出國報告（出國類別：參加國際會議）

2017 年 APEC 第 1 次貿易暨投資委員會生命科學創新論壇會議報告

服務機關：衛生福利部食品藥物管理署
姓名職稱：劉麗玲研究員
黃琴喨科長(藥品組)
林賢一高級審查員(藥品組)
派赴國家：越南
出國期間：106 年 2 月 18 日－2 月 23 日
報告日期：106 年 4 月 2 日

摘要

衛生福利部食品藥物管理(簡稱食藥署)出席 APEC 生命科學創新論壇(LSIF)法規協和指導委員會(RHSC)會議及 LSIF 規畫小組(Planning Group)會議，於 RHSC 會議報告「推動優良查驗登記管理(GRM)路徑圖」的最新成果，並報告「2016 APEC 優良查驗登記管理法規科學訓練卓越中心(CoE)先期研討會」成果及 CoE 的未來營運規劃，獲大會無異議全數通過，正式認可食藥署及美國醫療法規學會(RAPS)台灣分會聯名成為 APEC 優良查驗登記管理法規科學訓練卓越中心，這項成果是食藥署在國際合作上的重要突破。未來食藥署將與 LSIF 簽署合作備忘錄，每年針對 APEC 會員經濟體舉辦優良查驗登記管理相關訓練活動。

關鍵詞：APEC、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、法規科學訓練卓越中心

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壹、目的

本次出席 APEC 於越南芽莊召開的 LSIF 相關會議，有下列主要目的：

一、於 RHSC 會議報告「推動優良查驗登記管理路徑圖」的最新進展。

二、於 RHSC 會議報告「2016 APEC 優良查驗登記管理法規科學卓越中心先期研討會」成果及 CoE 的未來規畫，提請 RHSC 認可同意食藥署及美國醫療法規學會(RAPS)台灣分會聯名成為 APEC 優良查驗登記管理法規科學訓練卓越中心。

三、於 RHSC 預備會議與主要合作機構如日本 PMDA、亞洲生技製藥聯盟(APAC)、美國醫療法規學會(RAPS)台灣分會及墨西哥 COFEPRIS 等討論本(2017)年度研討會規劃事宜。

貳、行程安排

時間	行程
2 月 18 日	台北－越南芽莊
2 月 19 日	出席 Life Sciences Innovation Forum - Regulatory Harmonization Steering Committee (LSIF-RHSC) Meeting 會議地點：Liberty Central Hotel Nha Trang
2 月 20 日	出席 Life Sciences Innovation Forum - Regulatory Harmonization Steering Committee (LSIF-RHSC) Meeting 會議地點：Liberty Central Hotel Nha Trang
2 月 21 日	出席 Life Sciences Innovation Forum - Regulatory Harmonization Steering Committee (LSIF-RHSC) Meeting 會議地點：Liberty Central Hotel Nha Trang
2 月 22 日	出席 Life Sciences Innovation Forum (LSIF) - Planning Group Meeting 會議地點：Liberty Central Hotel Nha Trang
2 月 23 日	越南芽莊－台北

參、會議內容

一、Life Sciences Innovation Forum - Regulatory Harmonization Steering Committee (LSIF-RHSC) Meeting (2 月 19 日至 2 月 21 日，議程如附件 1)

(一)**LSIF-RHSC 預備會議(2 月 19 日)**：為促進優良查驗登記管理(GRM) 路徑圖(Roadmap)主辦機構對 GRM 法規科學訓練卓越中心(CoE)的督導，食藥署人員與日本 PMDA、JPMA、RAPS 台灣分會及墨西哥 COFEPRIS 等機構代表就推動優良查驗登記管理(GRM) 路徑圖(Roadmap)、法規科學訓練卓越中心(CoE) 2017 年訓練課程日期及內容、績效指標問卷設計及組成專家團隊提供實地訪視及輔導等進行討論，後續將就細部規劃召開電話會議討論。

(二)**LSIF-RHSC 正式會議(2 月 20 日及 2 月 21 日)**：本次會議由 RHSC 共同主席 Michelle Limoli (美國 FDA)及 Toshiyoshi Tominaga (日本 PMDA)聯合主持，審查 6 個重點工作領域(PWA)路徑圖及 CoE 的最新發展，並核准不同機構成為正式 CoE 或辦理先期 CoE 訓練活動，摘要報告如下：

1. 各 PWA 之最新發展：

(1) Multi-regional Clinical Trials and Good Clinical Practices Inspection Roadmap (Japan – PMDA and Thailand – FDA)

- **Update on Roadmap**
  - 本路徑圖自 2017 年至 2020 年為 Step 4: Training to reach the goal: Recommendations to further regulatory harmonization to be considered by RHSC。
  - RHSC 於本次會議認可 PMDA、Duke-NUS 及北京大學等 3 個機構為正式的 CoE，並認可 Harvard Brigham and Women's Hospital 辦理 CoE 先期訓練活動。
  - PMDA 除了於 2017 年 1 月 23 日至 26 日召開為期 3 天半的 PMDA-ATC Multi-Regional Clinical Trial (MRCT) Seminar 2017，亦於 1 月 26 日下午召開 APEC-LSIF-RHSC MRCT/GCP inspection Workshop，邀集路徑圖共同主辦機構泰國 FDA 及所有 MRCT CoE 主辦機構與會，Duke-NUS、北京大學及 PMDA 等 3 個 CoE 提出先期研討會成果報告，並檢討 MRCT/GCP inspection 課程的核心課綱修訂及未來方向。
- **CoE Update: MHLW/PMDA**
  - 從報告中了解學員招募對象得不限於 21 個 APEC 會員經濟體，在本次研討會的 32 名學員中，有 7 名來自非 APEC 會員經濟體，佔學員總人數的 22%，來自緬甸、斯里蘭卡、坦桑尼亞及尼泊爾。

- 從報告中了解 CoE 可於核心課綱外增加相關主題，如本次研討會增加 MRCT 運作考量點(Considerations for MRCT Operations)及國際合作與調和(International Cooperation and Alignment)等二主題。

- CoE Update: Singapore Duke/NUS
  - 該機構已於 2014 年及 2016 年二度舉辦 MRCT CoE 先期研討會，未來將依學員需求精進訓練內容，提供更多相關案例研究，並提供會後追蹤及聯繫。
- CoE Update: 北京大學
  - 預定於 2017 年 10 月至 12 月間舉辦 MRCT & GCP Inspection Workshop。
- CoE Update: The MRCT Center of Brigham & Women's Hospital (BWH) & Harvard
  - Harvard BWH MRCT Center 預定於 2018 年 4 月至 5 月間舉辦先期訓練，除核心課綱外，預定新增 ICH E17 (implications for design, planning and analysis of MRCTs)及 ICH E6 R2 revision 等主題。

(2) Biotechnological Products Roadmap (Korea – MFDS)

- Update on Roadmap
  - 本路徑圖自 2015 年至 2017 年為 Step 2: Training，2016 年共有 Northeastern University 及 Seoul National University 舉辦 CoE 先期研討會，RHSC 於本次會議認可 Northeastern University 為正式的 APEC CoE，並認可韓國 MFDS 及 AHC 於 11 月在拉丁美洲舉辦生技產品研討會，以促進拉丁美洲的能力建設及 APEC 的區域法規協和。
- CoE Update: Northeastern University
  - 經認可為正式 CoE 之後，Northeastern University 將於 2017 至 2018 年間依先期課程舉辦訓練活動，2018 年之後依回饋意見修訂課程。

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

- Update on Roadmap
  - 本路徑圖自 2017 年至 2019 年為 Step 3:Assessing the Impact of GRM，RHSC 於本次會議認可食藥署及 RAPS 台灣分會聯名成為正式的 APEC CoE，並認可墨西哥 COFEPRIS 辦理 CoE 先期訓練活動。食藥署的路徑圖簡報資料如附件 2。
- CoE Update: TFDA
  - 食藥署於 2016 年 11 月與美國醫療法規學會(RAPS)台灣分會(Taiwan Chapter)等機構合作辦理一場 2016 APEC 優良查驗登記管理(GRM)法規科學卓越中心(CoE)先期研討會，培訓 56 名來自 15 個 APEC 會員經濟體

的 GRM 種子師資，並於 2017 年 2 月與 RAPS 台灣分會聯名向 RHSC 提出申請成為正式的 APEC GRM CoE。

- 食藥署代表就 CoE 的最新進展及未來規劃於 RHSC 會議提出報告(簡報資料如附件 3)，獲與會主管機關及業界代表的熱烈迴響，並肯定此 CoE 對法規專業人員培訓的重要性。經 2 月 21 日 RHSC 委員會討論，無異議全數通過食藥署與 RAPS 台灣分會聯名成為「APEC 優良查驗登記管理法規科學訓練卓越中心」。
- 後續食藥署將與 APEC LSIF 簽署合作備忘錄(MoU)，每年主辦「APEC 優良查驗登記管理法規科學卓越中心」訓練課程，以推廣優良查驗登記觀念及相關教育訓練，提升 APEC 區域醫藥品審查品質及時效，並促進法規協和。

• CoE Update: COFEPRIS

- COFEPRIS 大致依核心課綱規劃 2017 年 6 月於墨西哥市舉辦的 GRM CoE 先期訓練課程，訓練對象包括墨西哥及拉丁美洲國家。
- 先期訓練課程結束後將上網公開訓練教材，並且建立專家網絡供學員諮詢或討論 GRM 相關問題。
- COFEPRIS 期望能夠於 2017 年獲認可為正式的 CoE。

(4) Pharmacovigilance and Medical Device Vigilance Roadmap (Korea – MFDS)

• Update on Roadmap

- RHSC 於本次會議認可 PMDA 為正式的 CoE，並認可 KIDS 辦理第 2 次 CoE 先期訓練活動。
- MFDS 及 KIDS 於 2016 年舉辦 PV workshop 及 CoE Pilot program，後續預定於 2017 年 9 月再次舉辦 PV workshop 及 CoE Pilot program。
- 有關醫療器材安全監視部份，MFDS 於 2016 年 9 月舉辦 AHC International Workshop for MDV (1st MDV workshop)，2017 年預定辦理差異分析，並於 9 月舉辦第二屆醫療器材安全監視研討會(2nd MDV workshop)。

• CoE Update: KIDS

- KIDS 代表報告 2017 APEC PV CoE Pilot Program 議題規劃。

• CoE Update: MHLW/PMDA

- PMDA 於 2017 年 2 月舉辦 PMDA-ATC Pharmacovigilance Seminar 2017，28 名學員中有 10 名來自非 APEC 會員經濟體的學員，佔學員人數的 36%，來自巴西、印度、緬甸、尼泊爾及波蘭。
- 下一次 PMDA-ATC Pharmacovigilance Seminar 預定於 2018 年 2 月舉行。

(5) Cellular Therapies Roadmap Update (Singapore - HSA)

- Update on Roadmap
- CoE Update
  - CoRE 預定於 2017 年 7 月舉辦先期訓練活動，地點在新加坡的 Duke-NUS 醫學院，將採用 2016 年研討會架構。

(6) Global Supply Chain Integrity Roadmap (US －FDA)

- Update on Roadmap
  - 本路徑圖由 APEC 多年期計畫資助，該計畫已執行完畢，US FDA 代表於本次會議報告最終產出，包括最終報告、10 個工作組產出的工具包(tool kits)及提供整體工具包的網頁，詳細內容請參照網頁連結 http://www.nifds.go.kr/apec/SupplyChain/APEC_SupplyChainToolkit_170317.pdf。
  - US FDA 徵求各國衛生主管機關專家加入 CoE 指導委員會，有意願者請聯繫路徑圖負責人 Ilisa Bernstein。
- CoE Update: University of Tennessee Health Sciences Center (UTHSC)
  - UTHSC 預定於 2017 年 6 月舉辦先期研討會，將聚焦於產品安全性及優良運銷規範(GDP)等主題，詳細內容請參照網頁 https://uthsc.edu/center-of-excellence/index.php。
- CoE Update: United States Pharmacopeia (USP)
  - USP 於 2017 年 3 月舉辦先期研討會，聚焦於以檢測技術確保供應鏈中的藥品品質，包括優良製造規範(GMP)、優良運銷規範(GDP)、優良藥局規範(Good Pharmacy Practice)及網路販售、篩選及檢測技術等主題，詳細內容請參照網頁 http://www.usp.org/securing-medical-product-quality-through-supply-chain。
- ABAC Track & Trace Project Update
  - 菲律賓食品藥物管理局(Philippine FDA)與 APEC 企業諮詢委員會(ABAC)於 2016 年 10 月在馬尼拉舉辦一場藥品追溯追蹤研討會，與會人員認同 ABAC 新創 SVSG 資料傳輸模式之優勢，菲律賓食品藥物管理局及衛生部將考慮於菲國執行先期計畫。
  - 有興趣與 ABAC 合作辦理相同研討會者，可與 ABAC 先期工作小組窗口 Eric Marshall 聯繫。

2. 其他議題：

(1) APEC Harmonization Center (AHC)報告：AHC 提供面對面培訓及線上培訓，並執行法規研究。值得我方留意的有下列二點：

- 線上培訓：ICH E2 指引的線上培訓課程已上線，提供所有使用者免費上網學習。AHC 預定於 2017 年初提供 ICH Q8、Q9、Q10 及生物治療基礎培訓課程。
- 法規研究：AHC 於 2014 至 2017 年間分年度進行 APEC 21 個會員經濟體的藥品管理框架研究，目前已將完成的 11 個會員經濟體藥品管理框架報告發表於 AHC 網站(http://www.nifds.go.kr/apec/index.do)，內容值得參考。

(2) RHSC 代表報告：

- AHC 報告代表 RHSC 出席 ICH/IPRF 會議成果。
- 印尼衛生部報告代表 RHSC 出席 IMDRF 會議成果，目前 IMDRF 有一個優良審查規範工作項目(Good Regulatory Review Practices - Competence and Training Requirements for Pre-market Reviewers and Product Specialist)，由美國 FDA 主導。

(3) APEC CoE SOP 及輔助文件討論：

- RHSC 成立志願性工作小組，協助建立 APEC CoE 資訊網頁，幫助未來有意辦理 APEC CoE 先期訓練計畫的機構獲取完整資訊。
- 將現有的 7 份文件重新彙整成 2 份文件，即 CoE Operating Model 及 Steps to Formalize a CoE，以方便使用。

(4) LSIF-RHSC 新提案：本次會議新增績效指標(Performance Indicators)、法規協和高階對話(High Level Dialogue on Regulatory Convergence)及 APEC CoE 資金(Funding)等提案，重要結論如下：

i. **績效指標評估表範本：**生物藥品(BIO)業界聯盟將依本次會議結論修訂範本，提供各路徑圖主辦經濟體訂定各 PWA 的績效指標評估表。

ii. **法規協和高階對話：**為盤點 LSIF-RHSC 8 年來推動法規協和的成果，宣達 RHSC 成立 APEC 法規科學訓練卓越中心，LSIF 預定於本(2017)年 8 月 18 日(SOM3 會議期間)於胡志明市舉辦一場法規協和高階對話(High Level Dialogue on Regulatory Convergence)，邀請各會員經濟體的醫藥品主管機關首長與會。

iii. **APEC CoE 資金：**LSIF 秘書處提案成立 APEC 子基金(Sub Fund)，供各會員經濟體申請辦理 APEC CoE 訓練活動，經費管理將遵循 Guidebook on APEC Projects 的規定。LSIF 秘書處將保留本議題供後續討論。

二、Life Sciences Innovation Forum (LSIF) - Planning Group Meeting (2 月 22 日)

(一)會議主席：本次會議由 RHSC 共同主席 Michelle Limoli (美國 FDA)代理主持。

(二)越南外交部代表報告 APEC 2017 Priorities。

(三)Research & Development Steering Committee – RDSC:

1. Thailand Center of Excellence for Life Sciences (TCELS)代表報告 APEC Bio-Medical Technology Commercialization Training Center 辦理人員培訓之成果，並徵求該訓練計畫的合作夥伴。
2. LSIF 秘書報告 APEC Framework for the Secondary Use of Medical Data in Health and Medical Research 工作小組的最新進展，並歡迎所有經濟體代表加入工作小組。

(四)APEC Program Director 報告 APEC 計畫管理現況。

(五)CTI 主席報告 CTI 的 2017 年優先工作重點。

(六)Economic Committee 主席報告 2016 APEC Economic Policy Report on Structural Reform and Services。

(七)Regulatory Harmonization Steering Committee – RHSC:

1. RHSC Co-Chair 報告 2 月 19 至 21 日 RHSC 會議成果。
2. AHC 代表報告 APEC Harmonization Center Update。
3. 越南代表及 LSIF 秘書處報告 APEC LSIF High Level Dialogue on Regulatory Convergence 的初步規劃。

(八)Health Policy and Innovation:

1. Advisor to the LSIF Co-Chairs 報告 APEC 2017 Health Financing Work Plan 及本年度預定召開的會議。
2. 越南衛生部代表報告 The 7th APEC High-Level Meeting on Health and the Economy 的初步規劃。
3. LSIF 秘書處報告加拿大提出的 APEC Digital Hub for Mental Health 計畫進展、相關文件及預定召開的會議。
4. 美國代表報告 APEC Cervical Cancer Initiative 計畫進展，該計畫由美國 NIH 下的 National Cancer Institute 主辦，已訂定 2016 年至 2020 年的路徑圖，目標為針對子宮頸癌的診斷與治療提升知識共享，增強對循證最佳做法 (evidence-based best practices)、實務經驗及創新策略的了解。該計畫將於本(2017)年度舉辦一場研討會，針對路徑圖議題進行討論。
5. 美國代表報告 Infection Prevention and Control / Antimicrobial Resistance 計畫現況。
6. 美國代表報告 Blood Supply Chain Initiative 計畫成果，包括 2016 年 12 月於越南河內召開兩場有關血液及血液產品 GMP 的研討會及 2017 年工作規劃。該計畫已建立一個 Blood Supply Chain Partnership Training Network 的專屬網頁，網址是 http://blood.apec.org/，食藥署及台灣血液基金會皆為本計畫的合作夥伴。

7. Professor Ian Wronski AO (LSIF Executive Board, James Cook University, Australia)報告 Tropical Health Workforce Development Hub Concept Note，LSIF 認可該提案。
8. Murdoch University (Australia)代表報告罕病提案，主題為 From the Shadows to the Spotlight: Accelerating Action on Rare Diseases in the APEC Region，預定舉辦政策對話及草擬 APEC Rare Diseases Action Plan，並成立 APEC 區域網絡以落實該行動計畫。
9. 越南 National Institute of Hematology and Blood Transfusion 代表提案於 2018 年辦理地中海型貧血症研討會，提案主題為 Workshop among APEC Member Economies on Sharing Experience in Thalassemia Management and Roles of Safe Blood Transfusion to Improve Quality of Life for Thalassemia Patients。

(九)LSIF 秘書處宣布 SOM3 LSIF 相關會議暫訂日期，如下：

- 8 月 15 日：LSIF Planning Group Meeting
- 8 月 16-17 日：LSIF-RHSC Meeting
- 8 月 18 日：LSIF High-level Dialogue on Regulatory Convergence
- 8 月 19-20 日：7th APEC High Level Meeting on Health and the Economy

三、雙邊會談

本署人員於會議期間把握機會與南向國家(包括印尼、泰國及菲律賓等國)代表分別進行雙邊會談，透過早餐或午餐時間，大家一起見面，雙方有初步認識，了解彼此藥政管理之現況，有助日後進行南向作業時之聯絡。簡述如下：

(一)印尼：會談對象包括該國藥品主管及醫療器材主管，初步了解這二類產品的管理分別由國家藥品食品管理局(National Agency of Drug and Food Control)及衛生部(Ministry of Health)主政，而藥師管理也是歸衛生部主政。該國近年積極參與國際法規協和相關會議，預定安排藥政管理首長參加今年 8 月召開的 LSIF High-level Dialogue on Regulatory Convergence，本署代表也請該國多派員來台參加 APEC GRM CoE 訓練活動。

(二)泰國：會談對象包括該國藥品主管及國際合作人員，了解該國即將調高藥品查驗登記審查費(user fee)收費標準，以增聘審查人員及提升內部作業。此外，雙方並就醫藥分業現況進行交流及分享。

(三)菲律賓：會談對象包括該國藥品主管、醫療器材主管及國際合作人員，該國代表表示願意跟我方就已簽署的「台菲健康產品備忘錄」規劃後續的實質合作內容。

肆、心得及建議事項

一、食藥署於本次會議獲 APEC LSIF-RHSC 認可為 APEC 優良查驗登記管理(GRM)法規科學訓練卓越中心(CoE)，係本署長期參與 RHSC 所獲得的國際認同。APEC 會員經濟體包括澳大利亞、汶萊、印尼、馬來西亞、紐西蘭、菲律賓、新加坡、泰國及越南等新南向政策國家，建議本署持續長期參與 RHSC，多派員出席 RHSC 會議及各重點工作領域舉辦的 CoE 訓練活動，並藉由在台舉辦 APEC GRM CoE 訓練活動來增進我國與 APEC 會員經濟體及新南向政策國家的法規交流合作。

二、除辦理 GRM 訓練活動外，建議本署開始準備 GRM 路徑圖的最終績效指標評估，以利於 2020 年有效完成路徑圖終點的績效指標評估，並實質促進 APEC 的區域法規協和。

三、RHSC 於 6 個不同重點工作領域透過 CoE 提供法規科學教育訓練，建議本署參加 CoE 訓練活動者將所獲得的資訊分享給署內同仁，以提升參加訓練活動的效益。

附件 **1、APEC LSIF-RHSC Meeting** 議程

APEC RHSC Meeting Agenda (version 2 15/17)

Liberty Central Hotel – Nha Trang, Vietnam
Meeting Room TBC

Preparatory Meetings – Sunday February 19, 2017:

08:30-12:00 Prep meetings Chinese Taipei and Japan (Closed meeting – by invitation)

16:00-20:00 Biotherapeutics/Biotechnology Coalition to discuss CoE-related Issues (Open)

RHSC Open Meeting–Monday, February 20, 2017: 10:00-18:00

Welcome and Introductions

Adoption of the Agenda

Review of Membership Lists

AHC Report (Yeowan Sohn)

Review of 2016 APEC Funding Criteria and Submission Cycles: (APEC Secretariat: David Wu)

RHSC Representatives' Reports: ICH (Speaker: Youngju Choi/AHC)
IPRF (Speaker: Youngju Choi/AHC)
IMDRF (Speaker: Arianti Anaya/Indonesia)

Multi-regional Clinical Trials and Good Clinical Practices Inspection Roadmap (Japan – PMDA and Thailand – TFDA)

Reference Documents:

Roadmap to Promote Multi Regional Clinical Trials and Good Clinical Practice Inspection (GCP Inspection) Project Update

- **Update on Roadmap**
- **CoE Update: MHLW/PMDA**
- **CoE Update: Singapore Duke/NUS (Silke Vogel)**
- **CoE Update: Peking University**
- **CoE Update: The MRCT Center of Brigham & Women's Hospital & Harvard (Rebecca Li)**

Working Lunch to Develop an SOP for Hosting an APEC CoE Pilot Program

Open Meeting for Volunteers: PWA Champions, Industry Coalitions, CoEs

Biotechnological Products Roadmap (Korea –MFDS)

Reference Documents:

APEC Biotherapeutic Products Roadmap: To reach a high level of regulatory convergence by 2020

Project Update

- **Update on Roadmap**
- **CoE Update: Northeastern University (David Luzzi)**
- **CoE Update: Seoul National University**

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

Reference Documents:

Roadmap to Promote Good Registration Management (GRM)

Project Update

- **Update on Roadmap**
- **CoE Update: TFDA**
- **CoE Update: COFEPRIS (Lahouari Belgharbi)**

Pharmacovigilance and Medical Device Vigilance Roadmap (Korea – MFDS)

Reference Documents:

Roadmap to Promote Pharmacovigilance and Medical Device Vigilance

Project Update

- **Update on Roadmap**
- **CoE Update: KIDS**
- **CoE Update: MHLW/PMDA**

Cellular Therapies Roadmap Update (Singapore - HSA)

Reference Documents:

Roadmap to Promote Prospective Regulatory Convergence in Cell- and Tissue-based Therapeutic Products

Project Update

- **Update on Roadmap**
- **CoE Update**

RHSC Open Meeting - Tuesday, February 21, 2017: 09:30

Global Supply Chain Integrity Roadmap (US –FDA)

Reference Documents:

Roadmap to Promote Global Medical Product Quality and Supply Chain Security

Project Update

- **Update on Roadmap (Ilisa Bernstein)**
- **CoE Update: University of Tennessee Health Sciences Center (Speaker: Ilisa Bernstein)**
- **CoE Update: United States Pharmacopeia (Speaker: Ilisa Bernstein)**
- **ABAC Track & Trace Project Update (Speaker: Richard Binos/Philippines FDA)**

Review and Discuss Proposal for Performance Indicators

Review and Discuss Proposal for High Level Dialogue on Regulatory Convergence

Review and Discuss Proposals for APEC CoE Funding

AHC 's Activities and Strategic Plan

Working Lunch to Develop an SOP for Hosting an APEC CoE Pilot Program

Open Meeting for Volunteers: PWA Champions, Industry Coalitions, CoEs

Review and Discuss CoE Supporting Documents

Reference Documents:

CoE Operating Model and Guidelines

CoE Operating Guidelines

Steps to Formalize an APEC CoE

CoE Pilot Program Application Form

CoE Pilot Program Authorization Letter Template

Formal CoE Application Form

Formal CoE Authorization Letter Template

MOU for a CoE Template

CoE Program Participant Certificate Template

RHSC Members Only CLOSED Meeting – Tuesday Feb 21: 15:00 – 17:00

(Participants: RHSC Regulatory Members and Industry Coalition Members Only)

Review Proposed 2017 CoE Pilot Programs

Review Formal CoE Applications Submitted

Finalize and Endorse CoE Documents

Confirm IMDRF APEC representatives and term

Any Other Business

RHSC OPEN Meeting – Tuesday, Feb 21: 17:00 – 18:00

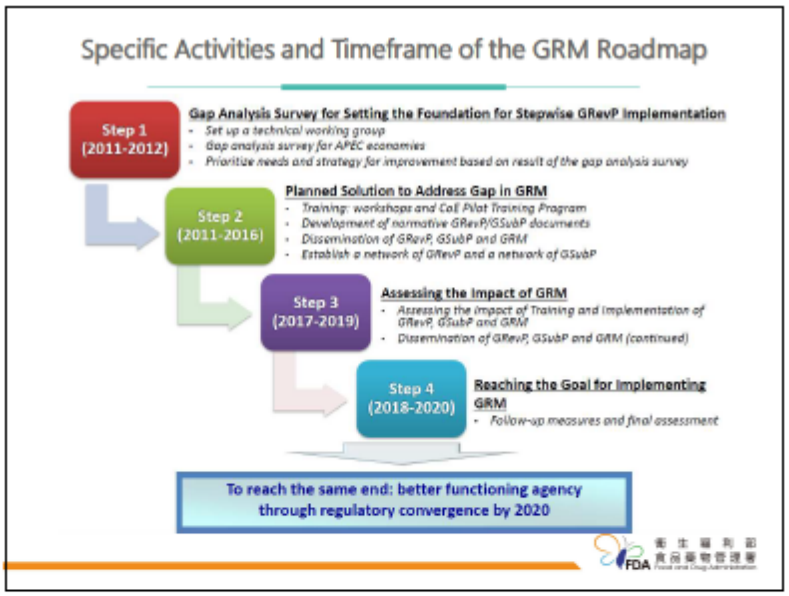
Review Decisions and Action Items

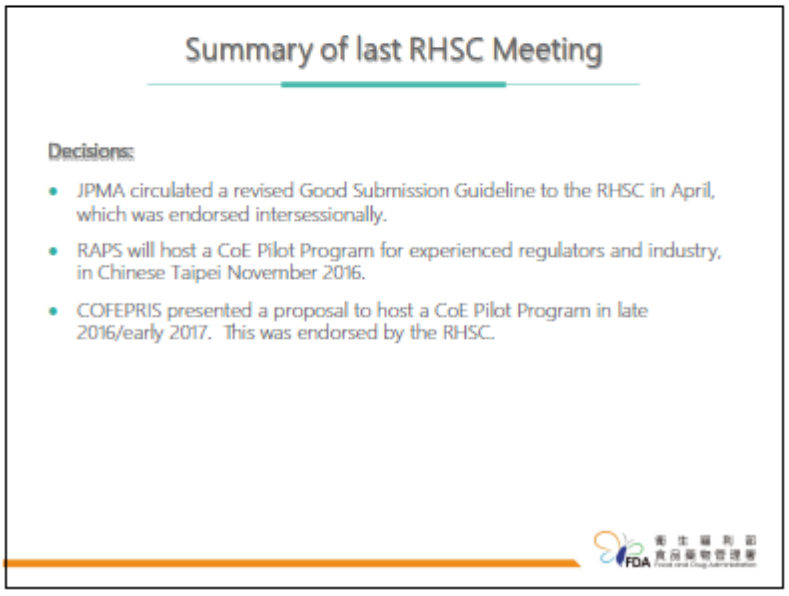
Dates for SOM-3 Meeting

Any other Business

Adjourn

附件 2、優良查驗登記管理路徑圖成果報告(GRM Roadmap Update)


Specific Activities and Timeframe of the GRM Roadmap
Step 1 (2011-2012)
Gap Analysis Survey for Setting the Foundation for Stepwise GRevP Implementation
Set up a technical working group
Gap analysis survey for APEC economies
Prioritize needs and strategy for improvement based on result of the gap analysis survey
Step 2 (2011-2016)
Planned Solution to Address Gap in GRM
Training: workshops and CoE Pilot Training Program
Development of normative GRevP/GSubP documents
Dissemination of GRevP, GSubP and GRM
Establish a network of GRevP and a network of GSubP
Step 3 (2017-2019)
Assessing the Impact of GRM
Assessing the impact of Training and Implementation of GRevP, GSubP and GRM
Dissemination of GRevP, GSubP and GRM (continued)
Step 4 (2018-2020)
Reaching the Goal for Implementing GRM
Follow-up measures and final assessment
To reach the same end: better functioning agency through regulatory convergence by 2020
FDA

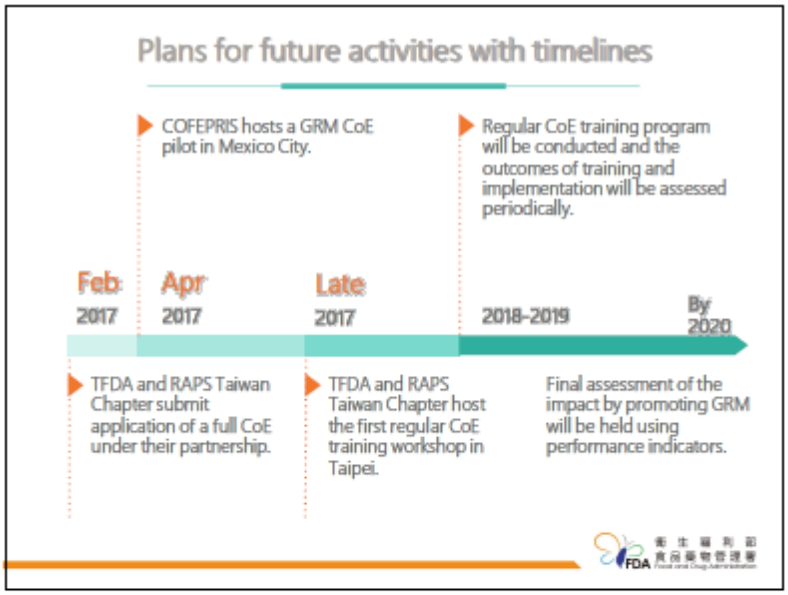

Summary of last RHSC Meeting
Decisions:
JPMA circulated a revised Good Submission Guideline to the RHSC in April, which was endorsed intersessionally.
RAPS will host a CoE Pilot Program for experienced regulators and industry, in Chinese Taipei November 2016.
COFEPRIS presented a proposal to host a CoE Pilot Program in late 2016/early 2017. This was endorsed by the RHSC.
FDA

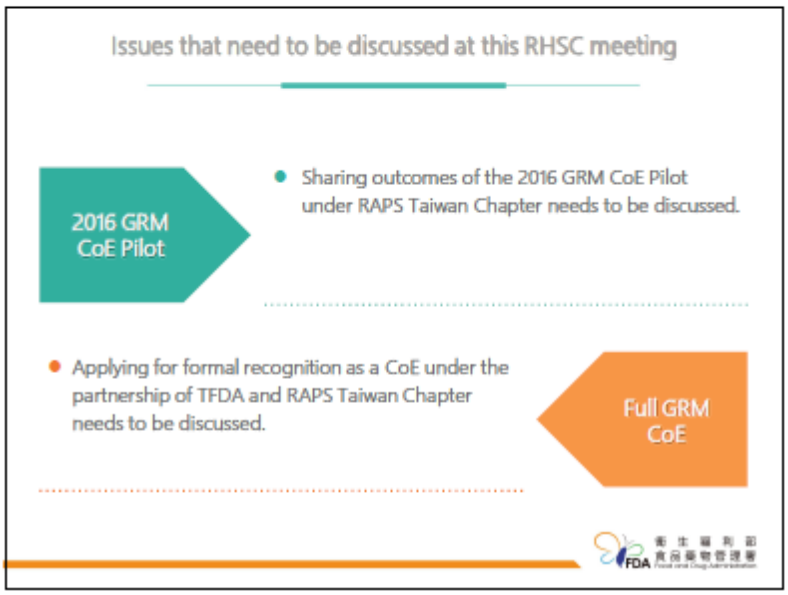
Summary of significant activity since last RHSC meeting (1)

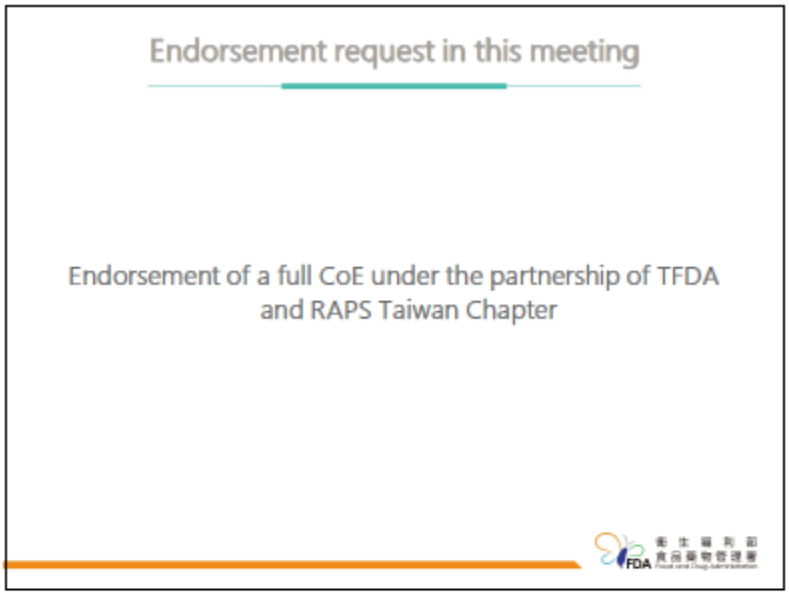
- **October 2016:** Pre-training materials for the 2016 GRM CoE pilot workshop was launched at the website of RAPS Taiwan Chapter.
- **November 2016:** The 2016 APEC Good Registration Management Regulatory Science Center of Excellence Pilot Workshop was held in Taipei from November 15 to 17, 2016.
  - This pilot workshop was co-hosted by RAPS Taiwan Chapter, TFDA, PMDA, APAC, and AHC.
  - A 3-day training program, including Common Sessions and concurrent Applicant-Specific Sessions and Reviewer-Specific Sessions, was developed.
  - Participants: (1) more than 30 international experts, (2) a total of 56 trainees (28 from industry, 26 from regulatory authorities and 2 from academia)from 15 different APEC member economies

Summary of significant activity since last RHSC meeting (2)

- November 2016:
  - The trainees received training on the concept and principles of good review and good submission through lectures, interactive discussions, and case studies.
  - On-site evaluation of the curriculum was conducted among the trainees through questionnaires. On a 5-point scale, the average score was 4.48. The workshop satisfaction was considered good.
- January 2017:
  - A face-to-face meeting was conducted between the champion economies in Taipei to discuss issues related to evaluation of the 2016 GRM CoE pilot workshop, application of a full CoE, and planning of the 2017 GRM training workshop.
  - A follow-up survey for 2016 APEC GRM CoE Pilot Workshop was conducted to understand the effectiveness in improving review or submission practices, facilitating dissemination of GRM, and achieving the goal of training the trainers for different APEC member economies.

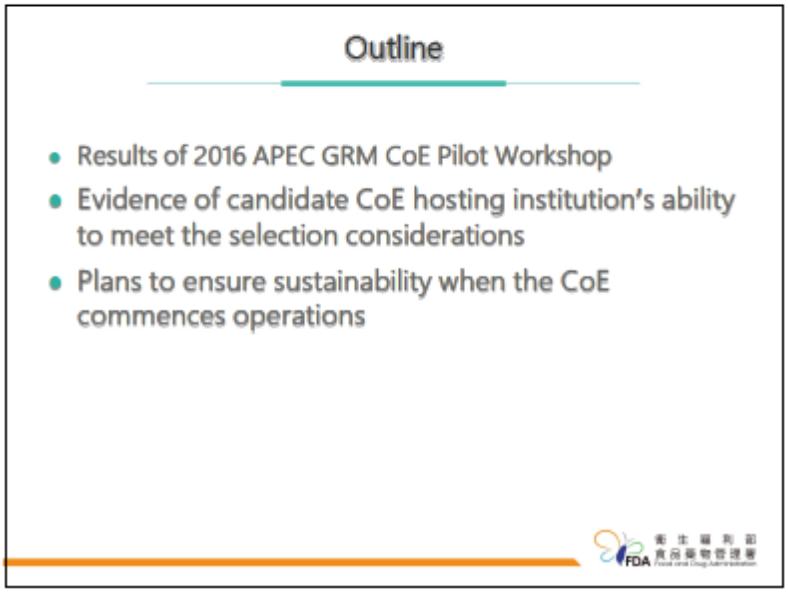

Plans for future activities with timelines
COFEPRIS hosts a GRM CoE pilot in Mexico City.
Regular CoE training program will be conducted and the outcomes of training and implementation will be assessed periodically.
Feb 2017
Apr 2017
Late 2017
2018-2019
By 2020
TFDA and RAPS Taiwan Chapter submit application of a full CoE under their partnership.
TFDA and RAPS Taiwan Chapter host the first regular CoE training workshop in Taipei.
Final assessment of the impact by promoting GRM will be held using performance indicators.


Issues that need to be discussed at this RHSC meeting
2016 GRM CoE Pilot
Sharing outcomes of the 2016 GRM CoE Pilot under RAPS Taiwan Chapter needs to be discussed.
Applying for formal recognition as a CoE under the partnership of TFDA and RAPS Taiwan Chapter needs to be discussed.
Full GRM CoE


Endorsement request in this meeting
Endorsement of a full CoE under the partnership of TFDA and RAPS Taiwan Chapter

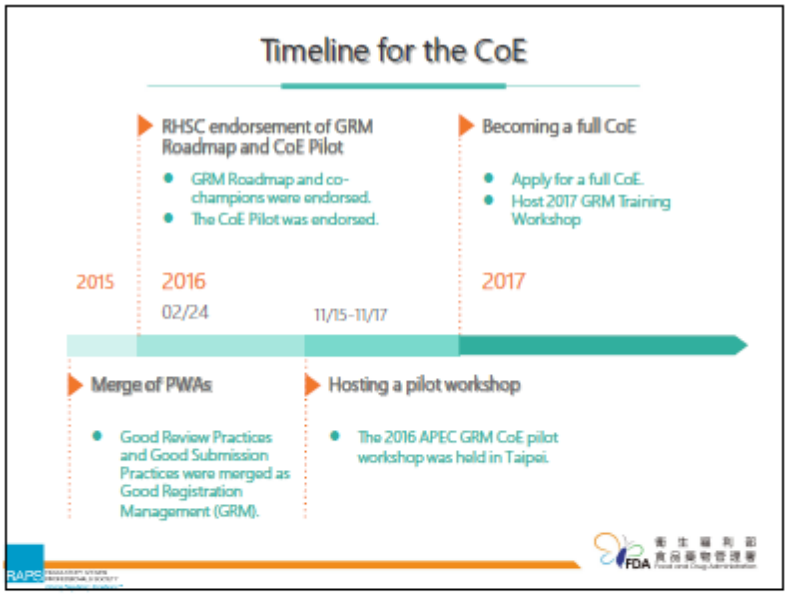

Food and Drug Administration, Ministry of Health and Welfare
Thank you for your attention.
衛生福利部
食品藥物管理署
Food and Drug Administration
http://www.fda.gov.tw/

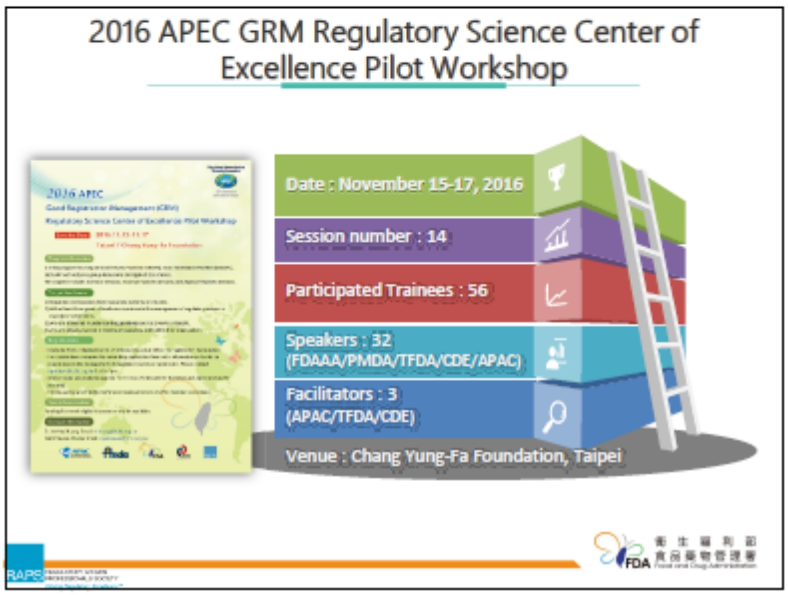
附件 3、優良查驗登記管理法規科學訓練卓越中心成果報告(CoE Update)

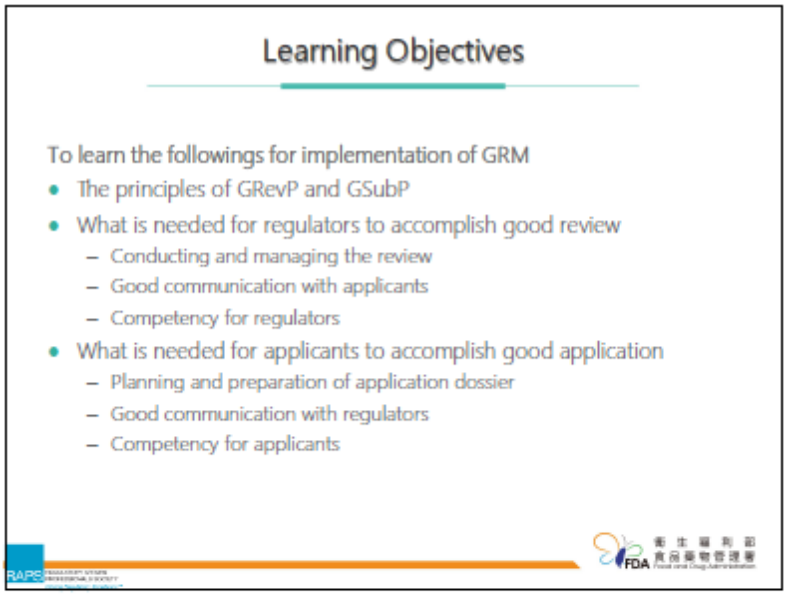


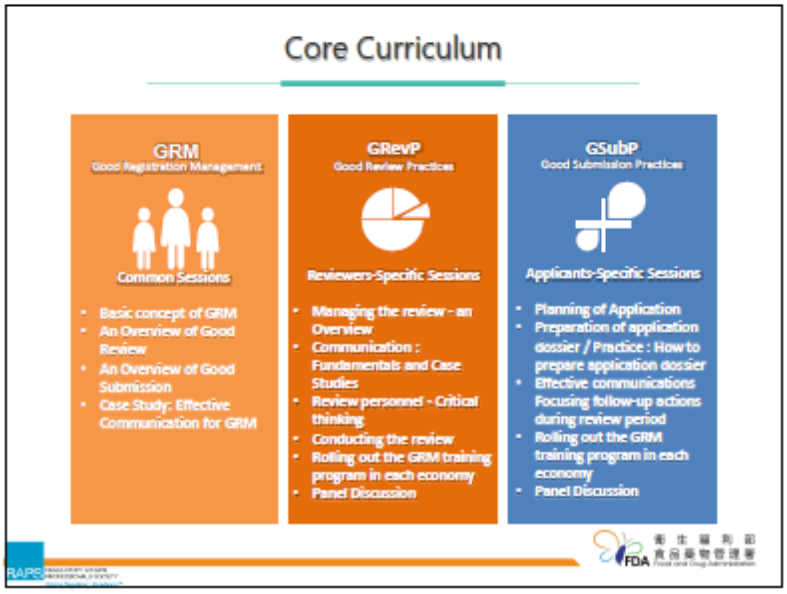

Food and Drug Administration, Ministry of Health and Welfare
Results of 2016 APEC GRM CoE Pilot Workshop
FDA
衛 生 福 利 部
食 品 藥 物 管 理 署
Food and Drug Administration
http://www.fda.gov.tw/


2016 APEC GRM CoE Pilot Workshop
Workshop co-organizers
APEC LSIF Regulatory Harmonization Steering Committee
Food and Drug Administration, Ministry of Health and Welfare, Taiwan (Chinese Taipei)
Pmda
Pharmaceuticals and Medical Devices Agency, Japan
Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs
APAC
Asia Partnership Conference of Pharmaceutical Associations
AHC
APEC Harmonization Center
RAPS
Regulatory Affairs Professionals Society (RAPS)
RAPS Taiwan Chapter
FDA


Timeline for the CoE
RHSC endorsement of GRM Roadmap and CoE Pilot
GRM Roadmap and co-champions were endorsed.
The CoE Pilot was endorsed.
Becoming a full CoE
Apply for a full CoE.
Host 2017 GRM Training Workshop
2015
2016
02/24
11/15-11/17
2017
Merge of PWAs
Good Review Practices and Good Submission Practices were merged as Good Registration Management (GRM).
Hosting a pilot workshop
The 2016 APEC GRM CoE pilot workshop was held in Taipei.


2016 APEC GRM Regulatory Science Center of Excellence Pilot Workshop
Date : November 15-17, 2016
Session number : 14
Participated Trainees : 56
Speakers : 32 (FDAAA/PMDA/TFDA/CDE/APAC)
Facilitators : 3 (APAC/TFDA/CDE)
Venue : Chang Yung-Fa Foundation, Taipei


Learning Objectives
To learn the followings for implementation of GRM
The principles of GRevP and GSubP
What is needed for regulators to accomplish good review
Conducting and managing the review
Good communication with applicants
Competency for regulators
What is needed for applicants to accomplish good application
Planning and preparation of application dossier
Good communication with regulators
Competency for applicants


Core Curriculum
GRM
Good Registration Management
Common Sessions
Basic concept of GRM
An Overview of Good Review
An Overview of Good Submission
Case Study: Effective Communication for GRM
GRevP
Good Review Practices
Reviewers-Specific Sessions
Managing the review - an Overview
Communication : Fundamentals and Case Studies
Review personnel - Critical thinking
Conducting the review
Rolling out the GRM training program in each economy
Panel Discussion
GSubP
Good Submission Practices
Applicants-Specific Sessions
Planning of Application
Preparation of application dossier / Practice : How to prepare application dossier
Effective communications Focusing follow-up actions during review period
Rolling out the GRM training program in each economy
Panel Discussion

Group photo of all GRM participants

Workshop photos

Participant analysis (1)

Total GRM Trainees
Chile (1)
China (3)
Hong Kong (2)
Indonesia (3)
Japan (2)
Korea (2)
Malaysia (3)
Mexico (2)
Papua New Guinea (2)
Peru (1)
Philippines (3)
Singapore (3)
Thailand (5)
Taiwan (23)
Vietnam (1)
56 APEC delegates
15 APEC member economies

Applicant-specific sessions

Applicants
China (3)
Hong Kong (2)
Japan (2)
Korea (2)
Malaysia (2)
Philippines (3)
Singapore (3)
Thailand (3)
Taiwan (9)
29 APEC delegates
9 APEC member economies

Reviewer-specific sessions

Reviewers
Chile (1)
Indonesia (3)
Malaysia (1)
Mexico (2)
Papua New Guinea (2)
Peru (1)
Thailand (2)
Taiwan (14)
Vietnam (1)
27 APEC delegates
9 APEC member economies

Participant analysis (2)

Question: How many years have you worked on the management of regulatory review or regulatory submission?

Reviewers	Responders (total 27)
about 3 years or less	11 (41%)
3 to 5 years	8 (30%)
5 to 10 years	3 (11%)
more than 10 years	5 (18%)

- 26 were from regulatory authorities and 1 was from academia.

Applicants	Responders (total 29)
about 3 years or less	3 (10%)
3 to 5 years	1 (4%)
5 to 10 years	5 (17%)
more than 10 years	20 (69%)

- 28 were from industry and 1 was from academia

Effectiveness Analysis

General Satisfaction with the Workshop

General Satisfaction	Response Average	Responders
Were level and amount of pre-training materials adequate?	4.33	42
Did the workshop enhanced your understanding of GRM concept?	4.49	42
Were your expectations for this workshop met?	4.33	42
Overall satisfaction	4.48	42

Scale 1 = Poor and 5 = Excellent
Average rating score is above 4. The pilot is considered with good satisfaction.

Curriculum Analysis (1)

Rating for Common Sessions

Common Sessions	Session 1 Basic concept of GRM		Session 2 An Overview of Good Review		Session 3 An Overview of Good Submission		Session 4 Case Study: Effective Communication for GRM	
	Response Average	Responder	Response Average	Responder	Response Average	Responder	Response Average	Responder
The adequacy of training materials	3.96	33	4.03	33	4.18	33	4.21	33
The adequacy of the time allocation for this session	4.27	33	4.30	33	4.24	33	4.27	33
Facilitation and presentation of the content	4.12	33	4.21	33	4.27	33	4.24	33
Total evaluation	4.15	33	4.24	28	4.34	32	4.27	33

Curriculum Analysis (2)

Rating for Reviewer-Specific Sessions

Reviewers-Specific Sessions	Session R1 Managing the review - an Overview		Session R2 Communication : Fundamentals and Case Studies		Session R3 Review personnel - Critical thinking		Session R4 Conducting the review		Session R5 Rolling out the GRM training program in each economy	
	Response Average	Responder	Response Average	Responder	Response Average	Responder	Response Average	Responder	Response Average	Responder
The adequacy of training materials	4.36	22	4.45	22	4.60	23	4.47	23	4.47	23
The adequacy of the time allocation for this session	4.40	22	4.54	22	4.60	23	4.52	23	4.52	23
Facilitation and presentation of the content	4.40	22	4.59	22	4.60	23	4.52	23	4.52	23
Total evaluation	4.40	22	4.59	22	4.60	23	4.60	23	4.52	23

Curriculum Analysis (3)

Rating for Applicant-Specific Sessions

Applicants-Specific Sessions	Session A1 Planning of Application		Session A2 Preparation of application dossier / Practice : How to prepare application dossier		Session A3 Effective communications Focusing follow-up actions during review period		Session A4 Rolling out the GRM training program in each economy	
	Response Average	Responder	Response Average	Responder	Response Average	Responder	Response Average	Responder
The adequacy of training materials	4.36	22	4.36	22	4.7	20	4.44	18
The adequacy of the time allocation for this session	4.40	22	4.36	22	4.45	20	4.42	19
Facilitation and presentation of the content	4.5	22	4.27	22	4.5	20	4.47	19
Total evaluation	4.47	21	4.47	22	4.55	20	4.47	19

Curriculum Analysis (4)

Rating for Panel Discussion on Regulatory Professionals' Competencies

Session A5/R6 Panel discussion	Response Average	Responder
The adequacy of training materials	4.26	37
The adequacy of the time allocation for this session	4.17	39
Facilitation and presentation of the content	4.25	39
Total evaluation	4.22	39

Curriculum Analysis (5)

Feedback from Trainees

Topics/presentations of the 2016 pilot workshop most useful to trainees

Applicants
Communication
Planning for submission
QC & Dossier Preparation
Case study & group discussion are very good.
All topics
The tools, the exercises.
Section A3. Effective communications - Focusing follow-up actions during review period / Practice: Case study of how to handle inquires

Topics/areas trainees would like to see in the future GRM workshop

Applicants
Effective communication
More case studies: implementation of GRM, submission to regulatory authorities among Asia/US/EU
Interactive sessions between reviewers and applicants
Others: tools for improving quality of submissions, project management, risk management, critical thinking

Curriculum Analysis (6)

Feedback from Trainees

Topics/presentations of the 2016 pilot workshop most useful to trainees

Reviewers
Critical thinking, Communication
Rolling out the GRM training program in each economy
Case studies
Group discussion
All topics
Conducting the review
Managing the Review

Topics/areas trainees would like to see in the future GRM workshop

Reviewers
Critical thinking in risk/benefit considerations, different product areas, review disciplines and post-approval modifications
Communication
Interactive sessions between reviewers and applicants
Others: effective tools and approaches used for GRevPs, key aspects to perform a review

Preliminary Results of the Follow-up Survey (1)

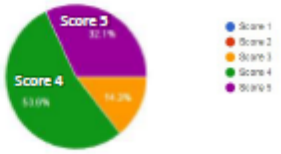
Trainees from 12 out of 15 APEC member economies have responded.

Total GRM Trainees
Chile
China
Hong Kong
Indonesia
Japan
Korea
Malaysia
Mexico
Papua New Guinea
Peru
Philippines
Singapore
Thailand
Taiwan
Vietnam

Preliminary Results of the Follow-up Survey (2)

Part 1. Effectiveness in improving practices

- **Are the contents of workshop applicable or helpful in improving your review or submission practices?**

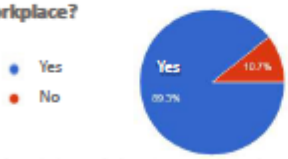


- **Will you recommend your colleagues to join the future GRM workshop?**

Preliminary Results of the Follow-up Survey (3)

Part 2. Facilitating dissemination of GRM & Effectiveness in achieving the goal of training the trainers for different APEC member economies

- **Have you taken or planned any action to promote the GRM concept and practices to colleagues in your workplace?**

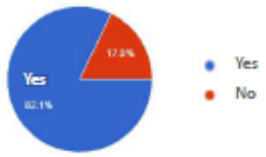


- **Have you planned to conduct local training of the GRM-related topics for colleagues in your economy?**

Preliminary Results of the Follow-up Survey (4)

Part 2. Facilitating dissemination of GRM & Effectiveness in achieving the goal of training the trainers for different APEC member economies

- **Do you plan to use the training manuals to organize GRM training?**



Conclusion and Discussion

- It was a successful CoE pilot with
  - good partnership and collaboration,
  - significant interactive elements, such as interactive discussions, group discussions, case studies, and practices, and
  - good rating and overall satisfaction.
- For the future training program, we plan to
  - create more collaborative sessions to allow trainees from industry to talk to regulators,
  - provide more case studies and interactive discussions, and
  - put more emphasis on the topics of "communication" and "critical thinking".

Plans for the Year 2017

- To be endorsed by APEC RHSC
  - A full CoE under the partnership of TFDA and RAPS Taiwan Chapter
- To plan and host an APEC GRM CoE Training Workshop in late 2017

CoE Configuration

- Hosting institution names:
  - TFDA: TFDA Training Center will be launched to serve as the physical location of the CoE in 2018.
  - RAPS Taiwan Chapter
- Collaborative partners and their roles:
  - PMDA ATC (GRM CoE Program Committee co-chair, provide oversight and guidance in program development)
  - APAC (GRM CoE Program Committee member, provide guidance in program development)
  - RAPS Global Headquarters (GRM CoE Program Committee member, provide support in program development)

National Biotechnology Research Park (Taipei)

- TFDA Training Center will be located at 2F of Building F for Food and Drug Administration. It will serve as the physical location of the CoE beginning 2018.
- Class rooms, meeting facilities and offices will be set up to support domestic training programs and international conferences.

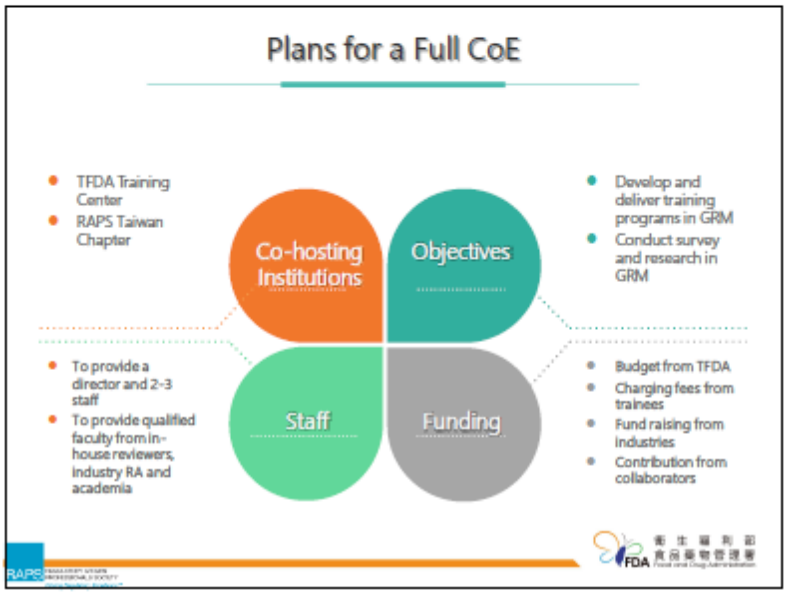
Why TFDA

- With substantial technical expertise and credibility in GRM:
  - Serve as RHSC GRevP roadmap champion and GRM roadmap co-champion
  - Involve in the drafting of GRevP guidelines and GSubP guidelines
  - Host GRevP, GSubP and GRM workshops
    - APEC Good Review Practice Workshops (2010, 2011 and 2012)
    - Good Submission Practice Workshops (2014 and 2015)
    - APEC GRM CoE Pilot Workshop (2016)
- Provide budget, faculty and staff to support promotion of GRM and operation of GRM CoE
- The location provides easy access by participants.

The CoE will meet selection considerations

- Trusted global educational/regulatory brand
- Ability to develop and deliver training program against priorities set by the APEC RHSC
- Willingness to provide a full or part-time Director and appropriate staff to manage the CoE
- Ability & commitment to achieve objectives as agreed in operating guidelines
- Ability to fund the administrative overhead over the life of the agreement (minimum 5 years)
- Credibility in the topic area
- Location that provides easy access by participants
- Ability to provide qualified faculty; this could be visiting regulatory staff or other experts as required by the training program
- Ability to receive funding to support specific aspects of CoE training (for instance, to fund student travel)


Food and Drug Administration, Ministry of Health and Welfare
Plans to ensure sustainability when the CoE commences operations
FDA
衛生福利部
食品藥物管理署
Food and Drug Administration
http://www.fda.gov.tw/


Plans for a Full CoE
TFDA Training Center
RAPS Taiwan Chapter
Co-hosting Institutions
Objectives
Develop and deliver training programs in GRM
Conduct survey and research in GRM
To provide a director and 2-3 staff
To provide qualified faculty from in-house reviewers, industry RA and academia
Staff
Funding
Budget from TFDA
Charging fees from trainees
Fund raising from industries
Contribution from collaborators


Food and Drug Administration, Ministry of Health and Welfare
Thank you for your attention.
FDA
衛 生 福 利 部
食 品 藥 物 管 理 署
Food and Drug Administration
http://www.fda.gov.tw/

附件 4、APEC LSIF Planning Group Meeting 議程

SOM1 2017 LSIF Planning Group (LSIF PG) Meeting

Wednesday, 22 February 2017

09:00 – 18:00

Liberty Central Hotel, Apollo 1

09 Biet Thu, Nha Trang, Viet Nam

PROGRAM AGENDA

Time	#	Topic
09:00 – 09:15	**1**	**Opening Session** 1.1. Welcome Remarks (LSIF Planning Group Chair) 1.2. Remarks by LSIF Executive Board Chair's Representative (Philippines)
09:15 – 09:30	**2**	**APEC 2017 Priorities** 2.1. APEC 2017 Priorities (Ministry of Foreign Affairs, Viet Nam)
09:30 – 10:00	**Research & Development Steering Committee – RDSC**	
	3	3.1. APEC Biomedical Technology Commercialization Training Center (Thailand) 3.2. Cross-fora Collaboration in APEC on the Use of Big Data in Medical Research (E-Commerce Steering Group - ECSG)

10:00 – 10:10	**4**	**APEC Management** 4.1. APEC Management Update (APEC Secretariat)
10:10 – 10:30	**Coffee Break and Photo**	
10:30 – 11:00	**5**	**Committee on Trade and Investment** 5.1. CTI Update (CTI Chair)
11:00 – 11:30	**6**	**Economic Committee** 6.1. Briefing on the 2016 APEC Economic Policy Report on Structural Reform and Services (EC Chair)
11:30 – 12:00	**Regulatory Harmonization Steering Committee – RHSC**	
	7	7.1. RHSC Update (RHSC Co-Chair)
12:00 – 13:00	**Lunch**	
13:00 – 14:00	**7**	7.2. APEC Harmonization Center Update (Korea) 7.3. LSIF High-Level Dialogue on Regulatory Convergence (Ministry of Health, Viet Nam and Representative of the Advisor to the LSIF Co-Chairs)
14:00 – 15:00	**Health Policy and Innovation**	

	8	*Cooperation with HWG and SFOM* 8.1. Fiscal and Economic Impacts of Ill Health – Proposed Dialogues with Senior Finance Officials and Finance Ministers (Representative of the Advisor to the LSIF Co-Chairs) 8.2. HWG 2017 Theme and Priorities (Viet Nam) 8.3. 7th APEC High-Level Meeting on Health & the Economy (Viet Nam)
15:00 – 15:20	**Coffee Break**	
15:20 – 16:30	**8**	*Projects* 8.4. Mental Health / APEC Digital Hub (Representative of the Advisor to the LSIF Co-Chairs) 8.5. HPV and Cervical Cancer (United States) 8.6. Infection Prevention and Control / Antimicrobial Resistance (United States) 8.7. Blood Supply Chain Partnership Training Network (United States) 8.8. Tropical Health Workforce Hub (LSIF Executive Board) 8.9. Rare Diseases 8.10. Thalassemia management (Viet Nam)
16:30 – 16:45	**9**	**Other Business**
16:45 – 17:00	**10**	**Recommendations to CTI**
17:00	**Adjourn**	

附件 5、會議剪影

	
GRM Side-Meeting 與會人員合影	RHSC 會議剪影
	
與 RHSC 美日共同主席合影	台菲雙邊會談
	
台印雙邊會談	台泰雙邊會談