出國報告（出國類別：參加國際會議）

2019 年 APEC SOM3 生命科學創新論壇(LSIF)會議報告

服務機關：衛生福利部食品藥物管理署

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派赴國家：智利 (Chile)

出國期間：108 年 8 月 11 日至 8 月 25 日

報告日期：108 年 11 月 11 日

摘要

衛生福利部食品藥物管理署(以下簡稱食藥署)代表我國長期參與亞太經濟合作(APEC)生命科學創新論壇(LSIF)，並出席每年 APEC 第一次資深官員會議(SOM1)及第三次資深官員會議(SOM3)期間召開的 LSIF 相關會議。2019 年 SOM3 期間的相關會議於 108 年 8 月 14 日至 21 日間於智利巴拉斯港召開，食藥署出席法規 LSIF 協和指導委員會會議、LSIF 規劃小組會議、LSIF 法規協和政策對話會議、LSIF 執行委員會會議及衛生與經濟高階會議，於本次會議向 RHSC 報告我國本署主導推動優良查驗登記管理(GRM) 之最新成果、9 月辦理 APEC GRM 法規科學訓練卓越中心研討會之議程規劃及 10 月辦理 APEC 醫療器材法規科學訓練卓越中心先期研討會之議程規劃，並由吳秀梅署長代表本署於法規協和政策對話會議演講，宣揚本署近年於促進法規協和的努力、對 APEC LSIF 的貢獻及本署的法規協和願景。本署代表於會中與各經濟體代表於工作計畫討論有密切良好的互動，提案及演講皆獲各國代表的支持及肯定，成果豐碩。

關鍵詞：亞太經濟合作，生命科學創新論壇，法規協和指導委員會，優良查驗登記管理，醫療器材，法規科學訓練卓越中心，LSIF 規劃小組，法規協和政策對話，LSIF 執行委員會，衛生與經濟高階會議

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壹、目的

本次出席 APEC 生命科學創新論壇(LSIF)於智利巴拉斯港召開的會議，有下列主要目的：

一、食藥署與日本 MHLW/PMDA 於 RHSC 共同主導「推動優良查驗登記管理」，於本次會議報告工作成果。

二、食藥署將於 108 年 9 月舉辦優良查驗登記管理法規科學訓練卓越中心研討會，於本次 RHSC 會議報告議程規劃。

三、食藥署代表 APEC RHSC 參加國際醫療器材主管機關論壇(IMDRF) 108 年 3 月於莫斯科召開之 IMDRF-15 會議，於會中報告 IMDRF-15 會議成果。

四、食藥署將於 108 年 10 月舉辦 APEC 醫療器材先期法規科學訓練中心研討會，於本次 RHSC 會議報告議程規劃，並尋求 RHSC 認可。

五、食藥署吳秀梅署長受邀於法規協和政策對話會議演講，宣揚本署近年於促進法規協和的努力，回顧本署對 APEC LSIF 的貢獻，並闡述本署的法規協和願景。

貳、行程安排

行程一：王兆儀研究員

時間	行程
8 月 11 至 12 日	自桃園機場搭機飛往智利巴拉斯港
8 月 13 日	抵達智利巴拉斯港
8 月 14 日	出席醫療器材會前會及卓越中心(CoE)主管會前會 會議地點：Enjoy Puerto Varas
8 月 15 日	出席 LSIF Life Science Innovation Forum - Regulatory Harmonization Steering Committee (RHSC) Meeting 會議地點：Enjoy Puerto Varas
8 月 16 日	資料整理
8 月 17 至 19 日	自智利巴拉斯港搭機返台
8 月 20 日	返抵桃園機場

行程二：黃玫甄科長、林賢一高級審查員

時間	行程
8 月 11 至 12 日	自桃園機場搭機飛往智利巴拉斯港
8 月 13 日	抵達智利巴拉斯港
8 月 14 日	出席Good Registration Management (GRM)會前會及卓越中心(CoE)主管會前會 會議地點：Enjoy Puerto Varas
8 月 15 日	出席 LSIF Life Science Innovation Forum - Regulatory Harmonization Steering Committee (RHSC) Meeting 會議地點：Enjoy Puerto Varas
8 月 16 日	資料整理
8 月 17 日	出席LSIF Planning Group Meeting & Policy Support

	會議地點：Enjoy Puerto Varas
8 月 18 日	出席 LSIF Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence 會議地點：Enjoy Puerto Varas
8 月 19 至 21 日	自智利巴拉斯港搭機返台
8 月 22 日	返抵桃園機場

行程三：吳秀梅署長

時間	行程
8 月 16 日	自桃園機場搭機飛往智利巴拉斯港
8 月 17 日	抵達智利巴拉斯港
8 月 18 日	出席 LSIF Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence 會議地點：Enjoy Puerto Varas
8 月 19 日	出席 LSIF Life Science Innovation Forum – Executive Board Meeting 會議地點：Enjoy Puerto Varas
8 月 20 至 21 日	出席 HLM 9th APEC High-Level Meeting on Health & the Economy - "Healthy Economies in an Aging World" 會議地點：Enjoy Puerto Varas
8 月 22 至 24 日	自智利巴拉斯港搭機返台
8 月 25 日	返抵桃園機場

參、會議內容

一、背景說明：

APEC 是亞太地區最大的經貿合作平台，目前有 21 個會員經濟體，我國以中華台北(Chinese Taipei)的名義參與，屬正式會員。APEC 於 2002 年成立生命科學創新論壇(Life Science Innovation Forum，簡稱 LSIF)，屬產官學界三方參與的平台，目的為開創對生命科學創新有利的政策環境。

LSIF 有鑑於法規協和對生命科學創新的重要性，於 2009 年成立法規協和指導委員會(Regulatory Harmonization Steering Committee，簡稱 RHSC)，其目標為促進 APEC 區域的醫藥品法規協和(regulatory convergence)。目前 RHSC 共同主席為美國 FDA Dr. Michelle Limoli 及日本 PMDA Dr. Nobumasa Nakashima，副主席為中國 Dr. Li He (中國藥學會副秘書長)，RHSC 現推動 Good Registration Management、Multi-regional Clinical Trials and Good Clinical Practices Inspection、Biotherapeutic Products、Global Supply Chain Integrity、Advanced Therapies、Pharmacovigilance 及 Medical Devices 等 7 個優先工作領域(Priority Work Area，簡稱 PWA)，由不同 APEC 會員經濟體的醫藥品主管機關主導推動，每個 PWA 下有經 RHSC 認可的 APEC 法規科學訓練卓越中心(Center of Excellence，簡稱 CoE)負責辦理人員培訓，期望藉由培訓、交流及合作達成 RHSC 推動 2020 年區域法規協和之任務。RHSC 於每年 APEC 第一次資深官員會議(簡稱 SOM1)及第三次資深官員會議(簡稱 SOM3)期間各召開一次會議，檢視各 PWA 及 CoE 的工作進展，PWA 主辦經濟體及 CoE 清單如附件 1。食藥署為 RHSC 的創始成員，自 2011 年起於 RHSC 主導優良審查規範路徑圖，2014 年起與日本製藥工業協會(JPMA)合作推動優良送審規範，RHSC 於 2016 年認可將「優良審查規範」及「優良送審規範」合併為「優良查驗登記管理」(Good Registration Management，簡稱 GRM)，我國及日本成為該優先工作領域的共同主辦經濟體。為推動 GRM 的法規科學教育訓練，食藥署及 RAPS 台灣分會於 2016 年完成先期研討會後，於 2017 年聯名申請並獲 RHSC 正式認可為「APEC 優良查驗登記管理法規科學訓練卓越中心」，並與 APEC LSIF 完成合作備忘錄的簽署，自此每年在台辦理 GRM 培訓活動，以促進 APEC 經濟體醫藥品優良送件及優良審查的落實及接軌。食藥署另於 2019 年 3 月獲認可為「APEC 醫療器材先期法規科學訓練卓越中心」，於本次會議報告 10 月在台辦理先期研討會的議程規劃，尋求 RHSC 對議程規劃的認可。除 GRM 及醫療器材外，食藥署亦積極參與其他 PWA 所辦理的活動，包括受邀參加指導委員會、擔任講師及參加培訓活動。

LSIF 於每年 SOM1 及 SOM3 各召開一次規劃小組(Planning Group)會議，由美國衛生與公共服務部的 Ms Erika Elvander 擔任主席，協調 LSIF 各項工作，討論議題包括研究開發(Research & Development)、法規協和指導委員會(RHSC)及衛生政策與創新(Health Policy & Innovation)等三大領域，RHSC 共同主席於規劃小組會議提報 RHSC 會議成果。LSIF 另於每年 SOM3 召開執行理事會會議(LSIF - Executive Board Meeting)，目前由我國衛生福利部陳時中部長擔任主席。

LSIF 於本次會議召開政策對話會議(Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence)，邀請藥品和醫療器材主管機關首長及來自業界和學術界的代表，共同思考 APEC 在法規協和方面的十年進展，展望下一輪區域願景，並探討法規體系及法規協和如何促進生命科學發展革新。食藥署吳秀梅署長受邀於法規協和政策對話會議演講，宣揚本署近年於促進法規協和的努力，回顧本署對 APEC LSIF 的貢獻，並闡述本署的法規協和願景。

LSIF 於每年 SOM3 與衛生工作小組(Health Working Group)合作辦理衛生與經濟高階論壇(APEC High-Level Meeting on Health & the Economy)，今年是第 9 屆，大會主題是老化世界中的健康經濟。衛生福利部陳時中部長受邀於會中擔任與談人，分享我國對「在 APEC 體現數位化未來以支持健康老齡化」議題之觀點。

二、Life Sciences Innovation Forum - Regulatory Harmonization Steering Committee (LSIF-RHSC) Meeting (8 月 14 至 15 日)

(一)RHSC 會前會(8 月 14 日)

1. APEC 優良查驗登記管理優先工作領域預備會議(GRM PWA Prep Meeting)

食藥署與日本 MHLW/PMDA 共同主導推動「優良查驗登記管理路徑圖」，8 月 14 日上午與日本代表討論：(1)「優良查驗登記管理」路徑圖及法規科學訓練卓越中心(CoE)成果簡報、(2)路徑圖評估指標問卷、(3)食藥署 9 月在台北辦理的法規科學訓練卓越中心研討會議程及(4)泰國(Thai) FDA 10 月在曼谷辦理的先期研討會議程。台日雙方就本次 RHSC 報告內容及工作方向達成共識。

2. 醫療器材法規科學訓練卓越中心會前會

食藥署代表於 8 月 14 日下午與日本 PMDA 醫療器材優先工作領域之主導經濟體代表及副主導 Japan Medical Imaging and Radiological Systems Industry Association (JIRA)代表開會，討論 10 月將於台灣召開之醫療器材先期 CoE 研討會的執行細節。

3. 卓越中心主管會前會(CoE Directors Pre-meeting)

本會議由法規科學訓練卓越中心(CoE)聯盟主席美國東北大學(Northeastern University) Dr. Jared Auclair 主持，討論各 CoE 在執行訓練與行政方面的問題，並將結論提供給 RHSC，於 RHSC 會議上討論與說明，討論議題如下：

(1) CoE operating model 更新，將於 RHSC 會議中說明，之後將尋求 RHSC 的認可，更新內容包括：

- 格式與文字的酌修。
- 移除較適於放在 RHSC terms of reference 文件的描述，例如如何成為優先工作領域的主導經濟體。
- 先期 CoE 與正式 CoE 的申請需要 RHSC 的認可，課程設計可與課程委員會討論，並在 RHSC 會議上報告或通知 RHSC，不需再尋求 RHSC 認可。
- CoE 主管會議將由 CoE 聯盟主導。

(2) 法規科學卓越中心的成效評估方式尚未訂定，希望各 CoE 可提供建議，包含由誰來執行及該怎麼執行等，評估方式不要太過複雜，另也須包含各

CoE 的經費來源，確認 CoE 的經營無虞，預計可以在明年 SOM1 或 SOM3 RHSC 會議上討論。

(3) 各 CoE 若有需要討論之事項可於會前提供給聯盟主席，且如果 CoE 的聯繫窗口或負責人有更動，請主動告知。

(4) CoE 成員及 RHSC 主席的其他建議：

- 學術機構辦理 CoE 需要 RHSC 提供更有效的招生協助。
- RHSC 主席建議可再精簡 pilot CoE 之申請表。
- PMDA 代表建議訂定 CoE 聯盟主席的資格及輪值年限。

(二) RHSC 會議(8 月 15 日，議程及會議記錄如附件 2)

1. LSIF 秘書處報告

LSIF 秘書處向 RHSC 報告今年 SOM3 舉辦的兩場活動，包含 8 月 18 日舉辦的 APEC LSIF 政策對話(LSIF Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence)及 8 月 20 至 21 日舉辦的第九屆衛生與經濟高階會議(9th APEC High Level Meeting on Health & the Economy)。8 月 18 日活動邀請各國藥品及醫療器材的主管機關首長、APEC LSIF 成員及鄰近國家阿根廷、巴西及哥倫比亞代表參加，回顧 RHSC 過去 10 年成果，討論 RHSC 未來的願景，並於會後成立工作小組撰寫 RHSC 2030 願景，預定於今年 11 月完成草案後蒐集意見，於明年 SOM1 在 RHSC 會議討論，並於 LSIF 規劃小組會議報告。

2. APEC Harmonization Center (AHC)報告

(1) AHC 自 2009 年起已協辦 41 場研討會及訓練活動，參加總人數為 9,500 人，計邀請 353 位講師。2019 年 APEC SOM3 將舉辦 1 場 APEC LSIF 政策對話，下半年也將舉辦 1 場 Biotherapeutics workshop 及協辦 2 場 pilot CoE 訓練，包括 Taylor's University 主辦的 Supply Chain CoE 先期研討會及 Thai FDA 主辦的 GRM CoE 先期研討會。

(2) 線上學習中心：AHC 報告提供 ICH 指引線上培訓課程的時程規劃，2019 年 5 月提供: ICH Q1A – E (Stability Test)課程，預計 2019 年第 4 季提供 ICH S2, S3, S7 (Safety Guideline)課程。

(3) 法規研究報告：執行 APEC 21 個會員經濟體的藥品管理框架研究，目前已於官網(www.apec-ahc.org)公告 21 個經濟體的藥品許可系統報告，預計 2019 年第三季公告 International Organizations (ASEAN, EAC, PANDRH) 和 Latin America (Brazil, Argentina, Ecuador)之報告，供使用者參考。已完成 2008 年至 2019 年的在關鍵績效指標(KPI)報告，預計將開始設計 2020 關鍵績效指標問卷調查。

(4) APEC LSIF 政策對話：為慶祝 AHC 成立十週年，於 8 月 18 日假智利巴拉斯港(Puerto Varas)舉辦 APEC LSIF 政策對話，回顧這十年 APEC LSIF 在法規協和上的成果以及對下個十年的展望，邀請各藥品與醫療器材法規主管機關、APEC LSIF 會員、產業界與學界代表一同參與。

(5) 2020 計畫申請：需要 AHC 支持其 pilot CoE 或 pre-CoE 活動之單位，需於 10 月 31 日前在 AHC 網站上報名，11 月將召開電話會議討論。

(6) 優先工作領域績效指標(Performance Indicator)：協助各優先工作領域訂定合適的的績效指標，期望可達到加強可追溯性，加強其準確性與可靠性及減少重複工作，目前各優先工作領域的進度如表一。

表一、各優先工作領域訂定績效指標現況

Priority Work Areas (PWAs)	Champion Economy	Status of PI Development
Biotherapeutics	Korea (MFDS)	Completed
Pharmacovigilance (PV)	Korea (MFDS)	Completed
Advanced Therapies	Singapore (HSA)	Under Discussion
Supply Chain Integrity	United States (US FDA)	N/A
Good Registration Management (GRM)	GRevP – Chinese Taipei (TFDA) GSubP – Japan (MHLW/PMDA)	Completed
Multi-regional Clinical Trials and Good Clinical Practice Inspection (MRCT-GCP)	MRCT – Japan (MHLW/PMDA) GCP – Thailand (Thai FDA)	Completed
Medical Device	United States (US FDA) Korea (MFDS) Japan (MHLW/PMDA)	Under Discussion * MDV PI Completed

3. RHSC 代表報告 – ICH/IPRP

AHC 代表 RHSC 參加 ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use)與 IPRP (International Pharmaceutical Regulators Forum，IPRP)，於本次會議上報告今年 6 月 ICH 與 IPRP 的會議成果。

4. RHSC 代表報告 – IMDRF

食藥署代表 RHSC 參加 IMDRF 論壇，負責於 IMDRF 論壇上報告 RHSC 醫療器材優先工作領域之進度及攜回 IMDRF 論壇於今年 3 月在莫斯科舉辦本年度第一次會議的最新進度，由食藥署代表於本次會議上報告，包含邀請之國際組織、觀察員組織及各工作小組的最新進度、邀請觀察員國的醫療器材法規介紹及新文件的公告等，今年 IMDRF 的輪職國為俄羅斯，明年為新加坡，食藥署簡報如附件 3。

5. RHSC 秘書處報告

RHSC 秘書處報告 RHSC 網頁建置進度，已於今年 7 月 29 日上線，裡面包含最近一次會議的最新資訊，另也包含 RHSC leadership、參與的經濟體主管機關、各優先工作領域資訊、正式 CoE 與先期 CoE 及其課程、RHSC 秘書處及 CoE 主管的聯繫方式等。

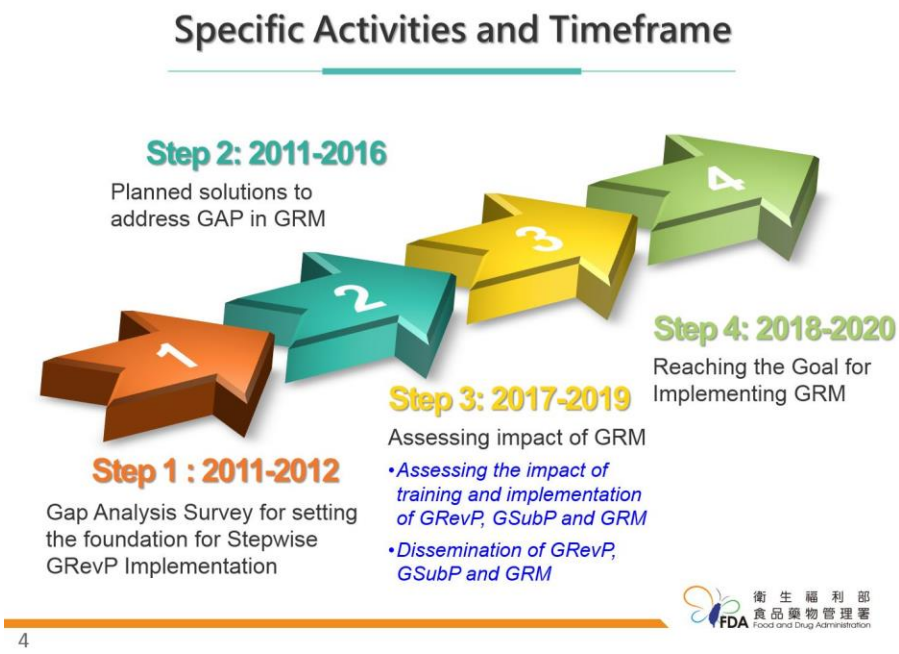
6. Good Registration Management Roadmap (Chinese Taipei – TFDA and Japan – PMDA)

優良查驗登記管理的共同主辦經濟體是中華台北及日本，並由食藥署及日本 MHLW/PMDA 共同負責，目前正式的法規科學訓練卓越中心為我國食藥署及 RAPS 台灣分會(TFDA/RAPS)，先期法規科學訓練卓越中心為泰國 FDA。

食藥署於會中提出 PWA Update (附件 4)及 CoE Update (附件 5)等二項工作簡報，優良查驗登記管理路徑圖(roadmap)的活動及時程如圖一所示，目前進行路徑圖的第三階段評估 GRM 的影響及第四階段達到實施 GRM 的目標，工作重點包括路徑圖績效評估及 GRM CoE 培訓課程及各階段的成果。由於 GRM 的目標之一是希望學員回國後成為種子學員並推廣 GRM，因此

本次會議食藥署報告已在各經濟體當地舉辦的小型 GRM 工作坊情形，另外也報告績效評估問卷內容、問卷對象及未來 GRM 活動實行時程。在問卷方面，GRevP 問卷及 GSubP 問卷已繳交 RHSC，RHSC 建議縮短 GRevP 問卷後委託 AHC 對 21 個 APEC 經濟體的藥品主管機關執行問卷調查，另同意 JPMA 對製藥業執行 GSubP 問卷調查。食藥署代表報告 9 月於台北舉辦 CoE 研討會之規劃，另為泰國 FDA 宣讀 10 月於曼谷舉辦先期 CoE 研討會之課程規劃摘要，獲 RHSC 認可。

圖一、優良查驗登記管理路徑圖



7. Multi-regional Clinical Trials and Good Clinical Practices Inspection Roadmap (Japan – MHLW/PMDA and Thailand – Thai FDA)

多區域臨床試驗及優良臨床規範稽查的共同主辦經濟體是日本及泰國，並由日本 MHLW/PMDA 及泰國 FDA 共同負責，目前正式的法規科學訓練卓越中心有 4 個機構，分別為中國北京大學、日本 PMDA、新加坡 Duke-NUS 醫學院 CoRE 及美國 MRCT Center of Brigham and Women's Hospital and Harvard，先期法規科學訓練卓越中心為韓國 KoNECT (Korea National Enterprise for Clinical Trial)。

這次會議中，日本 MHLW 報告該路徑圖成果，各卓越中心則分別報告訓練活動成果。該路徑圖目前正進行第四階段（2017-2020）：實現目標的培訓-進一步法規協和之建議。報告重點包括：(1)各正式 CoE 訓練舉辦時間；(2)介紹韓國 pilot CoE – KoNECT 及進度更新，韓國 KoNECT 於 SOM1 與 SOM3 期間獲得 RHSC 認可及(3)核心課綱的改進：包括 ICH E17 之訓練教材開發(影音與簡報)。日本 PMDA 已於 1 月完成今年度 CoE 訓練，預計明年 1 月再度進行 CoE 訓練；北京大學將於 9 月進行 CoE 訓練；美國 MRCT Center of Brigham and Women's Hospital and Harvard 在 2 月於加拿大進行 CoE 訓練及新加坡的 Duke-NUS 醫學院已於 7 月進行 CoE 訓練。

8. Biotechnological Products Roadmap (Korea – MFDS)

生物技術產品的主辦經濟體是韓國，並由韓國食品藥物安全部(Ministry of Food and Drug Safety, 以下簡稱 MFDS)負責，目前正式的法規科學訓練卓越中心(CoE)只有美國東北大學(Northeastern University)，試辦的法規科學訓練卓越中心則為新加坡 Duke-NUS 醫學院及日本神戶大學(Kobe University)。

MFDS 報告該路徑圖從 2013 年起至今每個階段目標的相關活動，目前執行路徑圖的第四階段：培訓以實現目標，重點工作項目包括 CoE 的培訓活動及提出提升法規調和的建議。由於該路徑圖是於 2014 年完成，目前正在編輯新版，9 月將召開工作坊進行該工作領域的差異分析以及成效評估。法規科學訓練中心的相關活動有美國東北大學報告 9 月舉辦之 CoE 訓練及日本神戶大學在此次會議報告先期 CoE 申請及進度規畫獲得 RHSC 認可，將於 11 月舉辦先期 CoE 訓練。

9. Global Supply Chain Integrity Roadmap (US FDA)

全球供應鏈完整性的主辦經濟體是美國，並由 U.S. Food and Drug Administration 負責，目前正式的法規科學卓越中心(CoE)有 2 個機構，分別為 United States Pharmacopeia (USP)及 University of Tennessee Health Sciences Center，先期法規科學卓越中心為馬來西亞 Taylor's University。

這次會議中，美國 FDA 報告路徑圖成果，簡報重點包括(1)推廣工具包(圖二)、(2)供應鏈安全性指導委員會工作進度及(3) 2019 年 CoE 培訓活動：USP 於 6 月在智利舉辦訓練，馬來西亞 Taylor's University 將於 9 月舉辦訓練。

圖二、醫藥品供應鏈安全性工具包

10. Advanced Therapies Roadmap Update (Singapore - HSA)

先進醫療產品的主辦經濟體是新加坡，並由新加坡 Health Sciences Authority (HSA)負責，目前試辦的法規科學訓練卓越中心有 2 個機構，分別為新加坡的 Duke-NUS 醫學院及美國的東北大學(Northeastern University)。

這次由 Bio 代新加坡 HSA 報告該優先工作領域的進度，包含路徑圖、

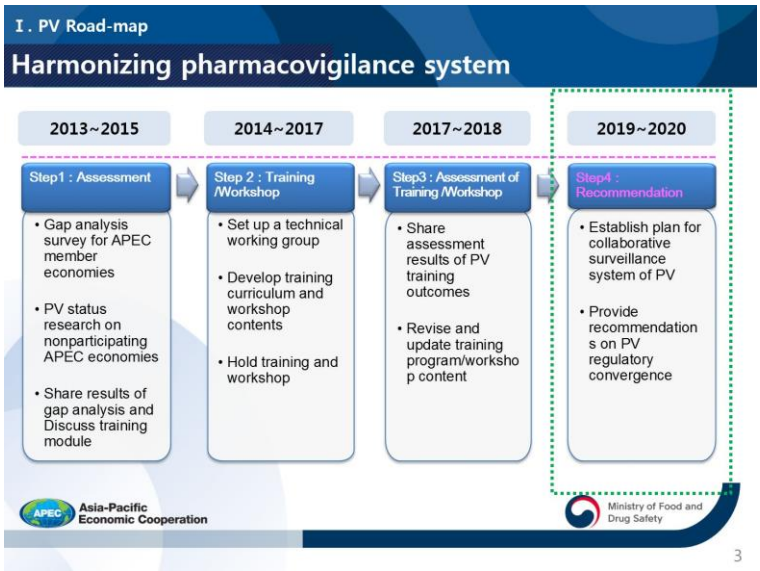
該優先工作領域委員會之成員及說明核心課綱將再增加內容，並介紹全球基因治療發展現況及說明 US、Japan、EU、China 及 UK 在基因治療產品法規規範涵蓋 clinical trials、manufacturing、supply chain、long term follow up、viral vectors、inspections 等，BIO 建議在基因治療的定義與專有名詞、品質、臨床與非臨床方面應及早法規調和，目前有 ICH、WHO、CMRA 及 APEC RHSC 開始訂定相關的指引或法規調和。有關培訓活動，美國的東北大學(Northeastern University)已於 7 月在韓國與 AHC 合辦 CoE 訓練，Duke-NUS Medical School CoRE 這次申請成為正式 CoE，並報告其 2017 及 2018 pilot CoE 的情況，RHSC 認可其申請，Duke-NUS Medical School CoRE 成為正式 CoE。

11. Pharmacovigilance Roadmap (Korea – MFDS)

藥品安全監視的主辦經濟體是韓國，並由韓國 MFDS 負責，目前正式的法規科學訓練卓越中心(CoE)有 2 個機構，分別為日本獨立行政法人醫藥品醫療機器總合機構(Pharmaceuticals and Medical Device Agency，簡稱 PMDA)，及韓國藥物安全與風險管理機構(Korea Institute of Drug Safety and Risk Management，簡稱 KIDS)，先期法規科學訓練卓越中心則為中國的北京大學。

這次會議中，韓國 MFDS 報告的藥品安全監視路徑圖(roadmap)如圖三所示，目前正進行路徑圖的第四階段，藥品安全監視系統的合作及對未來藥品安全監視系統優先工作領域的建議，2017 年已委託韓國成均館大學進行各經濟體藥品安全監視的問卷調查及差異分析(gap analysis)，由差異分析的結果擬訂教育訓練的核心課綱，核心課綱更新加入 ICH E2C、E2D、給藥錯誤通報系統與回饋、藥品流行病學及藥品安全監視查核，此外也更新路徑圖，路徑圖與核心課綱於會上獲得 RHSC 認可。有關 CoE 活動，日本 PMDA 報告於 2 月舉辦 CoE 訓練的成果及預告將於明年 2 月舉辦訓練；北京大學於去年 8 月 SOM3 會議上獲得 RHSC 認可為先期 CoE，今年 4 月舉辦先期 CoE 訓練，於本次會上報告其成效並申請成為正式 CoE，獲得 RHSC 認可；韓國藥品安全與風險管理機構(KIDS)報告其於 2018 年舉辦 CoE 訓練之成果及將於 9 月舉辦訓練。

圖三、藥品安全監視路徑圖



12. Medical Device PWA Update (Korea－MFDS; Japan－MHLW/PMDA; US－FDA)

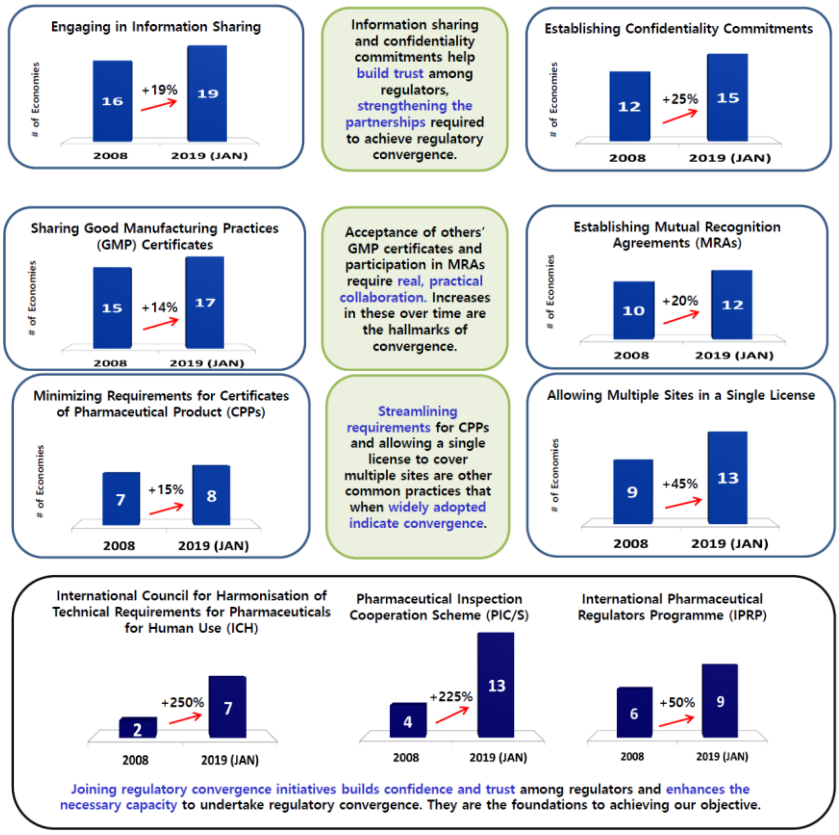
醫療器材的共同主辦經濟體是韓國、日本及美國，並由韓國 MFDS、日本 PMDA 及美國 FDA 共同負責，協辦單位(sub-champion)是日本 JIRA 及美國 Advanced Medical Technology Association (AdvaMed)，目前正式的法規科學訓練卓越中心(CoE)有 2 個機構，分別韓國國家醫療器材安全資訊研究所(National Institute of Medical Device Safety Information，簡稱 NIDS)主辦醫療器材安全監視培訓，美國南加州大學(University of Southern California，簡稱 USC)主辦上市前法規及協和培訓，先期法規科學訓練卓越中心有我國食藥署、日本 PMDA 及美國東北大學。

這次會議中，日本 PMDA 代表主導經濟體，介紹醫療器材優先工作領域路徑圖、路徑圖的發展階段、各 CoE 訓練開展之情況及副主導業界組織需做差異分析；此外，因應 IMDRF 多份指引公告，更新核心課綱內容，同時介紹用來評估優先工作領域成效的關鍵績效指標(KPI)，並於此次會上獲得 RHSC 認可。這次會議上，韓國 NIDS 報告去年 9 月舉辦之先期 CoE 訓練成效評估結果及今年 11 月要舉辦的 CoE 訓練之規劃，會上並申請成為正式 CoE，也獲得 RHSC 認可，因此 11 月是以正式 CoE 身分舉辦訓練；另美國南加大報告今年 4 月舉辦之先期 CoE 訓練成效評估結果，並申請成為正式 CoE，也於會上獲得 RHSC 認可;另日本 PMDA 報告今年 11 月舉辦之先期 CoE 訓練規劃，而我國食藥署於今年三月獲得認可成為先期 CoE 後，工研院醫療器材驗證室即積極協助籌辦 10 月之先期 CoE 訓練，食藥署也於這次會上報告 10 月將舉辦之先期 CoE 規劃，先期 CoE 申請之簡報資料如附件四，會上日本 PMDA 與食藥署之先期 CoE 訓練順利獲得 RHSC 認可;美國東北大學預告明年春天舉辦先期 CoE 訓練，課程尚在規劃中，未尋求認可。中國四川大學於會上報告其欲申請成為先期 CoE，惟尚未正式提出書面申請，將於會後尋求各會員認可，通過後將於 12 月舉辦先期 CoE 訓練，來自中國的 RHSC 副主席何莉，亦代表中國國家藥品監督管理局為其背書，支持其成為醫療器材優先工作領域先期 CoE。

13. RHSC Discussion on Performance Indicators

2008 年 RHSC 成立時，APEC 同意在 LSIF 之下由韓國支持成立 AHC 來協助推動藥品法規調和(regulatory convergence)，2018 年 2 月 RHSC 同意 AHC 開始訂定評估法規調和成效的 KPI，且必須跟 2008 年問卷調查的基線一致，2018 年 8 月 KPI 訂定完成，2019 年 2 月開始在各經濟體調查，2019 年 7 月完成圖表，於此次 SOM3 會議報告結果，結果顯示不管是在訊息交換(information sharing)、保密協定(confidentiality commitments)、承認他國藥品優良製造規範證書(Good Manufacturing Practices (GMP) Certificates)、簽定 MRAs (Mutual Recognition Agreements)、減少藥品上市證明的法規要求(minimizing requirements for certificates of pharmaceutical product (CPPs))及一證刊登多場的普及率都較 2008 年提高 14%到 45%，加入 ICH、PIC/S 及 IPRP 的經濟體也明顯增加很多，顯示這 10 年下來，在 RHSC 及各會員經濟體的努力下達到法規調和，圖表如圖四。

圖四、APEC 法規調和圖表



(3) Life Sciences Innovation Forum (LSIF) - Planning Group Meeting (8 月 17 日，議程如附件 7)

(一)議程包括研究發展、法規協和及衛生政策創新等三大領域。

(二)RHSC 共同主席於會中簡報 RHSC 會議成果，重點如下：

1. RHSC 現階段工作重點為推動在 7 個優先工作領域(PWA)下成立 CoE，提供法規科學培訓以促進法規協和。現階段共有 14 個正式的 CoE（包括食藥署辦理的優良查驗登記管理 CoE)，另有 3 個先期研討會(包括食藥署辦理的醫療器材先期 CoE 研討會)及 2 個先期 CoE 資格於本次會議獲 RHSC 同意。2019 年在 7 個 PWA 下共舉辦 23 場 CoE 及先期 CoE 研討會。
2. 其他會議討論重點包括：關鍵績效指標(KPI)、RHSC 官網上線、CoE 聯盟會議及修訂 CoE 運作模式文件。

(三)LSIF 顧問報告 RHSC 2030 願景規劃之作業時程：

1. 於 8 月 18 日政策對話會議鼓勵與會人員提出建言。
2. 於本年 8 月至 11 月由 LSIF 成立工作小組草擬「RHSC 2030 願景」。
3. 於本年 11 月將草案送交 RHSC 提供意見。
4. 於 2020 SOM-1 會議中討論，並提交 LSIF 規劃。

(四)LSIF 其他議題條列如下：

1. 研究及發展
   - 促進創新生命科學領域的投資（LSIF 顧問報告）
   - APEC 生醫技術產業化中心（泰國報告）

2. 衛生政策及創新
   - 熱帶衛生人力中心（澳洲 James Cook 大學報告）
   - 透過發展卓越中心實踐血液篩檢及處理的集中化（印尼提供白皮書一份）
   - 罕見疾病網絡（澳洲昆士蘭科技大學及智利衛生部）
   - 潛伏性結核
   - 亞太經合組織健康科學研究院（北京大學報告）
   - 第 9 屆衛生與經濟高階論壇（加拿大報告）
   - 創新醫療保健融資（LSIF 顧問報告）
   - 亞太經合組織精神衛生數位中心（加拿大報告）

(4) APEC LSIF Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence "A Decade of Regulatory Convergence in APEC: Learning from the Past, Looking to the Future" (8 月 18 日，議程如附件 8)

本次會議邀請藥品和醫療器材主管機關首長及來自業界和學術界的代表，共同思考 APEC 在法規協和方面的十年進展，並展望未來十年的區域願景。食藥署吳秀梅署長受邀於 Session 1: Keynote Remarks from Regulatory Authorities 演講(簡報如附件 9)，該場次共同主持人是 RHSC 主席 Dr. Michelle Limoli 及 Dr. Nobumasa Nakashima，同場次演講的還有食品及藥物安全部代表、馬來西亞國家藥品管理局首長及菲律賓食品藥物管理局代表。吳署長於本次演講闡述食藥署透過國際合作及法規更新加速法規協和，說明食藥署過去十年積極參與 APEC 法規協和活動之成果，包括在 APEC 推動 GRM、將 GRM 概念植入審查系統、辦理醫療器材先期卓越中心及參與不同 PWA 所辦理的活動等，並針對 APEC 促進未來十年進一步法規協和提出食藥署的觀點。LSIF 於會後認可一份會議報告，如附件 10。

(5) LSIF Life Science Innovation Forum – Executive Board Meeting (8 月 19 日)

由衛生福利部陳時中部長擔任主席，副主席由澳洲 the Victoria Institute of Strategic Economic Studies 的 Bruce Rasmussen、泰國生命科學 CoE 的 Nares Damrongchai 及法國 Latin America Business 的 Jean Jacques 擔任，討論議題包括法規協和、研究與發展、衛生政策與創新(包括醫療融資、全球衛生經濟、心理健康等)。

(6) HLM 9th APEC High-Level Meeting on Health & the Economy - "Healthy Economies in an Aging World" (8 月 20 至 21 日，議程如附件 11)

衛生福利部陳時中部長受邀於會中擔任與談人，分享我國對「在 APEC 體現數位化未來以支持健康老齡化」議題之觀點。衛生工作小組(HWG)及 LSIF 於會後認可一份聯合聲明，如附件 12。

肆、心得及建議事項

一、持續參與 APEC LSIF 法規協和指導委員會(RHSC)，並配合 RHSC 2030 願景規劃優良查驗登記管理 2020 年後的推動方向。

APEC LISF-RHSC 是食藥署在藥品及醫療器材領域能夠積極參與及扮演主導角色，並增進產官學界國際交流的重要法規協和平台。RHSC 採納 ICH、IMDRF 及 WHO 等國際法規協和組織訂定的指引(guidelines)，透過法規科學訓練及交流活動促進區域法規協和(regulatory convergence)，不僅提供本署參與不同國際組織的重要連結，更能夠透過積極參與強化我國於國際醫藥法規領域的能見度及影響力。

RHSC 目前共有 7 個優先工作領域(priority work area)，食藥署長期主辦「APEC 推動優良查驗登記管理(GRM)路徑圖」及「APEC 優良查驗登記管理(GRM)法規科學訓練卓越中心(CoE)」，並完成「APEC 醫療器材法規科學訓練卓越中心先期研討會(CoE Pilot)」，已實質強化我國在 APEC LSIF 扮演的角色。LSIF 及 RHSC 已成立 RHSC 2030 願景工作小組，預定於本(108)年 11 月公開草案給各方提供意見，食藥署也應配合 RHSC 2030 願景規劃優良查驗登記管理 2020 年後的推動方向。本次政策對話邀請產官學界對未來願景提供意見，參加會議所蒐集到的簡報資料及會議報告將作為規劃未來方向的參考。

二、將參與 LSIF 獲得資訊分享給衛生福利部相關單位。

食藥署長期擔任我國 LSIF 工作窗口，但 LSIF 所討論的研究發展及衛生政策與創新議題大多數非本署主政議題，未來將與衛生福利部國際合作組建立更好的橫向聯繫，以利將參與 LSIF 獲得資訊分享給衛生福利部及經濟部相關單位。

三、有系統培育我國醫療器材國際合作人才。

本次會議除了爭取 RHSC 認可食藥署辦理的醫療器材先期 CoE 研討會議程，同時也在會議期間邀請各經濟體派員來台與會，因此積極與各經濟體代表介紹我國舉辦之研討會，並熱情邀請派員參加，也因此更體認醫療器材國際合作人才的重要，故為長期經營與其他國家醫療器材法規單位之聯繫與交流，應有系統培育我國醫療器材國際合作人才。此次，食藥署透過舉辦 APEC 醫療器材先期 CoE 研討會安排同仁擔任講員及助教(facilitator)，未來應持續培訓及辦理相關活動，除可建立各國人脈，亦可強化與其他法規單位的溝通交流並增進台灣醫療器材法規管理於國際社會之能見度。

附件 1、RHSC 各 PWA 主辦經濟體及 CoE 清單

Formal CoE Institutions			
PWAs (Roadmap)	PWA Champion	Institution	Economy
Biotherapeutics	US / BIO (interim)	Northeastern University (NEU)	United States
Pharmacovigilance	Korea	PMDA Asia Training Center (PMDA-ATC)	Japan
		Korea Institute of Drug Safety & Risk Management (KIDS)	Korea
		Peking University (PKU)	China
MRCT-GCP Inspection	Japan / Thailand	Duke-NUS Centre of Regulatory Excellence (Duke-NUS CoRE)	Singapore
		PMDA Asia Training Center (PMDA-ATC)	Japan
		Peking University (PKU)	China
		Harvard Brigham Women's Hospital MRCT Center	United States
Good Registration Management (GRM)	Chinese Taipei / Japan	TFDA & Regulatory Affairs Professionals Society (RAPS) Taiwan	Chinese Taipei
Global Supply Chain Integrity	United States	United States Pharmacopeial Convention (USP)	United States
		University of Tennessee Health Science Center (UTHSC)	United States
Advanced Therapy Products	Singapore	Duke-NUS Centre of Regulatory Excellence (Duke-NUS CoRE)	Singapore
Medical Device	United States/Japan/Korea	National Institute of Medical Device Safety Information (NIDS)	Korea
		University of Southern California	United States

Pilot CoE Institutions			
PWAs (Roadmap)	PWA Champion	Institution	Economy
Medical Device	Korea / United States / Japan	Taiwan Food and Drug Administration	Taiwan
		PMDA Asia Training Center (PMDA-ATC)	Japan
		Sichuan University	China
		Northeastern University (NEU)	United States
MRCP-GCP Inspection	Japan / Thailand	Korea National Enterprise for Clinical Trials (KoNECT)	Korea
Good Registration Management (GRM)	Chinese Taipei / Japan	Thailand Food and Drug Administration	Thailand
Global Supply Chain Integrity	United States	Taylor's University	Malaysia
Advanced Therapies	Singapore	Northeastern University (NEU)	United States
Biotherapeutics	US / BIO (interim)	Kobe University	Japan
		Duke-NUS Centre of Regulatory Excellence (Duke-NUS CoRE)	Singapore

Regulatory Harmonization Steering Committee
APEC
Life Sciences Innovation Forum

APEC RHSC 2019 SOM-3 MEETING AGENDA

15 to 16 August 2019, Puerto Varas, Chile

(FINAL | Version 2 | 22 August 2019)

CoE Directors Meeting | Wednesday, 14 August 2019 **Venue: Enjoy**	
CoE Directors Meeting | 1700 - 1800 (by invitation only: the invitations for this meeting will be sent by the CoE Coalition.)	
RHSC SOM-3 Meeting | Thursday 15 August to Friday 16 August 2019 **Start time on 15 August: 9:30am** **Venue: Enjoy / Osorno A**	**Documents**
1 RHSC Welcome and Introductions	
2 LSIF Secretariat Update Presenter: LSIF Secretariat • LSIF will convene a drafting group to create a draft vision statement on regulatory convergence to 2030. It will be circulated for RHSC review in November 2019 this year and will be discussed in SOM-1 2020.	2.0) Slides_APEC LSIF Update to RHSC at SC
3 AHC Report	
3.1 Update from AHC Presenter: Mr Yeongseok Ko, AHC	3.1) Slides_AHC_Report_0
4 RHSC Representatives' Reports	
4.1 ICH /IPRP Presenter: Mr Yeongseok Ko, AHC	4.1) Slides_AHC_ICH-IPRP

4.2 IMDRF Presenter: Dr Chao-Yi Wang, TFDA, Chinese Taipei	4.2) Slides_IMDRF update (by TFDA for 2
5 RHSC Secretariat Update Presenter: Ms Serene Foo, RHSC Secretariat • RHSC website was launched under the main APEC website; the address is https://www.apec.org/rhsc • All documents and information on this website will be considered public information, i.e not password protected	5.0) Slides_RHSC 2019 SOM-3 RHSC W
6 Good Registration Management Roadmap (Champions: Chinese Taipei – TFDA and Japan – MHLW/PMDA)	6.0-A) 1.1_180809_ APEC RHSC Roadmap 6.0-B) 1.2_Good Registration Manager

6.1 PWA Update
 	
Presenter: Ms Mei-Chen Huang, TFDA, Chinese Taipei
 	
• PWA Champions hosted local Programmes to train the trainers:
  ○ Philippines: March 28 & 29
  ○ Chinese Taipei: June 12 & July 18
  ○ Indonesia: August 28 & 29
  ○ Malaysia: October 1 & 2
• Decision: PWA Champions have drafted a KPI survey for regulatory authorities and a separate survey for industry: The champions will revise the draft for regulators to make questions more concise and will collaborate with the AHC on the circulation to all the 21 member economies. A KPI survey of Good Submission Practices (GSP) by industry will be circulated by the industry coalition to individual companies for completion. Both of these surveys will cover pharmaceutical products only – not to include medical devices.
	6.1-A) Slides_GRM roadmap_PWA updat
	
	6.1-B) 3.1.2_E-GRM survey status_29 Jul.p
	
	6.1-C) 3.1.3_GRevP_Questio
	
	6.1-D) 3.1.4_GSubP Questionnaire_24Jun

6.2 CoE Update: TFDA, Chinese Taipei/RAPS Taiwan Chapter Presenter: Dr Hsien-Yi Lin, TFDA, Chinese Taipei • CoE Workshop to be held by TFDA/RAPS on September 17-19, 2019 in Chinese Taipei	6.2) Slides_4_GRM CoE Update-TFDA anc
6.3 CoE Pilot Update: TFDA, Thailand Presenter: Dr Hsien-Yi Lin (on behalf of) • Decision: CoE Pilot Workshop held by TFDA, Thailand was endorsed; the programme will be held on October 28-30, 2019 in Bangkok, Thailand	6.3-A) Slides_Thailand Prese 6.3-B) agenda pilot CoE in Thailand_revis

7	**Multi-regional Clinical Trials and Good Clinical Practices Inspection Roadmap** (Champions: Japan – MHLW/PMDA and Thailand – TFDA)	7.0-A) MRCT_GCP_Roadmap 7.0-B) GCP core curriculum.pdf 7.0-C) MRCT-GCP Inspection Core Curri

7.1 PWA Update Presenter: Mr Ryo Iwase, MHLW	7.1) Slides_MRCT GCP_PWA Champion_
7.2 CoE Update: The MRCT Center of Brigham and Women's Hospital and Harvard Presenter: Dr Jared Auclair, NEU (on behalf of) • Harvard MRCT Center CoE Training was held on February 26-28, 2019 in Ottawa, Canada (For Regulators only)	7.2) Slides_2019-07-17c M
7.3 CoE Update: Duke-NUS Medical School (CoRE) Presenter: Mr Neo Cherng Yeu • Duke-NUS/CoRE CoE Workshop was held on July 11-12, 2019 in Singapore (Open to Regulators & Industries)	7.3) Slides_RHSC CoE Update_MRCT worksh
7.4 CoE Pilot Update: KoNECT Presenter: Ms Mirinea Kim, MFDS (on behalf of) • Decision: KoNECT Pilot CoE was endorsed Intersessionally; CoE Pilot Workshop by KoNECT was endorsed and will be held from September 16-18, 2019 in Seoul, Korea (Open to Regulators & Industries)	7.4) CoE Pilot Update - KoNECT.pdf
7.5 CoE Update: PKU Presenter: Dr Xiaofang Zhang • PKU will hold a CoE Workshop on November 11-14, 2019 in Beijing, China (For Regulators only)	7.5) Update on PKU APEC Regulatory Scie
8 Biotherapeutic Products Roadmap (Champion: Korea – MFDS)	

8.1 PWA Update Presenter: Ms Mirinea Kim, MFDS (On behalf of)	8.1) 2019 SOM3_Puerto Varas_I
8.2 CoE Update: Northeastern University Presenter: Dr Jared Auclair • NEU held CoE Programme in Chile in March 2019 and will hold a CoE Workshop at NEU on September 16-18, 2019	8.2) Slides_Auclair_Biothe
8.3 Pilot CoE Application: Kobe University Presenter: Dr Ineui Lee • Decision: Kobe University Pilot CoE was endorsed; Kobe University will request to host a Pilot CoE workshop in December 2019	8.3-A) Slides_(Kobe Univ) Pilot_CoE_Appli 8.3-B) (Kobe Univ) Pilot_CoE_Application
9 Global Supply Chain Integrity Roadmap (Champion: US – FDA)	9.0) APEC Roadmap for Supply Chain Secu

9.1 PWA Update Presenter: Dr Michelle Limoli, US FDA • PWA Steering Committee engaged in a review and updating of the Toolkits housed on the AHC Website	9.1) Slides_RHSC SuppCh Feb2019 slid
9.2 CoE Update: USP Presenter: Mr Phillip Nguyen • USP CoE Regulators Dialogue was held in University of Chile on June, 2019	9.2) Slides_USP CoE aug19 update-fin.PN2
9.3 Pilot CoE Update: Taylor's University Presenter: Dr Michelle Limoli, US FDA (on behalf of) • Taylor's University in cooperation with NPRA to host a CoE Pilot on September 25-27, 2019 in Taylor's University, Malaysia	9.3) Slides_Taylor's COE for SOM Chile U
10 Advanced Therapy Products Roadmap Update (Champions: Singapore – HSA)	10.0-A) Advanced therapies-roadmap-Si 10.0-B) Adavnced therapy Roadmap Ste 10.0-C) APEC Advanced Therapy Pr

10.1 PWA update Presenter: Ms Lila Feisee, PWA Co-lead	10.1) Slides_APEC RHSC GT Update logc
10.2 CoE PIlot Update: Northeastern University Presenter: Dr Jared Auclair • NEU held a CoE Pilot Programme in Seoul, Korea on July 30-Aug will and will submit a Formal CoE Application for RHSC consideration intersessionally	10.2) Slides_(revised) Auclair_Adv Therapies
10.3 Formal CoE Application: Duke-NUS Medical School (CoRE) Presenter: Mr Neo Cherng Yeu • Decision: Duke-NUS/CoRE was endorsed as a Formal CoE	10.3-A) Slides_RHSC CoE Update_Full CoE , 10.3-B) (Revised) APEC_RHSC_CoE_forr
11 Pharmacovigilance Roadmap (Champion: Korea – MFDS)	11.0-A) (revised) APEC RHSC_Roadmaj 11.0-B) APEC PV Core curriculum(1907

11.1 PWA Update & Endorsement of Roadmap and Core Curriculum Presenter: Ms SeongEun Moon, MFDS • Decision: PWA Champion updated the Roadmap and Core Curriculum and was endorsed by the RHSC	11.1) Slides_(revised_2) 19(
11.2 CoE Update: KIDS Presenter: Dr SooYoun Chung • KIDS will hold a CoE Programme on September 4-5, 2019 in Seoul, Korea	11.2) Slides_190815_Updat
11.3 CoE Update: PMDA Presenter: Dr Yoshimasa Yokoyama • PMDA held a CoE Programme on February 4-7, 2019 in Tokyo, Japan	11.3) Slides_PhV CoE Update_SOM3_15 Au
11.4 Formal CoE Application: PKU Presenter: Dr Xiaofang Zhang • PKU held a Pilot CoE Programme on April 23-25, 2019 in Beijing, China • Decision: PKU received endorsement as a Formal CoE	11.4-A) Pilot PV Workshop-August Re 11.4-B) APEC_RHSC_CoE_forr 11.4-C) APEC_RHSC_CoE_forr
12 Medical Device PWA Update (Champions: Korea – MFDS, Japan – MHLW/PMDA and US FDA; Sub-Champions: AdvaMed and JIRA)	12.0-A) Medical Device Core Curriculu 12.0-B) Medical Device KPI.pdf 12.0-C) (Revised) RHSC Medical Device

12.1 PWA Update & Endorsement of Core Curriculum and KPIs Presenter: Dr Yoshimasa Yokoyama • Decision: RHSC endorsed the updated Core Curriculum and KPIs	12.1) Slides_190726_Medic
12.2 Formal CoE Application: NIDS Presenter: Mr Manho Ahn • NIDS conducted CoE Pilot Programme on September 13-14, 2018 in Seoul, Korea. • Decision: NIDS was endorsed as a Formal CoE	12.2-A) Slides_APEC CoE_MDV_NIDS_2019 12.2-B) (NIDS)APEC RHSC CoE formal app
12.3 Formal CoE Application: USC Presenter: Prof Frances J. Richmond • USC hosted a Pilot CoE Programme on April 30-May 3, 2019. • Decision: USC was endorsed as a Formal CoE • USC plans to post video recordings of the 2019 Pilot Programme on their website with a link to the RHSC website: other CoEs are encouraged to post any proceedings or video recordings from their programmes, as long as permission by the speaker is obtained	12.3-A) Slides_(revised) APEC 12.3-B) APEC_RHSC_CoE_For 12.3-C) (revised) APEC_RHSC_CoE_For
12.4 CoE Pilot Update: PMDA Presenter: Dr Yoshimasa Yokoyama • Decision: CoE Pilot Workshop by PMDA was endorsed; the workshop will be held on November 25-29, 2019	12.4) Slides_Program Draft Pilot WS _Medic
12.5 CoE Pilot Update: TFDA, Chinese Taipei Presenter: Dr Chao-Yi Wang • Decision: CoE Pilot Workshop by TFDA, Chinese Taipei was endorsed; the workshop will be held October 22-24, 2019	12.5) Slides_APEC RHSC MD PWA_2019
12.6 CoE PIlot Update: Northeastern University Presenter: Dr Jared Auclair	12.6) Slides_Auclair_Medica

12.7 Proposed CoE Pilot: Sichuan University Presenter: Dr Anyu Lee • Sichuan University will request to host a Pilot CoE Workshop in December 2019. They will submit a Pilot CoE Application requesting review by RHSC intersessionally	12.7) Slides_SichuanUniver:
13 CoE Coalition (Chair: NEU and CoRE; Vice-Chair: USP)	
13.1 CoE Coalition Update 1 (Topic: CoE Operating Model and Guidelines) Presenter: Dr Jared Auclair • Decision: Revisions to the Operating Model was reviewed by the CoE Coalition and the current version was endorsed by the RHSC, and will be posted on the RHSC website. Further clarifications one the CoE Coalition Co-Chairs' proposalwill be provided in the next revision before SOM-1 2020 • The CoE Coalition will consider parameters for eventual CoE assessments, now that CoEs have been in existence since 2017: a proposal will be delivered at SOM-1 2020	13.1-A) CoE Operating Model.pdf 13.1-B) CoE Operating Model and
13.2 CoE Coalition Update 2 (Topic: CoE Checklist) Presenter: Dr Jared Auclair	13.2) CoE Checklist_consensus F
14 APEC Secretariat Management Update Presenter: Mr Johnny Lin, APEC Secretariat • RHSC members were encouraged to submit concept notes for APEC funding of project proposals through the LSIF, and by working with APEC economies. • Requirements on having a quorum for fora and sub-fora was not passed in 2018. Any decisions on future quorum requirements will be shared by the APEC Secretariat	14) Slides_Sec_Managem

15 WHO Update Presenter: Dr Samvel Azatyan	15.0-A) WHO update APEC RHSC 15-08-20 15.0-B) Slides_WHO_ActionPl
16 RHSC Discussion on Performance Indicators • AHC presented the results of their KPI survey that will be thoroughly discussed at the APEC Regulatory dialogue on Aug 17, 2019 • A report on the ICH Guideline Implementation Survey will be released and shared with the RHSC later in 2019	
16.1 Key Performance Indicator Report by AHC Presenter: Mr Yeongseok Ko, AHC	16.1) Slides_(revised) AHC Key Performance
16.2 ICH Implementation Survey Project (PhRMA) Presenter: Ms Camille Jackson	
17 Review Decisions and Action Items Lead by RHSC Co-Chairs	
18 Review Plan for February 2020 SOM-1 Meeting Lead by RHSC Co-Chairs • SOM-1: Feb – Putrajaya • SOM-3: Aug – Malacca	
19 Adjourn	

附件 3、IMDRF 論壇簡報資料

Food and Drug Administration, Ministry of Health and Welfare

APEC Third Senior Officials' Meeting (SOM3) and Related Meetings
LSIF Regulatory Harmonization Steering Committee Meeting

4.2 IMDRF Update

Presenter: Taiwan Food and Drug Administration

August 15, 2019
Puerto Varas, Chile

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

http://www.fda.gov.tw/

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IMDRF Members

- Australia
- Brazil
- Canada
- China
- EU
- Japan
- Russia
- Singapore
- Korea
- United States of America

➢ The roles of IMDRF Chair and Secretariat rotate annually:
- 2019 Chair: Russia
  - IMDRF-15 (March 2019)
  - IMDRF-16 (September 2019)
- 2020 Chair: Singapore
- 2021 Chair: Korea

2

IMDRF-15 Meeting Agenda

	March 18	March 19	March 20	March 21
AM	IMDRF/DITTA **Joint Workshop** on "Optimizing Standards for Regulatory Use"	**Open Stakeholder Forum** • Regulatory updates by: ◦ MC members ◦ Working groups (WG)	**MC Meeting** • Open session with: ◦ Invited Observers ◦ Argentina ANMAT ◦ DITTA ◦ GMTA	**MC Meeting** • Closed session on: ◦ WG documents ◦ New Work Item Proposals ◦ New Work Item Extensions ◦ Procedural issues
		Lunch	Lunch	
PM		**Open Stakeholder Forum** • Stakeholder session with: ◦ Official Observer ◦ Regional Harmonization Initiatives (RHIs) ◦ Invited Observers • Special session on "Regulatory Approach for NGS Testing"	**MC Meeting** • Open session on: ◦ Medical device nomenclatures • Closed session on: ◦ WG documents ◦ Matters arising from the Open Stakeholder Forum and the session with invited observers & industry	

3

IMDRF-15 Participants

- ~300 participants (regulators, industry & research community)
- Management Committee (MC) members from 10 jurisdictions
- Official Observer
  - WHO (World Health Organization)
- Regional Harmonization Initiatives
  - **APEC LSIF RHSC**
  - AHWP (Asian Harmonization Working Party)
  - PAHO (Pan American Health Organization)
- Invited Observers
  - Eurasian Economic Commission
  - DITTA (Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association)
  - GMTA (Global Medical Technology Alliance)
  - IMEDA (International Medical Device Manufacturers Association)
  - IAMT (International Association of developers, producers and users of Medical Technique)
  - Saudi Arabia
  - Cuba
  - Republic of Kazakhstan
  - Kyrgyz Republic
  - Argentina (ANMAT)

4

APEC Representation in IMDRF-15

- For 2019, APEC LSIF RHSC representative to IMDRF is Chinese Taipei (represented by Taiwan Food and Drug Administration)
- Presentation of an update on RHSC's Medical Device PWA was given in the Open Stakeholder Forum on March 19:

- 2 Chinese Taipei delegates participated in this meeting at Moscow

5

IMDRF-15 MC Decisions (1/3)

- Guidance documents approved and finalized

Doc. No.	Document Title
N9 (Ed. 3)	Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)
N13 (Ed. 3)	In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)
N27	Assembly and Technical Guide for IMDRF Table of Contents Submissions
N43 (Ed. 3)	Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology structure and codes (Annex A-F)
N48	Unique Device Identification system (UDI system) Application Guide
N52	Principles of Labelling for Medical Devices and IVD Medical Devices

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IMDRF-15 MC Decisions (2/3)

- Information documents approved for web posting

Doc. No.	Document Title
N53	Use of UDI Data Elements across different IMDRF Jurisdictions
N54	System requirements related to use of UDI in healthcare including selected use cases

- Draft documents approved for public consultation

Consultation Item
Personalized Medical Devices – Regulatory Pathways
Proposed update to Clinical Evaluation documents

7

IMDRF-15 MC Decisions (3/3)

- Closed the Unique Device Identification System Working Group
- Approved New Work Item Proposals (NWIP)
  - Review and Update of the GHTF Principles of In-Vitro Diagnostic (IVD) Medical Devices Classification (GHTF/SG1/N45:2008)
  - IMDRF Standard Developing Organizations (SDO) Liaison Program
- Approved changes to IMDRF Standard Operating Procedures
  - NWIP adoption process
  - Updating membership criteria
  - Finalizing a Record of Discussion process and format
- Discussed a document which indicates the implementation of IMDRF documents by member jurisdictions (will be further discussed in IMDRF-16)
- Acknowledged that South Korea (MFDS) volunteered to serve as the 2021 IMDRF Chair (host of IMDRF-19 & IMDRF-20)

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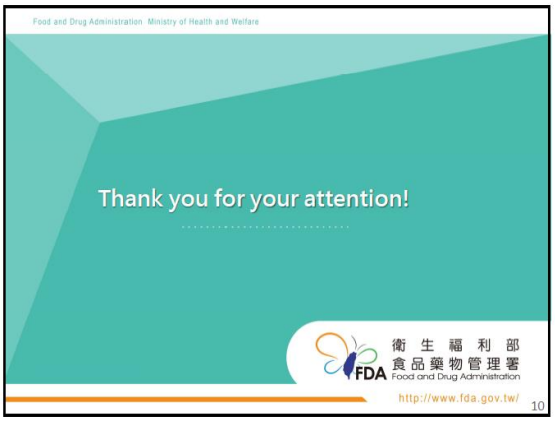
IMDRF-16 Meeting
Yekaterinburg, Russia
Sep. 16-19, 2019
Sep. 16
IMDRF/DITTA Joint Workshop on "Artificial Intelligence in Healthcare"
Sep. 17
Open Stakeholders Forum
Sep. 18 & 19
Management Committee Sessions
Venue: Hyatt Regency Yekaterinburg
Registration: http://www.imdrf2019.ru
9


Food and Drug Administration, Ministry of Health and Welfare
Thank you for your attention!
衛生福利部
食品藥物管理署
Food and Drug Administration
http://www.fda.gov.tw/
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附件 4、優良查驗登記管理優先工作領域成果報告（PWA update）

Food and Drug Administration, Ministry of Health and Welfare

APEC RHSC 2019 SOM-3 MEETING

Good Registration Management Roadmap (TFDA- Chinese Taipei and MHLW/PMDA –Japan)

6.1 PWA Update

Mei-Chen Huang
Division of Medicinal Products
Taiwan Food and Drug Administration
Ministry of Health and Welfare
August 15, 2019

衛生福利部 食品藥物管理署 Food and Drug Administration
http://www.fda.gov.tw/

1

Outlines

- Goal of the GRM roadmap
- Specific Activities and Timeframe
- Milestones of the GRM Roadmap
- CoE and Pilot CoE
- Summary of significant activities since last RHSC meeting
- Plans for future activities with timelines
- Endorsement

2

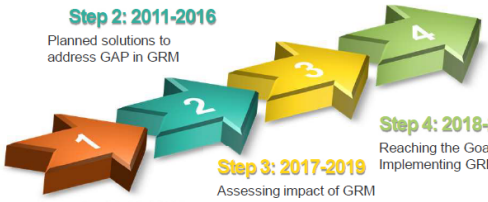
Goal of the GRM roadmap

- **Purpose:** To promote GRevP and GSubP cooperatively
- **Long-term goals:**
  - Promote the concept of GRM
  - Enhance mutual trust for regulatory convergence among APEC member economies by 2020

Good Review Practices (GRevP)	Good Submission Practice (GSubP)
To help achieve timeliness, predictability, consistency, transparency, clarity, efficiency and high quality in the content and management of reviews	To enhance the quality and efficiency of the medical product registration process by improving the quality and management of submission

3

Specific Activities and Timeframe



Step 1 : 2011-2012
Gap Analysis Survey for setting the foundation for Stepwise GRevP Implementation

Step 2: 2011-2016
Planned solutions to address GAP in GRM

Step 3: 2017-2019
Assessing impact of GRM
- *Assessing the impact of training and implementation of GRevP, GSubP and GRM*
- *Dissemination of GRevP, GSubP and GRM*

Step 4: 2018-2020
Reaching the Goal for Implementing GRM

4

Milestones of GRM Roadmap (Step 1)

Step 1	Step 2	Step 3	Step 4
2011-2012	2011-2016	2017-2019	2018-2020
Gap Analysis Survey for setting the foundation for Stepwise GRevP Implementation	Planned solutions to address gaps GRM CoE Pilot	Assessing impact of GRM using Performance indicators (PIs)	Reaching the Goal for Implementing GRM

GRevP PWA endorsed (2011)
GRevP Roadmap endorsed (2013)


2011 APEC GRevP Workshop


2012 APEC GRevP Workshop

Gap analysis of GRevP completed (2012)

Journal publication:
- GRevP gap analysis (2013)
- GRevP workshop report (2015)

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Milestones of GRM Roadmap Step 2

Step 1	Step 2	Step 3	Step 4
2011-2012	2011-2016	2017-2019	2018-2020
Gap Analysis Survey for setting the foundation for Stepwise GRevP Implementation	Planned solutions to address gaps	Assessing impact of GRM using Performance indicators (PIs)	Reaching the Goal for Implementing GRM

GSubP PWA endorsed (2014)
GRM Roadmap endorsed (2016)

Guidelines published
- GRevP (WHO, 2015)
- GSubP (APEC RHSC, 2016)

GRM CoE
- Core curriculum Developed (2016)
- Pilot: TFDA/RAPS TW (2016)

6

Milestones of GRM Roadmap (Step 3-4)

Step 1	Step 2	Step 3	Step 4
2011-2012	2011-2016	2017-2019	2018-2020
Gap Analysis Survey for setting the foundation for Stepwise GRevP Implementation	Planned solutions to address gaps GRM CoE Pilot	Assessing impact of GRM using Performance indicators (PIs)	Reaching the Goal for Implementing GRM

APEC GRM Training Activities

1. TFDA/RAPS (formal CoE)
   - 2016 pilot (Nov 2016, Taipei)
   - 2017 workshop (Oct 2017, Taipei)
   - 2018 workshop (Sep 2018, Taipei)
   - 2019 workshop (Sep 2019, Taipei)
2. COFEPPRIS (pilot)
   - 2017 pilot (Jun 2017, Mexico City)
3. Thai FDA (pilot)
   - 2019 pilot (Oct 2019, Bangkok)
4. Local Training
   - 2017: Singapore, Chinese Taipei
   - 2018: Chinese Taipei, Thailand, Malaysia
   - 2019: Chinese Taipei, Philippines, Indonesia

GRM Steering Committee (2018)

Discussion of KPI, Planning of survey to understand positive impacts and gaps (2018-2019)

Finalize the GRevP and GSubP Questionnaire (2019)

7

CoE and Pilot CoE

CoE Activities in 2019

- **CoE:** TFDA/RAPS Taiwan Chapter will host 2019 GRM CoE Workshop on September 17-19, 2019.
- **Pilot CoE:** Thai FDA was endorsed as a pilot CoE in Feb, 2019 and will host a pilot GRM workshop on October 28-30, 2019.

Name of institution	Topic	
	Good Review Practices	Good Submission Practices
CoE: TFDA/RAPS Taiwan Chapter	✓	✓
Pilot CoE: Thai FDA	✓	✓

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Summary of significant activities since last RHSC meeting

February 2019 – August 2019

1. Conference
   - The 8th APAC meeting in Tokyo (April 9, 2019), RA Session Topics: Good Registration Management-Success of "Train the Trainers"
2. Local training
   - Philippines: March 28 & 29
   - Chinese Taipei: June 12, July 18
   - Indonesia: August 28 & 29
   - Malaysia: October 1 & 2
3. Preparation of GRM CoE or pilot CoE workshop
   - 2019 APEC GRM CoE Workshop in Taipei (Sept 17-19)
   - 2019 GRM CoE Pilot Workshop in Bangkok (Oct 28-30)
4. GRM Roadmap assessment
   - Discussion of GRevP and GSubP questionnaires and the way to conduct survey



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GRM Local Training Activities

Success of Train the Trainers

Economy	Activities	Topics	
		GRevP	GSubP
Chinese Taipei	2017 training (Nov 2017)	V	V
	2018 training (Mar/Aug 2018)		V
	2018 training (Nov 2018)	V	V
	2019 training (June/July 2019)	V	V
Singapore	2017 training (Apr 2017)		V
Thailand	2018 training (June 2018)	V	V
Malaysia	2018 training (July 2018)		V
The Philippines	2019 training (Mar 2019)	V	V
Indonesia	2019 training (August 2019)	V	V

Understanding of concept of GRM& Implementation of GRM

10

Questionnaire for assessing the Impact of GRevP

Survey Items of GRevP Questionnaire
Reviewer Competency and Training • Implementation of technical training programs and soft skills training • Number of training certificates issued for qualified trainers • Intention of holding a GRM/GRevP training program
Implementation of GRevP • Use of templates and procedures • Degree of adherence required for following SOP
The Outcomes of GRM for Regulatory Authorities • Type of information accessible by public online • Involvement of stakeholders • Establish checkpoints and set target timelines for review, and determine how many reviews have met these targets • Adoption of peer review • Establishment of a quality system
The Impact/Gaps of GRM for Regulatory Authorities • Questions to address the impact/gaps of GRM

GRevP Survey Respondents:
Drug regulatory authorities of 21 APEC member economies

Ongoing work: Reduce the length of questionnaire and incorporate one or two GSubP questions to become a GRM questionnaire for regulators

11

Questionnaire for assessing the Impact of GSubP

Survey Items of GSubP Questionnaire
Applicants Competency and Training • Implementation of technical training programs and soft skills training • Number of training certificates issued for qualified trainers • Number of training certificates for applicants
Quality of Submission (potential evaluation item) • Number of major deficiencies/rejection at filing • Number of SOPs and templates available • Degree of adherence to each item of the principles of good submission

GSubP Survey Respondents:
CoE-training participants and APAC associations

Draft questionnaires are available. The way to conduct survey will be discussed at the SOM-3 Meeting.

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Current Status of GSubP questionnaire

- GSubP questionnaire has been finalized after being reviewed by stakeholders, such as APAC RA-EWG member, TFDA and CIRS.
- However, opinion that it should be reduced due to too many questions is received.

- Need discussion of detailed implementation method
  - Should reduce the number of questions??
  - Need to consider target economies
  - Requester (from where)
  - Timing of survey
  - Implementation method

Latest of GSubP questionnaire → Microsoft Word ?

APAC Asia Partnership Conference of Pharmaceutical Associations

GRM survey: GSubP questionnaire

[Target economies in 2019]
- Plan to request to CoE-training participants + APAC member associations in 2019.
- In addition, making a request to the economy where APAC RA-EWG can find the contact information of APEC (except APAC).
  - Reason: APAC RA-EWG does not have the contact of each economy.

[Note]
- Due to support from APAC RA-EWG member, APAC has the contact of APAC member associations plus Mexico, Chile, Peru, US, at this moment.
- No contact of Australia, New Zealand, Canada, Mexico, Russia, Papua New Guinea, Brunei.

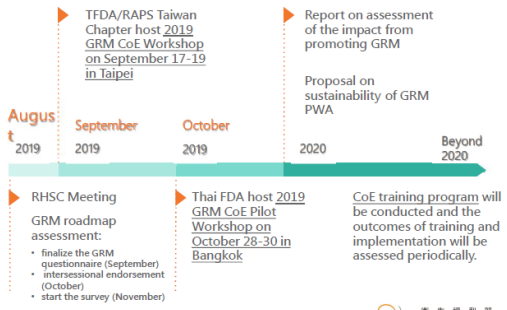
[Requester (from where)]
- Plan to request from APAC RA-EWG at this moment, but would like to confirm if there is another way (such as, from AHC or RHSC)

[Timing of Survey]
- Under discussion

[Implementation method]
- Web questionnaire.

APAC Asia Partnership Conference of Pharmaceutical Associations

Plans for future activities with timelines



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RHSC endorsement requests

Endorsement of the:
- **2019 Good Registration Management (GRM) Regulatory Science CoE Pilot Workshop program**
- **GSubP Questionnaire to focused industries in parallel with GRM Questionnaire to 21 economies in APEC**

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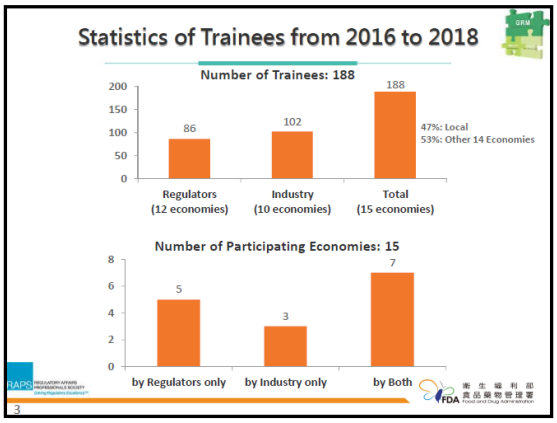
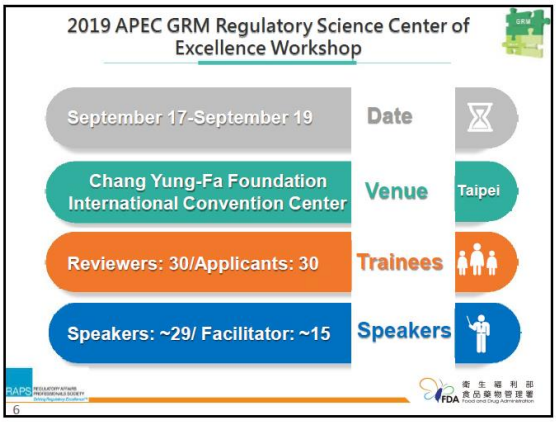
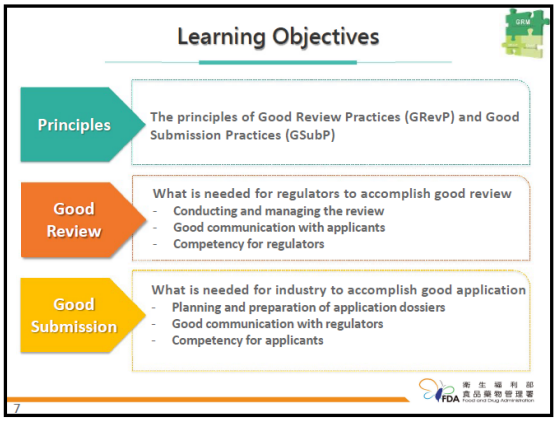
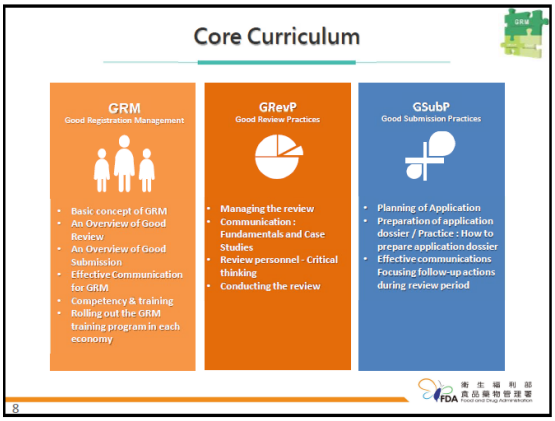
附件 5、優良查驗登記管理法規科學訓練卓越中心成果報告（CoE Update）









Pre-training materials

1. GRM Roadmap
2. GRevP Guidelines (WHO)
   GSubP Guidelines (APEC RHSC)
3. Trainees' Questionnaire for Session 6 Application of the GRM Concept to the Entire Product Life Cycle
4. PowerPoint Presentations for Session 6 Application of the GRM Concept to the Entire Product Life Cycle

9

Program of 2019 APEC GRM CoE Workshop

Application of GRM to the Entire Product Life Cycle

Sep 17	Sep 18	Sep 19
Common Sessions	*Common Sessions*	*Common Sessions*
Keynote Speech • *Product development & Regulatory approval* Introduction of GRM (C1) Topics of Special Interests • *Implementation & KPI*	Managing and Conducting the review (C4)	Application of the GRM Concept to the Entire Product Life Cycle (C6) • *Postmarket Surveillance*
Lunch	Lunch	Lunch
Common Sessions	*Common Sessions*	*Common Sessions*
Planning of Applications (C2) Preparation of Application Dossier/ Practice: How to Prepare Application Dossier (C3)	Critical thinking and regulatory decision making (C5) • *Regulators' perspectives* • *Industry perspectives*	Communications (C7) Competencies and Training for Reviewers and Applicants (C8)

http://www.raps-in-taiwan.org.tw/CoE_2019/2019_CoE_agenda.html

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Food and Drug Administration Ministry of Health and Welfare

GRM

Future plans

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

http://www.fda.gov.tw/

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Future Plans

- Plan to collaborate with interested APEC member economies in organizing local training
- Plan to assess the outcomes of GRM CoE training

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Food and Drug Administration Ministry of Health and Welfare

Thank you for your attention.

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

http://www.fda.gov.tw/

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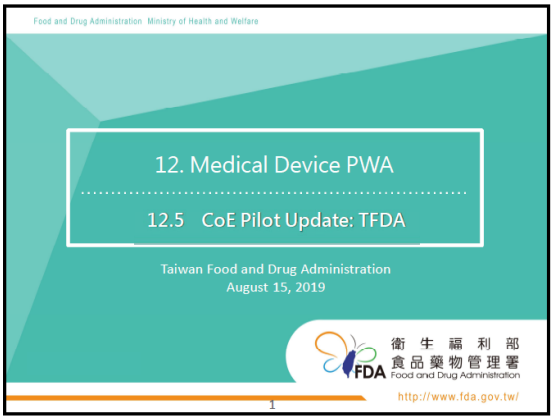
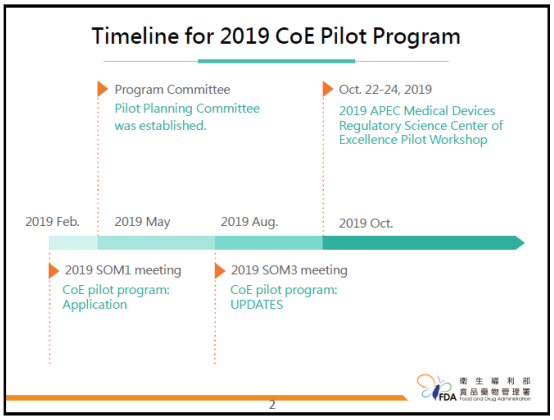
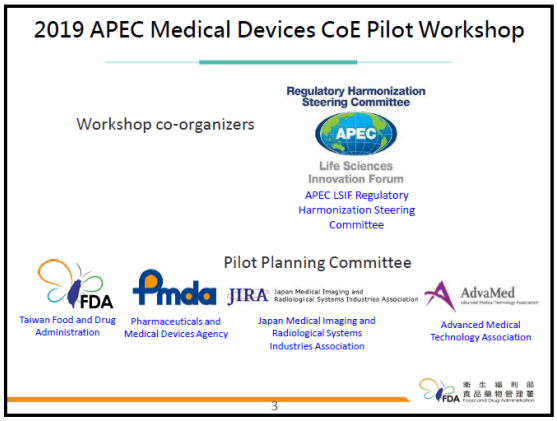
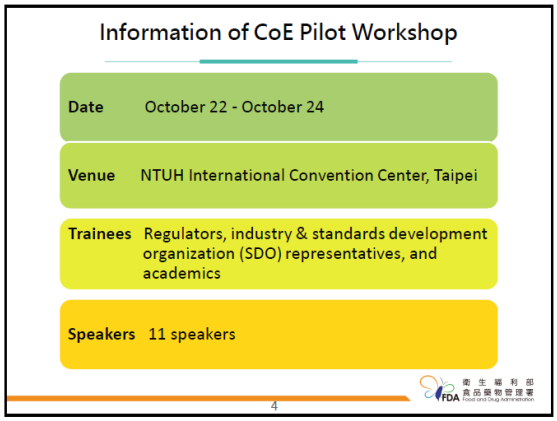
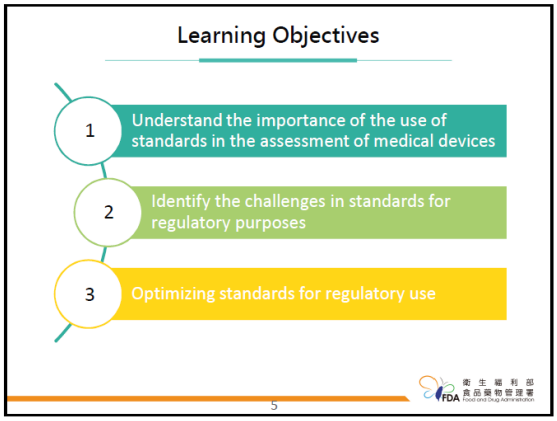
附件 6、醫療器材先期 CoE 進度報告簡報資料

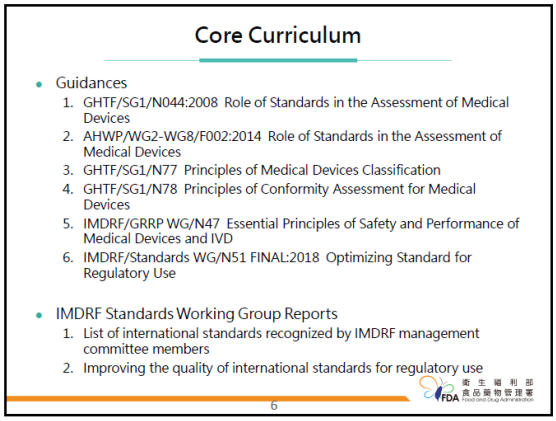


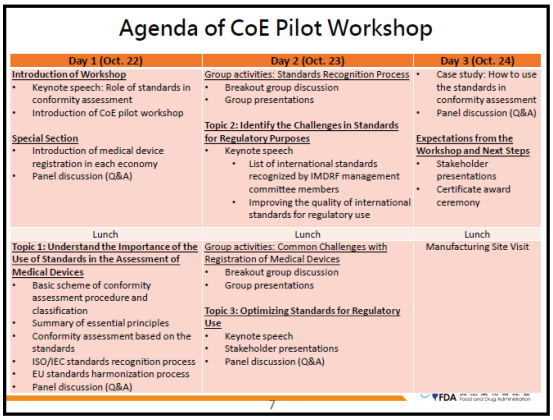


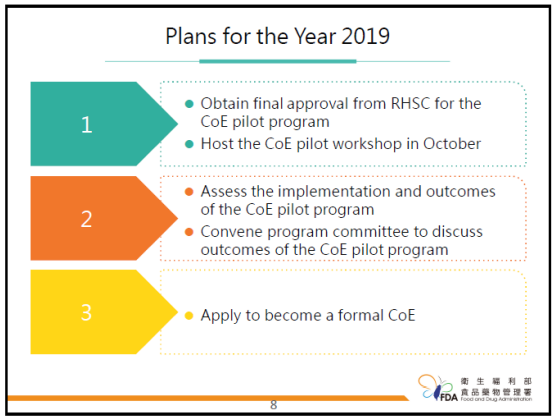












附件 7、SOM3 2019 LSIF Planning Group (LSIF PG) Meeting 議程

SOM3 2019 LSIF Planning Group (LSIF PG) Meeting

Saturday, 17 August 2019
09:30 - 17:00

Enjoy Hotel, Osorno A | Puerto Varas, Chile

AGENDA

Time	#	Topic
09:30 – 09:35	**1**	**Opening Session** 1.1. Welcome Remarks (LSIF Planning Group Chair)
09:35 – 10:00	**2**	**APEC 2019 Priorities** 2.1. APEC 2019 Priorities (Ministry of Foreign Affairs, Chile) 2.2. APEC 2019 Health and Life Sciences Priorities (Institute of Public Health, Chile) 2.3. APEC Management Update (APEC Secretariat)
10:00 – 10:20	**Research & Development**	
	3	3.1. Enabling Investment in the Innovative Life Sciences Sector (LSIF Advisor) 3.2. APEC Biomedical Technology Commercialization Center – TCTC (Thailand)
10:20 – 10:50	**Coffee Break and Photo**	
10:50 – 12:30	**Regulatory Harmonization Steering Committee – RHSC**	
	4	4.1. RHSC Update (RHSC Co-Chairs - United States and Japan) 4.2. APEC Harmonization Center Update (Korea - AHC) 4.3. Key Performance Indicators (Korea - AHC) 4.4. LSIF High-Level Dialogue on Regulatory Convergence (LSIF Advisor) 4.5. Vision 2030 Drafting Group (LSIF Advisor) 4.6. Securing Upstream and Downstream Supply Chain Integrity (US Pharmacopeia) 4.7. Quality control tests for Biotechnological products in APEC economies (Peru) 4.8 WHO Regulatory update
12:30 – 14:30	**Lunch Break**	

14:30 – 17:00	**Health Policy & Innovation**	
	5	5.1. Tropical Health Workforce Hub (James Cook University, Australia) 5.2. Blood Screening and Processing Centralization through Development of "Center of Excellence" (Indonesia) 5.3. Rare Disease Network (Queensland Univ of Technology & Ministry of Health of Chile) 5.4. Latent Tuberculosis 5.5. APEC Health Sciences Academy (Peking University, China) 5.6. 9th APEC High-Level Meeting on Health & the Economy (Canada) 5.7. Innovative Healthcare Financing (LSIF Advisor) 5.8. APEC Digital Hub for Mental Health (Canada) - *1 hour presentation*
17:00 – 17:10	**6**	**Document Classification (APEC Secretariat)**
17:10 – 17:20	**7**	**LSIF Meetings in 2020 (Malaysia)**
17:20 – 17:40	**8**	**Closing Session**
17:40	**Adjourn**	

附件 8、APEC LSIF Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence 議程

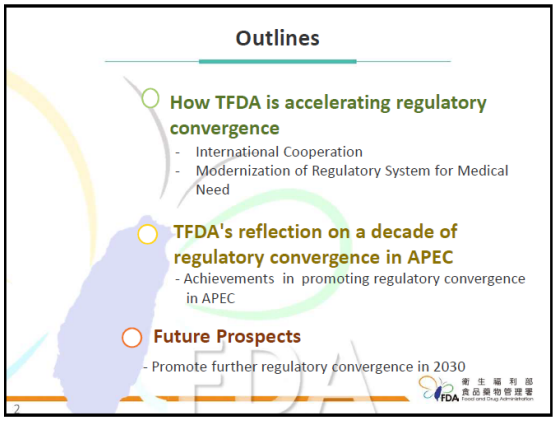
UPDATED 15 AUGUST 2019

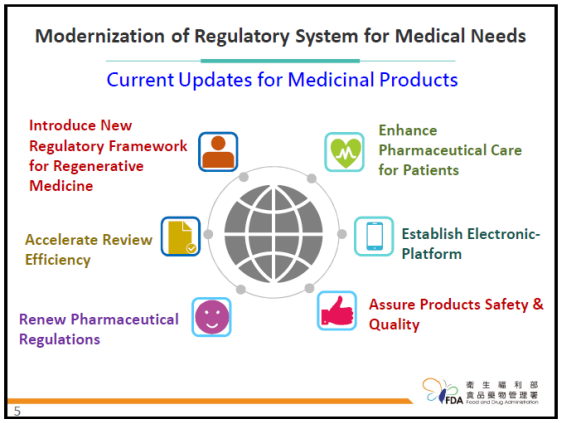
APEC LSIF Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence
"A Decade of Regulatory Convergence in APEC: Learning from the Past, Looking to the Future"
August 18, 2019 | Osorno B, Enjoy Hotel | Puerto Varas, Chile

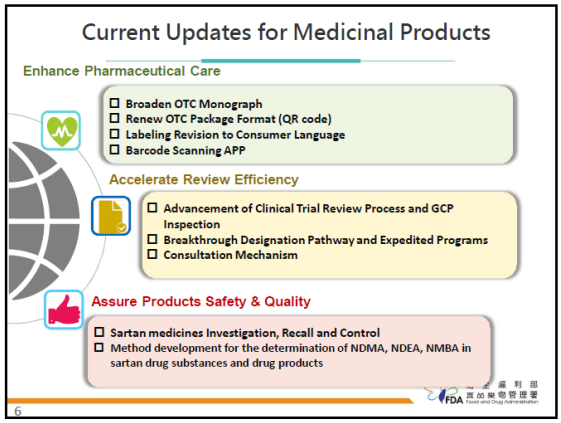
8:30-9:00	Arrival, Registration, and Networking
9:00-9:20	**Opening Remarks** • **Ms Erika Elvander**, Chair, APEC LSIF Planning Group; Director, Asia-Pacific, Office of Global Affairs, Department of Health and Human Services, The United States • **Mr Carlos Bravo Goldsmith**, Head, National Medicines Agency Department (ANAMED), Chile • **Dr Mijeong Kim,** Cardiovascular & Neurology Products Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Korea
9:20-10:20	**Setting the Scene: APEC Progress Towards Regulatory Convergence** This session will showcase the results of the joint AHC–LSIF project to track key performance indicators (KPIs) measuring progress towards regulatory convergence among APEC economies. How have we performed? Where might future efforts be focused? Are we tracking the right KPIs? (*Moderator*) **Ms Patricia Wu**, LSIF Advisor • **Dr Mijeong Kim,** Cardiovascular & Neurology Products Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Korea • **Prof John Lim,** Professor & Executive Director, Center for Regulatory Excellence (CoRE), Duke-National University of Singapore
10:20-10:30	Official Photograph & Coffee/Tea Break
10:30-12:00	**Session 1: Keynote Remarks from Regulatory Authorities** This session will explore diverse perspectives on how APEC regulatory authorities are accelerating regulatory convergence, their reflections on a decade of regulatory work in APEC, and their thoughts on future efforts. (Co-*Moderators*) **Dr Michelle Limoli**, Co-Chair, APEC RHSC; Senior International Health Science Advisor, Food and Drug Administration, The United States; **Dr Nobumasa Nakashima**, Co-Chair, APEC RHSC; Senior Director for International Programs, Pharmaceutical and Medical Device Agency, Japan • **Dr Mijeong Kim,** Cardiovascular & Neurology Products Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Korea • **Datin Dr Faridah Aryani Binti Md. Yusof**, Head, National Pharmaceutical Regulatory Authority, Malaysia • **Dr Oscar Guitierrez**, Officer-in-Charge, Policy & Planning Service, Food and Drug Administration, The Philippines • **Dr Shou-Mei Wu**, Director General, Taiwan Food and Drug Administration, Chinese Taipei
12:00-13:30	Lunch
13:30-14:30	**Session 2: Lessons on Innovation & Regulatory Convergence from Beyond APEC** This session will present unique perspectives, insights, and best practices from neighboring non-APEC economies on their own efforts to accelerate life sciences innovation and to promote regulatory convergence regionally and globally. (*Moderator*) **Mr Carlos Bravo Goldsmith**, Head, National Medicines Agency Department, Chile • **Ms Daniela Marreco Cerqueira**, Deputy Director, National Health Surveillance Agency (ANVISA), Brazil • **Ms Judith Mestre**, Director of Medicines and Biologic Products, National Institute of Food & Drug Surveillance (INVIMA), Colombia • **Mr Rafael Díaz-Granados**, Executive Director, Latin American Federation of Pharmaceutical Industry (FIFARMA) • **Dr James Fitzgerald**, Director, Health Systems and Services, Pan American Health Organization (PAHO)

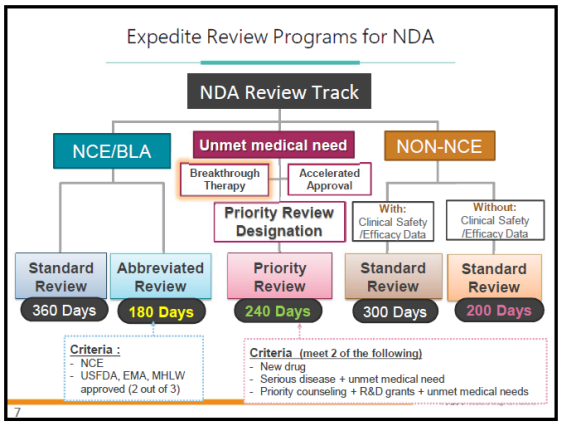
14:30-16:00	**Session 3: Industry Perspectives on Regulatory Convergence & the Future of Health Care** This session will examine how medical products industries are accelerating regulatory harmonization, how progress benefits consumers and patients, their reflections on a decade of regulatory convergence in APEC, and their thoughts on future efforts in APEC. (*Moderator*) **Ambassador Robert Holleyman**, President & CEO, Crowell & Moring International **Medical Devices** • **Ms Nicole Taylor Smith**, APEC RHSC Medical Device Industry Coalition Member; Vice President, Medtronic • **Mr Naoki Morooka**, APEC RHSC Medical Device Industry Coalition Coordinator; Vice Division Chairman, Regulatory & Safety, Japan Medical Imaging & Radiological Systems Industries Association (JIRA) **Research-Based Pharmaceuticals & Biotechnological Products** • **Ms Camille Jackson**, APEC RHSC Research-Based Pharmaceutical Industry Coalition Coordinator; Associate Vice President, Pharmaceutical Researchers & Manufacturers of America (PhRMA) • **Mr Kazuharu Matsuoka**, APEC RHSC Research-Based Pharmaceutical Industry Coalition Coordinator; Director, Japan Pharmaceutical Manufacturers Association (JPMA) • **Ms Lila Feisee**, APEC RHSC Biotechnological Products Industry Coalition Coordinator; Vice President, International Affairs, Biotechnology Innovation Organization (BIO)
16:00-17:00	**Session 4: Academic and Institute Perspectives** In 2019, RHSC's network of Training Centers of Excellence for Regulatory Science is expected to hold over 20 regulatory training programs, reaching hundreds of regulators. This session will highlight how these institutions are facilitating regulatory convergence through research, education, and capacity-building, their reflections on a decade of regulatory convergence in APEC, and their thoughts on future efforts in APEC. (*Moderator*) **Dr Samvel Azatyan**, Group Lead, Capacity Building, Regulatory Systems Strengthening Team, World Health Organization (WHO) • **Prof Gong Chen,** Secretary-General, APEC Health Science Academy, Executive Deputy Director, Institute of Population Research, Peking University • **Dr Jared Auclair**, Co-Chair, APEC RHSC Centers of Excellence Coalition; Associate Teaching Professor & Director, Northeastern University (NEU) • **Dr Ronald Piervincenzi**, Alternate Co-Chair, APEC RHSC Centers of Excellence Coalition; CEO, United States Pharmacopeia (USP) • **Mr Cherng Yeu Neo**, Co-Chair, APEC RHSC Centers of Excellence Coalition; Associate Director, Center of Regulatory Excellence (CoRE), Duke-National University of Singapore (Duke-NUS)
17:00-17:50	**Concluding Observations, Recommendations, and Remarks** (*Moderator*) **Ms Erika Elvander**, Chair, APEC LSIF Planning Group; Director, Asia-Pacific, Office of Global Affairs, Department of Health and Human Services, The United States • **Prof John Lim**, Professor & Executive Director, Center for Regulatory Excellence (CoRE), Duke-National University of Singapore • **Dr Mijeong Kim,** Cardiovascular & Neurology Products Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Korea • **Dr James Fitzgerald**, Director, Health Systems and Services, Pan American Health Organization (PAHO)
17:50-18:00	Walk to El Humedal Restaurant (*Turismo 145, Puerto Varas, Chile*; 170 meters / 2 minutes from Enjoy Hotel)
18:00-19:30	**Reception: 10th Anniversary Celebration of the APEC Harmonization Center** • **Dr Mijeong Kim,** Cardiovascular & Neurology Products Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Korea • **Ms Erika Elvander**, Chair, APEC LSIF Planning Group; Director, Asia-Pacific, Office of Global Affairs, Department of Health and Human Services, The United States

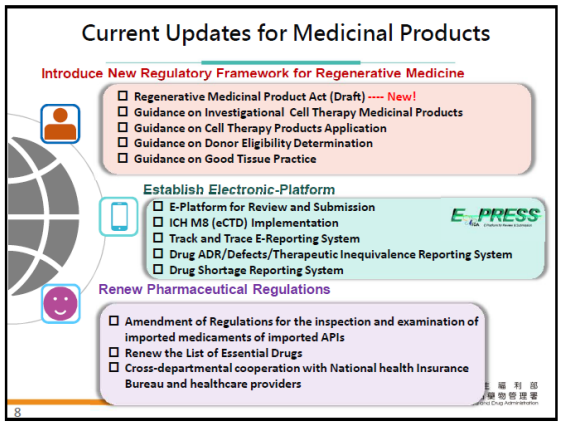
附件 9: Facilitating Regulatory Convergence to Address Medical Needs from Chinese Taipei's Perspectives 簡報











A new regulatory framework for regenerative medicinal products and medical treatment

Regulation Governing the Application of Specific Medical Examination Technique and Medical Device (RSMET, Amendment-Sep 2018)

Medical institute
- Medical Technique
- Medical institute
- GTP

Cell Processing Unit

Pharmaceutical Affairs Act
Regenerative Medicinal Product Act (Draft-Oct 2018)

Pharma
- Medical Product
- Pharmaceutical Industry
- GMP for RMPs

Manufacture site

Mitigate the gap of medical product and technique
Patient-Focused Drug Development (PFDD)
Application based on Real World Data

9

Track-and-Trace System

LAW
1. Pharmaceutical Affairs Act article 6-1
2. Regulations Governing the Trace and Track System for Medicinal Products

Announce drug items to be tracked and traced

Expected Benefits
1. To avoid counterfeit medicine entering supply chain under co-operation with GDP.
2. To commence drug recalls in a speedy manner when adverse drug events happen.

E-reporting system
(upload drug information, *e.g.* name, lot, shelf life)

Manufacturer → Supplier → Dealer → Hospital, clinic and pharmacies

10

Refining Regulations/Guidance of Medical Devices for Evolving New Digital Era

- Initiated the draft of Medical Devices Act
- Developed technical guidance on the regulation of newly emerging medical devices for medical needs and to advance industry development

Technology Development

April 13, 2015
Reference Guidance on Medical Software Classification and Categorization

Dec. 15, 2017
Guidance on Medical Device Software Validation

Jan. 12, 2018
Guidance for the Management of Additive Manufactured (3D Printing) Medical Devices

Dec. 17, 2018
Guidance on Laboratory Developed Test and Service (LDTS) for Precision Medicine Molecular Testing

11

Cosmetic Hygiene and Safety Act

(take effect on July 1, 2019)

Cosmetic Hygiene and Safety Act

Statute for Control of Cosmetic Hygiene

Emphasis on industry self-regulation

- Cosmetics definition amendment
- Product Notification
- Product Information File (PIF)
- Good Manufacturing Practice (GMP)
- Abolition of pre-market approval of colorants
- Pre-market approval for specific purpose cosmetics (during 5-year transition period)
- Regulation of recall and withdrawal
- Border inspection
- SAE & hazards reporting
- Increase of administrative fine
- Abolition of criminal punishment

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Food and Drug Administration Ministry of Health and Welfare

TFDA's Reflection on A Decade of Regulatory Convergence in APEC

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

http://www.fda.gov.tw/

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Promotion of Good Registration Management in APEC

GRM Roadmap Co-Champion and CoE

Step 1	Step 2	Step 3	Step 4
2011-2012	2011-2016	2017-2019	2018-2020
Gap Analysis Survey for setting the foundation	Planned solutions to address gaps in GRM	Assessing impact of GRM	Reaching the Goal for Implementing GRM

Roadmap Champion
- 2011-15: GRevP Roadmap champion (Chinese Taipei)
- 2014-15: GSubP co-champion (Chinese Taipei/Japan)
- 2016-20: GRM Roadmap co-champions (Chinese Taipei/Japan)

Center of Excellence (CoE)
TFDA/RAPS
- 2016: CoE Pilot
- 2017-21: Formal CoE, hosting annual training

Embedded the GRM Concepts into TFDA Review System

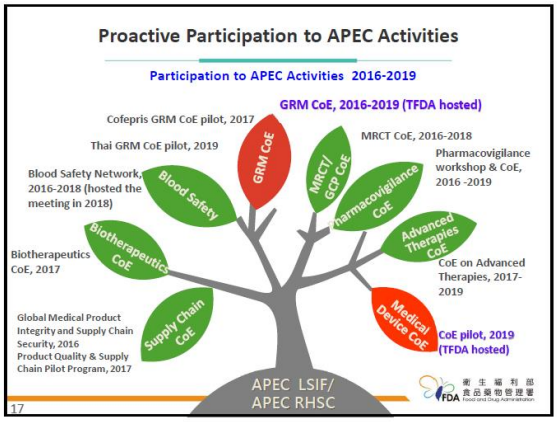
- Establishing integrated E- System (IND, NDA, post marketing, e-labeling, QR code, etc)
- TFDA /CDE Review Cooperation
- Holding periodical QA/QC meetings, review timeline management
- Continue refining regulations
- Publish points to consider and checklists
- Establish professional review team
- Personnel trainings, Capacity building
- Consultation mechanism
- Refuse to File
- Expedited review programs

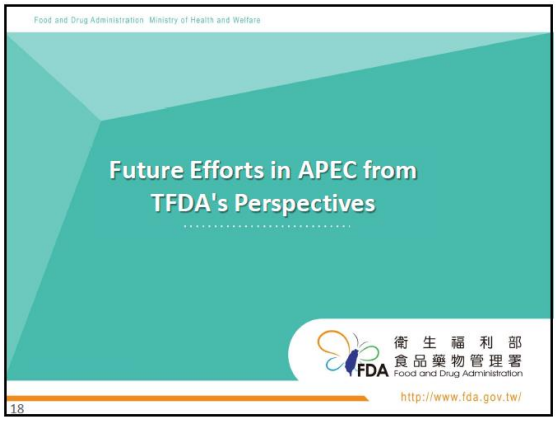
15

CoE Pilot Program under Medical Device PWA

- Represented APEC LSIF RHSC to the IMDRF Management Committee meetings in 2015 and 2019
- Proposed a Center of Excellence (CoE) Pilot Program under Medical Device PWA of RHSC
  - Program endorsed by RHSC in March 2019
  - CoE pilot workshop to be held in October 2019 on medical device standards
- Apply to become a formal CoE under Medical Device PWA of RHSC in 2020
  - Keep on hosting CoE training programs once endorsed

16


Proactive Participation to APEC Activities
Participation to APEC Activities 2016-2019
GRM CoE, 2016-2019 (TFDA hosted)
Cofepris GRM CoE pilot, 2017
Thai GRM CoE pilot, 2019
MRCT CoE, 2016-2018
Pharmacovigilance workshop & CoE, 2016 -2019
Blood Safety Network, 2016-2018 (hosted the meeting in 2018)
Biotherapeutics CoE, 2017
CoE on Advanced Therapies, 2017-2019
Global Medical Product Integrity and Supply Chain Security, 2016
Product Quality & Supply Chain Pilot Program, 2017
CoE pilot, 2019 (TFDA hosted)
GRM CoE
MRCT/ GCP CoE
Pharmacovigilance CoE
Blood Safety
Advanced Therapies CoE
Biotherapeutics CoE
Supply Chain CoE
Medical Device CoE
APEC LSIF/ APEC RHSC
17


Food and Drug Administration Ministry of Health and Welfare
Future Efforts in APEC from TFDA's Perspectives
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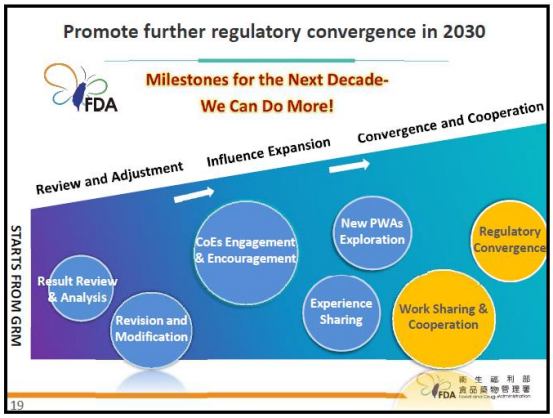
食品藥物管理署
Food and Drug Administration
http://www.fda.gov.tw/
18


Promote further regulatory convergence in 2030
Milestones for the Next Decade-
We Can Do More!
Review and Adjustment
Influence Expansion
Convergence and Cooperation
STARTS FROM GRM
Result Review & Analysis
Revision and Modification
CoEs Engagement & Encouragement
New PWAs Exploration
Experience Sharing
Work Sharing & Cooperation
Regulatory Convergence
19


2019 CoE Workshops in Taipei
See you in Taipei
WELCOME
✓ GRM CoE Workshop, 17-19 September
Organizers:
✓ Medical Device Pilot CoE Workshop, 22-24 October
Organizer:
Pilot Planning Committee:
20


Food and Drug Administration Ministry of Health and Welfare
Thank You
for Your Attention
衛 生 福 利 部
食品藥物管理署
Food and Drug Administration
http://www.fda.gov.tw/
21

附件 10、APEC LSIF Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence 會議報告

ENDORSED 20 SEPTEMBER 2019

Asia-Pacific Economic Cooperation (APEC)
Life Sciences Innovation Forum (LSIF)

Report of the

Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence

"A Decade of Regulatory Convergence in APEC: Learning from the Past, Looking to the Future"

18 August 2019
Puerto Varas, Chile

Purpose

This report serves as a summary of outcomes from the APEC Life Sciences Innovation Forum (LSIF) Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence (PD), held 18 August 2019 in Puerto Varas, Chile, including recommendations for consideration by the APEC High Level Meeting on Health & the Economy (HLM), APEC Ministers, and APEC Leaders.

Background

The PD was organized by the LSIF under the leadership of Ms. Erika Elvander (LSIF Planning Group Chair) with support from the APEC Harmonization Center (AHC) under the leadership of Dr. Dong-hee Lee (Director) and from Chile as the APEC 2019 Host Economy.

The PD built upon the LSIF's long-standing recognition of the critical role that the life sciences sector plays in promoting public and economic health and the role that strong and efficient regulatory systems play in enabling life sciences innovation.

The PD convened the leaders of drug and medical device regulatory authorities and representatives from industry and academia to reflect on a decade of progress towards regulatory convergence[1] in APEC and to envision the next iteration of a regional vision for how regulatory systems and regulatory convergence may accelerate life sciences innovation and make new medical products available to populations across APEC economies.

See Annex 1 for the agenda of the PD as executed on 18 August 2019 in Puerto Varas, Chile.

Outcomes

1. **The PD concluded with a strong affirmation that the RHSC should continue its work beyond 2020 and accelerate APEC's regulatory convergence efforts** for a number of key reasons:
    a. Regulatory convergence **protects people's safety**: when we take advantage of testing, inspections, and reviews already done by high-performing regulators around the region, we can efficiently ensure approved products are both effective and safe, and work together to watch for safety issues in our collective population.
    b. Regulatory convergence **makes products available**: when we leverage the assessment work already done by high-performing regulators on a particular life-saving product, we can approve that product more quickly and ensure it is readily available on the market to those who need it.
    c. Regulatory convergence **saves public resources**: when we tap into the expertise and work of other high-performing regulators around the region, we can avoid unnecessary duplication and limit wasteful spending so we save our precious public health resources for use elsewhere.
    d. Regulatory convergence **attracts investment**: when we shorten burdensome procedures and adopt best practices by trusting the processes of high-performing regulators, we can

[1] The RHSC defines "regulatory convergence" as a voluntary process whereby the regulatory requirements across economies become more similar or "aligned" over time as a result of the gradual adoption of internationally recognized technical guidance documents, standards and scientific principles (harmonization) and common or similar practices and procedures. It does not represent the harmonization of laws and regulations, which is not necessary to allow for the alignment of technical requirements and for greater regulatory cooperation.

reduce uncertainty and delays so that both local and international firms find it easier to do business in our economies, invest their capital, and create jobs.

e. Regulatory convergence **prevents corruption**: when we avoid duplicate inspections and lengthy approval procedures, we can reduce the time it takes to respond to an application, so we prevent opportunities for corrupt or dishonest behavior.
f. Regulatory convergence **improves global standing**: when we share the load with other regulators and join international initiatives, we show our willingness to cooperate and support best practices, which strengthen the global community and enable investment in our economies.

The PD therefore strongly reaffirmed the statement made by APEC Ministers in 2011 to "…achieve convergence on regulatory approval procedures for medical products by 2020, which will allow patients more timely access to innovations" and **urged an extension and acceleration of efforts to meet the convergence goal by 2030**.

Looking ahead to 2030, the PD participants **encouraged the RHSC to consider the following additions to its strategy for the next decade:**

a. Establishing a 'regulatory sandbox' to enable piloting innovative regulations;
b. Supporting 'horizon scanning' exercises led by regulators with experience in novel products;
c. Interacting with patients, healthcare providers, and political leaders including legislators ;
d. Improving participation from APEC member economies in RHSC meetings and activities; and,
e. Improving outreach and communications both within and outside of APEC; and,
f. Improving connection to other regulatory harmonization initiatives and mechanisms such as ICH, IPRP, PIC/S, IMDRF, PANDRH, and MDSAP.

2. **PD participants reflected on RHSC key performance indicators (KPIs)[2] tracking regulatory convergence over the last decade and now on an annual basis (conducted as an LSIF-AHC Project).**

Endorsed in 2017, the KPIs measuring progress towards achieving regulatory convergence include:

a. Number of economies engaging in information sharing;
b. Number of economies establishing confidentiality commitments;
c. Number of economies sharing Good Manufacturing Practices (GMP) certificates;
d. Number of economies establishing Mutual Recognition Agreements (MRAs);
e. Number of economies minimizing required Certificates of Pharmaceutical Product (CPPs);
f. Number of economies allowing multiple sites in a single license; and,
g. Number of economies joining regulatory harmonization initiatives including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), Pharmaceutical Inspection Cooperation Scheme (PIC/S), and International Pharmaceutical Regulators Programme (IPRP).

The PD participants acknowledged that the KPIs endorsed by RHSC to date are focused on regulatory convergence of drug and vaccine approvals, and **welcomed KPIs to monitor and evaluate regulatory convergence of medical device approvals as well.** The PD participants encouraged the

[2] Chong, S.S.F., Lim, J.C.W. & Tominaga, T. "Developing key performance indicators to measure the progress of regional regulatory convergence and cooperation in APEC." *AAPS Open* (2018) 4: 4. doi.org/10.1186/s41120-018-0024-2

RHSC to not only continue tracking the KPIs on an annual basis, but also to **develop more specific KPIs to track progress within each priority work area (PWA).**

The PD participants emphasized that KPIs should not be used to single out economies but, rather, should be used to **ensure that "no economy is left behind" in support of "inclusive growth".**

See Annex 2 for an illustration of KPI data collected and analyzed by AHC, from 2008 to 2019.

3. **PD participants reflected on the next decade of a regional vision for how regulatory systems and regulatory convergence may accelerate life sciences innovation and make new medical products available to populations across APEC economies.** Leaders of regulatory authorities and other PD participants urged the RHSC to consider focusing new efforts on:
    a. Reliance on stringent regulatory authorities;
    b. Creation and expansion of expedited or facilitated regulatory pathways;
    c. Use of third-party reviews for low-risk medical devices;
    d. Collection and use of real world evidence;
    e. Digital technologies (for research and development); and,
    f. Patient-centered drug development.

4. **PD participants applauded the RHSC for continuing to improve and scale its network of Training Centers of Excellence for Regulatory Science (CoEs) to build skilled human capacity, and urged regulatory authorities to send participants and also provide support in the form of faculty**. PD participants noted that CoEs will continue to serve as a key pillar to advancing the RHSC's regulatory convergence goal.

    It was also noted that the CoE network complements ICH and IMDRF by helping supporting the gradual adoption of internationally recognized technical guidance documents, standards and scientific principles through training. As of 2019 across nine APEC economies there are 16 Centers of Excellence hosting 23 workshops this year, which will train hundreds of regulators.

    The PD participants encouraged RHSC and CoEs to **develop and track KPIs to measure not only the outputs and outcomes of training activities, but their impact both the short- and long-term.** Improving the impact of training activities may also require renewed focus on developing consistently recurring, long-term programs to teach and test students instead of single, *ad hoc* programs.

    The PD participants urged RHSC and CoEs to **consider strategies to increase the geographic diversity and reach of training programs, such as through 'roadshows' and other traveling or remote programs, as well as strategies to improve the financial sustainability of programs.**

    See Annex 3 for CoEs that have been endorsed by the RHSC and are now operational, as well as pilots for additional CoEs have been endorsed by the RHSC.

5. **PD participants concluded that all relevant stakeholders – among them regulators and regulated industry – should appropriately prioritize and resource regulatory convergence efforts within the context of their own economies.** This includes promoting the use of existing international guidelines, supporting a strategic and coordinated approach to regulatory convergence, and building

human and regulatory capacity, such as the approach taken by the RHSC and its partners such as the LSIF and AHC.

In addition, stakeholders should promote complementary action and make maximum use of resources, for example by maintaining a focus on using the ICH, IMDRF, and others to develop guidelines while leveraging RHSC to implement such guidance by building skilled human capacity.

6. **The PD included a session on "Innovation and Regulatory Convergence from Beyond APEC" with invited guests from Brazil, Colombia, and the Pan American Health Organization, and reflected on future collaboration and coordination with non-APEC economies** in areas such as:
    a. Sharing training opportunities with non-APEC economies as interested parties;
    b. Special briefings for regulatory authorities and leaders in non-APEC economies; and,
    c. Standing invitations for non-APEC economies to observe RHSC meetings.

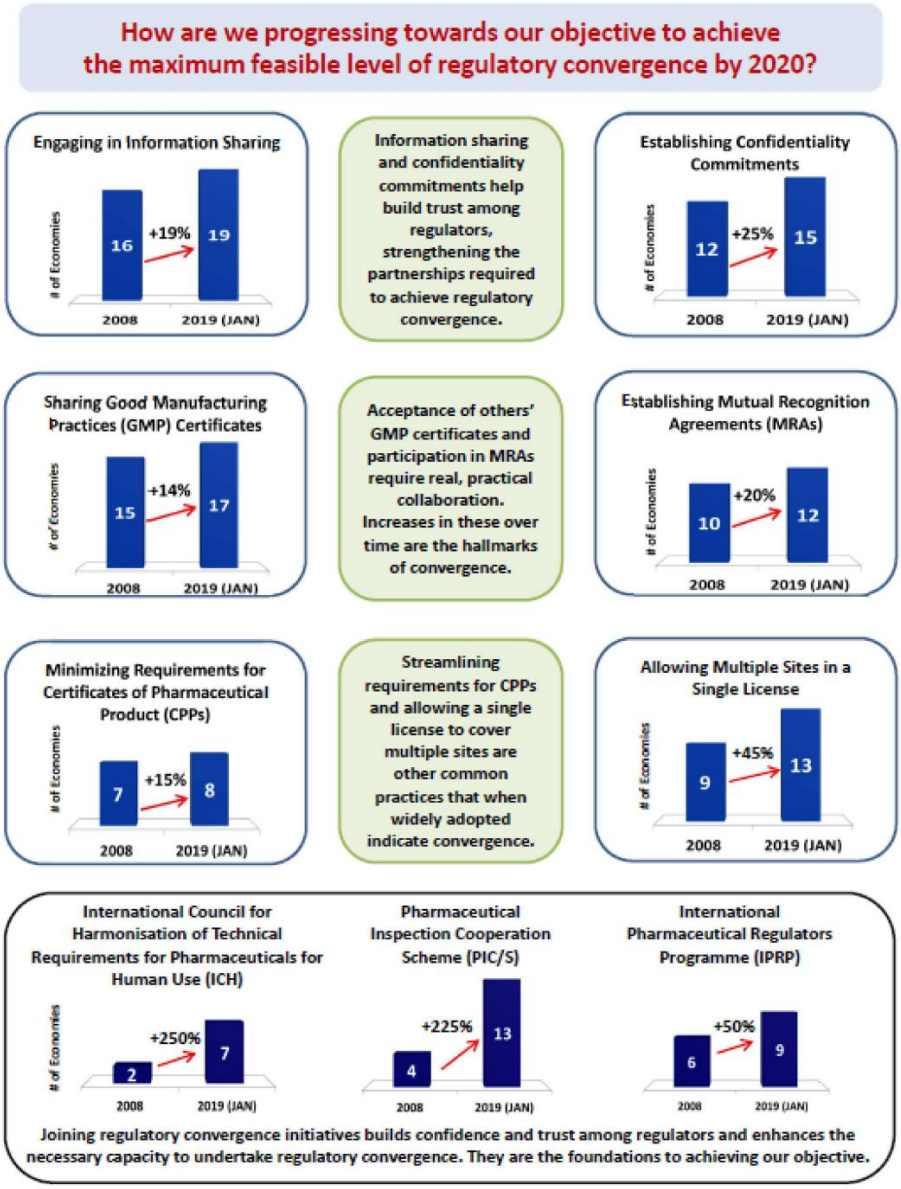
7. **PD participants thanked AHC for its support over the last decade for pilot CoEs and other training programs, workshops, and the CoE website; and asked the AHC to continue their involvement in the RHSC**, focusing their efforts on assisting pilot CoEs, organizing special workshops, and helping lead strategic and high-level projects such as the survey and analysis of the KPIs.

Annex 1: Agenda

8:30-9:00	Arrival, Registration, and Networking
9:00-9:20	**Opening Remarks** • **Ms Erika Elvander**, Chair, APEC LSIF Planning Group; Director, Asia-Pacific, Office of Global Affairs, Department of Health and Human Services, The United States • **Mr Carlos Bravo Goldsmith**, Head, National Medicines Agency Department (ANAMED), Chile • **Dr Mijeong Kim,** Cardiovascular & Neurology Products Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Korea
9:20-10:20	**Setting the Scene: APEC Progress Towards Regulatory Convergence** This session will showcase the results of the joint AHC–LSIF project to track key performance indicators (KPIs) measuring progress towards regulatory convergence among APEC economies. How have we performed? Where might future efforts be focused? Are we tracking the right KPIs? (*Moderator*) **Ms Patricia Wu**, LSIF Advisor • **Dr Mijeong Kim,** Cardiovascular & Neurology Products Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Korea • **Prof John Lim,** Professor & Executive Director, Center for Regulatory Excellence (CoRE), Duke-National University of Singapore
10:20-10:30	Official Photograph & Coffee/Tea Break
10:30-12:00	**Session 1: Keynote Remarks from Regulatory Authorities** This session will explore diverse perspectives on how APEC regulatory authorities are accelerating regulatory convergence, their reflections on a decade of regulatory work in APEC, and their thoughts on future efforts. (Co-*Moderators*) **Dr Michelle Limoli**, Co-Chair, APEC RHSC; Senior International Health Science Advisor, Food and Drug Administration, The United States; **Dr Nobumasa Nakashima**, Co-Chair, APEC RHSC; Senior Director for International Programs, Pharmaceutical and Medical Device Agency, Japan • **Dr Mijeong Kim,** Cardiovascular & Neurology Products Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Korea • **Datin Dr Faridah Aryani Binti Md. Yusof**, Head, National Pharmaceutical Regulatory Authority, Malaysia • **Dr Oscar Guitierrez**, Officer-in-Charge, Policy & Planning Service, Food and Drug Administration, The Philippines • **Dr Shou-Mei Wu**, Director General, Taiwan Food and Drug Administration, Chinese Taipei
12:00-13:30	Lunch
13:30-14:30	**Session 2: Lessons on Innovation & Regulatory Convergence from Beyond APEC** This session will present unique perspectives, insights, and best practices from neighboring non-APEC economies on their own efforts to accelerate life sciences innovation and to promote regulatory convergence regionally and globally. (*Moderator*) **Mr Carlos Bravo Goldsmith**, Head, National Medicines Agency Department, Chile • **Ms Daniela Marreco Cerqueira**, Deputy Director, National Health Surveillance Agency (ANVISA), Brazil • **Ms Judith Mestre**, Director of Medicines and Biologic Products, National Institute of Food & Drug Surveillance (INVIMA), Colombia • **Mr Rafael Díaz-Granados**, Executive Director, Latin American Federation of Pharmaceutical Industry (FIFARMA) • **Dr James Fitzgerald**, Director, Health Systems and Services, Pan American Health Organization (PAHO)

14:30-16:00	**Session 3: Industry Perspectives on Regulatory Convergence & the Future of Health Care** This session will examine how medical products industries are accelerating regulatory harmonization, how progress benefits consumers and patients, their reflections on a decade of regulatory convergence in APEC, and their thoughts on future efforts in APEC. (*Moderator*) **Ambassador Robert Holleyman**, President & CEO, Crowell & Moring International **Medical Devices** • **Ms Nicole Taylor Smith**, APEC RHSC Medical Device Industry Coalition Member; Vice President, Medtronic • **Mr Naoki Morooka**, APEC RHSC Medical Device Industry Coalition Coordinator; Vice Division Chairman, Regulatory & Safety, Japan Medical Imaging & Radiological Systems Industries Association (JIRA) **Research-Based Pharmaceuticals & Biotechnological Products** • **Ms Camille Jackson**, APEC RHSC Research-Based Pharmaceutical Industry Coalition Coordinator; Associate Vice President, Pharmaceutical Researchers & Manufacturers of America (PhRMA) • **Mr Kazuharu Matsuoka**, APEC RHSC Research-Based Pharmaceutical Industry Coalition Coordinator; Director, Japan Pharmaceutical Manufacturers Association (JPMA) • **Ms Lila Feisee**, APEC RHSC Biotechnological Products Industry Coalition Coordinator; Vice President, International Affairs, Biotechnology Innovation Organization (BIO)
16:00-17:00	**Session 4: Academic and Institute Perspectives** In 2019, RHSC's network of Training Centers of Excellence for Regulatory Science is expected to hold over 20 regulatory training programs, reaching hundreds of regulators. This session will highlight how these institutions are facilitating regulatory convergence through research, education, and capacity-building, their reflections on a decade of regulatory convergence in APEC, and their thoughts on future efforts in APEC. (*Moderator*) **Dr Samvel Azatyan**, Group Lead, Capacity Building, Regulatory Systems Strengthening Team, World Health Organization (WHO) • **Prof Gong Chen,** Secretary-General, APEC Health Science Academy, Executive Deputy Director, Institute of Population Research, Peking University • **Dr Jared Auclair**, Co-Chair, APEC RHSC Centers of Excellence Coalition; Associate Teaching Professor & Director, Northeastern University (NEU) • **Dr Ronald Piervincenzi**, Alternate Co-Chair, APEC RHSC Centers of Excellence Coalition; CEO, United States Pharmacopeia (USP) • **Mr Cherng Yeu Neo**, Co-Chair, APEC RHSC Centers of Excellence Coalition; Associate Director, Center of Regulatory Excellence (CoRE), Duke-National University of Singapore (Duke-NUS)
17:00-17:50	**Concluding Observations, Recommendations, and Remarks** (*Moderator*) **Ms Erika Elvander**, Chair, APEC LSIF Planning Group; Director, Asia-Pacific, Office of Global Affairs, Department of Health and Human Services, The United States • **Prof John Lim**, Professor & Executive Director, Center for Regulatory Excellence (CoRE), Duke-National University of Singapore • **Dr Mijeong Kim,** Cardiovascular & Neurology Products Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Korea • **Dr James Fitzgerald**, Director, Health Systems and Services, Pan American Health Organization (PAHO)

Annex 2: Key Performance Indicators



Annex 3: APEC Training Centers of Excellence for Regulatory Science

As of 2019 across nine APEC economies there are 16 Centers of Excellence hosting 23 workshops this year, which will train hundreds of regulators.

- **Multi-regional Clinical Trials (MRCT) and Good Clinical Practices (GCP) Inspection**
  1. Duke-National University of Singapore (Duke-NUS) – Singapore
  2. Peking University – P.R. China
  3. Pharmaceuticals and Medical Devices Agency (PMDA) – Japan
  4. MRCT Center of Brigham & Women's Hospital and Harvard University – United States

- **Biotechnological Products (Biotherapeutics)**
  1. Northeastern University – United States
  2. APEC Harmonization Center – Republic of Korea
  3. Duke-NUS – Singapore
  4. Kobe University – Japan (***Pilot***)

- **Good Registration Management (GRM)**
  1. Taiwan Food and Drug Administration (TFDA), Chinese Taipei in cooperation with Regulatory Affairs Professional Society (RAPS) – Chinese Taipei
  2. COFEPRIS – Mexico
  3. Thailand Food & Drug Administration (Thai FDA) – Thailand (***Pilot***)

- **Pharmacovigilance**
  1. PMDA – Japan
  2. Korean Institute for Drug Safety (KIDS) – Republic of Korea
  3. Peking University – P.R. China

- **Global Supply Chain Integrity**
  1. U.S. Pharmacopeia (USP) – United States
  2. University of Tennessee Health Science Center – United States
  3. Taylor's University – Malaysia (***Pilot***)

- **Advanced Therapies (Cell, Gene, and Tissue-Based Therapies)**
  1. Northeastern University – United States
  2. Duke-NUS – Singapore

- **Medical Devices**
  1. University of Southern California (USC) – United States
  2. National Institute of Device Safety (NIDS) – Republic of Korea
  3. PMDA – Japan (***Pilot***)
  4. TFDA, Chinese Taipei in cooperation with RAPS – Chinese Taipei (***Pilot***)
  5. Northeastern University – United States (***Pilot***)

附件 11、HLM 9th APEC High-Level Meeting on Health & the Economy - "Healthy Economies in an Aging World"議程

Asia-Pacific Economic Cooperation

Draft 5 August

9th APEC High-Level Meeting on Health & the Economy

"Healthy Economies in an Aging World"

20-21 August 2019 | Puerto Varas, Chile

DAY ONE – Tuesday, 20 August	
14:00 – 14:20	**OPENING SESSION** **Welcome Remarks** ▪ **Ms. Tammy Bell**, Co-Chair, APEC Health Working Group and Health Canada ▪ **Ms. Erika Elvander**, Chair, Life Sciences Innovation Forum Planning Group and Department of Health and Human Services, United States **Welcome Message** (*via video message*) ▪ **Ms. Cecilia Morel**, First Lady of Chile
14:20 – 14:35	**CHAIR'S ADDRESS** ▪ **Hon. Dr. Jaime Mañalich**, Minister of Health, Chile
14:35 – 14:50	**Official Photo – APEC Heads of Delegation**
14:50 – 16:00	**SESSION ONE: THE ECONOMIC IMPERATIVE FOR ACTING ON HEALTHY AGING IN APEC** *Each speaker will have 10 minutes for remarks. The moderator will then ask a series of questions for 15 minutes. Followed by 15 minutes for questions from other APEC Ministers and Heads of Delegation.* **Panel Discussion:** ▪ **Dr. Yasuhiro Suzuki**, Vice-Minister for Health, Ministry of Health, Labour and Welfare of Japan ▪ **Mr. James Fitzgerald**, Director, Health Systems and Services at Pan-American Health Organization / World Health Organization ▪ **Mr. Lance Robertson**, Assistant Secretary for Aging and Administrator for the Administration for Community Living, United States ▪ **Prof. Dr. Dennis Ostwald**, Chief Executive Officer, WifOR Institute *Speaker and Moderator:* **Francesca Colombo**, Head of the Health Division, Organization for Economic Co-operation and Development (OECD)
16:00 – 16:30	**Coffee Break**
16:30 – 18:15	**SESSION TWO: ADAPTING HEALTH SYSTEMS TO SUPPORT HEALTHY AGING – LESSONS LEARNED AND FUTURE STRATEGIES**

Asia-Pacific Economic Cooperation

9th APEC High-Level Meeting on Health & the Economy

"Healthy Economies in an Aging World"

20-21 August 2019 | Puerto Varas, Chile

	Each speaker with have 5 minutes for introductory remarks. The moderator will then ask a series of questions for 20 minutes. Followed by 15 minutes for questions from other APEC Ministers and Heads of Delegation. **Panel Discussion:** ▪ **Ms. Elmira Vergazova**, Deputy Director, Department of the Organization of Medical Care of the Russian Ministry of Health ▪ **Mr. Jeong Hong-geun**, Director General for International Cooperation, Ministry of Health and Welfare, Republic of Korea ▪ **Dr. Nanako Tamiya**, Professor and Chair, Department of Health Services Research, University of Tsukuba, Japan ▪ **Mr. Jean-Jacques Bresson**, Head of Latin America, Sanofi ▪ **Dr. Ignacio Pérez,** Integral Center for a Happy Ageing, Faculty of Medicine of Universidad de los Andes, Chile *Moderator:* **Dr. Paula Daza**, Undersecretary of Public Health, Ministry of Health, Chile
CULURAL EVENT	
19:30 – 21:30	**Cultural Event**

Asia-Pacific Economic Cooperation

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"Healthy Economies in an Aging World"

20-21 August 2019 | Puerto Varas, Chile

DAY TWO – Wednesday, 21 August	
09:00 – 09:05	**Welcome Remarks** ▪ **Ms. Tammy Bell**, Co-Chair, APEC Health Working Group and Health Canada ▪ **Ms. Erika Elvander**, Chair, Life Sciences Innovation Forum Planning Group and Department of Health and Human Services, United States
09:05 – 10:15	**SESSION THREE: EMBRACING THE DIGITAL FUTURE IN SUPPORT OF HEALTHY AGING IN APEC** **Panel Discussion:** ▪ **Hon. Shih-Chung Chen**, Minister of Health and Welfare, Chinese Taipei ▪ **Dr. Benjamin Koh Khay Wee,** Deputy Secretary (Development), Ministry of Health Singapore ▪ **Mr. Lance Robertson**, Assistant Secretary for Aging and Administrator for the Administration for Community Living, United States ▪ **Dr. Leslie Mancuso**, President & CEO, Jhpiego ▪ **Ms. Nácia Pupo Taylor,** Senior Director, Global Health Policy, Johnson & Johnson *Moderator*: **Ambassador Robert Holleyman**, President & CEO, C&M International
10:15 – 10:30	**Coffee Break**
10:30 – 11:15	**SESSION FOUR: EXPLORING REGIONAL SOLUTIONS TO ADDRESS ELDERLY CARE NEEDS IN APEC** **Panel Discussion:** ▪ **Mr. Sebastian Villarreal**, Undersecretary of Social Services, Ministry of Social Development, Chile ▪ **Dr. Jane Barratt**, Secretary General of the International Federation on Ageing ▪ **Ms. Penny Wan**, Regional Vice President and JAPAC General Manager, Amgen ▪ **Professor Ian Wronski AO**, Deputy Vice Chancellor of the Division of Tropical Health and Medicine, James Cook University ▪ **Mr. Mario Cruz Peñate**, Advisor on Health Systems and Services, Pan American Health Organization/World Health Organization *Speaker and Moderator*: **Dr. Michael Hodin**, CEO, Global Coalition on Aging
11:15 – 12:15	**SESSION FIVE: REGIONAL ACTION TO IMPROVE WELLNESS AND DISEASE MANAGEMENT AMONG AGING POPULATIONS** **Panel Discussion:** ▪ **Hon. Dr. Elizabeth Zulema Tomas Gonzales**, Minister of Health of Peru ▪ **Ms. Francisca Retamal**, Head of the Department of Social Tourism, National Service of Tourism, **Chile** ▪ **Dr. Jane Barratt**, Secretary General of the International Federation on Ageing

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20-21 August 2019 | Puerto Varas, Chile

	Speaker and Moderator: **Dr. Diego Guarin**, Head Market Access Execution and Capabilities Latin America, Merck KGaA
12:15 – 13:15	**Lunch**
13:15 – 14:45	**SESSION SIX: UNLOCKING REGIONAL COLLABORATION TO ACCELERATE PROGRESS ON DEMENTIA** *Each panelist will have will have 5-7 minutes for remarks. The moderator will then facilitate 10 minutes of questions. Economies are welcome to ask questions and the moderator will have a series of questions prepared as well if necessary. This will be followed by a 45-minute roundtable where each member economy will have the opportunity to spotlight a project or initiative that their economy has implemented to address dementia that highlights the innovative approaches they are taking to promote healthy aging (2 minutes per presentation). Each of the projects or initiatives shared by APEC economies will be collated to create a compilation of APEC initiatives and projects that address dementia in the APEC region. Dementia Spotlight: A Compilation of Initiatives to Address Dementia in the Asia-Pacific Region will allow the sharing of successful policies and programs that have been implemented across the region and encourage collaboration between APEC economies by allowing the development of partnerships between economies that may face similar contextual challenges in meeting the needs of an aging population.* **Panel:** ▪ **Ms. Natalia Altamirano**, Care-provider (family member) - Corporación Alzheimer ▪ **Dr. Chien Kuang Lee**, General Manager, Southern Cone, Eli Lilly International ▪ **Dr. Matias Irarrazaval**, Chile Dementia National Plan Health professional ▪ **Dr. Jane Barratt**, Secretary General of the International Federation on Ageing (IFA) *Moderator*: **Mr. Octavio Vergara**, Director of National Service for the Elderly, Chile **Roundtable:** ▪ Representatives from all economies
14:45 – 15:00	**Coffee Break**

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"Healthy Economies in an Aging World"

20-21 August 2019 | Puerto Varas, Chile

15:00 – 15:45	**SESSION SEVEN: APEC ACTION TO ENABLE INVESTMENT AND SUSTAINABLE FINANCING IN THE HEALTH AND HEALTH CARE OF OUR AGING POPULATIONS** **Panel Discussion:** ▪ **Professor Bruce Rasmussen**, Director, Victoria Institute of Strategic Economic Studies ▪ **Dr. Solana Terrazas Martins**, Head, Division of Health Planning, Ministry of Health, Chile ▪ **Ms. Anupama Tantri**, Executive Director, Global Vaccine Public Policy Development, MSD *Moderator*: **Dr. Ryan MacFarlane**, Director, Crowell & Moring International
15:45 - 16:45	**SESSION EIGHT: APEC'S ROLE IN SUPPORTING THE GLOBAL AGING AGENDA** **Panel Discussion:** ▪ **Mr. James Fitzgerald,** Director, Health Systems and Services at Pan-American Health Organization / World Health Organization ▪ **Dr. Islene Araujo**, Senior Advisor, Aging and the Life Course, World Health Organization ▪ **Mr. Lance Robertson**, Assistant Secretary for Aging and Administrator for the Administration for Community Living, United States ▪ **Ms. Marta Diez**, President, Chamber of Pharmaceutical Innovation of Chile *Moderator*: **Dr. Paula Daza**, Undersecretary of Public Health, Minister of Health, Chile
16:45 - 17:00	**CLOSING SESSION** ▪ **Ms. Tammy Bell**, Co-Chair, APEC Health Working Group and Health Canada ▪ **Ms. Erika Elvander**, Chair, Life Sciences Innovation Forum Planning Group and Department of Health and Human Services, United States **APEC 2020 Invitation** ▪ **Dr. Chen Chaw Min**, Secretary General, Ministry of Health, Malaysia **Closing Remarks** ▪ **Dr. Paula Daza,** Undersecretary of Public Health, Ministry of Health, Chile

附件 12、9th APEC High-Level Meeting on Health and the Economy Joint Statement

Asia-Pacific Economic Cooperation

9th APEC HIGH-LEVEL MEETING ON HEALTH AND THE ECONOMY JOINT STATEMENT

"Healthy Economies in an Aging World"

August 20-21, 2019 | Puerto Varas, Chile

The 9th APEC High-Level Meeting on Health and the Economy (HLM9) explored the opportunities and challenges that aging populations present in enabling sustainable economic growth and development across economies.

We welcomed Chile's theme for 2019, "Connecting People, Building the Future", and particularly Chile's priorities "Women, SMEs and Inclusive Growth" and "Digital Society". Inclusive economic growth relies on healthy populations and addresses the challenges of an aging world, while new technologies contribute to the development of innovative and efficient digital solutions that favor healthy societies and economies.

APEC economies include the most rapidly aging populations in the world, a demographic change that has implications for sustainable economic growth and development. HLM9 highlighted the positive social and economic impacts associated with the active participation of older persons in the economy. HLM9 also recognized that the promotion of "Healthy Aging" is critical for mitigating the added health burden and costs associated with an aging population. Additionally, APEC economies recognized that optimizing opportunities for good health at all stages of life is necessary to facilitate healthy aging, promote the health and well-being of older people, and ensure economic growth across society for all citizens.

PROMOTING HEALTHY AGING IN THE APEC REGION

APEC economies recognized the value of effectively addressing the needs of aging populations in order to work towards the Sustainable Development Goals (SDGs), and achieve the *Healthy-Asia Pacific 2020 Initiative*'s to develop sustainable and high-performing health systems by integrating health into all policies and considering health across the life course. As the aging of populations accelerates, integrated care[1] and people-centered approaches are critical to ensuring the optimal well-being of an aging population and encouraging healthy aging. However, APEC economies have not seen optimal transformation of health systems to achieve this goal. HLM9 underscored the importance of considering the needs of older persons when pursuing UHC.

HLM9 recognized prevention as a key driver of healthy aging across the life course to address the many health conditions, social determinants and economic costs, that affect the later part of a person's life. Prevention programs, which include screening, advice for active lifestyles and good nutrition, smoking cessation, reduction of alcohol-related harms and immunization, particularly adult vaccines, have an important role to play in ensuring older persons can remain

[1] Integrated Care is defined as health care that is managed and delivered in a way that ensures people receive a continuum of health promotion, disease prevention, diagnosis, treatment, disease management, rehabilitation and palliative care services, at the different levels and sites of care within the health system, and according to their needs, throughout their whole life.

active contributors to the economy and maintain their functional ability as they age. APEC economies also emphasized the role of prevention and care in supporting the 71 million people projected to have dementia in the Asia-Pacific by the year 2050[2]. With an estimated cost of US$ 182 billion, HLM9 reaffirmed the need to increase funding for dementia research, to share knowledge and best practices in the region, and the incorporation of care provider experiences when developing dementia policies. HLM9 also highlighted the importance of integrating preventative approaches and creating age-friendly environments across a variety of sectors in addition to health, including long-term care, elder home care, transportation, housing, labor, and social protection and support.

APEC economies also stressed that health care systems should support healthy aging by preventing of the spread of infectious diseases, which affect older individuals disproportionally. HLM9 reaffirmed vaccination across the life course as a pillar of preventative healthcare, noting that vaccination prevents illnesses, enabling populations to remain healthy, and reduces related expenditures over time.

HLM9 acknowledged that older populations may run into challenges that can affect their health and quality of life, including financial insecurity, loneliness, social isolation and mental distress, and noted the importance of promoting and protecting the mental health and wellbeing of older persons through a multi-disciplinary and multi-sectoral approach.

HLM9 reiterated the need to ensure sufficient and sustainable domestic public spending on health care in light of the increasing burden of disease and aging populations in APEC economies. Elder care and, in particular, home care, should be considered as an investment to support continued independence and reduce spending on the aged. HLM9 reaffirmed the need for a whole-of-government and multisector approach and welcomed the continued collaboration between APEC Finance Ministers and the APEC Business Advisory Council to share best practices, better quantify the value of innovative medicines, and explore innovative health financing solutions and partnerships.

HLM9 recognized the value of aligning APEC's work on healthy aging with the broader global health agenda and reaffirmed the importance of continued partnership and collaboration with other multilateral fora, civil society organizations, the private sector, and other partners.

LOOKING AHEAD

HLM9 recognized that the exchange of international and APEC region experiences and best practices helps to shape and inform innovative policies and public services that not only improve health systems, but help entire economies adapt to an aging population.

[2] Alzheimer's Disease International, Alzheimer's Australia. Dementia in the Asia Pacific Region [Internet]. London: 2014. P.64. Available from: Alzheimer's Disease International; https://www.alz.co.uk/adi/pdf/Dementia-Asia-Pacific-2014.pdf

附件 13、會議剪影

LSIF RHSC Meeting 大合照 (2019.8.15)

LSIF Planning Group Meeting 大合照 (2019.8.17)

LSIF Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence 大合照 (2019.8.18)

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