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)會議及 DIA 新加坡年會出國報告

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、丁家崴技士

派赴國家：新加坡

出國期間：113 年 7 月 16 日至 113 年 7 月 20 日

報告日期：113 年 7 月 31 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。

本次 RHSC 會議於新加坡召開，且時間與 DIA 新加坡年會相近，衛生福利部食品藥物管理署分別於 RHSC 會議、DIA 新加坡年會中，報告及推廣 GRM 之理念、工作進度、成果及未來規劃等，內容獲得各界肯定。

RHSC 如今已正式回歸 APEC，改隸於 SCSC 項下，為確保 RHSC 能持續維持運作，將由 RHSC 領導階層與各 PWA 主責單位共同合作，加強對各 CoE 的監督。

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、藥物資訊協會、Drug Information Association、DIA

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。

RHSC 原隸屬於生命科學創新論壇(Life Science Innovation Forum, LSIF)項下，因 LSIF 已於 2021 年屆滿落日，而有鑒於 RHSC 之重要性，多數 APEC 經濟體成員支持其繼續運作。標準及符合性次級委員會(SCSC)已同意將 RHSC 納入其下屬機構(subsidiary body)，且該項決議業經 SCSC 之上級機構貿易暨投資委員會(Committee on Trade and Investmen, CTI) 於 2024 年 3 月採認，爰目前 RHSC 已正式改隸於 SCSC 項下。

RHSC 會議未來每年預定召開 2 次，且將配合於每年第一次、第三次資深官員會議（Senior Officials' Meeting, SOM-1& SOM-3）期間，由 APEC 當年度之主辦經濟體於當地召開。因 APEC 今年度之主辦經濟體祕魯原先無安排 RHSC 會議規劃，且多數成員亦未有編列至祕魯開會之經費，經協調後，爰擇定於 RHSC 秘書處所在地新加坡召開會議。

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)。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。

藥物資訊協會(Drug Information Association, DIA)為一個國際性組織，致力於推動全球健康，促進藥物研發和生物醫學技術創新，定期召開會議邀集各國政府法規人員、學術界人員、製藥產業人員、生技醫藥研發人員等，交流藥物研發經驗和藥政管理趨勢，藉此實現跨領域的產業交流和經驗分享。適逢本次RHSC會議於新加坡召開，且會議時間與DIA新加坡年會相近，DIA新加坡年會爰特別邀請RHSC各優先工作領域出席分享活動近況及成果。

綜上，本次出席RHSC會議及DIA新加坡年會，主要目的如下：

一、 了解 RHSC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。

四、 於DIA新加坡年會中報告GRM理念、工作成果及近期活動資訊。

貳、會議過程

行程紀要

日期	行程
7/16	桃園機場出發，抵達新加坡樟宜機場
7/17	參加 DIA 新加坡年會
7/18~7/19	參加 APEC 法規協和指導委員會(RHSC)會議
7/20	新加坡樟宜機場出發，抵達桃園機場

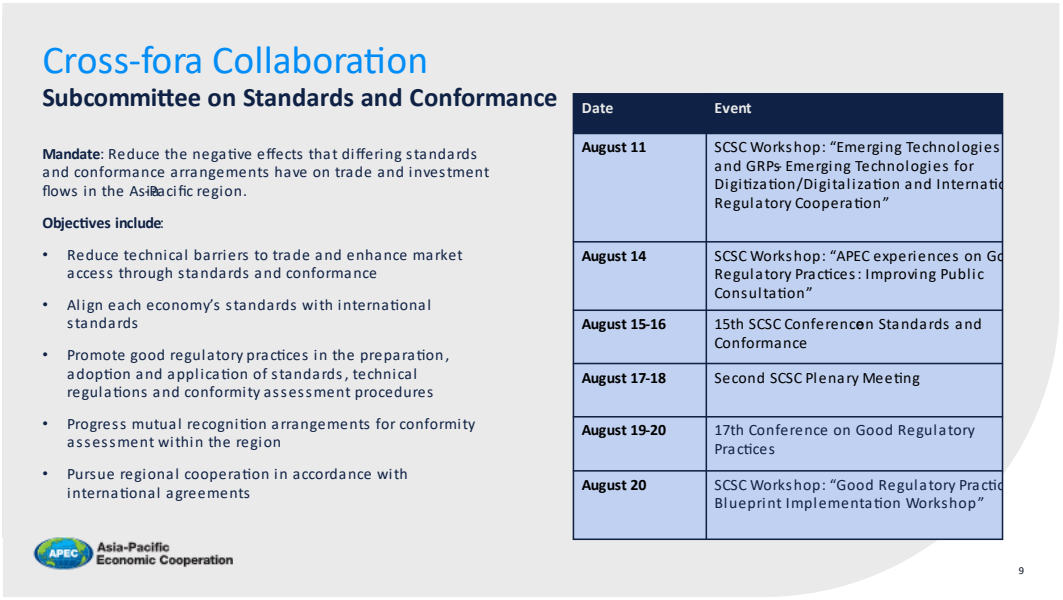
會議內容摘要

一、RHSC 領導階層報告(RHSC Leadership Welcome, Introductions and Updates)及 RHSC 顧問辦公室報告(RHSC Advisor’s Office Update)：

RHSC 所提交職權範圍(Terms of Reference, ToR)草案，已於 2024 年 2 月於祕魯利瑪召開之 SOM-1 會議中通過，並已於 2024 年 3 月經全數 21 個 APEC 經濟體簽署通過。RHSC 在長達 2 年地位不明的處境後，如今終於已回歸正常運作，未來 RHSC 將向 SCSC 進行報告，如有必要時，亦得向 CTI 進行報告。

一般而言，SCSC 項下的各 ToR 效期為四年，目前 SCSC 項下之各 ToR 均將於 2025 年 12 月期滿。RHSC ToR 雖甫經認可通過，惟其效期仍與 SCSC 項下其他 ToR 相同，意即將於 2025 年 12 月期滿。為了辦理 ToR 的展延作業，RHSC 預計將於 2025 年 1 月起，對各經濟體、PWA、CoE 辦理調查作業，並預計於 2025 年 3 月進行新版 ToR 內容討論，以利後續送交 SCSC 審查。另未來 RHSC 執行相關業務時，均應遵從 APEC 所公布之各項指引，例如於 APEC 之各項活動、文件中，不可使用「國家(country)」一詞，而應使用「成員(member)」、「economy (經濟體)」、「經濟體成員(economy member)」等。

由於 SCSC 之主要目標，著重於降低亞太地區各經濟體間，由於不同標準、規範，對貿易、投資方面所造成的負面影響。而 RHSC 主要致力於促進醫療產品的法規協和，除經貿方面之考量外，亦應注意促進公共衛生、改善人民健康福祉等相關議題，建議可加強與 APEC 衛生工作小組(Health Working Group, HWG)跨論壇間的合作。

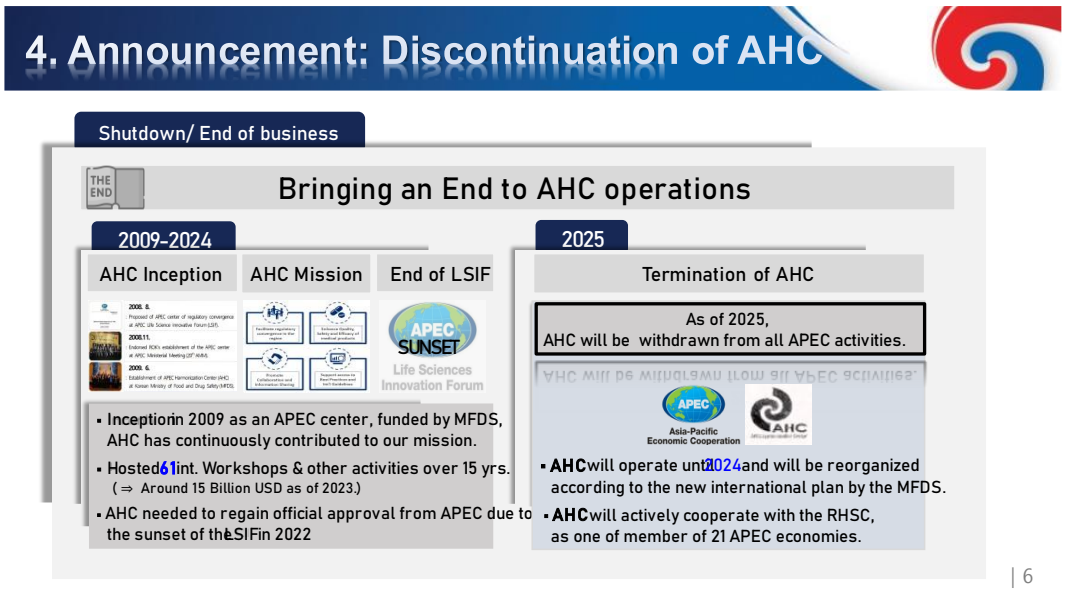


二、APEC 法規協和中心報告(APEC Harmonization Center Update)：

AHC訂於 2024 年 10 月 28 日~29 日於韓國首爾辦理Global Supply Chain Integrity Workshop，且訂於 2024 年 11 月中(確切日期待訂)於韓國首爾辦理 Biosimilars Workshop，預訂自 2024 年 8 月起開始接受報名，歡迎有興趣者踴躍報名參加，本次活動除實體參加外，亦可線上參加。

AHC 自 2009 年起由韓國食品醫藥品安全處(Ministry of Food and Drug Safety, MFDS)出資支持其執行 APEC 業務，運作至今已 15 年餘，期間已辦理 61 場國際性工作坊等活動。由於韓國 MFDS 政策調整之故，AHC 將自 2025

年進行重組，並將全面退出 APEC 相關活動。故自 2025 年起，AHC 將不再資助辦理 Pilot or Pre-CoE，爾後 Pilot or Pre-CoE 均須自籌經費辦理，至 2024 年原已核定予以資助者，並不受影響。



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

由於 AHC 目前擔任 RHSC 於 ICH 及 IPRP 之代表一職，未來須將重新討論新任代表人選。ICH/IPRP 會議已於 2024 年 6 月 1 日至 6 月 5 日在日本福岡召開，本次 ICH 會議同意約旦食品藥物管理局(Jordan Food and Drug Administration, JFDA)、阿根廷國家食品藥物管理局(Administración Nacional de Medicamentos, Alimentos y Tecnología, ANMAT)成為會員。

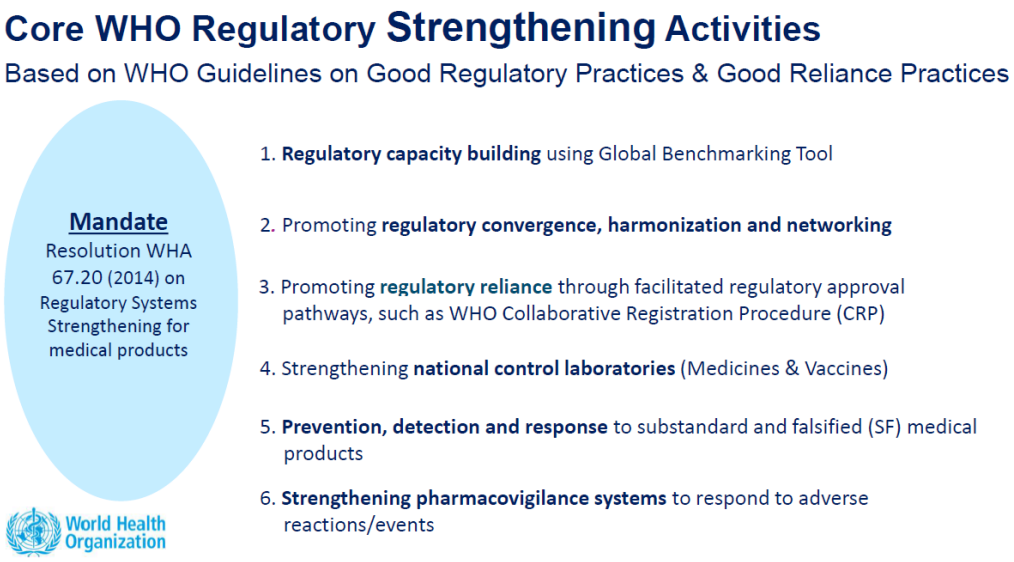
ICH 將成立新指引 M7 Addendum (Safety assessment and establishment of appropriate controls for nitrosamine impurities) 工作小組。指引 M12 Drug Interaction Studies Guideline and Q&As 已進入 Step 4 並獲得 ICH 大會採認。另下次 ICH/IPRP 會議訂於 2024 年 11 月 5 日至 7 日於加拿大蒙特羅召開。

IMDRF 會議已於 2024 年 3 月 11 日至 15 日在美國華盛頓特區召開，本次 IMDRF 會議約有 1,200 人(實體約 400 人、線上約 800 人)參與。IMDRF 管理委員會(Management Committee)同意薩爾瓦多國家藥品管理局(DIRECCIÓN

NACIONAL DE MEDICAMENTOS, DNM)、衣索比亞食品藥物管理局(Ethiopian Food and Drug Administration, EFDA)、約旦食品藥物管理局(Jordan Food and Drug Administration, JFDA)、肯亞藥物及毒品委員會(Pharmacy and Poisons Board, PPB)、墨西哥聯邦健康風險保護委員會(Comision Federal para la Proteccion contra Riesgos Sanitarios, COFEPRIS)、 奈及利亞國家食品藥物監督管理總局(National Agency for Food and Drug Administration and Control, NAFDAC)、坦尚尼亞藥品及醫療器材管理局(Tanzania Medicines & Medical Devices Authority, TMDA)成為附屬會員(Affiliate Member)。另下次 IMDRF 會議訂於 2024 年 9 月 16 日至 20 日於美國西雅圖召開。

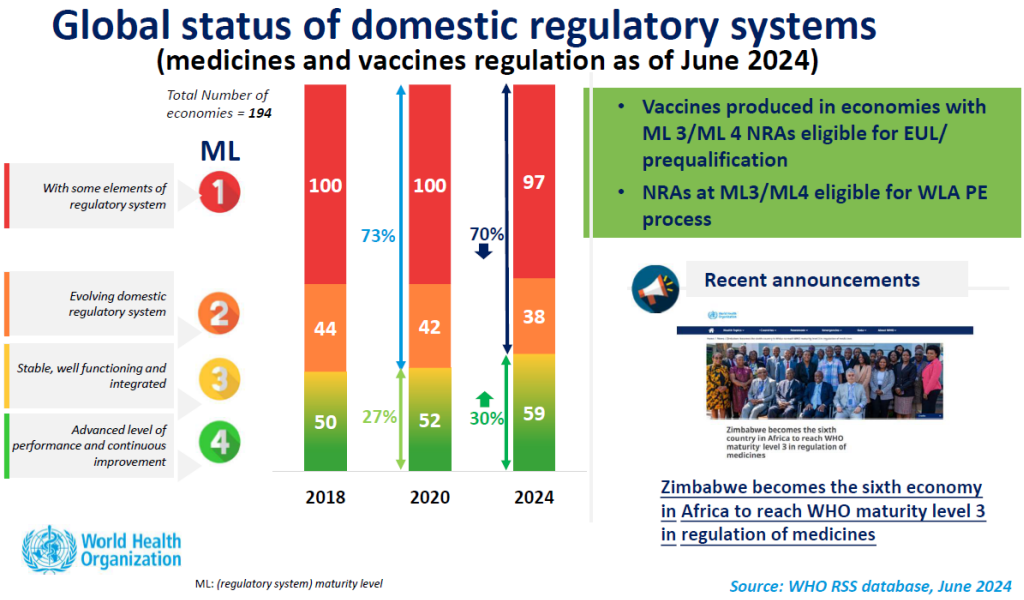
四、世界衛生組織報告(WHO Update)

WHO 為加強各國醫療產品監管體系，採行了運用 WHO 之 Global Benchmarking Tool(GBT)進行醫療產品監管體系能力建構、促進法規協和、透過 WHO 合作註冊程序（Collaborative Registration Procedure, CRP）促進法規信賴(regulatory reliance)、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、強化藥品不良反應/不良事件安全監視系統等措施。



目前不合格或偽造的醫療產品，仍於現實世界中流竄，光是在 2023 年，WHO就一共發布了 8 則全球性醫療產品警訊。這些不合格或偽造的醫療產品，除了可能會造成經濟上的損失外，更可能造成許多兒童不必要的死亡或疾病。估計約有 7 萬~17 萬名感染肺炎的兒童，因使用了不合格或偽造的藥品，而最終導致死亡。因此強化各國對於醫療產品的監管體系，確實有其必要性。

WHO 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。



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)。另食藥署所新修訂之路徑圖(roadmap)，亦已於本次 RHSC 會議中，獲得全數出席經濟體代表同意採認。

食藥署報告之內容著重於 2024 年上半年工作成果及 2024 年 GRM CoE 活動規劃，GRM PWA 已分別於 2024 年 4 月及 6 月召開二次 Steering Committee，經協調食藥署與泰國食品藥物管理局(Thailand Food and Drug Administration, Thai FDA)，已約定未來雙方輪流以實體、線上方式舉辦 GRM CoE Workshop，並配合 RHSC 改隸 SCSC 項下，已重新檢討路徑圖(roadmap)草案、核心課綱等項目。另就 GRM PWA 未來規劃、各 GRM CoE 未來規劃進行報告，GRM PWA 未來將持續定期召開 Steering Committee，審閱 GRM 相關文件、推動策略，以及指導及協調各 GRM CoE。

食藥署亦於會中報告 GRM CoE 近況(簡報內容詳附錄三)，報告內容著重於 2024 年 GRM CoE 規劃。食藥署已訂於於 2024 年 9 月 3 日至 5 日辦理 GRM 實體訓練課程，邀請來自美國南加州大學(University of Southern

California, USC)、歐盟 EMA、日本 PMDA、亞洲製藥協會(Asia Partnership Conference of Pharmaceutical Associations, APAC)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，特別納入近年蓬勃發展之再生醫療製劑相關課程 Conducting the Review in Regenerative Medicine。食藥署未來將持續辦理 GRM 訓練課程，以強化區域合作與法規協和，另經與泰國 Thai FDA 協調後，食藥署於 2025 年將以線上方式辦理 GRM CoE Workshop。

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，主要係配合 AHC 將退出 APEC 活動，且不再給予 Pilot or Pre-CoE 資助，刪修相關文字內容，後續將提供修正後版本予各經濟體進行審閱。另 CoE 聯盟主責單位再次提醒，目前多數 CoE 之 MOU 內容已逾期，如今 RHSC 已正式回歸 APEC，應儘早啟動再評估機制，以期順利通過展期。

七、戰略討論(Strategic Discussions)

經參考 APEC 各論壇之作法，並非所有 CoE 均須正式簽署 MOU，因此 RHSC 同意未來亦不再要求 CoE 應簽署 MOU，而為確保 CoE 的品質，將由 RHSC 領導階層與各 PWA 主責單位共同合作，加強對各 CoE 的監督。

根據 CoE Operating Model 規定，每三年均應對所有 CoE 進行一次正式評估，因此 RHSC 請所有 PWA 立即對項下之各 CoE 啟動評估作業，且應於 2025 年 SOM-1 會議前提交預計完成 CoE 評估作業的工作計劃及時程。另請 CoE 聯盟提供評估指引，包含如何評估訓練是否與核心課程相符等內容，以期確保評估作業之一致性。

由於 AHC 自 2025 年起不再提供資助辦理 Pilot or Pre-CoE，未來 Pilot or Pre-CoE 應審慎思考其資金來源以及確保能維持運作之模式，以利未來轉為正式 CoE。另為鼓勵申請成為 Pilot or Pre-CoE，請 CoE 聯盟負責協助研

擬相關資助辦法，並於下次會議中討論。

八、新 PWA 提案 (New PWA Proposals)

本次 RHSC 會議共計接獲三項欲成立新 PWA 的提案需求，分別為 Pharmaceutical Quality、Data Standards 及 Orphan Medical Products。經討論後，原則同意成立 Pharmaceutical Quality 及 Data Standards 這二個新 PWA，請提案者持續完善提案內容、路徑圖等文件，並歡迎有興趣之各經濟體，成為共同主導者。

至於Orphan Medical Products，各出席代表雖均認為此為重要之議題，惟其工作計畫內容，究應單獨成立新 PWA，或是與現行既存之 PWA 共同合作推動，仍待商榷，爰請提案者重新修正提案內容後，再送交 RHSC 進行討論。

九、下次 RHSC 會議資訊及其他事項(Any Other Business)

2025 年 APEC 主辦經濟體目前已預定由韓國擔任，下次 RHSC 會議將配合 2025 年 APEC SOM-1 會議時程召開，估計是在 2025 月 2 月下旬，請各經濟體之代表先預留時間，待有進一步詳細會議資訊時，APEC 秘書處及 RHSC 秘書處會儘速通知。

由於目前 RHSC 已回歸正常運作，為了確保與各經濟體代表間溝通順暢，後續 RHSC 秘書處將會請各經濟體確認窗口名單，以及是否須調整擔任 RHSC 於各國際組織(ICH/IPRP 及 IMDRF)的代表人選。

十、DIA 新加坡年會

本次 DIA 新加坡年會特別規劃「APEC Regulatory Harmonization Steering Committee (RHSC) Special Feature: Advancing Regulatory Convergence」主題，邀請 RHSC 成員分別就 Overview of the RHSC、MRCT/GCP、Global Supply Chain Integrity、Good Registration Management、Biotherapeutics and Advanced Therapies、Update on APEC RHSC Pharmacovigilance Status、RHSC Centers of Excellence Overview & Operations 等進行報告。

Good Registration Management 部分由食藥署代表進行報告，內容著重於推廣 GRM 理念及目標，並說明近年已達成之成果。食藥署並於會中說明已訂於 2024 年 9 月 3 日~5 日於台北辦理 GRM CoE Workshop，內容除涵蓋 Critical thinking and regulatory decision-making、Planning of Application 等 GRM 核心課綱相關課程外，亦特別納入近年蓬勃發展之再生醫療製劑相關課程 Conducting the Review in Regenerative Medicine，歡迎各界報名參與。

於問答環節時，與會者對於食藥署規劃之 GRM CoE Workshop，將法規單位之審查人員及業界的送件申請者，安排在一起進行分組討論，是否會引起雙方立場不同而有爭議提出疑問。經食藥署現場說明，此設計是期能藉由審查人員、申請者雙方，針對課程所提供個案進行討論，能提升對彼此不同立場間之思考模式、想法之認知，進而增進未來送件或審查案件時之品質，減免因雙方認知落差太大，導致未來案件審查時程延宕，對此，與會者多數表示認同食藥署之理念。

叁、心得與建議

一、 建議持續積極參與 RHSC 會議，善盡 GRM PWA 及 GRM CoE 職責，並評估是否爭取負責未來新成立之 PWA 或 CoE

1. 食藥署自 2009 年起長期參與 RHSC 至今，且負責 GRM PWA、GRM CoE 等重要工作。RHSC 雖曾遭遇 LSIF 屆滿落日，導致地位不明情形，RHSC 各經濟體仍自主維持其運作，如今 RHSC 終於回歸正常運作，建議持續積極參與 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. 食藥署目前為負責 GRM PWA 及 GRM CoE 之單位，RHSC 現已要求各 PWA 對項下各 CoE 啟動評估機制，將汰除不適任之 CoE，爰建議持續善盡 GRM PWA 及 GRM CoE 職責，方可確保食藥署未來仍可持續負責相關工作。
3. 未來 RHSC 將成立二項新的 PWA，包括 Pharmaceutical Quality 及 Data Standards，俟相關路徑圖(roadmap)擬定完成後，建議可評估是否爭取負責未來新成立之 PWA 或 CoE，以持續提升食藥署於 RHSC 中重要性。

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，並積極派員至其他經濟體舉辦之活動，擔任 GRM 課程講師

1. 邀請各經濟體會員藥政機關人員參加我方辦理之 GRM 訓練課程，除可與其交流查驗登記法規，掌握相關經濟體之法規及管理現況外，亦可與其建立聯繫管道，擴展人脈網絡。未來更可進一步尋求加深合作交流機會，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. 本次參與 RHSC 會議與 DIA 新加坡年會期間，接獲多名其他經濟體之人員反映，表示亦希望能將 GRM 理念攜回推廣，以提升其查驗登記送件品質、審查效率等，進而提升病人取得新興藥品的可近性。爰此，建議未來如有其他經濟體舉辦查驗登記或 GRM 相關活動時，可積極派員

擔任 GRM 課程講師，以提升我國影響力。

附錄一、RHSC 會議議程

Regulatory Harmonization Steering Committee (RHSC) Meeting

APEC Secretariat Office – Singapore

July 18-19, 2024

Schedule Overview:

July 16-17: DIA-Singapore Meeting at Voco Orchard
July 17: PWA Prep Meetings at Duke NUS Medical School
July 18-19: RHSC Meeting (09:00 – 17:00) APEC Secretariat Office

Agenda: DIA-Singapore Meeting

Date: 16 – 17 July 2024

Location: Voco Orchard, 581 Orchard Rd, Singapore 238883

July 16-17: DIA-Singapore Meeting (RHSC panel July 17 afternoon)
Contact DIA-Singapore directly for more information

Agenda: PWA Steering Committee Preparatory Meetings*

Date: 17 July 2024

09:00 – 12:00 Medical Device PWA (Meeting Room 2C, Level 2)

09:00 – 12:00 Pharmacovigilance PWA (Meeting Room 4D, Level 4)

Location: Duke-NUS Medical School, 8 College Road, Singapore 169857

*Teleconference Meeting Details for virtual attendees may be arranged by respective PWA Champions. Please contact PWA Champions directly for more information

Agenda: RHSC Meeting

Date: Thursday, 18 July 2024, 09:00 - 18:00

Friday, 19 July 2024, 09:00 -16:00

Location: APEC Secretariat Office/4th floor Conference Room, 35 Heng Mui Keng Ter, Singapore 119616

***Teleconference Meeting Details (For virtual attendees)**

Day	Virtual Meeting Link
18 July 2024 (Thursday)	Join Teams on your computer, mobile app,or room device **Join the meeting now** Meeting ID: 497 932 701 198 Passcode: N68XuX
19 July 2024 (Friday)	

*Please note that the start and end times for each session are subject to change depending on the pace of meeting discussion.

Introductions and Updates

Item 1 (25 mins)

RHSC Leadership Welcome, Introductions and Updates

Dr. Michelle LIMOLI
US Food and Drug Administration (US FDA), United States

Dr. Naoyuki YASUDA
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Ms. Bazilah ('Baz') Abu BAKER
RHSC Secretariat

Ms Elaine LIN
Interim RHSC Secretariat

Mr. Cesar Bernabe Perez (recorded)
SCSC Chair

Ms. Piang-or WACHARAPRAPAPONG
SCSC Program Director/APEC Secretariat

Item 2 (15 mins)

RHSC Advisor's Office Update

Speaker: Ms. Patty WU
Access Partnerships

Item 3 (10 mins)

AHC Update Report

Speaker: Ms. Jooyoung LEE
APEC Harmonization Centre

Item 4 (10 mins)

RHSC Representatives' Reports

Item 4.1

ICH/IPRP
Speaker: Mr. Hyungok CHUN
APEC Harmonization Centre

Item 4.2

IMDRF
Speaker: Mr Ching-Wei CHANG (Virtual)
Taiwan Food and Drug Administration, Chinese Taipei (TFDA)

Item 5 (10 mins)

WHO Update

Speaker: Ms Christine Guillard
World Health Organization

Priority Work Area Updates

Item 6 (30 mins)

Global Supply Chain Integrity PWA
(Champion: US – FDA)

- PWA Update
- CoE Update: USP
- CoE Update: Taylor's University
- CoE Pilot Application: Rx-360

Item 6.1

PWA Champion
Dr. Leigh VERBOIS
U.S. Food and Drug Administration (US FDA), United States

CoE

Item 6.2

No CoE updates received
Mr. Michael Schmitz (virtual)
United States Pharmacopeia (USP), United States

Item 6.3

No CoE updates received
Taylor's University, Malaysia

Item 6.4

Pilot CoE Proposal: Rx-360
Speaker: Ryan KELLY and Jim FRIES (virtual)

Item 7 (30 mins)

Advanced Therapies and Biotechnological Products PWA
(Champions: US FDA, Singapore – HSA; Sub-Champions: BIO)

- PWA Update
- CoE Update: Northeastern University
- CoE Update: Duke-NUS Medical School (CoRE)
- CoE Update: USP
- CoE Update: Kobe University

Item 7.1

PWA Champion
Mrs. Judith ARCIDIACONO
US Food and Drug Administration (US FDA), United States

CoE

Item 7.2

No CoE updates received
Speaker: Mr. Michael SCHMITZ (virtual)
United States Pharmacopeia (USP), United States

Item 7.3

No CoE updates received
Speaker: Prof. Jared AUCLAIR
Northeastern University (NEU), United States

CoE

Item 7.4

Speaker: Dr. Tomoaki TAKAKURA
Kobe University, Japan

Item 8 (30 mins)

Multi-regional Clinical Trials and Good Clinical Practices Inspection PWA
(Champions: Japan – MHLW/PMDA and Thailand – TFDA)

- PWA Update
- CoE Update: PKU
- CoE Update: PMDA with NCC
- CoE Update: The MRCT Center of Brigham and Women's Hospital and Harvard
- CoE Update: KoNECT

Item 8.1

PWA Champion
Speaker: Ms Rei NAKAGAWA
Ministry of Health, Labour and Welfare, Japan

CoE

Item 8.2

Speaker: Ms Rei NAKAGAWA
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Item 8.3

Speaker: Ms Kelly HAN
Korea National Enterprise for Clinical Trials (KoNECT), Korea

Item 8.4

No CoE updates received
Peking University (PKU), China

Item 8.5

Speaker: Prof. Jared AUCLAIR
On behalf of The MRCT Center of Brigham & Women's Hospital &Harvard, US

Item 9 (45 mins)

Medical Device PWA
(Champions: Korea – MFDS, Japan – MHLW/PMDA and US FDA; Sub-Champions: AdvaMed and JIRA)

- PWA Update
- CoE Update: SCH

- CoE Update: USC
- CoE Update: PMDA
- CoE Update: TFDA
- CoE Update: SCU
- CoE Pilot Application: Malaysia

Item 9.1

PWA Champion
Speaker: Ms. Michelle Noonan
US FDA

CoE

Item 9.2

Speaker: Prof You Kyoung LEE
Soonchunhyang University (SCH) Medical Device Clinical Research Center, Republic of Korea

Item 9.3

No CoE updates received
University of Southern California (USC), United States

Item 9.4

Speaker: Ms. Rei NAKAGAWA
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Item 9.5

Speaker: Mr Ching-Wei CHANG (Virtual)
Taiwan Food and Drug Administration (TFDA), Chinese Taipei

Item 9.6

Speaker: Dr Aijing LU
Sichuan University (SCU), China

Item 9.7

Speaker: Dr. MURALITHARAN Paramasua
CoE Pilot Application: Malaysia

Item 10 (30 mins)

Pharmacovigilance PWA
(Champion: Korea – MFDS)

- PWA Update
- CoE Update: KIDS
- CoE Update: PKU
- CoE Update: PMDA

Item 10.1

PWA Champion
Speaker: Ms Sunim PARK

Ministry of Food and Drug Safety (MFDS), Korea

CoE

Item 10.2

Speaker: Ms E Na Song
Korea Institute of Drug Safety and Risk Management (KIDS), Korea

Item 10.3

No CoE updates received
Peking University (PKU), China

Item 10.4

Speaker: Ms. Rei NAKAGAWA
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Item 11 (20 mins)

Good Registration Management PWA

(Champions: Chinese Taipei – TFDA and Japan – MHLW/PMDA)

- PWA Update
- CoE Update: TFDA

Item11.1

PWA Champion

Speaker: Mr Kuo-Teng HUNG
Taiwan Food and Drug Administration, Chinese Taipei (TFDA)

CoE

Item11.2

Speaker: Mr Kuo-Teng HUNG
Taiwan Food and Drug Administration, Chinese Taipei (TFDA)

Coalition Reports

Item 12 (60 mins)

CoE Coalition Report

(Chair: NEU and CoRE; Vice-Chair: USP)

Speaker: Prof. Jared Auclair
Northeastern University (NEU), United States

Speaker: Assoc. Prof. Silke Vogel
Centre of Regulatory Excellence (CoRE), Singapore

Strategic Discussions

Item 13(60 mins)

RHSC Discussion and Endorsement:

- **Review Revised Operating Model**
- **Reassessment of Formal CoEs**
- **New MoUs for all CoEs**

- **Sunsetting of any Current PWAs**

Item 14 (30 mins)
New PWA Proposals

Item 14.1
Pharmaceutical Quality

Speaker: Ms Janet VESSOTSKIE
PhRMA Coalition

Item 14.2
Data Standards

Speaker: Dr Ron FITZMARTIN
US Food and Drug Administration (US FDA), United States

Item 14.3
Orphan Medical Products

Speaker: Mr Eric OBSCHERNING
Access Partnerships, on behalf of Global RD Policy Network

Item 15 (5 mins)
Next Meeting

Item 16 (15 mins)
Any other Business

Item 17 (20 mins)
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 2024

Item	Q1	Q2	Q3	Q4
	• Coordination between GRM PWA CoEs			
Steering/ Program Committee Meeting		• 1st GRM PWA Steering Committee Virtual Meeting (April) • 2nd GRM PWA Steering Committee Virtual Meeting (June)		• 3rd GRM PWA Steering Committee Virtual Meeting (November)
RHSC Meeting			• RHSC Meeting (Singapore, July)	
CoE Workshop			• Thai FDA GRM CoE Workshop (Virtual, August) • TFDA GRM CoE Workshop (Taipei, September)	

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Coordination between GRM CoEs

- In February 2024, TFDA CoE and Thai FDA CoE reached an agreement that the two CoEs will alternate in hosting one in-person workshop and one virtual workshop each year.

	TFDA	Thai FDA
2024	In-Person September 3-5, 2024	Virtual August 23, 2024
2025	Virtual	In-Person

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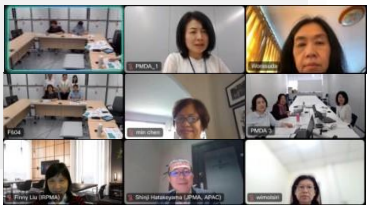
2024 1st Steering Committee Meeting



Date: April 15, 2024

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:

- PWA Co-Champion provided an update regarding the RHSC as a formal body of APEC under SCSC and the coordination between CoEs in hosting annual workshops.
- TFDA presented draft agenda and timeline for preparing a 3-day workshop scheduled for September 3 to 5 in Taipei.
- Thai FDA presented draft agenda and timeline for preparing a 1-day virtual workshop scheduled for August 23.

Outcomes:

- The Committee encouraged exchange of outcomes from the workshops hosted by the two CoEs.

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5

2024 2nd Steering Committee Meeting

Date: June 17, 2024

GRM PWA Steering Committee Members:

- TFDA, MHLW, PMDA, Thai FDA
- APAC, IRPMA
- Subject Matter Experts
- USC DK Kim International Center for Regulatory Science

Discussion Topics

- Review and Discuss the GRM PWA Roadmap
- TFDA and Thai FDA each provide a CoE update in workshop preparation

Outcomes

- The Committee supported the proposal to include promoting reliance to the strategic goal of this PWA and suggested an appropriate measurement must be developed to monitor its progress. The Core Curriculum, Library of Standards & Guidelines, and KPIs were updated accordingly.
- The Committee supported the proposal to include Regulatory Competency Framework from WHO and RAPS as examples in the Core Curriculum.

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6

Upcoming PWA activities in 2024

August 23th

- Thai FDA GRM CoE Virtual Workshop

September 3rd-5th

- TFDA 2024 APEC GRM CoE Workshop
- For more details, please refer to https://www.apecgrmcoe.tw/2024CoE/

November

- 2024 APEC GRM PWA Steering Committee Meeting
- Objective: Review of 2024 Outcomes and Plan for 2025

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7

Thank you for your attention.

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

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TFDA (Chinese Taipei) & MHLW/PMDA (Japan)

Good Registration Management (GRM) - CoE Update

Ms. Chia-Wei Ting
Associate Technical Specialist, Division of Medicinal Products,
Taiwan Food and Drug Administration (TFDA)
Ministry of Health and Welfare (MOHW)

July 18-19, 2024

GRM Workshop Hosts & Organizers

2024 GRM CoE Workshop

Host
- Taiwan Food and Drug Administration (TFDA)

Co-Organizer
- APEC RHSC
- MHLW
- PMDA
- APAC

Participating Organizations
- EMA
- CDE
- IRPMA

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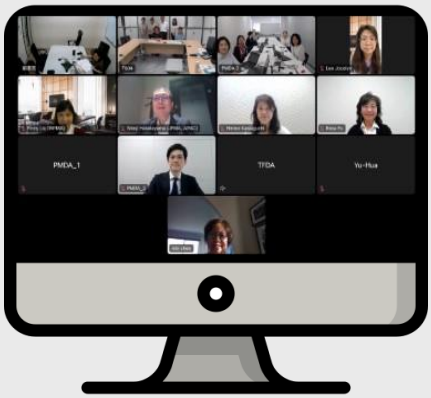
Planning the Workshop

Convene GRM CoE Program Committee Meeting on April 15, 2024



1. **Discussion on the 2024 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**

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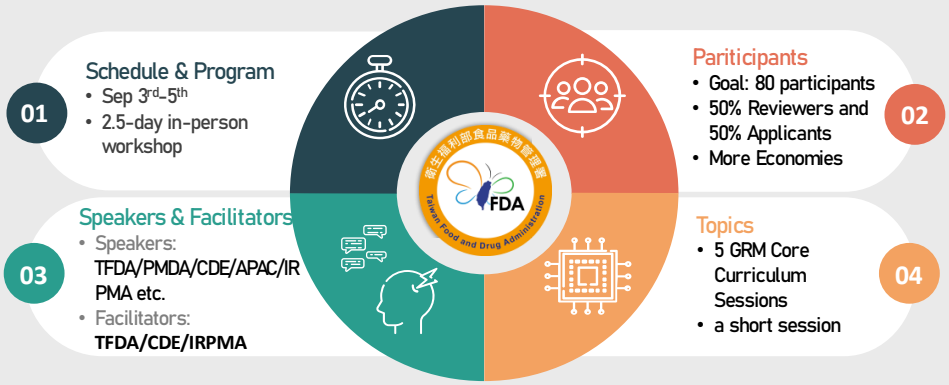
3

Outline of the Upcoming Workshop



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4

Workshop Program (1/3)

- 2024.09.03 (Day 1)

Guided Reading (Video, Free Participation)
- Introduction of GRM
- Video
- Free Participation
- TFDA

Opening Remarks
- TFDA
- PMDA
- APAC

Session 1: Critical thinking and regulatory decision-making
- Benefit-Risk Assessment in Regulatory Decision-Making for Market Authorization of Medicinal
- Regulatory/Academic/EMA/PMDA/Industry
- Lectures/Panel Discussion

Session 2: Communication
- Communication of benefit and risk for pre-market approval and post-market surveillance
- Regulators' Aspects/Industry Aspects(APAC)

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5

Workshop Program (2/3)

- 2024.09.04 (Day 2)

Session 3: **Status of Implementation of GRM in the Economies**
- Representatives from 3 economies

Session 4: Planning of Application
- Planning for a successful submission to expedite early approval
- How to develop a good Generic registration plan?
- Lectures/ Group Discussion/Group Presentation
- IRPMA

Session 5: Preparation of Application Dossier
- Think about preparing your current and future applications
- Standard process of application dossier preparation
- Support tools
- Lectures/ Group Discussion/Group Presentation
- APAC

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6

Workshop Program (3/3)

- 2024.09.05 (Day 3)

Session 6: Conducting the Review in Regenerative Medicine

- Regulatory Updates for Regenerative Medicine in Taiwan/Japan.
- GRevP of Quality part regarding CMC/Clinical consideration
- PMDA/TFDA/Industry

Closing Remarks

- Certificate Award Ceremony
- Closing Remarks

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CoE Plan for 2025

- TFDA plans to host 2025 APEC GRM CoE Virtual Workshop.
- CoE Program Committee meetings will be convened to plan this workshop.

Photo caption:

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8

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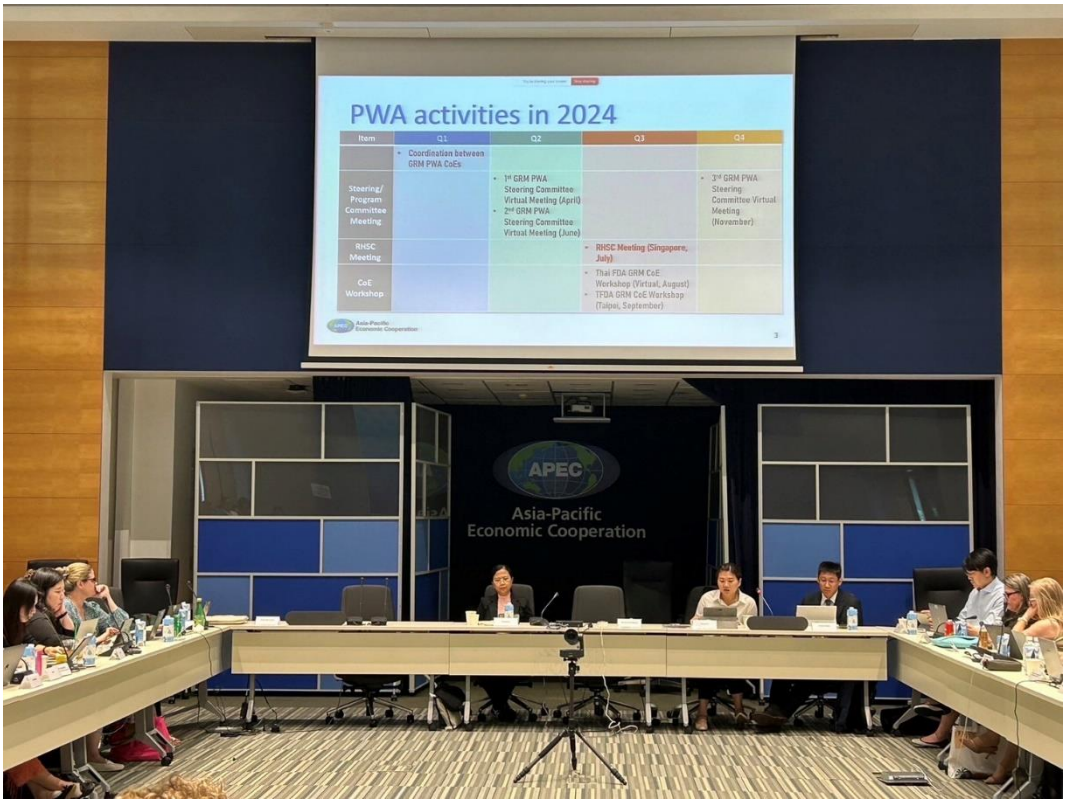
附錄四、RHSC 會議剪影及與會人員合照



附錄五、DIA 新加坡年會議程

AGENDA | July 16, 2024 | Day 1 | ALL TIMINGS IN SGT

8.00 – 8.30 am	Registration
8.30 – 8.45 am	**Opening Remarks**
8.45 am – 10.15 am	**Plenary Session -** **Senior Regulator's Perspectives : What Should the Future Regulatory Ecosystem Look Like?** In this session, senior regulators will provide an update on their current regulatory system, initiatives and plan to reflect the changing regulatory landscape. They will also share their thoughts and challenges on hot topics, such as - reliance and working toward regulatory convergence - adopting digital technologies, such as DCT, RWD/RWE, eCTD and e-labeling In the Plenary Panel Discussion, Regulators, Patient and Industry Representative will discuss and make recommendations on new ways of working to ensure that the regulatory system is efficient, sustainable and fit-for-purpose to enable faster approval of innovative healthcare products, as well as what should be considered regarding regulatory agility, alignment and harmonisation.
Session Chairs	**Finny Liu, MSc, RPh** APAC Regional Regulatory Policy Lead Roche, Singapore **Martin Lim, MBA** Co-Founder and CEO ONWARD Health Research, Singapore
8.45 – 9.15 am	PMDA's vision in New(Fifth) Mid-term Targets
	Yuriko Takemura Coordinator, Division of Asia II, Office of International Programs, PMDA JAPAN
9.15 – 9.45 am	The recent regulatory updates on MFDS,Korea
	Heesung Kim, PhD, Director of Biologics Division National Institute of Food and Drug Safety Evaluation (NIFDS), Ministry of Food and Drug Safety (MFDS)
9.45 – 10.15 am	Regulatory System of Medicine in Indonesia
	Tri Asti Isnariani, MPharm, Director of Drug, Narcotics, Psychotropics, Precursors and Addictive Substances Standardization, Badan Pengawas Obat dan Makanan (BPOM)
10.15 – 10.45 am	Tea / Coffee Break
10.45 – 11.45 am	**Panel Discussion + Q&A**
	Moderator : **John C W Lim,** Duke-NUS Medical School Panellists: **Yuriko Takemura,** PMDA **Heesung Kim**, MFDS **Tri Asti Isnariani**, BPOM Industry representatives : **Wassim Nashabeh, Ph.D** Pharma Technical Regulatory Genentech Patient advocacy: **Nidhi Swarup,** Founding Chair, Alliance of Patients' Organisations Singapore
11.45 – 12.45 pm	**Lunch & Network**
12.45 – 1.35 pm	**Innovation Hub**
12.45 – 1.00 pm	Revolutionizing CTD with LLMs: One-Click Translation and Writing
	Xing Li, Msc, Founder, DEEP INTELLIGENT PHARMA (SG) PRIVATE LIMITED
1.00 – 1.15 pm	Fast-track clinical trials with leading generative AI-powered digital
	Alice Hsu, MHS, MS, SVP of Clinical Technology Services & Consulting, Alphalife Sciences
1.15 – 1.25 pm	**Introduction of DIA Asia Meeting 2024**
	Yil-Seob Lee, MD, PhD, Chairperson for DIA Asia Meeting 2024

1.45 – 5.30 pm	**Session 1.** **Accelerating and Streamlining Regulatory Processes**
	The recent pandemic highlighted an extraordinary global collaboration among regulators. Utilizing digital tools, establishing new regulatory pathways, and implementing regulatory agility have significantly accelerated and streamlined approval processes for the benefits of patients. In this session, we will provide an update and reflect on various recent innovative regulatory initiatives and pilots, such as reliance, collaborative, and expedited programs. Industry experts will share their experiences and best practices through insightful case studies. The panel discussion with regulators will offer perspectives and explore the potential evolution of these initiatives in the future.

Session Chairs

Helene Sou, MSc, RAC Global Regulatory Policy and Innovation, Takeda Pharmaceutical Company Limited, Singapore	**Sannie S Foong Chong, Ph.D.** Senior Director, Global Regulatory Policy MSD International, Singapore	**Thean Soo Lo, BPharm, MSc** Regulatory Affairs Management Consultant, TS Consultung, Singapore

1.45 – 1.55 pm	**Introduction** - Overview of Ways to Accelerate and Streamline Regulatory Processes
	Helene Sou, MSc, RAC Global Regulatory Policy and Innovation, Takeda Pharmaceutical Company Limited, Singapore

Session 1a Focus on New Product Registration

Session Chairs

Helene Sou, MSc, RAC Global Regulatory Policy and Innovation, Takeda Pharmaceutical Company Limited, Singapore	**Thean Soo Lo, BPharm, MSc** Regulatory Affairs Management Consultant, Singapore

1.55 – 2.10 pm	Industry sharing : Hybrid ACCESS/ORBIS type C pathway: 1st industry experience, process, benefits and considerations
	Mi-Young Park, Senior Regulatory Affairs Director, Growth and Emerging Markets, Takeda
2.10 – 2.25 pm	Industry sharing : ASEAN Country Specific Requirements for New Product Registrations: Challenges and Opportunities to streamline and achieve faster registrations
	Edana Loke, Director, Regulatory Policy and Intelligence, Australia, China, Japan, and Asia (JAPAC), Abbvie
2.25 – 2.55 pm	Regulator's sharing : SRA's documents/tools and support to enable or facilitate reliance pathways
2.25 – 2.40 pm	**Paul Huleatt**, Indo-Pacific Regulatory Strengthening Program International Regulatory Branch | TGA
2.40 – 2.55 pm	**Yuriko Takemura** Coordinator, Division of Asia II, Office of International Programs, PMDA JAPAN
2.55 – 3.20 pm	**Panel Discussion + Q&A**
	Moderator : **Helene Sou,** Takeda Panellists : Regulators - **Yee Hoo LOOI**, HSA | **Paul Huleatt**, TGA | **Yuriko Takemura,** PMDA Industry - **Mi-Young Park,**Takeda | **Edana Loke**, Abbvie
3.20 – 3.45 pm	Tea / Coffee Break

Session 1b focus on Post-Approval Changes

Session Chairs

Sannie S Foong Chong, Ph.D. Senior Director, Global Regulatory Policy MSD International, Singapore	**Helene Sou, MSc, RAC** Global Regulatory Policy and Innovation, Takeda Pharmaceutical Company Limited, Singapore

3.45 – 4.00 pm	Industry sharing : Ignite the Future - Our Exciting PAC Reliance Journey with 48 NRAs
	Suat Gnoh Por, International Regulatory, Roche
4.00 – 4.15 pm	Industry sharing : ASEAN Country specific requirements for post-approval changes: current challenges and what can be streamlined/ harmonized to achieve more efficiency in regulatory processes for PACs.
	Sia Lee Yoong, PhD, Global Regulatory Policy and Intelligence, GlaxoSmithKline Singapore Pte. Ltd

4.15 – 4.30 pm	Regulator's sharing : Recent and Ongoing Improvements and Streamlining of Regulatory Processes for PACs: Philippines , Thailand
	MA. THERESA PIA C. YAP, Registration Section, Licensing and Registration Division (LRD), Center for Drug Regulation and Research (CDRR), FDA Philippines
4.30 – 4.45 pm	Regulator's sharing : Thai FDA : MA and Post Approval Changes Update
	Morakot Papassiripan, ATMPs and biological product subdivision, the Medicine Regulation Division of Thai FDA
4.45 - 5.15 pm	**Panel Discussion + Q&A**
	Moderator : **Sannie Chong,** MSD Panellists : **Suat Gnoh Por**, Roche, **Sia Lee Yoong,** GSK, **Jeffrey Schnack, MBA**, Accumulus Synergy Regulators : **Mei-Ling Chan, PhD**, Taiwan FDA, **MA. THERESA PIA C. YAP**, PFDA, **Paul Huleatt**, TGA
5.15 – 5.20 pm	Closing Remarks & Day 1 End

AGENDA | July 17, 2024 | Day 2 | ALL TIMINGS IN SGT

8.30 am – 1.00 pm	**Session 2. (Parallel Session)** **Drug Development and Innovation in Clinical Research.**

Transformative approaches to drug development have the potential to improve efficiency in R&D, bringing new therapies and innovations to market earlier as well as provide better prediction and outcome of patient response. In this session, industry speakers will delve into the use of innovative approaches in drug development, the potential of radiopharmaceuticals in oncology trials, advances in liquid biopsy technology, integration of real-world evidence and the impact of patients' voice in accelerating drug development. Finally, in our dynamic healthcare ecosystem, patient involvement and engagement are no longer optional, they are essential drivers of safer, more effective care. We will explore how patients are at the heart of this transformative journey.

2a Session Chairs

Audrey Ooi, MSc
Head- Business Development
Clinical Research Malaysia, Malaysia

Vicky Han
Senior Director, Head of Regulatory Policy for Asia Pacific,
Johnson & Johnson Pte. Ltd.

2b Session Chairs

Senthil Sockalingam
Head of Medical Affairs, APAC, BeiGene

Ellyne Setiawan, MPharm
Head of Research & Development Quality (Asia Pacific),
Daiichi Sankyo Singapore Pte. Ltd.

	Session 2a
8.30 – 8.50 am	Innovations in the conduct of early phase clinical trials
	Aaron Tan, Medical Oncologist, National Cancer Centre Singapore
8.50 – 9.10 am	Opportunities and Challenges in Radioligand Therapy Trials
	HV Bimba, Senior Clinical Research Medical Advisor Global Drug Development, Novartis Singapore Pte. Ltd.
9.10 – 9.30 am	Revolutionizing Oncology Drug Development with Circulating Tumor Cells-Derived Organoids from Solid Tumors
	Shian-Jiun Shih, CEO and co-founder, Cellentia, Inc.
9.30 – 9.50 am	The use of Real-World Data (RWD) in accelerating development of an indication
	Susan Song, Director, Real World Evidence Growth, Parexel, Singapore,
	Session 2b
9.50 – 10.30 am	Tea / Coffee Break
10.30 – 11.00 am	Patient's voice in the clinical journey
	Nidhi Swarup, Founding Chair, Alliance of Patients' Organisations Singapore
11.00 – 11.30 am	Patient's access to clinical trials: What we can do differently?
	Kate Lawrey, Director and Head of APAC Patient Recruitment, IQVIA RDS East Asia, Singapore
11.30 – 12.00 pm	Clinical trials without borders: Patient Concierge and other modalities
	Siew Lee Goh, Director, Patient Recruitment and Retention Management, Syneos Health
12.00 – 1.00 pm	**Lunch & Network**

8.30 am – 1.00 pm	**Session 3. (Parallel Session)** **New Regulatory Fields and Trends**

Regulatory Affairs has always been an exciting and evolving field, exacerbated with rapid advances in technology. In this session, we will start with exploring AI products regulatory frameworks. Through insightful case studies, we will uncover the intersection of innovation and regulation, offering valuable insights for navigating this dynamic terrain. Then, we will dive into a cloud web-based dossier technology and its fascinating impact on expediting regulatory approval processes in an era where time is of the essence. Next, we will look at creative regulatory pathways and unique strategies employed in Hong Kong and the Greater Bay Area. By embracing unconventional approaches, these regions have carved out distinctive regulatory landscapes, fostering innovation and driving economic growth. Next, we will delve into the regulatory environment for longevity products. Longevity products hold immense promise for improving health and well-being. Our discussions will shed light on the unique challenges and opportunities and essential regulatory considerations for responsibly bringing these transformative products to market. Finally, we will discuss the flexible and innovative regulatory approaches applied in continuous manufacturing of drug substances and products as outlined in the latest ICH Q13. Embracing continuous manufacturing offers unprecedented opportunities for enhancing efficiency, reducing costs, and ensuring product quality.

Session Chairs

Jack Wong
Founder, Asia Regulatory Professionals Association (ARPA), Singapore

Finny Liu, MSc, RPh
APAC Regional Regulatory Policy Lead
Roche, Singapore

8.30 – 8.55 am	Regulatory framework for AI products
	Kwan Ling TAN , Senior Regulatory Specialist, Medical Devices Cluster, HSA
8.55 – 9.20 am	Industry case study: AI in Action : Real-World Regulation
	Greg Michels, CEO, PV.app
9.20 – 9.45 am	Accumulus Synergy & Regulatory Innovation in the Cloud: What Does this Mean for Asia?
	Jeffrey Schnack, MBA Accumulus Synergy, Regulatory Policy Lead - Japan & Asia
9.45 – 10.30 am	Tea / Coffee Break
10.30 – 11.00 am	Hong-Kong and Greater Bay Area (GBA) Innovative Regulatory Pathway
	Jack Wong, Founder, Asia Regulatory Professionals Association (ARPA), Singapore
11.00 – 11.30 am	Longevity Regulatory: how to regulate anti-aging health supplements?
	Christine Yuan HUANG, MD, PhD, Co-founder, Asia Longevity Professionals Association (ALPA)
11.30 – 12.00 noon	Continuous Manufacturing Overview, Current Regulatory Landscape and Future Considerations
	Kai Yin Po, Associate Principle Scientist, Regulatory Affairs, MSD
12.00 – 1.00 pm	**Lunch & Network**

1.00 – 2.30 pm	**Session 4.** **ASEAN Townhall : What is the Influence of Emerging Regulatory Strategies and Trends on the Surveillance of Medicines after They Have Been Approved?**

The ASEAN Town Hall is a key session of DIA Singapore that brings together ASEAN regulators and important industry players such as Clinical Research, Regulatory and Pharmacovigilance professionals. The ASEAN townhall serves as a valuable platform for discussing the current "hot topics" in the evolving regulatory landscape with a key area of focus on addressing operational issues and policy barriers that impact the healthcare sector in the ASEAN region. This collaborative approach is crucial for enhancing the overall quality and accessibility of healthcare services for our patients in need.

This year, the dialogue will revolve around how the current changes or trends in the regulatory landscape (such as risk-based reviews, RWD, use of digital tools etc.) not only bring opportunities for an accelerated development and/or approval timeline for a medicine but also may have an impact on the post-approval monitoring, and pharmacovigilance approaches. We will hear perspectives from ASEAN regulators as well as industry experts.

Session Chairs

Thean Soo Lo, BPharm, MSc
Regulatory Affairs Management Consultant,
TS Consulting, Singapore

Helene Sou, MSc, RAC
Global Regulatory Policy and Innovation,
Takeda Pharmaceutical Company Limited, Singapore

1.00 – 1.20 pm	A comprehensive approach to the Benefit-Risk Assessment of new drugs throughout its lifecycle
	Muzzaffar Halli, Senior Manager RA/PV, South East Asia, Novo Nordisk
1.20 – 1.40 pm	The Transformative Impact of AI and the Social Media in Post-Marketing Surveillance
	Asmaa Asim, MBA, RA/PV Lead, South, East & Southeast Asia, Organon Asia
1.40 – 2.00 pm	A New Era of Pharmacovigilance – Learnings and Opportunities (Singapore's Perspective)
	Sreemanee DORAJOO, **BSc(Pharm) Hons, PhD**, Senior Data Analyst, HSA
2.00 – 2.30 pm	**Panel Discussion + Q&A**
	Moderators : **Thean Soo Lo, BPharm, MSc,** TS Consulting, **Helene Sou, MSc, RAC,** Takeda Panellists : **Sreemanee DORAJOO**, **BSc(Pharm) Hons, PhD**, HSA **Morakot Papassiripan**, Thai FDA **MA. THERESA PIA C. YAP**, PFDA **Tri Asti Isnariani** , BPOM **Asmaa Asim, MBA,** Organon Asia **Muzzaffar Halli**, Novo Nordisk

2.30 – 3.30 pm	APEC Regulatory Harmonization Steering Committee (RHSC) Special Feature: Advancing Regulatory Convergence

Session Chairs

Sannie S Foong Chong, Ph.D.
Senior Director, Global Regulatory Policy
MSD International, Singapore

Kum Cheun Wong, PharmD
Head Asia Pacific Regulatory & Development Policy,
Novartis Asia Pacific Pharmaceuticals Pte. Ltd., Singapore

2.30 - 2.35	Welcome and Introductions
	Sannie Chong, MSD **& Kum Chuen Wong,** Novartis
2.35 - 2.45	Overview of the RHSC
	Michelle Limoli, USFDA
2.45 - 2.50	MRCT/GCP
	Naoyuki Yasuda, PMDA
2.50 - 2.55	Global Supply Chain Integrity
	Leigh Verbois, USFDA
2.55 - 3.00	Good Registration Management
	Kuo-Teng Hung, TFDA
3.00 - 3.05	Biotherapeutics and Advanced Therapies
	Judith Arcidiacono, USFDA

3.05 - 3.10	Update on APEC RHSC Pharmacovigilance Status
	Sunim Park, MFDS
3.10 - 3.15	RHSC Centers of Excellence Overview & Operations
	Jared Auclair, Associate Teaching Professor, Chemistry & Chemical Biology Northeastern University
3.15 - 3.25	Q&A
3.25 - 3.30	Concluding Remarks & Adjourn
	Chairs
3.30 – 4.00 pm	Tea / Coffee Break
4.00 – 5.30 pm	**Session 5.** **Clinical Research Regulations : Critical Aspects that Impacts Clinical Research Practices**
	Dive deep into the intricacies of ICH E6 R3 at the final session of DIA Singapore, where we dissect the updated guidelines with precision, focusing on the critical aspects that impacts clinical research practices. Explore strategies for navigating regulatory landscapes, ensuring compliance, and optimizing clinical research practices. Gain invaluable insights into how the highest standards of quality are maintained through the evolving role of technology and its advances.
Session Chairs	**Senthil Sockalingam** Head of Medical Affairs, APAC, BeiGene **Ellyne Setiawan, MPharm** Head of Research & Development Quality (Asia Pacific), Daiichi Sankyo Singapore Pte. Ltd.
4.00 – 4.20 pm	ICH E6 R3 Data Governance: Moving the needle to the next level of data stewardship.
	Peter Twomey, Head of Inspections, Quality and Safty Medicines Department, EMA
4.20 – 4.40 pm	ICH E6 R3 DCT – A Clinical Trial Odyssey.
	Cathy Dove, Director Quality and Risk Management, Dove Quality Solutions
4.40 – 5.00 pm	Regulatory landscape of Decentralised Clinical Trials in Asia Pacific
	Sandy Chan, Associate Director Global Regulatory Policy & Intelligence, Johnson & Johnson
5.00 – 5.15 pm	**Panel Discussion + Q&A**
	Moderators : **Senthil Sockalingam**, APAC, BeiGene, **Ellyne Setiawan, MPharm,** Daiichi Sankyo Singapore Panellists : **Rosemarie Corrigan**, Worldwide Clinical Trials **Peter Twomey**, EMA **Cathy Dove**, Dove Quality Solutions **Sandy Chan**, Johnson & Johnson **Xing Li, Msc,** Deep Intelligent Pharma **Sharon Chen,** Alphalife Sciences
5.15 – 5.30 pm	Closing Remarks and Conference end

附錄六、食藥署於 DIA 新加坡年會中報告「Good Registration Management」投影片

2024 Singapore Annual Meeting

"Cultivating Synergies in Clinical Research
and the Regulatory Environment to innovate healthcare"

July 16-17, 2024 | Voco Orchard Road, Singapore

Session 4:

APEC Regulatory Harmonization Steering Committee (RHSC) Special Feature: Advancing Regulatory Convergence

- Good Registration Management

Kuo-Teng Hung, TFDA

DIA

Outline

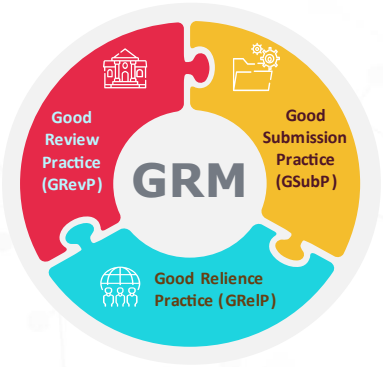
DIA

 | Page 2

Basic Concept of GoodRegistrationManagement(GRM)

Concept

A concept to promote efficient registration process for medicinal products by promoting **Good Review Practice (GRevP) , Good Submission Practice (GSubP) and GoodReliencePractice (GReIP).**



Goal

a) Enhance mutual trust for **regulatory convergence** among APEC economies.
b) Benefit the patients with timely access to high -quality, safe and effective medical products.

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Achievement of APEC Roadmap to promote GRM

STEP 1 (2011-2012)
Gap Analysis Survey for Setting the Foundation for Stepwise GRevP Implementation

STEP 2 (2011-2016)
Planned Solution to Address Gap in GRM

STEP 3 (2017-2019)
Assessing the Impact of GRM

STEP 4 (2017-2019)
Reaching the goal for implementing GRM

2011 2012 2014 2016 2017 2018 2019 2020

GRevP was endorsed as PWA, championed by TFDA

GsubP was endorsed as PWA

2016
GRM Roadmap was endorsed, co championed by TFDA and MHLW/PMDA

2017
TFDA/RAPS Taiwan Chapter became formal CoE, hosting annual training

2020
- **Conduct/Analyze GRM & GSubP KPI Survey**
- **Thai FDA became the second formal GRM CoE**

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Update of the Training Activities

2016-2023 Training Programs by TFDA

- **7 GRM CoE workshops :** 1 pilot + 6 formal workshops
- **509 participants:** 213 reviewers + 296 applicants
- **107 international experts:** i.e., experts from TFDA, PMDA, EMA, CDE, IRPMA, APAC, US FDA, Health Canada, TGA, Australian Department of Health and Aged Care, Danish Medicines Agency, BfArM, MHRA, etc

DIA

Objectives of 2024 APEC GRMGRM CoE Workshop

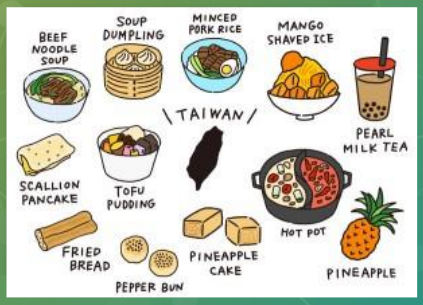
WELCOME!

Date: September 3-5th Venue: Taipei, Taiwan

	September 3rd (TUE)	September 4th (WED)	September 5th (THU)
Morning	• Introduction of GRM (Video) • Opening Remarks • Session 1: Critical thinking and regulatory decision - making	• Session 3: Status of Implementation of GRM in the Economies • Session 4: Planning of Application	• Session 6: Conducting the Review in Regenerative Medicine • Certificate Award Ceremony • Closing Remarks
Afternoon	• Session 1 (continue) • Session 2: Communication	• Session 5 : Think about preparing your current and future applications • Special Thanks	

DIA

- Extended enrollment until 31th July .
- Reigster & more details: https://www.apecgrmcoe.tw/2024CoE/



Questions?

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