出國類別：出席國際會議

2017「第九屆中國國際藥物信息大會(DIA)中國年會」出國報告

服務機關：衛生福利部食品藥物管理署 藥品組

姓名職稱：黃琴嘵科長

派赴國家：中國

出國期間：106 年 5 月 22 至 5 月 25 日

報告日期：106 年 7 月 5 日

目錄

摘要

第九屆 DIA 中國年會以「恪守臨床價值導向，引領藥物研發新趨勢」為主題，於 2017 年 5 月 21-24 日在上海國際會議中心舉行。今年以醫藥創新和改革的方向聚集全球對藥政法規、藥物研發與學術醫療領域的專業人員與會，且首次舉行「DIAmond 鑽石經典分會研討」，在此研討會上專家討論有關臨床研究、如何有效率的審核藥品，替病人提供安全有效的藥品。透過此大型多元之專業會議，與世界各國專家學者進行經驗分享與交流。

會議第一日(5/21)為會前專題研討會，第二日 (5/22)為全體大會與特別論壇，第三日至第四日(5/23-24)為大會研討會。本次受邀於第四日 (5/24)專題一「監管科學」，分享主題：” APEC Working Group Review and Submission Best Practice Sharing-from Regulator’ s Perspective”就我國近年於 APEC 中推動藥物優良查驗登記管理之相關辦理經驗與成果進行報告。

透過參加此次會議與各國交流法規制定與查驗經驗，看到中國大陸對於醫藥法規和藥物研發的實力接快速提升中。

壹、目的

此次受邀參與會議，與各國藥政法規單位、各國醫藥業者進行交流與管理經驗分享，並於會議中簡介我國近年於 APEC 中推廣查驗登記管理，與我國去年(105)11 月舉辦之「2016 APEC 優良查驗登記管理法規科學訓練卓越中心先期研討會」之相關辦理經驗，同時也宣傳今年 (106)年將於我國辦理之「2017 APEC 優良查驗登記管理法規科學卓越中心訓練研討會」，讓各國參與代表了解台灣在藥品管理的嚴謹與積極。

貳、過程(行程表)

日期	具體任務
106 年 5 月 22 日	台北至上海
106 年 5 月 23 日	參加第九屆 DIA 中國年會研討會
106 年 5 月 24 日	1. 參加第九屆 DIA 中國年會研討會，並發表演講，講題為「APEC Working Group Review and Submission Best Practice Sharing-from Regulator’ s Perspective」。 2. 參加大會舉辦之演講交流活動
106 年 5 月 25 日	上海返台北

參、參加會議

第九屆 DIA 中國年會以「恪守臨床價值導向，引領藥物研發新趨勢」為主題，於 2017 年 5 月 21-24 日在上海國際會議中心舉行。各國醫藥管理機關、醫藥研究人員、學術機構與醫院管理人員皆齊聚一堂，熱烈地於本次會議中討論最新的藥政改革與新藥研發帶來的機會與挑戰。

研討會及演講

DIA 研討會進行之方式為同時間、不同專題在不同的會場舉行，同時在會議場外亦舉辦商展 (此次商展超過一百個展位)。議題主題廣泛，此次議題如下：

專題一　監管科學

Regulatory Science

專題二　國家食品藥品監督管理總局

China Food and Drug Administration (CFDA) Town Hall

專題三　多方合作，共同打造高質量臨床研究

Multi-collaborations-A Pathway to High Quality Studies

專題四　腫瘤藥物開發

Oncology Drug Development

專題五　變革中的定量科學

Quantitative Science in Transformation

專題六　恪守臨床價值，滿足患者需求

Focus on Medical Value to Satisfy Unmet Patient Needs

專題六之二 臨床申報文件：如何應對新的監管要求

Clinical Submission Documents-Embrace New Regulatory Requirements

專題七　生物藥和生物類似藥的開發與監管

Development and Regulation of Biologicals & Biosimilar

專題八　患者安全－持續關注的焦點

Patient Safety-A Constant Focus

專題九　創新藥物早期研發戰略與戰術

The Strategy and Implementation of Early Clinical Development for Innovative Drugs

專題十　立足中國的新藥開發和創業論壇

China-Anchored Drug Development and Entrepreneurship Forum

專題十一　熱點話題

Hot Topics & Late Breaker

專題十二　罕見病論壇

Rare Disease: Unsatisfied Market Demand

專題十三　展商學術交流研討會

White Paper Showcase

5 月 23 日於專題一之監管科學，上午第一場由強生亞太製藥部全球法規事務亞太區法規政策事務負責人、高級總監趙風雲先生主持: 科學監管的國際新熱點。第一位由美國 FDA 藥品評價和研究中心 (CDER)新藥/抗菌產品辦公室主任 Dr. Edward Cox 講授「抗菌藥耐藥性管理的最新進展」。第二位由強生公司製藥部全球法規事務部疫苗及科學創新項目負責人、副總裁 Dr. Adam Hacker 談論「疾病的攔截」對於疾病的治療和控制，在早期加入干預疾病病程發展的藥物，攔截疾病繼續發展。第三位由 Biologics Consulting Group 高級顧問/FDA 同仁會國際部主席胡勁捷博士講授「藥物伴隨治療」，講解美國頒布 21 世紀治癒法案，與 FDA 在藥物和器械以及疾病診斷等多方面進行改革。第二場由瀋陽藥科大學亦宏商學院院長張象麟院長主持:我國實施 ICH 技術指導原則的思考和探討。第一位由鄭州大學陳震教授講授「ICH 指導員則在我國實施的基礎、存在的問題和困難以及實施的建議」。第二位由美國新機制藥全球法規事務副總裁 Dr. Florence Houn 講授「國際技術標準協調過程對監管體系的影響」。第三位由美國 FDA 藥品評價和研究中心 (CDER)仿製藥辦公室全球事務副主任李自力博士與此場第一及第二位講者共同討論「中國實施 ICH 對創新、仿製、國際化及監管改革的影響」，中國監管機構和研發型企業在國際化的過程中，不斷思考 ICH 在中國的實施路徑，在 ICH 影響中國監管體制的同時也為制定技術指導原則提供參考。

下午參加專題二國家食品藥品監督管理總局，由 CFDA 各機關分別介紹。中國藥化註冊司介紹法規進展，包含藥品註冊分類調整與藥品上市許可制度。中檢院如何提高仿製藥治療標準。中國藥審中心介紹 105 年藥品審查報告以及如何提高審查效率。核查中心介紹 105 年 GCP 與 GMP 實施狀況與 106 年工作重點。CFDA 也特別強調，近年改革藥政重心在增加審查人力與加速審核效率，預計 2020 年其 CDE 團隊將從 600 人增至 1600 人。106 年 3 月 17 日發布「關於調整進口藥品註冊管理有關事項的決定(徵求意見稿)」旨在降低國外新藥進入中國的政策門檻，5 月連續公布第 52 至 55 號文件，尤其「審評機構自受理之日起 60 個工作日後，沒有給出否定或質疑的審查意見即視為同意，申請人可按照遞交的方案開展臨床試驗。」，此舉將大幅提升國際大廠進軍中國，也是給予我國藥品西進開啟一扇大門。

5 月 24 日於專題一之監管科學，上午第一場由中國羅氏投資有限公司亞太區法規部門呂玉真負責人主持。首先由科睿唯安產品與解決方案顧問李寅博士主講「他山之石-借力監管科學成果提升審評質量」。再由瀋陽藥科大學國際食品藥品政策與法律研究中心楊悅主任講授「監管科學的基本概念與原則」。透過講者說明，並且分享近年來 FDA、EMA 和近年顯著進步的 PMDA 審查數據分，進一步闡明監管科學的發展。第二場由百濟神州高級副總裁及藥政事務閣小軍負責人主持。第一位由德國獨立顧問王雅敏博士介紹「新藥研發的新路徑」，再由美國 FDA 同仁會國際部成員 Mark Goldberger 介紹「美國 FDA 藥物加快審評綜述和案例」。下午場由上海復星醫藥集團副總裁兼研發中心主任邵穎博士為主持人，和專家們討論藥品質量控制和監管。第一位由美國 FDA 中國辦公室助理主任 Dr. Lane Christensen 介紹「國際 GXP 的監管模式」，第二位由諾和諾德公司全球質量部門副總張慶博士分享「從企業角度看全球質量監管趨勢」，共同探討中國 GXP 管理制度的發展方向。

5 月 24 下午舉行之 DIAmond 鑽石經典分會為 DIA 首次舉行，此創新形式為本次會議亮點，由強生亞太製藥部全球法規事務亞太區法規政策事務負責人、高級總監趙風雲先生主持:加快審評審批為病人提供安全、有效和高質量的藥品-良好審評和提交規範的作用。首先由國家食品藥品監督管理總局黃青竹講述「CFDA 良好審評與提交規範經驗分享」。再來由職代表藥政管理部門的觀點分享「APEC 工作組良好審評與提交規範經驗分享」向與會者簡介我國近年於 APEC 中推廣藥物優良查驗登記管理 (Good Registration Management)之經驗，及我國去年 (105)11 月舉辦之 APEC 優良查驗登記管理法規科學訓練卓越中心先期研討會之相關辦理經驗與成果，同時也宣傳我國今年十月底至十一月初預辦理之「2017 APEC Good Registration Management Regulatory Science Center of Excellence Workshop」研討會，同場也有日本 JPMA 代表 Shinji Hatakeyama 博士從業界的觀點分享「APEC 工作組良好審評與提交規範經驗分享」、美國 FDA 藥品評價研究中心主任李自力博士等人員共同探討如何加速藥物審查速度。透過此場分會和專家們相互分享在藥品查登規範性的重要想法，鼓勵申請者不要僅注意上市前、申請查登的最後階段，而是在整個研發過程中，和相關單位保持有效的溝通，以便有效提高整個過程的效率。

肆、心得及建議

此次應邀至上海參與 2017 第九屆 DIA China 年會向國際分享我國於 APEC 優良常驗登記管理法規科學訓練卓越中心之辦理經驗，藉分享之餘也宣傳推廣今年 2017 十月底將辦理之 GRM 計畫研討會。同場也聽取日本業界、美國 FDA 及中國大陸藥物查驗中心等專業人員的簡介，共同探討如何增加藥物審查效率。加快藥物審查效率，提供病人安全有效的藥品是藥政管理機關和業界的共同責任。參與此會，與各國專家交流以瞭解各國具體審查機制如何運作;同場多達一百個展為的商展，更可得知中國醫藥業者對於推展海外市場的創新與積極。

另 CFDA 已通過 ICH 成員國的申請，無疑是顯示中國藥政機關將在審查領域與國際接軌，進一步提升中國藥品研發水準與審查水平，同時意味著其將在國際法規科學上取得更多的發言權、參與決策權，可能更加快全球藥品審查的改革速度。我國目前為 ICH 之觀察員，也正積極參與國際法規協和、合作等，此 DIA 藥物資訊年會為全球藥物研發資訊與法規管理之重大會議，在亞洲地區為 DIA Japan 和 DIA China，使產官學研等會員能藉此機會交流與溝通，本署長官與同仁也多次應邀出席該二會議並擔任講員，展現我國藥政管理能和國際接軌。DIA 年會的議題也相當多元且具深度，從藥政法規管理、新藥開發至臨床試驗的管理，能從中學習各國優點與擷取他國經驗的好機會。建議各單位能派員參與，且積極爭取與會中擔任講員之機會，以宣傳我國藥政法規協和與各國簽署備忘錄等合約之實施情形;並鼓勵國內業者也多報名參加，除了透過此會了解各國法規之發展、提升產業的辦事力，同時增加我國能見度且實質加強國際交流提升合作機會。

伍、附件

(一)、DIA 中國年會議程

(二)、DIAmond 經典分會內容與講員

星期二, 2017年5月23日 | 星期三, 2017年5月24日　专题 1

分会场 0106 | 2017年5月24日　同传
10:30-12:00 | 三层，黄河厅

加快新药研发和审批的思考和案例分享
分会场主持人
闫小军
百济神州高级副总裁及药政事务部负责人

在过去的若干年里，很多国家的药品监管机构纷纷推出了加快临床急需新药的支持政策以推动新药研发和审批。本专题将邀请药品监管机构和工业界的讲者介绍相关的加快审评政策及成功案例分享

支持新药研发的新路径--EU PRIME
王雅敏 博士
德国独立顾问

美国FDA药物加快审评综述和案例
Mark Goldberger MD MPH LLC独立顾问
美国FDA同仁会国际部成员
前美国FDA药品评价和研究中心（CDER）
新药办公室抗菌产品办公室主任

题目待定
陈晓媛
国家食品药品监督管理总局药品审评中心化药临床一部

分会场 0107 | 2017年5月24日　同传
13:30-15:00 | 三层，黄河厅

药品质量控制和监管
分会场主持人
邵颖 博士
上海复星医药集团副总裁兼研发中心主任

随着我国制药企业质量管理能力的不断提升，技术标准和国际监管共识日趋一致，我国药品监管部门正在不断探索药品生命周期的管理新方式。作为药品生命周期中保障药品质量的重要监管措施，GXP管理制度的改革势在必行。自2015年8月国务院发布“关于改革药品医疗器械 审评审批制度的意见”以来，我国药品监管部门正在探索建立以监管科学为核心，基于风险控制，兼顾效率和综合成本平衡的GXP管理制度，例如：基于技术审评需要和风险评估的核查制度，高度专业与专职的GXP核查队伍等等，以解决数据真实性、标准规范性和管理效率等问题。在本分会中我们将邀请中美监管机构以及工业界的代表来分享GXP管理及质量管理的经验，共同探讨中国的GXP管理制度的发展方向。

国际GXP的监管模式
Lane CHRISTENSEN 博士
美国FDA中国办公室助理主任

从企业角度看全球质量监管趋势
张庆 博士
诺和诺德公司全球质量部门副总裁

中国GXP监管的现状和变革趋势
CFDA讲者已邀请

分会场 0108 | 017年5月24日　同传
15:30-17:00 | 三层，黄河厅

DIAmond 钻石经典分会

加快审评审批为病人提供安全、有效和高质量的药品——良好审评和提交规范的作用
分会场主持人
韩凤云
强生亚太制药部全球法规事务亚太区法规政策事务负责人，高级总监

加快药品审评审批准为病人提供安全，有效的高质量药品是药监部门和药业的共同责任。上市申请审评的规范化和申请提交的规范化，意义重大。然而，本单元的重点不只是介绍具体的审评操作流程和业界提交合格的申请资料的具体要求。本次会议邀请了经验丰富的药品审评机构的专家和业界精英，与大家分享他们对良好审评以及提交规范重要性的理解和想法，并讲解指导性原则。旨在鼓励申请者和审评员，不要只盯在上市审评和申请提交阶段这个最后阶段，而是在整个研发过程中，保持着有效的交流和沟通，关注整个药物研发项目的缜密和合理。本单元帮助听众通过对良好审评和提交规范的重要性的认识，提升其战略性思维和远见。本单元不仅面向创新型药物的研发人员，还面向从事仿制药的研发人员，帮助大家从全球的角度和战略的角度理解药物研发和注册。

CFDA良好审评与提交规范经验分享
黄清竹
国家食品药品监督管理总局药品审评中心业务管理部

APEC工作组良好审评与提交规范经验分享
来自监管部门的观点
黄琴晓

APEC工作组良好审评与提交规范经验分享
来自工业界的观点
Shinji HATAKEYAMA 博士

良好提交规范
猪绘华
罗氏中国注册事务副总监

专题讨论与互动

1. 良好递交规范对提高仿制药首轮审评批准率的重要意义
2. 有效沟通
3. 研发策略制定
4. 注册申请计划和资料准备
5. 审评员和注册人员的核心能力和主要资质
6. 通过上市申请的规范化真正享受美国FDA仿制药付费法案的益处

以上讲者及
李自力 医学博士，公共卫生硕士
美国FDA药品评价和研究中心（CDER）
仿制药办公室全球事务副主任

TUESDAY, 23 MAY | WEDNESDAY, 24 MAY

THEME 1

Yue YANG, Professor
Director, International Food and Drug Policy and Law Research Center, Shenyang Pharmaceutical University

Panel Discussion

Session 0106 | MAY 24, 2017

Simultaneous Translation

10:30-12:00 | 3rd Floor, Yellow River Hall

CONSIDERATION AND CASE STUDY OF EXPEDITING DEVELOPMENT AND REVIEW OF NEW DRUGS
SESSION CHAIR

Wendy YAN, MD, MBA
Senior Vice President, Head of Regulatory Affairs, BeiGene (Beijing) Co., Ltd.

Over the years, health authorities from many countries released guidelines or programs to expedite the development and review of innovation drugs. In this session, speakers from both health authorities and industry will elaborate the expedited program and guidance and sharing the successful cases.

EU PRIME as a New Way to Further Support Drug Development

Yamin WANG, PhD
Independent Consultant, Germany

Expediting Drug Development at the US FDA

Mark J. GOLDBERGER, MD, MPH
Independent Consultant, Mark Goldberger MD MPH LLC.
Member of FDA Alumni Association International Network (FDAAA)
Former Director, the Office of Antimicrobial Products, within the Office of New Drugs, FDA/CDER

Topic TBD

Xiaoyuan CHEN
Office of Clinical Review I, Center for Drug Evaluation, CFDA

Session 0107 | MAY 24, 2017

Simultaneous Translation

13:30-15:00 | 3rd Floor, Yellow River Hall

PRODUCTS REGULATORY SUPERVISION AND QUALITY CONTROL
SESSION CHAIR

Ying SHAO, PhD
Vice President and Director of R&D Center, Shanghai Fosun Pharmaceutical (Group) Co., Ltd.

With the continuous improvement of the quality management ability of Chinese pharmaceutical enterprises and harmonization of technical standards, China Food and Drug Administration (CFDA) is constantly exploring new ways of life cycle management. As an important measure to ensure drug quality during the product life cycle, the reform of GXP system is imperative. Since the State Council issued the "Opinions on Reforming the Review and Approval System for Drugs and Medical Devices " in August 2015, CFDA has started to explore a new GXP system, which is based on regulatory science, risk-assessment and balances efficiency and cost, to solve the issues of data integrity, inconsistent standards and loss of efficiency. Several measures are under development, such as review-based [illegible] inspection, highly professional and full-time from CFDA and US FDA and industry to share their experience on GXP management and quality management, and to discuss the trend of China's GXP system.

International GXP Supervision Model

Lane CHRISTENSEN, PhD
Assistant Country Director, FDA China Office

Trend of Global Quality Supervision from Industry Perspective

Andrew CHANG, PhD
Vice President, Product Supply Quality, Novo Nordisk Inc., USA

Today's China GXP and Transformation Trends

CFDI Speaker Invited

Session 0108 | MAY 24, 2017

Simultaneous Translation

15:30-17:00 | 3rd Floor, Yellow River Hall

DIAmond Session

TO ACCELERATE REGULATORY APPROVAL OF AND PATIENT'S ACCESS TO SAFE, EFFECTIVE AND QUALITY MEDICINE —— THE ROLE OF GOOD REVIEW AND SUBMISSION PRACTICE
SESSION CHAIR

Vicky HAN
Senior Director, Policy Group Lead for Asia Pacific, Global Regulatory Affairs, Janssen Asia Pacific

It requires the joint effort of regulatory agencies and pharmaceutical industry to accelerate regulatory approval of and patient's access to safe, effective and quality medicine. The Good review practice for the regulatory agencies and good submission practice for the industries play a critical role. The session is not designed to provide detailed regulatory review processes nor the instructions on how to conduct each submissions to regulatory agencies. Instead speakers will share their thoughts on the importance of such practices from both agency and industry perspectives, and also outline the guiding principles that go beyond the period of drug application submission and regulatory review to encourage effective communication and a robust drug development program over the entire drug development process. The audiences of the session will gain a strategic view on the critical role of good review practice and good submission practice and the session will benefit the audiences from both new drug and generic drug industry in their strategic drug development and registration planning from a global perspective.

CFDA Review and Submission Best Practice Sharing

Qingzhu HUANG
Office of Operations Management, Center for Drug Evaluation, CFDA

APEC Working Group Review and Submission Best Practice Sharing -- from Regulator's Perspective

Chyn-liang HUANG

APEC Working Group Review and Submission Best Practice Sharing -- from Industry's Perspective

(三)、DIAmond 經典分會討論會

與 JPMA 代表 Shinji Hatakeyama 博士合影

與 Janssen Asia Pacific 韓風雲資深總監合影

(四)、DIA China 網站報導

DIA 年会速递丨DIA 年会最后一天：DIAmond 钻石经典分会，四场直播，热度不减，明年再聚

原创 2017-05-25 储旻华 DIA订阅号 DIA订阅号 DIA_China分享最新医药研发资讯 点击上方“DIA订阅号” 可以订阅哦！

今天是 **2017 中国国际药物信息大会暨第九届 DIA 中国年会**的第三天，也是最后一天。无论讲者还是听众，热情不减，各个分会场仍然人头济济。今天的 **DIAmond 钻石经典分会**是：加快审评审批为病人提供安全、有效和高质量的药品——良好审评和提交规范的作用。

这个分会场的主持人是强生亚太制药部全球法规事务亚太区法规政策事务负责人，高级总监韩凤云，会议邀请了经验丰富的药品审评机构的专家和业界精英，与大家分享他们对良好审评以及提交规范重要性的理解和想法，并讲解指导性原则。

加快药品审评审批准为病人提供安全、有效的高质量药品是药监部门和药业的共同责任。上市申请审评的规范化和申请提交的规范化，意义重大。在场的专家不仅介绍具体的审评操作流程和提交合格的申请资料的具体要求，而且鼓励申请者和审评员，不要只盯在上市审评和申请提交阶段这个最后阶段，而是在整个研发过程中，保持着有效的交流和沟通，关注整个药物研发项目的缜密和合理。帮助创新型药物的研发人员，和从事仿制药的研发人员，从全球的角度和战略的角度理解药物研发和注册。

(五)、本次簡報資料

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Outline

- Promotion of Good Registration Management (GRevP and GSP) in APEC
- GRM Pilot CoE workshop: Reviewers training
- Conclusion and Future Plan

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Goals of the APEC GRM Roadmap

- GRM:
  - A concept to promote efficient registration process for medical products by promoting GRevP and GSP cooperatively
- Goals of Roadmap:
  - To promote the implementation of GRM
  - To enhance mutual trust for regulatory convergence among the APEC member economies by 2020

Good Review Practice (GRevP)	Good Submission Practice (GSP)
To strengthen the **performance**, **predictability**, and **transparency** of regulatory agencies through the implementation or enhancement of GRevP and quality measures stepwise in each interested APEC economy.	To enhance the **quality** and **efficiency** of the medical product registration process by **improving the quality of submission** as well as its management.

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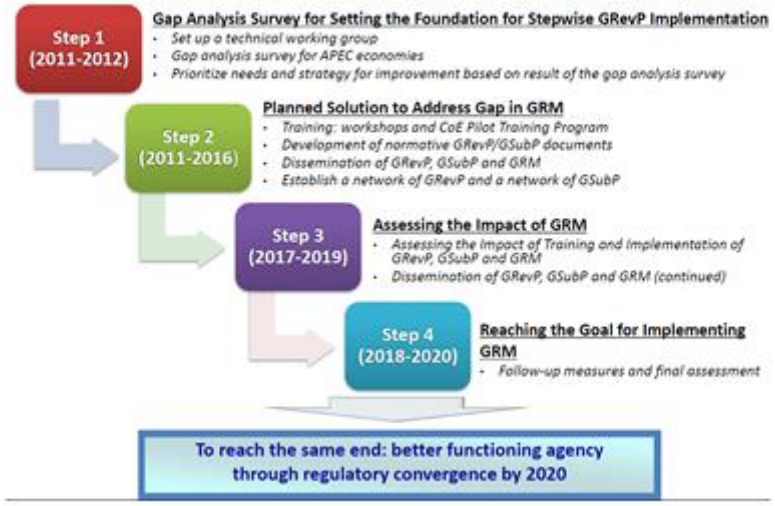
Specific Activities and Timeframe of the GRM Roadmap



Milestones of the GRM Roadmap

Year	Milestone
2011	Good Review Practice (GRevP) was endorsed as a priority work area (PWA) by APEC LSIF-RHSC. Chinese Taipei was endorsed as the champion.
2013	APEC 2020 Roadmap for GRevP on Medical Products was endorsed.
2014	Good Submission Practice (GSP) was endorsed as a PWA by RHSC.
2014-2015	Good review practices: guidelines for national and regional regulatory authorities was adopted and published by WHO.
2016	Good Submission Practice Guideline for Applicants was endorsed by RHSC. GRevP and GSP were merged as a PWA entitled Good Registration Management (GRM). A combined roadmap was endorsed by RHSC. Chinese Taipei and Japan were endorsed as the co-champions. RAPS Taiwan Chapter was endorsed as a Center of Excellence (CoE) for GRM pilot program by RHSC. A CoE Pilot Workshop was held in Taipei in Nov 2016. Mexico Cofepris was endorsed as a CoE for GRM pilot program by RHSC.
2017	TFDA in partnership with RAPS Taiwan Chapter was endorsed as a formal APEC GRM CoE by RHSC.

2016 APEC GRM Regulatory Science Center of Excellence Pilot Workshop

http://www.raps-in-taiwan.org.tw/apec/index.html

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Participant Analysis

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

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

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

* Most of the trainees had more than 3 years of hands-on experiences in review or submission.

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Learning objectives and core curriculum were developed based on GRevP guidelines and GSP guidelines

GRevP Guidelines (WHO)

Table of Contents

1. Introduction
2. Glossary
3. **Principles of a good review**
4. **Managing the review**
   - Project management • Quality management
   - SOPs • Review process stages
5. **Communications**
   - Intra-agency • Interagency • With applicants
   - With external experts • With the public
6. **Review personnel**
   - Reviewer expertise, competencies and training
   - Critical thinking
7. **Conducting the review**
   - Key elements in defining a review strategy
   - Applying the review strategy

Bibliography

GSP Guidelines (APEC RHSC)

Table of Contents

1. INTRODUCTION
2. **PRINCIPLES OF A GOOD SUBMISSION**
3. **MANAGEMENT OF SUBMISSION**
   - Planning for Submission
   - Preparation and Submission of Application Dossier
   - Quality Check
4. **COMMUNICATIONS**
   - Communications with the Review Authorities
   - Communication within Applicants' Organization
5. **COMPETENCY AND TRAINING**
   - Core Competency of Applicants
   - Training and Capacity Building
6. GLOSSARY
7. REFERENCE

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Learning Objectives

Principles

- The principles of Good Review Practices (GRevP) and Good Submission Practices (GSP)

Good Review

- What is needed for regulators to accomplish good review
  - Conducting and managing the review
  - Good communication with applicants
  - Competency for regulators

Good Submission

- What is needed for applicants to accomplish good application
  - Planning and preparation of application dossier
  - Good communication with regulators
  - Competency for applicants

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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
- Communication : Fundamentals and Case Studies
- Review personnel - Critical thinking
- Conducting the review
- Rolling out the GRM training program in each economy
- Panel Discussion (competencies)

GSP
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 (competencies)

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Group photo for all workshop participants

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Workshop photos

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Reviewers Training (1)

Day 1 Common Sessions

- **Basic Concept of GRM**
  - APEC Roadmap to Promote GRM; overview of GRM curriculum
- **An Overview of Good Review**
  - principles of a good review; overview of GRevP guidelines; challenges
- **An Overview of Good Submission**
  - principles of a good submission; overview of GSubP guidelines
- **Case study: Effective Communication for GRM**
  - Effective communications between applicants and regulatory authorities throughout product life cycle - practices in PMDA

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Reviewers Training (2)

Day 2 Reviewer-Specific Sessions

- **Managing the review**
  - An introductory overview of managing the review
  - Experience sharing: how US FDA, PMDA and TFDA/CDE manage the review
  - Group discussions to understand the current practices, challenges and gaps in managing reviews among different APEC member economies
- **Communication: Fundamentals and case studies**
  - An overview of good communications for a regulatory authority
  - Practices in PMDA
  - An interactive session with case studies

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Reviewers Training (3)

Day 3 Reviewer-Specific Sessions and Combined Panel Discussion

- **Review Personnel – Critical Thinking**
  - How to apply critical thinking in conducting reviews and making decisions
- **Conducting the Review**
  - Points to be considered for a good review
- **Rolling out the GRM training program in each economy**
  - How to develop local GRevP training by following trainer's manual
- **Panel discussion on regulatory professionals' competencies**
  - RAPS' Regulatory Competency Framework; identify competency gaps

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Feedback from Onsite Survey (Reviewers)

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

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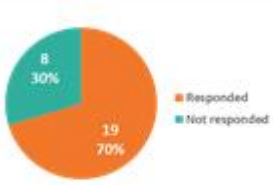
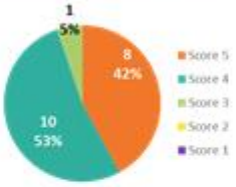
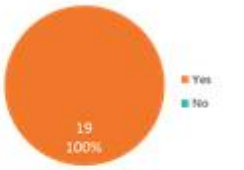
Follow-up survey 2 months after the pilot (Reviewers)



(1) Response rate 19/27 (70%)

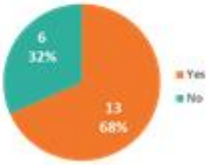


(2) Very helpful in improving review practices 18/19 (95%)



(3) Will recommend colleagues to participate in the workshop 19/19 (100%)

(4) Take action to promote GRM 16/19 (84%)



(5) Plan to conduct local training 13/19 (68%)

(6) Will use the training manuals to organize training 14/19 (74%)

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Challenges from Organizer Perspectives

- Provide a curriculum which meets the need of all individual trainees with variability in background.
  - For Reviewer-Specific Sessions, participants are from different APEC member economies with **different levels of regulatory sophistication** and with **focus in different review disciplines**.
  - For Applicant-Specific Sessions, case studies were provided based on the experiences of **well-resourced companies** which focus on registration of new drugs.
- Provide more opportunities for regulators and applicants to efficiently interact with each other.

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Conclusion and Future Plan

- It was a successful CoE pilot with
  - good partnership and collaboration
  - significant interactive elements, such as interactive discussions, group discussions, case studies, and practices
  - good rating and overall satisfaction
  - endorsed as a formal APEC CoE by APEC RHSC in February 2017
- For the next workshop in late 2017, we plan to
  - create more collaborative sessions to allow trainees from industry to talk to regulators
  - provide more case studies and interactive discussions, and
  - Incorporate case studies for submission and review of generic drug applications.

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2017 APEC GRM CoE Training Workshop

- **Date:** October 31 to November 2, 2017
- **Venue:** National Taiwan University Hospital (NTUH) International Convention Center, Taipei, Taiwan
- **Target audience:**
  - Senior regulators with at least 3 years of hands-on experience in the management of regulatory reviews
  - Industry managers with at least 3 years of hands-on experience in the management of regulatory submissions
- The details will be announced soon.

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