行政院及所屬各機關出國報告

（出國類別：開會）

出席 APEC 法規協和指導委員會(RHSC)會議出國報告

服務機關：衛生福利部食品藥物管理署

姓名職稱：洪國登科長

派赴國家：美國

出國期間：112 年 11 月 30 日至 112 年 12 月 7 日

報告日期：112 年 12 月 18 日

摘要

衛生福利部食品藥物管理署為 RHSC 創始會員，長期參與 RHSC，為優良查驗登記管理 GRM PWA 之主導經濟體，亦為 GRM 法規科學訓練卓越中心，負責辦理法規人才培訓相關訓練課程。

RHSC 於 112 年 12 月在美國奧克蘭召開會議，衛生福利部食品藥物管理署於會議中報告本年度 GRM PWA、GRM CoE 之工作進度、成果及未來規劃，相關工作成果及報告內容獲得 RHSC 肯定。

另目前 APEC 對於 RHSC 之未來歸屬，已有初步共識，未來 RHSC 將改隸於標準及符合性次級委員會(SCSC)項下。

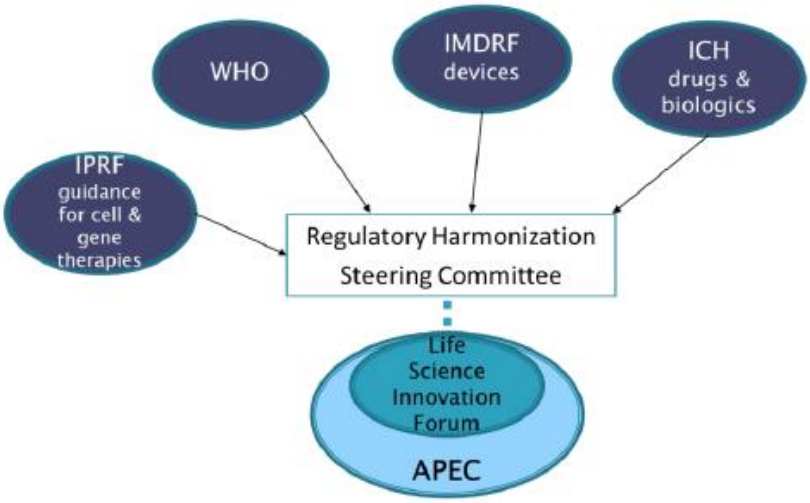
關鍵字：亞太經濟合作、法規協和指導委員會、優良查驗登記管理、法規科學訓練卓越中心、APEC、Regulatory Harmonization Steering Committee、RHSC、Good Registration Management、GRM、Center of Excellence、CoE

目錄

壹、目的

亞太經濟合作會議(Asia-Pacific Economic Cooperation, APEC)為亞太地區最重要的經貿合作論壇，目前共有 21 個會員經濟體，均在環太平洋地區。我國係以中華台北(Chinese Taipei)名義參與，除我國外，其他會員經濟體包含等美國、日本、中國大陸、加拿大、韓國、馬來西亞、澳大利亞、紐西蘭、智利、秘魯等。

基於法規協和(Regulatory Convergence)之重要性，APEC 於 2009 年 6 月成立法規協和指導委員會(Regulatory Harmonization Steering Committee, RHSC)，RHSC 致力於促進 APEC 經濟體間關於醫療產品(Medical product)的合作交流及法規協和。另 RHSC 原隸屬於生命科學創新論壇(Life Science Innovation Forum, LSIF)項下，惟 LSIF 已於 2021 年屆滿落日，而有鑒於 RHSC 之重要性，多數 APEC 經濟體成員雖支持其繼續運作，然至今仍未能決定其最終歸屬。



衛生福利部食品藥物管理署(以下簡稱食藥署)為RHSC創始會員，長期參與RHSC，自2011年起負責指導優良審查規範 (Good review practices, GRevPs)，並自2014年起與日本合作推動優良送審規範(Good Submission Practice, GSubP)。RHSC於2016年起，將前述二者合併為優良查驗登記管理 (Good Registration Management, GRM)」，並由食藥署、日本厚生勞働省(Ministry of Health, Labour and Welfare, MHLW)及獨立行政法人醫藥品醫療機器綜合機構(Pharmaceuticals and Medical Devices Agency, PMDA)為GRM優先工作領域(Priority Working Area, PWA)之共同主導經濟體(Co-Champion)。

另食藥署亦為RHSC認可之GRM法規科學訓練卓越中心(Center of Excellence, CoE)，負責辦理法規人才培訓相關訓練課程。綜上，本次出席RHSC會議，主要目的如下：

一、了解 RHSC 未來歸屬最新進展及未來重要發展工作計畫。

二、於RHSC會議中報告本年度GRM PWA工作進度及未來規劃。

三、於RHSC會議中報告本年度GRM CoE工作成果及未來規劃。

貳、會議過程

行程紀要

日期	行程
11/30	桃園機場出發，抵達美國舊金山機場
12/1~12/4	參加 APEC 法規協和指導委員會(RHSC)會議
12/5~7	美國舊金山機場出發，抵達桃園機場

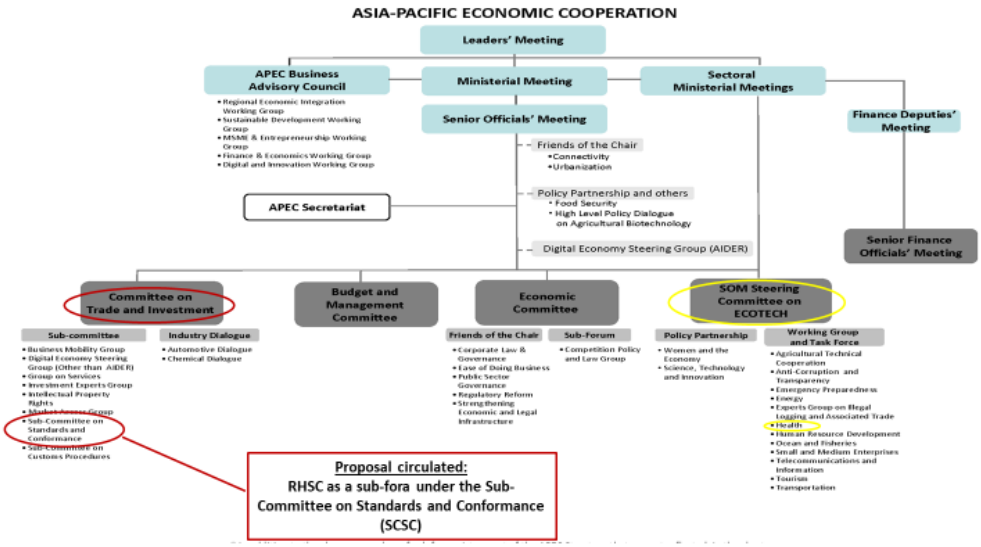
會議內容摘要

一、RHSC 顧問辦公室報告(RHSC Advisor’s Office Update)：

2023年8月於美國西雅圖召開之13th High-Level Meeting on Health and the Economy(HLM13)會議中，多數APEC經濟體認同RHSC在APEC法規協和工作中所扮演之角色具有重要價值，支持RHSC繼續運作，但其組織之最終歸屬未來仍需繼續討論以取得共識。

2023年11月於美國舊金山召開之APEC Ministerial Meeting會議中，多數APEC經濟體已有共識期望於2024年初批准RHSC之職權範圍(Terms of Reference, ToR)。另已提案將RHSC改隸至標準及符合性次級委員會(Sub-Committee on Standards and Conformance, SCSC)項下。

RHSC將儘速修訂ToR草案，並規劃於2024年第一次資深官員會議（Senior Officials' Meeting, SOM-1）會議前或會議期間，將最終版ToR草案送交SCSC審查。而在確定RHSC之最終歸屬前，RHSC則暫先向貿易暨投資委員會(Committee on Trade and Investmen, CTI)及衛生工作小組(Health Working Group, HWG)陳報其工作成果。



二、APEC 法規協和中心報告(APEC Harmonization Center Update)：

APEC Harmonization Center(AHC)於 2023 年已辦理 3 場研討會/訓練課程，主題分別為 ICH Q12: Post-Approval Change Management Protocols、Post-Pandemic Regulatory Environment Changes in Clinical Trials、Medical Device Regulatory Convergence，合計共約 412 名學員參加，且學員滿意度均約達 90 分。

另 AHC 持續針對 ICH 指引(Efficacy: E2A-F, E3, E6, E8, E9, E17、Safety: S2, S3, S7、Quality: Q1, Q3, Q8, Q9, Q10、Multidiscipline: M7)於其線上學習網站 e-Learning Center(http://edu.apec-ahc.org)辦理免費線上訓練課程，迄今已有分別來自 98 個經濟體共 3,891 學員參與。

倘 Pilot or Pre-CoE 規劃於 2024 年辦理研討會/訓練課

程者，得於 2023 年 12 月 29 日前向 AHC 申請資助，AHC 將於 2024 年 1 月開會討論審核其所接獲之資助申請案件。另已成為正式 CoE 者，不得向 AHC 申請資助。

三、RHSC 代表報告(RHSC Representatives' Reports)：

ICH/IPRP 會議已於 2023 年 10 月 31 日至 11 月 2 日在捷克布拉格召開，本次 ICH 會議同意香港藥劑業及毒藥管理局(Pharmacy & Poisons Board of Hong Kong, PPBHK)成為 ICH 觀察員，本次 IPRP 會議同意阿爾及利亞國家藥品管理局(Agence Nationale des Produit Pharmaceutique, ANPP), 約旦食品藥物管理局(Jordan Food and Drug Administration, JFDA)成為 IPRP 會員。

ICH 指引 Q5A(R2) Viral Safety Evaluation of

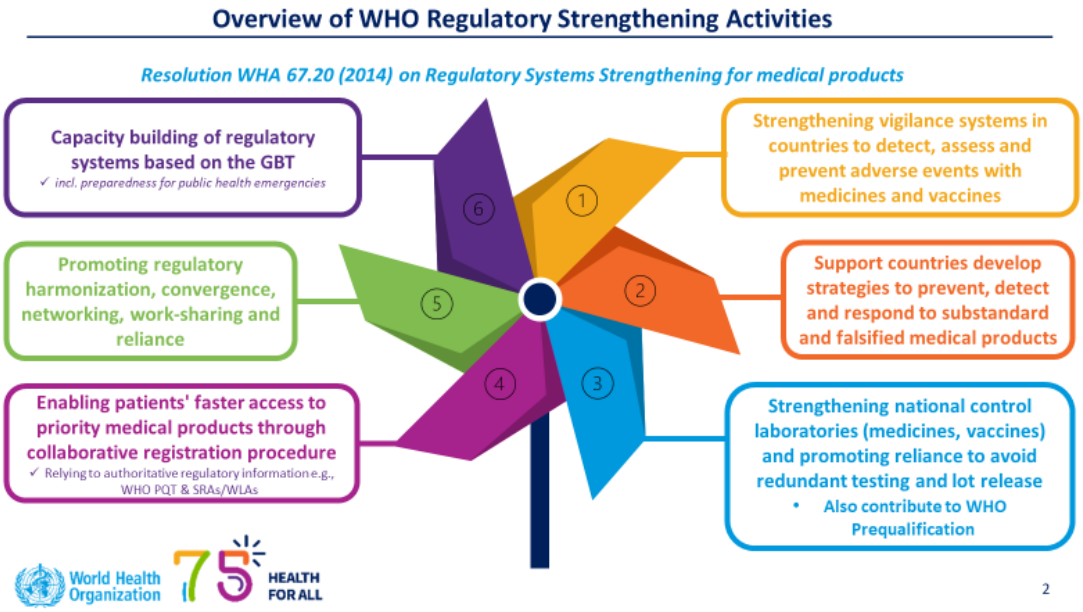
Biotechnology Product Derived from Cell lines of Human or Animal Origin、Q2(R2) Validation of Analytical Procedures / Q14 Analytical Procedure Development 已進入 Step 4 並獲得 ICH 大會採認。另下次 ICH/IPRP 會議訂於 2024 年 6 月 4 日至 6 日於日本福岡召開。

IMDRF 會議已於 2023 年 9 月 25 日至 29 日在德國柏林召開，本次 IMDRF 會議同意非洲醫療器材論壇(African Medical Devices Forum, AMDF)成為區域法規協和組織(Reginal Harmonization Initiative, RHI)，另同意蒙特內哥羅 Institute for medicines and medical devices of Montenegro(CInMED)、古巴 Centro para el Control Estatal de Medicamentos, Eqiposy Dispositivos Medicos(CECMED)、以色列 Medical Technology Health Information Innovation and Research Directorate(MTIIR)、智利 Public Health Institute of Chile(ISP)、埃及 Egyptian Drugs Authority(EDA)成為附屬會員(Affiliate Member)。

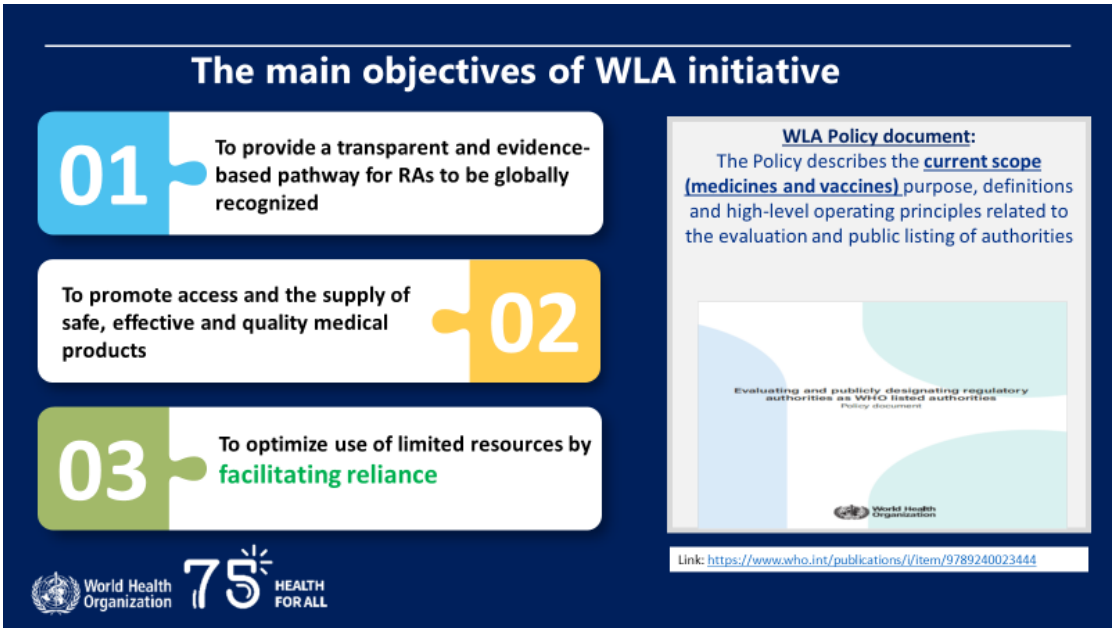
四、世界衛生組織報告(WHO Update)

WHO 為加強各國醫療產品監管體系，採行了強化各國藥品及疫苗不良事件警戒系統、支持發展處理偽劣藥品策略、強化

國家藥品及疫苗實驗室量能、透過 WHO PQT & SRAs/WLAs 等機制加速病人取得藥品、促進法規協和、運用 WHO 之 Global Benchmarking Tool(GBT)進行醫療產品監管體系能力建構等措施。



根據 GBT 就各項指標評估後，可將各國醫療產品監管體系依據其發展成熟度(maturity level)由低至高，分為 4 個級別 ML1~ML4，而迄今全球仍有 70%的國家處於 ML1 及 ML2 較為薄弱之階段。為了持續強化各國醫療產品監管體系，WHO 近期著重於推動 WHO Listed Authorities(WLA)，WLA 是促進監管信賴的獨特工具，其主要有三大目標：為各國主管機關獲全球認可提供透明且基於證據的途徑、促進安全有效的醫療產品取得與供應、透過促進依賴(facilitating reliance)優化有限資源之使用。



五、GRM PWA 及 CoE 報告 (Good Registration Management PWA - PWA Champion Update& CoE Update: TFDA)

GRM PWA 由食藥署與日本 MHLW/PMDA 共同主導，本次 GRM PWA 由食藥署代表進行報告(簡報內容詳附錄二)，報告內容著重於 2023 年工作成果及 2024 年規劃。GRM PWA 已分別於 2023 年 6 月及 11 月召開二次 Steering Committee，討論路徑圖(roadmap)草案、實施 GRM 所面臨的挑戰問卷草案、核心課綱、GRM PWA 未來規劃、各 GRM CoE 未來規劃等項目。GRM PWA 未來亦將持續定期召開 Steering Committee，審閱 GRM 相關文件、推動策略，以及指導及協調各 GRM CoE。

目前 GRM PWA 項下共有二個 GRM CoE，分別為食藥署與泰國食品藥物管理局(Thailand Food and Drug Administration, Thai FDA)，因 Thai FDA 於 2023 年並未舉辦 GRM 研討會/訓練

課程，亦未派員出席本次 RHSC 會議，故本次 RHSC 會議僅有食藥署進行 GRM CoE 報告(簡報內容詳附錄三)，報告內容著重於 2023 年工作成果及 2024 年規劃。食藥署已於 2023 年 9 月 6 日至 8 日辦理 GRM 實體訓練課程，邀請來自美國 FDA、歐盟 EMA/丹麥 DKMA、日本 PMDA、馬來西亞 NPRA、印尼 BPOM、美國 USC 大學之專家學者擔任講師，課程內容除涵蓋 GRM 核心課程 7 大領域外，並蒐集近年各界關注之議題，特別納入分散式臨床試驗(decentralized clinical trial, DCT)相關內容。本次訓練課程共計有分別來自 6 個經濟體共 81 學員參與，學員對本次訓練課程之整體滿意度達 4.5(非常滿意)，且依據訓練課程之前測、後測結果，亦可明顯觀察到經由本次訓練課程，確實有助於提升學員對於 GRM 之相關知能。食藥署亦已規劃 2024 年持續辦理 GRM 訓練課程，以強化區域合作與法規協和。

六、CoE 聯盟報告(CoE Coalition Report)

RHSC 各經濟體代表於會中針對 CoE Operating Model、CoE Assessment Plan 等文件進行討論及審查。

CoE Operating Model 之主要刪修內容包含：申請成為正式 CoE 之資格條件、PWA 主導者(PWA Champion)之責任、PWA 協辦者(PWA Sub-Champions) 之定義、刪除與 LSIF 相關文字等。

CoE Assessment Plan 之主要刪修內容包含：建立 CoE 定期評估機制，將於各合作備忘錄(memorandum of understanding, MOU)屆期前六個月進行、評估內容包含研討會/訓練課程內容是否涵蓋全部核心課綱或僅部分課綱、滿意度調查、成效評估、前測後測結果等。

囿於會議時間因素，本次會議無法完成全部文件內容之修訂及審查，後續將先由 CoE 聯盟針對各經濟體代表意見撰擬草案，並提出各 KPI 指標、開發 CoE 評估模板，預計於 2024 年 1 月底前提供各 RHSC 各經濟體代表審閱，並將在下次 RHSC 會議中進行最終審查及定案。另提醒在 RHSC 確認最終歸屬後，目前既存之合作備忘錄均將失效。

七、其他事項(Any Other Business)

RHSC之ToR草案將於會後儘速寄送給RHSC各經濟體審閱，為了順利於 2024 年 SOM-1 會議前或會議期間，將 ToR 草案提交予 SCSC 進行審查，對於 ToR 草案內容如有修正建議者，請於 2023 年 12 月 18 日前提交 RHSC 秘書處，屆期未回覆者，則將視為同意 ToR 草案內容。

另有關下次 RHSC 會議時間，考量本次會議時間距離 2024 年 SOM-1 會議時間較近，會後將調查 2024 年是否將循例配合

SOM-1、SOM-3 會議時間，召開 2 次 RHSC 會議，抑或僅於 SOM-3 期間召開 1 次 RHSC 會議即可。

叁、心得與建議

一、建議持續積極參與 RHSC 會議，密切關注 RHSC 最終歸屬及其 ToR 異動情形，並適時與 RHSC 重新簽訂合作備忘錄

1. 食藥署為 RHSC 創始會員，有賴於多年耕耘，目前能於 RHSC 中負責 GRM PWA、GRM CoE 等領域重要工作，誠屬不易。建議持續參與 RHSC 會議，強化與各 APEC 經濟體間之交流及合作，提升我國於國際間之能見度。

2. 因 RHSC 原所隸屬之 LSIF 業已落日，導致現行 RHSC 至今仍處於妾身不明之尷尬情境，而原 RHSC 所簽署之合作備忘錄亦多已逾期，亟需重新簽訂方能使各 PWA、CoE 名正言順執行相關業務。雖目前 APEC 多數成員已有將 RHSC 改隸於 SCSC 項下之初步共識，惟目前 RHSC 之 ToR 仍未有定案，亦尚未經 SCSC 簽署，爰建議密切關注 RHSC 最終歸屬及其 ToR 異動情形，並適時與 RHSC 重新簽訂合作備忘錄，以確保我國能持續參與 RHSC 會議，並可持續負責 RHSC 相關 PWA、CoE 工作。

二、建議持續辦理 GRM 訓練課程，邀請各經濟體會員藥政機關人員參加，並與 Thai FDA 協調 GRM CoE 之區隔或尋求合作模式

1. 透過辦理 GRM 訓練課程，邀請各經濟體會員藥政機關人員參加，可建立與各經濟體會員藥政機關人員之聯繫管道，擴展人脈網

絡，除有利於我國未來參加國際活動外，甚或可尋求與各經濟體會員之藥政主管機關加深合作交流機會，例如：簽訂查驗登記合作備忘錄、建立培訓雙方審查人員機制、共同審查制度、建立查驗登記資料交換機制等。

2. 目前除食藥署為 GRM CoE 外，Thai FDA 亦同為 GRM CoE，雖近年 Thai FDA 並未舉辦 GRM 訓練課程，但 Thai FDA 已規劃自 2024 年起重新舉辦 GRM 訓練課程。為避免食藥署與 Thai FDA 舉辦之 GRM 訓練課程，時間過於相近或課程內容相近，而產生同質化競爭，進而影響雙方聘任講師、學員參與意願、訓練課程成效等，建議可透過 GRM PWA 平台，與 Thai FDA 協調 GRM CoE 之區隔或尋求合作模式，以利雙方順利辦理 GRM 訓練課程，並讓學員們有機會參加更多元化、內容豐富的 GRM 訓練課程，達成多贏局面。

附錄一、RHSC 會議議程

Regulatory Harmonization Steering Committee (RHSC)
Preparatory and Main Meeting
Meeting Agenda & Documents
Venue: Northeastern University, Oakland Campus
*1-4 December 2023

*Corresponds to Pacific Standard Time (PST), UTC -8

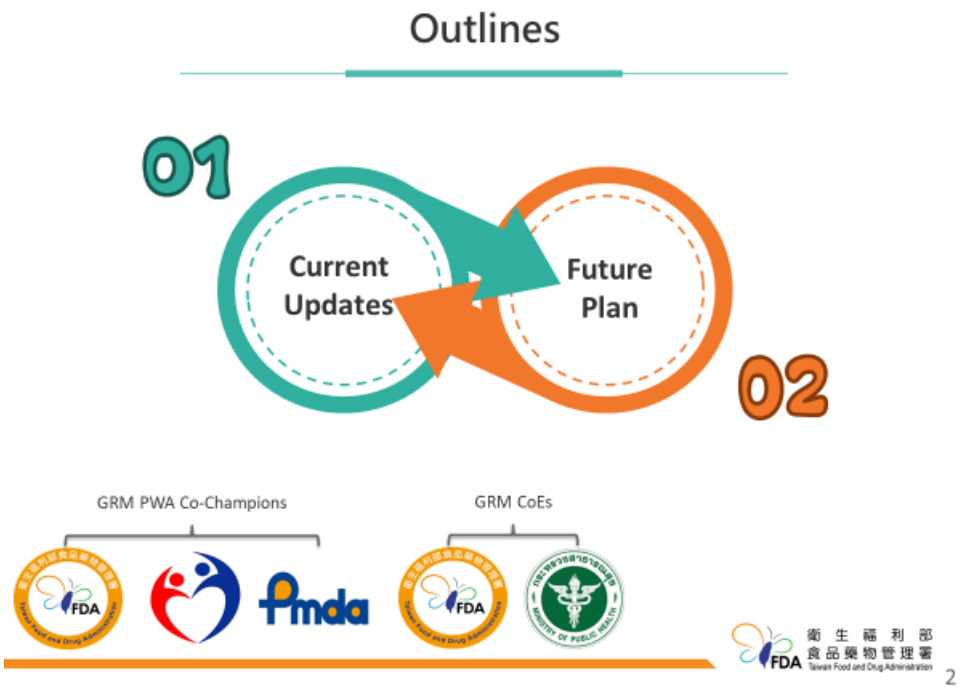
Agenda Item	Time	Topic	Speaker/Organisation	Format
1	10 min	**RHSC Co-Chairs Welcome and Introductions**	**Dr. Michelle LIMOLI** US Food and Drug Administration (US FDA), United States **Dr. Naoyuki YASUDA** Pharmaceuticals and Medical Devices Agency (PMDA), Japan	**In-person**
2	15 min	**RHSC Advisor's Office Update**	**Ms. Patty WU** Crowell & Moring International	**In-person**
3	15 min	**AHC Update Report**	**Mrs. Helen JANG** APEC Harmonization Centre	**Virtual**
4	15 min	**RHSC Representatives' Reports**		
4.1		• ICH/IPRP	**Mrs. Helen JANG** APEC Harmonization Centre	**Virtual**
4.2		• IMDRF	**Ms. Cheng-Ning (Emily) WU** Taiwan Food and Drug Administration, Chinese Taipei (TFDA)	**Virtual**
5	15 min	**WHO Update**	**Dr. Samvel AZATYAN** World Health Organization	**In-person**
		PWA Updates		
6	45 min	**Medical Device PWA Update** *(Champions: Korea – MFDS, Japan – PMDA and US FDA; Sub-Champions: AdvaMed and JIRA)*		
6.1		• PWA Champion Update	**Ms. Ahram CHO** Ministry of Food and Drug Safety (MFDS), Republic of Korea	**Virtual**
6.2		• CoE Update: SCH	**Dr. Ei Shwe Yi PHOO** Soonchunhyang University (SCH), Republic of Korea	**In-person**
6.3		• CoE Update: USC	**Ms. Apurva Uniyal** University of Southern California (USC), United States	**In-person**

Agenda Item	Time	Topic	Speaker/Organisation	Format
6.4		• CoE Update: PMDA	**Ms. Miwa KANEMATSU** Pharmaceuticals and Medical Devices Agency (PMDA), Japan	**In-person**
6.5		• CoE Update: TFDA	**Mr. Hsiu-Te LIN** Taiwan Food and Drug Administration (TFDA), Chinese Taipei	**Virtual**
6.6		• CoE Update: SCU	**Prof. Anyu LEE** Sichuan University (SCU), China	**In-person**
7	**30 min**	**Multi-Regional Clinical Trials and Good Clinical Practices Inspection PWA** *(Champions: Japan – PMDA and Thailand – TFDA)*		
7.1		• PWA Champion Update	**Ms. Miwa KANEMATSU** Pharmaceuticals and Medical Devices Agency (PMDA), Japan	**In-person**
7.2		• CoE Update: PKU	**Ms. Sandy ZHANG** Peking University (PKU), China	**Virtual**
7.3		• CoE Update: PMDA with NCC	**Ms. Miwa KANEMATSU** Pharmaceuticals and Medical Devices Agency (PMDA), Japan	**In-person**
7.4		• CoE Update: The MRCT Center of Brigham and Women's Hospital and Harvard	**Prof. Jared AUCLAIR** On behalf of The MRCT Center of Brigham and Women's Hospital and Harvard, United States	**In-person**
7.5		• CoE Update: KoNECT	**Ms. Suji YOO** Korea National Enterprise for Clinical Trials (KoNECT), Republic of Korea	**Pre-recorded with audio in slides**
8	**30 min**	**Pharmacovigilance PWA** *(Champion: Korea – MFDS)*		
8.1		• PWA Champion Update	**Ms. Mi-ja PARK** Ministry of Food and Drug Safety (MFDS), Republic of Korea	**Virtual**
8.2		• CoE Update: KIDS	**Ms. E Na SONG**	**Virtual**

Agenda Item	Time	Topic	Speaker/Organisation	Format
			Korea Institute of Drug Safety and Risk Management (KIDS), Republic of Korea	
8.3		• CoE Update: PKU	**Ms. Wan SUN** Peking University (PKU), China	**Virtual**
9	**30 min**	**Good Registration Management PWA** *(Champions: Chinese Taipei – TFDA and Japan – PMDA)*		
9.1		• PWA Champion Update	**Mr. Kuo-Teng HUNG** Taiwan Food and Drug Administration, Chinese Taipei (TFDA)	**In-person**
9.2		• CoE Update: TFDA	**Mr. Kuo-Teng HUNG** Taiwan Food and Drug Administration, Chinese Taipei (TFDA)	**In-person**
10	**30 min**	**Global Supply Chain Integrity PWA** *(Champion: US – FDA)*		
10.1		• PWA Champion Update	**Dr. Leigh VERBOIS** U.S. Food and Drug Administration (US FDA), United States	**In-person**
10.2		• CoE Update: USP	**Mr. Michael SCHMITZ** United States Pharmacopeia (USP), United States	**In-person**
11	**20 min**	**Advanced Therapies PWA** *(Champions: US FDA, Singapore – HSA; Sub-Champions: BIO)*		
11.1		• PWA Champion Update	**Dr. Michelle LIMOLI** US Food and Drug Administration (US FDA), United States **Mrs. Judith ARCIDIACONO** US Food and Drug Administration (US FDA), United States	**In-person**
11.2		• CoE Update: USP	**Mr. Michael SCHMITZ** United States Pharmacopeia (USP), United States	**In-person**

Agenda Item	Time	Topic	Speaker/Organisation	Format
11.3		• CoE Update: Northeastern University	**Prof. Jared AUCLAIR** Northeastern University (NEU), United States	**In-person**
12	**20 min**	**Biotechnological Products PWA** *(Interim PWA Lead: US and Singapore, Sub-Champion: BIO)*		
12.1		• Interim PWA Lead Update	**Dr. Michelle LIMOLI** US Food and Drug Administration (US FDA), United States **Mrs. Judith ARCIDIACONO** US Food and Drug Administration (US FDA), United States	**In-person**
12.2		• CoE Update: Northeastern University	**Prof. Jared AUCLAIR** Northeastern University (NEU), United States	**In-person**
13	**30 min**	**CoE Coalition Report** *(Chair: NEU and CoRE; Vice-Chair: USP)*	**Prof. Jared AUCLAIR** Northeastern University (NEU), United States	**In-person**
14	**15 min**	**Any Other Business**		
15	**15 min**	**Review Decisions and Action Items**		
		Adjourn		

附錄二、食藥署於 RHSC 會議中報告「Good Registration Management (GRM) PWA Update」投影片



PWA activities in 2023

1st GRM PWA Steering Committee Meeting
- Draft roadmap in new template
- Draft questionnaire to address the challenges in implementing GRM

2nd GRM PWA Steering Committee Meeting
- PWA update and CoE update
- Planning for 2024 APEC GRM CoE Workshop

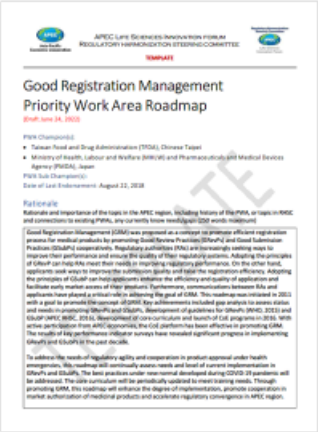
04/12-14 | 06/06 | 09/06-08 | 11/16

RHSC Meeting 12-14 April, 2023
- PWA Update
- CoE Update: TFDA

2023 APEC GRM CoE Workshop
- Hosted by TFDA
- 3-day in-person program

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

RHSC Meeting (12-14 April, 2023)



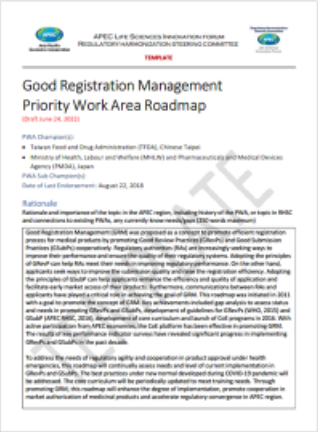
Good Registration Management Priority Work Area Roadmap

GRM PWA Update
- Revising GRM PWA Roadmap in new template with update in core curriculum and other sections
- Convening biannual GRM PWA Steering Committee meetings
- Hosting APEC GRM CoE workshops

CoE Update: TFDA
- Outcomes of 2022 APEC GRM CoE Workshop (virtual)
- Planning to host 2023 APEC GRM CoE Workshop on September 6-8 (In-Person)

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

Revise GRM PWA Roadmap in new template (1)



Good Registration Management
Priority Work Area Roadmap

Update contents in various sections

- Rationale
- Scope
- Core Curriculum
- Key Performance Indicators
- PWA CoE Steering Committee Members

Solicit input from GRM PWA Steering Committee

Further revise the roadmap based on comments

Revise GRM PWA Roadmap in new template (2)

Update contents in various sections

Rationale	Keep promoting GRM based on WHO GRevP guidelines and APEC RHSC GSubP guidelines. Update CoE training programs from time to time.
Scope	Cover the submission and review of safety, efficacy and quality data for market authorization of medicinal products in their entire product life cycle.
Core Curriculum	Integrate Common Training, Reviewer Training and Applicant training into one GRM Training module. Allow flexibility in session format (plenary vs. con-current) and to conduct workshops on focused topics.

Updated GRM Core Curriculum

Current Core Curriculum

Proposed Revision

GRM Training
- Basic concept of GRM
- GRevP topics
- GSubP topics
- Rolling out GRM training program in each economy
- **Topics of special interests**

Promote dialogues between regulators and industry

Examples for topics of special interests
- Implementation of GRevPs and GSubPs
- Best practices for review and submission under public health crisis
- Promoting regulatory cooperation and reliance
- Application of GRM to the entire product life cycle
- Application of RWD/RWE in regulatory decision-making

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

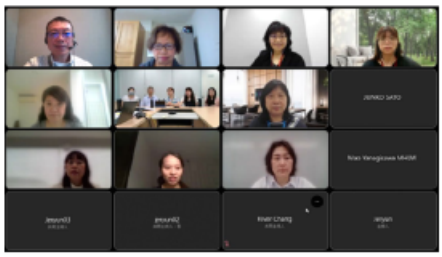
Revise GRM PWA Roadmap in new template (3)

Update contents in various sections

KPIs for Operational Measurements	• GRM CoE workshops • Local training programs
KPIs for Strategic Measurements	• Pre-submission scientific advice • Regular dialogues with industry stakeholders • Shared or joint review • Regulatory pathways using review outcomes from other regulatory authorities • Publication of summary of grounds on which approval was granted

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

1st GRM PWA Steering Committee Meeting



Date: June 6, 2023

GRM PWA Steering Committee Members:
- TFDA, MHLW, PMDA
- APAC, IRPMA
- Temple University School of Pharmacy
- Subject Matter Experts

Discussion Topics
- Draft roadmap in new template
- Draft questionnaire to address the challenges in implementing GRM

Outcomes and Action Items
- The committee had no new comment to the draft roadmap (version June 24 2022).
- The committee raised comments to the proposed questionnaire. Further consideration was needed to determine the next step.

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

9

2023 APEC GRM CoE Workshop

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

10

2nd GRM PWA Steering Committee Meeting

Date: November 16, 2023

GRM PWA Steering Committee Members:
- TFDA, MHLW, PMDA, Thai FDA
- APAC, IRPMA
- USC DK Kim International Center for Regulatory Science
- Subject Matter Experts

Discussion Topics
- GRM PWA Update and CoE Update
- Planning for 2024 APEC GRM CoE Workshops

Outcomes and Action Items
- The committee supported the addition of digital transformation-related elements to the core curriculum.
- The committee supported further development of questionnaire to inform the issues of GRM implementation.
- Both TFDA CoE and Thai FDA CoE plan to host GRM workshops in 2024.

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

11

PWA Plan for 2024

GRM PWA Steering Committee meetings will be convened periodically.
- To review PWA roadmap and core curriculum
- To discuss work plan and strategic directions
- To support and coordinate CoE activities

Tentative schedule for APEC GRM CoE Workshops in 2024
- Thai FDA CoE: August 2024
- TFDA CoE: September 2024

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

12

附錄三、食藥署於 RHSC 會議中報告「Good Registration Management (GRM) CoE Update」投影片

Planning the Workshop

Convene GRM CoE Program Committee Meeting on June 6, 2023

1. Discussion on the 2023 APEC GRM CoE Workshop Program Draft Agenda
2. Update on the progress of workshop preparation and future timeline
3. Participating Organizations: APAC, IRPMA, MHLW, PMDA, TFDA, Temple University

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

3

Workshop Summary

Schedule & Program	Participants	Speakers & Facilitators	Topics
3-day in-person workshop Sep 6th- Sep 8th	Total: 81 participants Reviewers: 18 Applicants: 63 6 Economies	23 Speakers (TFDA/CDE/ PMDA/DKMA/ FDA/NPRA/ BPOM/APAC/ IRPMA/USC) 20 Facilitators (TFDA/CDE/ IRPMA)	7 GRM Core Curriculum Sessions 3 Topic of Special Interest GRevP & Global clinical data Assessment of global clinical data in Europe DCT

＊6 Economies: Malaysia, Philippines, Singapore, Chinese Taipei, Thailand, Botswana

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

4

Workshop Program (1/2)

Day 1 (September 6th)
Opening Remarks • Shou-Mei Wu (TFDA) • Ayumi Endo (PMDA) • Shinji Hatakeyama (APAC & Eisai)
Keynote Speech 1 **Good Review Practices and Regulatory Convergence in Accepting Global Clinical Data for Regulatory Approval** • Herng-Der Chern (TsRAP)
Keynote Speech 2 **Assessment of Global Clinical Data for Drug Approval in Europe** • Aaron Sosa Mejia (DKMA & EMA)
Session 1 **Introduction of GRM** • Kuo-Teng Hung (TFDA)

Day 1 (September 6th)
Session 2 **Managing and Conducting the Review** • Yueh-Tung Tsai (TFDA) • Kanae Ohara & Ayumi Endo (PMDA) • Cheong Ooi Jin (NMPA) • Vringga Sandia Surya (Indonesia FDA)
Session 3 **Regulatory Competency Framework** • Lawrence Liberti (USC) • Hiroko Kawaguchi (MSD & APAC Japan)

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

5

Workshop Program (2/2)

Day 2 (September 7th)
Session 4 **Planning of Applications** • Finny Liu (Roche) • Jocelyn Lee (Shenhwa)
Session 5 **Preparation of Application Dossier / Practice: How to Prepare Application Dossier** • Yukiko Noguchi (Astellas & APAC Japan) • Kumiko Hikida (Mitsubishi Tanabe & APAC Japan) • Masaaki Kanno (Astellas & APAC Japan) • Shinji Hatakeyama (Eisai & APAC Japan)
Session 6 **Communication** • Min Chen (US Pharmacovigilance) • Wimolsiri Punjatanasak (MSD & APAC Thailand

Day 3 (September 8th)
Session 7 **Critical Thinking and Regulatory Decision-Making** • Lawrence Liberti (USC) • Chi-Hsun Chen (CDE) • Wei-Lun Peng (CDE) • Yi Lin Wang (CDE)
Keynote Speech 3 **Modernizing Clinical Trials: A Focus on Decentralized Clinical Trials** • M. Khair ElZarrad (U.S. FDA)
Closing Remarks • Shou-Mei Wu (TFDA)

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

6

Feedbacks-General Satisfaction

With the average score of 4.5, the 2023 APEC GRM CoE could be considered as very good satisfying to the participants.

General Satisfactions	Average Satisfaction
Q1: Did the workshop strengthen your understanding of GRM concept?	4.5
Q2: Did the workshop meet your expectation?	4.5
Q3: Overall Satisfaction	4.5

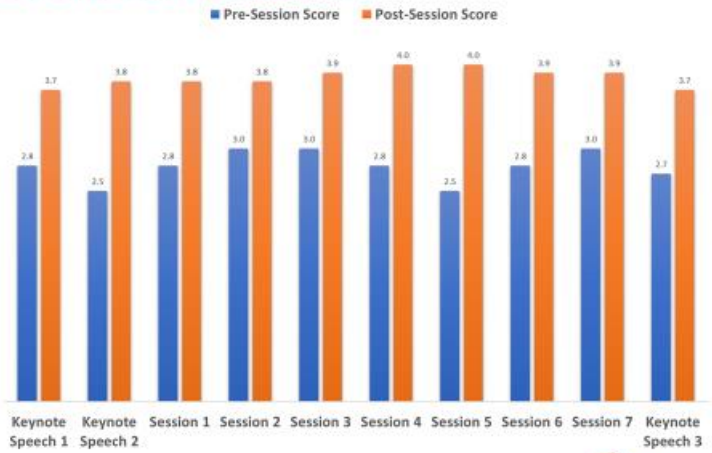
*Scale 1: poor and Scale 5: excellent

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

7

Knowledge Level of Each Session

Conclusion : The average knowledge level scores increased after completing each session.



衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

8

Summary of Feedback

Most sessions received very good satisfaction and feedback !!

Session	Topic	Average Score
3	Regulatory Competency Framework	4.7
Keynote Speech 2	Assessment of Global Clinical Data for Drug Approval in Europe	4.6
Keynote Speech 3	Modernizing Clinical Trials: A Focus on Decentralized Clinical Trials	4.6

Topics or presentations most useful to participants:

- ✓ Planning of application
- ✓ Critical thinking and regulatory decision-making
- ✓ Bridging study evaluation (BSE)
- ✓ Communication
- ✓ Good submission practices
- ✓ Dossier preparation
- ✓ Registration processes presented by regulators of each economy

衛生福利部 食品藥物管理署 FDA Taiwan Food and Drug Administration

9

Workshop Photos (1/2)








衛生福利部 食品藥物管理署 FDA Taiwan Food and Drug Administration

10

Workshop Photos (2/2)






Suggestions from Program Committee

Post-workshop Program Committee Meeting

Date: September 8, 2023

The Program Committee shared observation and suggestions for the next workshop.

- It is preferable to include participants from regulatory authorities and industry at almost equal number for group discussions.
- To have more time for group discussion or to introduce new topics, basic topics can be pre-recorded and completed online before the in-person workshop.
- Deep-dive into benefit-risk decision making in the next workshop, including the concept behind and how regulators in the world look at benefit-risk assessment qualitatively and quantitatively.

CoE Plan for 2024

TFDA plans to host 2024 APEC GRM CoE Workshop.

- CoE Program Committee meetings will be convened to plan this workshop.

附錄四、RHSC 會議剪影及與會人員合照