WG5 合作進行 GHWP guidance document on Clinical Evaluation for IVD related to Covid 19 PCR testing devices。
WG3	1. 通過採認 WG1、WG2、WG3 共同提出的「Categorisation of Changes to a Registered Medical Device」指引文件。 2. 與 WG1、WG2、WG3 共同修訂 Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)中。 3. White paper on Pre-market initial Submission format for SaMD、Guidance document on Cyber Security for SaMD 及 White paper on SaMD change management – Requirements and Processes 文件採認工作進行中。
WG4	1. 持續更新 Post-market Resource Centre 之資訊。 2. 完成 GHWP 上市後指引採認會員間差異分析。 3. 持續調查各地區因應疫情之上市後支持政策。 4. 持續調查人工智慧醫療器材及網路安全上市後趨勢。
WG5	1. 完成全球法規臨床調查。 2. 與 WG2 合作進行 GHWP guidance document on Clinical Evaluation for IVD related to Covid 19 PCR testing devices。 3. 完成 IMDRF 及 GHWP 醫療器材臨床證據差異分析。
WG6	指引 A guidance to understanding best practices in audit life cycle management、A guidance to understanding presently available audit duration determination systems 及 A guidance for auditing supplier to medical devices manufacturers 處於收集意

	見狀態。
WG7	1. 製造業與輸入業品質管理系統需求指引徵求公開意見中。 2. 發展基於風險方法之品質管理系統指引。
WG8	1. 提出「Medical Gas System – Essential Principles of Safety and Performance – Standards for Demonstrating Compliance」指引文件。 2. 發展醫療器材良好工程維護管理規範文件並經 ISO TC 210 委員會同意為技術規格。
WG9	1. GHWP UDI RULE 大會採認相關工作。 2. 持續觀察 WHO 和 GMDN 的醫療器材命名工作變化，持續參與醫材命名協調工作。 3. 將規劃了解會員醫療器材命名現狀，未來逐步建立諧和的醫療器材命名系統，達成快速識別和準確追溯的目的。

2 月 16 日為 GHWP 年會(Annual Meeting)，會上先通過第 25 屆 GHWP 年會會議紀錄，本屆大會主席 Mr. Ali M. AL-DALAA 及大會技術委員會主席 Mrs. Salbiah Yaakop 說明 GHWP 現況及各工作小組進度，另由各國介紹其醫療器材管理相關法規更新，摘要如下：

(一)、 澳洲

澳洲 Therapeutic Goods Administration 說明其國內有 90% 以上的醫療器材許可是基於歐盟認證，歐盟推動之 MDR 將對該國造成衝擊，因此澳洲政府發展以醫療器材業者參與下之基於風險流程的溝通策略，並向醫院部門和臨床醫生傳達相關的醫療器材變更，另澳洲擔任 2022 年 IMDRF 的主席與秘書處，並積極參與 IMDRF 不良事件、人工智慧醫療器材、優良法規審查、網絡安全、客製化醫療器材、監管產品上市前申請、醫療器材軟體等工作小組。

(二)、 歐盟

歐盟修正 Regulation (EU) 2017/745 on medical devices (MDR)及 Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)，目的是為了確保病患取得安全有效醫療器材、避免業者在醫材供應鏈中採用不必要地處置手段及讓 Notify Body 有足夠時間完成 MDR 符合性評估，因此將延長過渡期時間，對於 III 級醫療器材及 IIb 級醫療器材延到 2027 年底(扣除部分已有良好發展技術之品項)，對於所有 IIa 級醫療器材、I 級無菌、測量或可重複使用的手術儀器、已有良好發展技術之 IIb 級植入式醫材、IIb 級非植入式醫材延到 2028 年底，但延長過渡期必須符合下列條件：持續符合歐盟相關醫材法規、醫材無重大變更、對健康或安全無不可接受之風險、在 2024 年 5 月前完成 MDR 的品質管理系統、在 2024 年 5 月前正式申請符合性評估等條件。

(三)、 日本

1. 修訂 Pharmaceuticals and Medical Devices Act (PMD Act)，來達成緊急上市許可之目標(Marketing Approval in Emergencies 2022)，對於此類緊急上市許可的醫療器材，將原本要求經確認之效能報告，更改成接受預測之效能報告，來達成醫材提早上市解決如疫情帶來之緊急需求。
2. 對於國內採用尖端技術研發醫療器材軟體的業者，提供統一的諮詢服務，並協助建立該國醫療器材的審核制度知識，另對醫療器材軟體上市後變更建立 Post Approval Change Management Protocol (PACMP)機制，對於人工智慧醫材的效能變更，提供更具彈性的方式來縮短原本變更審查上市時間。

(四)、 沙烏地阿拉伯

1. Saudi Food & Drug Authority (SFDA)對於創新醫療器材(Innovative Medical Device)獲得上市許可在不影響其安全性和有效性的方式下可以免除部分上市前要求；另符合下列條件者可稱為創新醫療器材：如以創新科技設計功能之醫療器材並在市場上沒有類似品；或提供足夠的臨床/醫療優勢替代現行治療方案者；或由 SFDA 訂定的其他條件。
2. 沙烏地阿拉伯鼓勵醫療器材投資者及製造業者轉移至沙烏地阿拉伯生產醫療器材，另 SFDA 成立了一國家委員會以確保該國醫學診斷影像品質水準。

(五)、 中國

中國國家藥品監督管理局將持續完善法規標準體系，提升與國際標準一致性比率；優化審批制度，加速創新醫材上市時效；強化全生命週期管理；改善管理能力，如設立 1 間國家級評估中心，2 間國家級評估次中心；執行國際法規合作如採納 IMDRF 或 GHWP 之指引文件。

(六)、 韓國

1. 韓國 Ministry of Food and Drug Safety 自 2021 年起新建立下列部門來對應相關醫材議題，如 Innovative and Diagnostic Medical Devices Policy Division (Feb 2021)以及 Digital Health Devices Division (Feb 2022)，並建立與 Digital Health Devices 相關之指引計 24 份、IVDD 相關指引 10 份。
2. 韓國於 2023 年執行以政府為起始之體外診斷試劑效能評估中心之工作；另品質管理系統部分，韓國規劃加入醫療器材單一稽核計畫(Medical Device Single Audit Program, MDSAP)成員。

(七)、 美國

1. 為確保病患能夠及時獲得安全、有效、高品質的醫療器材，並且對於創新式的醫材，有一條清晰、可預測的上市前路徑，醫療器材業界使用者費用修正法案(Medical Device User Fee Amendments, MDUFA)每 5 年調整一次，本次調整後適用年份為 2023-2027。
2. 美國 FDA 對於國際調和有下列作法：通過與國際主管機關和其他主要利益相關者一起參與論壇、工作組、專案和委員會，擴大對國際調和工作的參與；通過機制與其他主管機關合作，達成法規協和；評估 IMDRF 指引的應用程

度；透過創建論壇，讓相關利益方參與，尋找最佳的決策方式；參與其他主管機關的活動來達成調和。

GHWP 年會之報告，除各國醫療器材相關法規更新外，尚有國際醫療器材法規管理論壇(The International Medical Device Regulators Forum, IMDRF)、東南亞國家協會(Association of Southeast Asian Nations, ASEAN)、亞太醫療科技協會(Asia Pacific Medical Technology Association, APACMed)、全球診斷成像醫療保健(ICT)和放射治療貿易協會(The Global Diagnostic Imaging, Healthcare ICT, and Radiation Therapy Trade Association, DITTA)、全球標準壹(Global Standard 1, GS1)、全球醫療器材命名機構(Global Medical Devices Nomenclature Agency, GMDN)、全球醫療科技聯盟(Global Medical Technology Alliance, GMTA)及美洲醫療技術法規融合聯盟(Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector, IACRC)等重要國際組織，進行各組織之醫療器材相關標準更新說明，重點如下：

(一)、 國際醫療器材法規管理論壇(IMDRF)：

IMDRF 主席 Dr. Andrzej Rys 說明 IMDRF 狀態重要更新，該組織有新的會員資格 Affiliate Members(附屬會員)，主管機關非正式觀察員但採用 IMDRF 文件作為其法規管理基礎者可申請參加，通過後可參加 IMDRF open meeting、open working group 及在 open consultation 提供意見，IMDRF 目前有 8 個工作小組，優先重點在發展人工智慧醫材、優良法規施行(Good Regulatory Practice)、網路安全等指引文件。

(二)、 東南亞國家協會(ASEAN)：

依據 ASEAN Medical Device Committee (AMDC) Action Plans 2016-2025，加強標準調和以達市場一致性，在第 11 屆 AMDC 會議，295 個風險分類及 194 個產品已調和一致。

(三)、 亞太醫療科技協會(APACMed)：

亞太醫療科技協會 2023 發展重點在推動法規教育訓練及數位健康領域醫療器材適合的調和架構。

(四)、 全球診斷成像醫療保健(ICT)和放射治療貿易協會(DITTA)：

DITTA 優先目標為積極參與 IMDRF 網路安全工作小組，發展如 “Cybersecurity for Legacy MD”及“SBOM”等相關指引文件，並採納 IMDRF/AIMD WG /N67:2022 “Machine Learning enabled Medical Devices: Key Terms and Definitions ”文件，作為人工智慧醫療器材之參考。

(五)、 全球標準壹(GS1)：

為了病患安全與醫療器材的可追溯性，強調積極與 IMDRF 及各國主管機關調和 Unique Device Identification guidance 之重要性。

(六)、 全球醫療器材命名機構(GMDN)：

持續依循品質管理系統發展醫療器材命名系統，並引入新分析工具讓健康照護提供者持續免費登入使用。

(七)、 全球醫療科技聯盟(GMTA)：

全球醫療科技聯盟的目標是支持安全、有效和創新的醫療技術，強調與IMDRF 等關鍵組織合作，實現加速新醫療技術的法規融合。

(八)、 美洲醫療技術法規融合聯盟(IACRC)：

目前有 18 個會員，重點在依循優良法規施行(Good Regulatory Practice)辦理相關教育訓練，如 ISO 13485、MDSAP、UDI 等，參加人數超過 8,000 人次，成效卓著。

另外，於本次年會上，大會宣布以下重要事項：

(一)、 第 27 屆之 GHWP 年會，預訂在中國上海辦理，詳細日期將另外宣布。

(二)、 本次 GHWP 年會通過以下決議：

1. 通過日本(Japan)成為會員。
2. 通過採認 WG1、WG2、WG3 共同提出的「Categorisation of Changes to a Registered Medical Device」指引文件。
3. 通過採認 WG8 提出的「Medical Gas System – Essential Principles of Safety and Performance – Standards for Demonstrating Compliance」指引文件。
4. 本次大會適逢 2023-2025 之大會主席、技術委員會主席及各工作小組主席選舉，我國推派蔡文偉科長及簡俊仁技正分別爭取 WG2 主席之連任與 WG3 主席之新任，皆順利成功當選，為我國爭取國際能見度，本次選舉當選名單詳如附件 3。

參、心得與建議

一、建議食藥署持續積極參與 GHWP 相關事務

GHWP 組織日益壯大，近年更新增會員國美國與日本，GHWP 已成全球重要之醫療器材法規調和國際組織之一。GHWP 年會系列會議為醫療器材法規交流之年度盛會，除 GHWP 會員多國官方代表與業界專家出席與會外，亦有其他國際組織擔任大會專題講者及顧問，分享與研討醫療器材管理之最新國際趨勢。參加 GHWP 年會系列會議及相關事務，可持續蒐集醫療器材管理最新資訊，做為研訂我國管理方向之重要參考，故建議應持續參與 GHWP 之相關事務。

二、鼓勵國內醫療器材產業參與 GHWP 活動

GHWP 年會系列會議為國際官方及業界交流醫療器材管理之重要平台，GHWP 所制訂之國際指引與規範，亦作為各國醫療器材管理之參考，建議應鼓勵國內廠商多參與此類組織活動，及早瞭解其所研討或訂定之指引規範，並建立國際人脈，瞭解各組織、國家醫材法規最新動態，有利產品國際布局推向國際市場。

三、建議持續透過 GHWP 組織平台，鏈結重要國際組織

可藉由 GHWP 年會系列會議，對參與該活動之重要國家官方代表或相關國際組織重點人物(如：IMDRF 等)，建立關係及瞭解與醫療器材相關之重要國際工作與活動，提升我國在國際上的能見度。

附件 1

Program

The 26th GHWP Annual Meeting Program

Day 3 Agenda: 15 February 2023 (Wednesday)

Venue: Crowne Plaza Riyadh RDC Hotel & Convention, Riyach, Saudi Arabia

26th GHWP Technical Committee (GHWP TC) Meeting

Time (KSA GMT+3)	(AHWP/GHWP TC Leaders Meeting)	Responsible Person(s)
09:00 - 10:45	GHWP TC & WG Leaders Meeting with TC Advisors (1hr45mins) (Closed-Door Meeting)	Mr. Ali M. Al-Dalaan (proposed) GHWP Chair Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia Mr. Guobiao Gao (proposed) GHWP Vice-Chair Secretary of Leading Party Group, Center for Medical Device Evaluation, NMPA, People's Republic of China Ms. Quan Tran (proposed) GHWP Vice-Chair Vice President, QARA, APAC, Baxter, Singapore Mrs. Salbiah Yaakop GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Ministry of Health, Malaysia Dr Jeong-Rim LEE GHWP TC Co-Chair Ministry of Food and Drug Safety , Republic of Korea Er. Alfred KWEK GHWP TC Co-Chair Director, Public Affairs, Edwards Lifesciences Asia Pte. Ltd. Supported by Ms. Miang TANAKASEMSUB GHWP TC Secretary Head of Regulatory Affairs, Asia Pacific, Johnson & Johnson Vision Ms. Carol Jirui YAN GHWP TC Secretary Senior Consultant, Founder of Yrsagacity Limited, People's Republic of China
10:45 - 11:15	**TEA BREAK**	
11:15 - 11:20	Welcome Speech (5mins)	Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia
11:20 - 11:35	Opening of TC Meeting (15mins) -Roll call -Adoption of Agenda -Adoption of 25th GHWP TC Meeting Minutes	Mrs. Salbiah Yaakop (Chair) Director of Policy, International Affairs & Industry Facilitation Division Medical Device Authority, Ministry of Health - Malaysia

		Dr. Jeong-Rim LEE (Co-Chair) Director, Cardiovascular Devices Division Ministry of Food and Drug Safety (MFDS) - Republic of Korea Mr. Alfred KWEK (Co-Chair) Director, Public Affairs Edwards Lifesciences Asia Pte. Ltd. - Lao PDR Supported by TC Secretary Ms. Miang TANAKASEMSUB Head of Regulatory Affairs, Asia Pacific, Johnson & Johnson Vision Mr. Jack WONG Associate Vice President Regulatory Affairs, Asia Pacific, Middle East & Africa, Allergan - Hong Kong SAR, China Ms. Carol YAN Senior Consultant, Founder of Yrsagacity Limited, People's Republic of China Dr. Adelheid Schneider Head of Quality and Regulatory Affairs Asia Pacific Roche Diagnostics Asia Pacific, Singapore
11:35 – 12:45 5mins + 5mins Q&A each)	Working Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: IVDD Work Group 3 (WG3) - Pre-market: Software as a Medical Device Work Group 4 (WG4) - Post-Market Work Group 5 (WG5) - Clinical Evidence for Performance and Safety Work Group 6 (WG6) - Quality Management System: Audit & Assessment Work Group 7 (WG7) - Quality Management System: Operation & Implementation	Work Group 1 (WG1) Chair - Dr. Seil Park, Ministry of Food and Drug Safety, Republic of Korea Co-Chair - Ms. Mandy Myoung Shim Kim, Johnson & Johnson Medical, Republic of Korea Work Group 2 (WG2) Chair - Mr. Wen-wei TSAI, Food and Drug Administration, Chinese Taipei Co-chair - Ir. Prof. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong SAR, China Work Group 3 (WG3) Chair - Mr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong SAR, China Work Group 4 (WG4) Chair - Mr. Yorkie Chow, Department of Health, Hong Kong SAR, China Co-chair - Ms. Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair -Mr. Fikriansyah Bin Imran, Ministry of Health, Republic of Indonesia Co-chair - Ms. Sumati Randeo, Danaher Corporation, India Work Group 6 (WG6) Chair - Mr. Abdullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Vincent Chee-Choong Lam, TUV SUD Product Service, Malaysia Work Group 7 (WG7) Chair - Mrs. CHEN Yan, National Medical Products Administration, China Co-chair - Mr. Ee Bin Liew, Access-2-Healthcare, Singapore
12:45 - 14:00	**LUNCH / PRAYER TIME**	
	26th GHWP Technical Committee (GHWP TC) Meeting	

14:00 - 14:20	Working Group Updates and Next Steps (Cont'): Work Group 8 (WG8) - Standards Work Group 9 (WG9) - UDI & Nomenclature	Work Group 8 (WG8) Chair - Mrs. Salbiah Yaakop, Ministry of Health, Malaysia Co-chair - Mr. Tony Low, Commissioning Agents International, Malaysia Work Group 9 (WG9) Chair - Ms. Jun Li, National Medical Products Administration, China Co-chair - Ms. Victoria Qu, Global Strategic Regulatory Abbott, China
14:20 - 14:30	TC Advisors Summary Report	Representatives of TC Advisory Panel
14:30 - 14:35	Closing Remarks for Day 3	Mr. Alfred KWEK (GHWPTC Co-Chair) Director, Public Affairs Edwards Lifesciences Asia Pte. Ltd. - Lao PDR
14:35	Adjourn	
END OF DAY 3		
14:35 - 15:15	**TEA BREAK**	
15:15-16:45	GHWP Leadership and IMDRF Management Committee Meeting (CLOSED-DOOR) [TBC]	
GALA DINNER (Dinner starts at 19:00)		

Program

The 26th GHWP Annual Meeting Program

Day 4 Agenda: 16 February 2023 (Thursday)

Venue: Crowne Plaza Riyadh RDC Hotel & Convention, Riyadh, Saudi Arabia

Time (KSA GMT+3)	(AHWP/GHWP TC Leaders Meeting)	Responsible Person(s)
08:55 - 09:00	Announcement by MC (SFDA) (5mins)	Master of Ceremony (MC) by Saudi FDA Announcement
09:00 - 09:30	Opening Ceremony (30mins) - Welcome Address (7mins) - Opening address (7mins) - Group Photo (16mins)	Welcome Address- Dr. Hisham bin Saad Aljadhey Chief Executive Officer, Saudi Food and Drug Authority Kingdom of Saudi Arabia Opening Address- Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia
09:30 - 09:40	Main Meeting - Roll Call (8mins) - Adoption of Agenda (1min) - Adoption of 25th GHWP Annual Meeting Minutes (1min)	Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China
09:40 - 10:10	GHWP Status Reports - GHWP Overall Status Report (10mins + 5mins Q&A) - GHWPTC Status Report (10mins + 5mins Q&A)	Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Mrs. Salbiah Yaakop GHWPTC Chair Director of Policy, International Affairs & Industry Facilitation Division Medical Device Authority, Ministry of Health , Malaysia
10:10 -10:40	**TEA BREAK**	
10:40 - 10:55	IMDRF Status Updates (10mins+5mins)	Dr. Andrzej Rys IMDRF Chair 2023 Principal Scientific Adviser Directorate-General for Health and Food Safety (DG SANTE) European Commission
10:55 - 11:25	International Organizations & Harmonization Efforts (10mins+5mins Q&A each) a) APEC Harmonization Center (AHC) b) ASEAN	a) Dr. Jeewon Joung Ph.D., Director, Pre-submission Consultation Team, Ministry of Food & Drug Safety(MFDS), Republic of Korea, APEC Harmonization Center (AHC) b) Mrs. Salbiah Yaakop, Director of Policy, International Affairs & Industry Facilitation Division, MDA, Ministry of Health , Malaysia. ASEAN

11:25 - 12:25	GHWP Liaison Member Updates (5mins + 5mins Q&A each) a) Asia Pacific Medical Technology Association (APACMed) b) Global Diagnostic Imaging, Healthcare IT& Radiation Therapy Trade Association (DITTA) c) GS1 d) Global Medical Devices Nomenclature Agency (GMDN Agency) e) Global Medical Technology Alliance (GMTA) f) Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)	a) Mr. Anirudh Sen, Director, Regulatory Affairs, Asia Pacific Medical Technology Association (APACMed) b) Mr. Yuji Yanagida, GRP WG Vice chair, DITTA c) Ms. Géraldine Lissalde-Bonnet, Vice-President Healthcare, GS1 Global Office, GS1 d) Mrs. Deniz Bruce, Chief Executive Officer, Global Medical Devices Nomenclature Agency (GMDN Agency) e) Ms. Diana Kanecka, Strategies, Special Projects & International Affairs, Senior Manager International Affairs, Global Medical Technology Alliance (GMTA) f) Ms. Sandra Ligia Gonzalez, Executive Secretary, Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)
12:25 - 12:45	Country/Region Updates (5mins+5mins Q&A each) a) Australia [Online] b) European Commission	a) Ms. Tracey Duffy, First Assistant Secretary, Medical Devices & Product Quality, Therapeutic Goods Administration (TGA), Australia [Online] b) Ms. Nada Alkhayat, Policy Officer, Directorate-General for Health and Food Safety (DG SANTE) European Commission
12:45 - 14:00	**LUNCH / PRAYER TIME**	
14:00 - 15:00	Country/Region Updates (Cont') (5mins+5mins Q&A each) c) Japan d) Kingdom of Saudi Arabia e) People's Republic of China f) Republic of Korea g) Thailand h) United States of America	c) Ms. TOGASHI Mika, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan d) Eng. Abdullah AlGuraibi, Saudi Food and Drug Authority (SFDA), Kingdom of Saudi Arabia e) Dr. Xu Jinghe, Deputy Comissioner, National Medical Products Administration (NMPA), People's Republic of China f) Dr. Jeong-Rim LEE, (GHWPTC Co-Chair), Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety (MFDS), Republic of Korea g) Mr. Varavoot Sermsinsiri, Director, Medical Device Control Division, Food and Drug Administration, Thailand h) Ms. Melissa Torres, Associate Director for International Affairs, The United States Food and Drug Administration (US FDA), United States of America
15:00 - 15:30	**TEA BREAK**	
15:30 - 15:45	Resolution and Endorsement (15mins) 1. Resolutions - Amendment 8 to the Global Harmonization Working Party House Rules on GHWP Strategic Advisory Board (SAB) 2. Endorsement of Strategic Framework - Global Harmonization Working Party Strategic Framework towards 2026 3. Endorsement of White Paper - Medical Device Regulatory Authorities Training Curriculum White Paper 4. Endorsement of Guidance Documents from Working Gr oups (WG) -WG1, WG2&WG3 - Categorisation of Changes to a Registered Medical Device - WG8 - Medical Gas System – Essential Principles of Safety and Performance – Standards for Demonstrating Compliance 5. Endorsement of New Member - Japan	Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China

15:45 - 15:50	Short Speech by New Member (5mins)	Mr TAKAHATA Masahiro Director, Office of Regnerative Medicines Products Evaluation Ministry of Health, Labour and Welfare (MHLW) Japan
15:50 - 16:45	Election and Endorsement of GHWP Office Bearers (55mins) [including 1minute self-introduction by each candidate before election and endorsement (25mins)] - Briefing on Election and Endorsement Procedures - Election of GHWP Chair and Vice Chairs - Election of GHWPTC Chair and Co-Chairs - Election of Working Groups Chairs and Co-Chairs	Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China
16:45 - 16:55	Speech by GHWP Chair-Elect (10mins - including any translation)	GHWP Chair-Elect
16:55 - 17:15	Presentation of Certificates and Recognition Award on Stage (20mins)	Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia and GHWP Chair-Elect
17:15 - 17:20	Announcement of next GHWP Annual Meeting Host & Short Speech (5mins)	Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia and 27th GHWP Annual Meeting Host
17:20 - 17:25	Closing Remarks (5mins)	Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia
17:25	Adjourn	
END OF DAY 4		
18:00 - 18:30	GHWP ASL Annual General Meeting [For ASL Members only] (at another meeting room)	

GHWP 26th Annual Meeting
Feb 15th, 2023

WG2 – Pre-market: IVDD

Chair: Dr. Wen-Wei TSAI
Co-Chair: Ir Prof. Albert KF POON
Advisor: Ms. Shelley TANG

WG2 Membership Updates

50 members from **20** economies

- Incl. 1 advisor and 2 observers
- 3 new members:
  1. Mr. Shang-Ching LIN (Regulatory Authority, Chinese Taipei)
  2. Ms. Ning Zhen Justina Lee (Industry, Singapore)
  3. Ms. Yon Ju Kang (Industry, Republic of Korea)

WG2 Project Activities in 2022

Date	Activity
Feb. 15	WG2 1st Teleconference
Jun. 17	WG2-5 Initial Meeting for "Guidance document on Clinical Evaluation for IVD related to COVID 19 PCR testing devices"
Jul. 21	WG1-2-3 Initial Meeting for "Revisit a GHWP Document (Categorisation of Changes to a Registered Medical Device, AHWP/WG2-WG1-WG3/F001:2019)"
Aug. 24	WG1-2-3 Joint Work Group meeting (Taipei FTF + WebEx)
Oct. 18	WG1-2-3 Joint meeting for WG1 Work Item 2: eIFU document revisit
Oct. 19	WG2 meeting: 19th October (Taipei FTF + WebEx)

- Project Core member discussion: Jul. 4 & 19, Aug. 23, Dec. 6


WG1-2-3 Joint Work Group meeting (Aug. 24)


WG2 meeting (Oct. 19)

WG2 Progress in 2022

Work Item	Deliverables	Timeline	Progress Update
Development of GHWP Guidance Document	Categorisation of Changes to a Registered Medical Device (collaboration with WG1 & WG3)	Jan. 2022 – Jan. 2023	Under the document endorsement procedure
	Survey on Good Reliance Practice across GHWP members	May 2022 – 2023	Drafting in progress Designing the questionnaire, including the definition of reliance
	Regulatory Requirements for Electronic Instructions for Use (eIFU) (collaboration with WG1 & WG3)	2022 – 2023	Drafting in progress

WG2 Proposed Work Plan in 2023

- **Meetings in 2023 (tentative schedule)**
  - WG2 kick-off meeting (online): late February
  - WG2 FTF meeting: July
  - WG2 online meeting: October
- **Work Items**

Work Item	Deliverables	Timeline	Progress Updates
1 Confirmation of WG membership	WG2 member list	– Jun. 2023	Contact members who have not participated in any WG2 activities for a certain period (e.g., 2 years) to confirm their memberships

WG2 Proposed Work Plan in 2023

Work Item	Deliverables	Timeline	Planned Progress
2 Development of GHWP Document (*Tentative*)	Good Reliance Practices for MD, IVD and SaMD across the life cycle • Survey on Good Reliance Practice across GHWP members • Guidance document for Good Reliance Practices	2022 – (*Tentative*)	Drafting in progress (NWIP of the survey approved on 24th May 2022)
	Review and update GHWP/WG1-WG2-WG3/F002:2019-Regulatory Requirements for Electronic Instructions for Use (eIFU) (cooperate with WG1 & WG3)	2022 – 2023	Drafting in progress (NWIP approved on 29th August 2022)
	Review and update Merge GHWP/WG2-WG1-WG3/F001:2019- Categorisation of Changes to a Registered Medical Device and GHWP/WG1/F001:2020 Guidance for Minor Change Reporting (cooperate with WG1 & WG3)	2023	Will be determined by late February
	Review and update GHWP/WG2/F001:2017 - Guidance for Additional Considerations to support Conformity Assessment of Companion In vitro Diagnostic Medical Devices	TBD	

WG2 Further Work Plan

Work Item	Deliverables	Timeline
Development of GHWP Document (*Tentative*)	Grouping of IVD for Product Registration	2024 – 2025 (*Tentative*)
	Review and update GHWP/WG2/F001:2016 - Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	2025 (*Tentative*)
	Regulatory Practices on "RUO" Labelled Products and Laboratory Developed Products / Requirements and specifications for in-house developed and produced in vitro diagnostic medical devices	TBD
	Review and update GHWP/WG2/F001:2014 - Comparison between CSDT and STED IVDDs	TBD
	Conformity Assessment of AI-based Digital Pathology Software	TBD

WG2 Achievements (since 2018) (1/3)

Work Item	Deliverables	Endorsed in
1 Development of GHWP Guidance Document	Labelling for In Vitro Diagnostic Medical Devices	2018
	Categorisation of Changes to a Registered Medical Device (collaboration with WG1 & WG3)	2019
	Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU) (collaboration with WG1 & WG3)	2019
	Clinical Evidence for IVD Medical Devices - Clinical Performance Studies for In Vitro Diagnostic Medical Devices (collaboration with WG5)	2021
	Replacement Reagent and Instrument Family Policy	2021
	Regulatory Mechanism for Medical Devices Including In Vitro Diagnostic Medical Devices and Software as Medical Devices During A Public Health Emergency (collaboration with WG1 & WG3)	2021

WG2 Achievements (since 2018) (2/3)

Work Item	Contribution to	Period	Achievements
2 Participation in International / Global Organization collaboration and activities	International IVD Standards	2018 – 2022	WG2 has joined ISO/TC 212 as liaison member to participate in standard discussion and contribution from regulators and industry's point of view.
	IMDRF, in IVD Guidance	2019 – 2022	➢ Participated in IMDRF Working Group on "Principles of IVD medical devices Classification" ■ IMDRF/IVD WG/N64FINAL:2021 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification ➢ Participating in IMDRF New Working Group on "Clinical evidence for IVD medical devices"

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WG2 Achievements (since 2018) (3/3)

Work Item	Contribution to	Period	Achievements
2 Participation in International/ Global Organization collaboration and activities	WHO Technical Specification Documents	2018 –	➢ Continuous contact with WHO IVD PQ team to maintain technical communication ➢ Collect and consolidate comments from WG2 members on the WHO documents, including: ■ TSS-6: Syphilis Rapid diagnostic tests ■ TSS-7: Rapid diagnostic tests to detect hepatitis C antibody or antigen ■ TSS-8: Immunoassays to detect hepatitis C antibody and/or antigen ■ TSS-10: In vitro diagnostic (IVDs) medical devices used for the qualitative and quantitative detection of Hepatitis C ribonucleic acid ■ TSS-11: In vitro diagnostic (IVDs) medical devices used for the quantitative detection of HIV-1 nucleic acid ■ TSS-12: In vitro diagnostic (IVDs) medical devices used for the qualitative detection of HIV-1 and HIV-2 nucleic acid ■ SS-13: Rapid diagnostic tests to detect hepatitis B surface antigen ■ TSS-14: Immunoassays to detect hepatitis B virus surface antigen ■ TSS-15: In vitro diagnostics (IVDs) medical devices used for the quantitative detection of Hepatitis B nucleic acid ■ TSS-17: In vitro diagnostic (IVD) medical devices used for the qualitative detection of Mycobacterium tuberculosis complex (MTBC) and mutations associated with drug-resistant tuberculosis (DR-TB) ■ **TSS-18: Haemoglobin A1c point of care analysers for professional use (DRAFT)**

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Thank you for your attention

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附件 3

GHWP Office Bearers, TC Office Bearers and WGs Chairs and Co-Chairs 2023-2025

GHWP Office Bearers	Position	Name	Post Title	Member Country/ Region
	Chair	Dr. Xu Jinghe	Deputy Commissioner National Medical Products Administration (NMPA)	People's Republic of China
	Vice Chair (Regulator)	Mr. Lupi Trilaksono	Team Lead Medical Device Local Content & Production Improvement Ministry of Health	Indonesia
	Vice Chair (Industry)	Ms. EunHee Cho	RA Director Abbott Medical Korea	Republic of Korea

GHWP TC Office Bearers	Position	Name	Post Title	Member Country/ Region
	Chair	Mr. Abdullatif S. AlWatban	Executive Director Medical Devices Evaluation Saudi Food & Drug Authority (SFDA)	Kingdom of Saudi Arabia
	Co-Chair (Regulator)	Ms. Li Jun	Deputy Director General Department of Medical Device Regulation National Medical Products Administration (NMPA)	People's Republic of China
	Co-Chair (Industry)	Ms. Miang Tanakasemsub	Head of Regulatory Affairs (RA) Asia Pacific (AP) Johnson & Johnson Vision	Thailand

WG	Position	Name	Post Title	Member Country/ Region
WG1 Pre-Market Submission and CSDT	Chair	Dr. Seil Park	Assistant Director Ministry of Food and Drug Safety	Republic of Korea
	Co-Chair	Ms. Mandy Myoung Shim Kim	Head of Regulatroy Affairs MedTech Korea Johnson & Johnson MedTech Korea	Republic of Korea
WG2 Pre-market: IVDD	Chair	Dr. Wen-Wei Tsai	Section Chief Food and Drug Administration Ministry of Health and Welfare	Chinese Taipei
	Co-Chair	Dr. Adelheid Schneider	Regional Head of Quality and Regulatory Affairs Roche Diagnostics Asia Pacific	Singapore
WG3 Pre-market: Software as a Medical Device	Chair	Mr. Chun-Jen Chien	Technical Specialist Food and Drug Administration Ministry of Health and Welfare	Chinese Taipei
	Co-Chair	Mr. Tony Yip	Associate Director Regulatory Affairs Asia Pacific Grifols (HK) Limited	Hong Kong SAR

WG4 Post-market	Chair	Dr. Ambrose Chi Hong Wong	Senior Medical Officer (Medical Device) Department of Health	Hong Kong SAR
	Co-Chair	Ms. Kitty Mao Yiqing	RA Director GE HeakthCare	Singapore
WG5 Clinical Performance & Safety	Chair	Mr. Fikriansyah Bin Irman	Medical Device Reviewer Ministry of Health	Indonesia
	Co-Chair	Ms. Ong Yean Ting	Head Quality and Regulatory Roche Diagnostics Malaysia Sdn Bhd	Malaysia
WG6 Quality Management System: Audit & Assessment (To be combined with WG7)	Chair			
	Co-Chair			
WG7 Quality Management System: Operation & Implementation	Chair	Ms. Yan Chen	Director Division of Inspection Five Center for Food and Drug Inspection (CFDI) of NMPA	People's Republic of China
	Co-Chair	Mr. Liew Ee Bin	Group Executive Director Access-2-Healthare	Singapore
WG8 Standards	Chair	Mrs. Salbiah Yaakop	Director of Policy, International Affairs & Industry Facilitation Division Medical Device Authority Ministry of Health	Malaysia
	Co-Chair	Mr. Tony Low	Director of Human Performance and Medical QA/RA Commissioning Agents International (CAI)	Malaysia
WG9 UDI + Nomenclature	Chair	Ms. Zhou Wenwen	Deputy Director Medical Device Registration Department National Medical Products Administration (NMPA)	People's Republic of China
	Co-Chair	Ms. Lilo (Meng) Li	Associate Regulatory Affairs Director Becton Dickinson and Company	People's Republic of China