研討會成果報告

2022 年食藥署 APEC 優良查驗查驗登記管理法規科學卓越中心(GRM CoE)研討會

2022 APEC Good Registration Management (GRM) Regulatory Science Center of Excellence Workshop

＊[1]如需參考更多資訊，請查詢研討會網址: https://www.apecgrmcoe.tw/2022CoE/

[1]

前言

衛生福利部食品藥物管理署（以下簡稱食藥署）於 2022 年 8/29~9/15 期間成功辦理「2022 年 APEC 優良查驗登記管理法規科學卓越中心研討會（2022 APEC GRM CoE Workshop）」。食藥署長期參與 APEC LSIF-RHSC 所倡議之區域法規調和，主導促進優良查驗登記管理理念推廣，並於 2017 年食藥署與 RAPS 台灣分會共同正式被認可為「APEC 優良查驗登記管理法規科學卓越中心」，自此後每年舉辦推廣優良查驗登記管理的法規科學培訓。APEC 優良查驗登記管理法規科學卓越中心研討會的持續辦理對推動 GRM 理念導入及法規專業人員能力建設上有相當重要的貢獻及意義。

研討會議程、邀請講師及參與學員

食藥署持續於 2022 年主辦「2022 年 APEC 優良查驗登記管理法規科學卓越中心研討會」。2022 年 APEC 優良查驗查驗登記管理法規科學卓越中心視訊研討會分成兩部分辦理，第一部分為線上學習課程：學員於 8/29 ~ 9/11 期間通過研討會網站線上課程平台瀏覽 8 門預錄講座影片；第二部分為於 9/13~9/15 三天於台北白天時段舉行三場線上會議，研討會學員於線上會議接受案例分組討論、組員代表分享及聆聽特別講座之課程安排。研討會課程內容包括 GRM 核心課綱(優良審查及優良送審規範)制定課題外，另規劃三項 Special Topics of Interests 課程，分別為「罕見孤兒藥品審查法規」，「RWE/RWD 於法規科學決策的應用」及「業界及審查界法規專家於國際審查合作之經驗分享」。議程請詳閱下頁研討會議程。

2022 年大會共邀請 19 位法規科學專家講授優良審查及優良送審專業課程，專家任職單位包括食品藥物管理署 TFDA、澳洲藥品主管機關 Australian Department of Health and Aged Care、歐洲藥品主管機關 EMA、日本藥品主管機關 PMDA、美國 Temple 大學、財團法人醫藥品審查中心 CDE、亞洲製藥聯盟 APAC 及其他國際藥業專家等。

此次大會總計招收 104 人次之學員，包含 54 名審查人員及 50 名業界申請人員完成此次 GRM 理念的教育訓練，上述學員分別來自 12 個國家(11 個 APEC 會員經濟體及 1 個非 APEC 會員經濟體)，除我國外，包括香港、印尼、日本、馬來西亞、秘魯、菲律賓、俄羅斯、新加坡、泰國、越南及哥倫比亞。

2022 APEC Good Registration Management (GRM)_Agenda

PART 1: Online Self-Learning Lecture (Pre-recorded) from August 29th to September 11th

	TOPICS	TIME	AFFILIATION
Content 1	**Welcome Letter**	N/A	**Shou-Mei Wu** Director General Taiwan Food and Drug Administration (TFDA)
Session 1	**Introduction of GRM** ◆ Concept of GRM ◆ Achievements of APEC Roadmap to promote GRM ◆ Objectives of this year's workshop	17 Mins	**Chia-Ping Liu** Section Chief Division of Medicinal Products Taiwan Food and Drug Administration (TFDA)
Session 2	**Planning of Application** ◆ Planning of New Drug Application & Example of Registration ◆ Planning of Generic Drug Application & Example of Registration	30 Mins	**Finny Liu** APAC Regional Regulatory Policy Lead Roche Singapore
		33 Mins	**Jocelyn Lee** Senior Regulatory Manager Project & Regulatory Affairs Division TTY Biopharm Co., Ltd
Session 3	**Preparation of Application Dossier** ◆ Standard process of application dossier preparation ◆ Support tools (template, glossary, checklist & timeline table)	23 Mins	**Kumiko Hikida** Manager Global Regulatory Affairs Department Mitsubishi Tanabe Pharma Corporation APAC

Session 4	**Managing and Conducting the Review** ◆ An introductory overview of managing the review ◆ Example of implementing GRevP in the review process	20 Mins	**Wan-Yu Chao** Specialist Division of Medicinal Products Taiwan Food and Drug Administration (TFDA)
Session 5	**Using Facilitated Regulatory Pathways (FRPs) for Special Case Authorizations** ◆ Understanding FRP and work sharing models as they apply to special authorizations ◆ Practical cases: How these pathways have been used for • COVID-19 authorizations • Orphan Drugs • Advanced Therapeutic Medicinal products ◆ Barriers and promotors	50 Mins	**Lawrence Liberti** Adjunct Research Professor Reg Affairs and Quality Assurance Graduate Program Temple University School of Pharmacy
Session 6	**Communication with Applicants-Regulator's Aspects** ◆ Effective Communication ◆ Communication with Applicants in Taiwan ◆ Case Scenario-Consultation	10 Mins	**Ting-Yao Wang** Project Manager Division of Regulatory Affairs and Compliance Center for Drug Evaluation
	Communication ~Industries' Aspects~ ◆ Sharing importance of effective communication based on APEC RHSC Good Submission Practice Guideline for Applicants	10 Mins	**Shinji Hatakeyama** Leader Regulations and Approvals Expert Working Group (RA-EWG) APAC

Topic of Special Interest I: Orphan Drug Regulations			
Session 7	**Regulatory Perspective of Orphan Drug Development for Rare Diseases**	12 Mins	**Yen-Hui Wu** Deputy Director Division of New Drugs Center for Drug Evaluation
	An Overview of the European Orphan Regulation ◆ Procedure for orphan designation ◆ Marketing authorisations of orphan drugs ◆ International Collaboration ◆ Tips and tricks (i.e., lessons learned over the years)	28 Mins	**Kristina Larsson** Head of Office Orphan Medicines Human Medicines EMA
Topic of Special Interest II: RWD/RWE for regulatory decision-making			
Session 8	**The Challenges of the application of RWD/RWE in regulatory decision making from PMDA's perspective**	18 Mins	**Atsushi Noguchi** Deputy Review Director Office of New Drug V PMDA
	Evolving Role of Real-Word Data (RWD) & Evidence (RWE) in Drug Development	30 Mins	**Alexander Liede** Senior Director Head of Evidence and Partnerships Global Epidemiology, Pharmacovigilance and Patient Safety (PPS) AbbVie

Part 2: Webinar

DAY 1: September 13th 14h00-17h00 (GMT+8 Time)

TOPICS	TIME	MODERATOR/FACILITATOR
Group Discussion 1: Case Study: Planning of Submission and Preparation of Application Dossier		
Overview on New Drugs & Generic Drugs Cases	14h00-14h15	【**Moderator**】 **Rosa Fu** Associate Director Regulatory Affairs Eli Lilly and Company (Taiwan) IRPMA 【**Speaker**】 **Finny Liu** APAC Regional Regulatory Policy Lead Roche Singapore **Jocelyn Lee** Senior Regulatory Manager Project & Regulatory Affairs Division TTY Biopharm Co., Ltd. 【**Facilitator**】 IRPMA & TFDA/CDE Members
Discussion on New Drugs & Generic Drugs Cases (4 groups of New Drugs/ 3 groups of Generic Drugs)	14h15-15h15	
Break Time	15h15-15h25	
Group Presentation I (4 groups of New Drugs, around 8 mins/group)	15h25-16h10	
Group Presentation II (3 groups of Generic Drugs, around 8 mins/group)	16h10-16h50	
Q&A / Wrap Up	16h50-17h00	

Day 2: September 14th 14h00-16h40 (GMT+8 Time)

TOPICS	TIME	MODERATOR/FACILITATOR
Group Discussion II: Review of Biosimilar Products: Basic Principles		
Overview of the session	14h00-14h10	**【Moderator】** **Chi-Hsun Chen** Senior Clinical Section Chief Center for Drug Evaluation **【Speaker】** **Chi-Hsun Chen** **【Facilitator】** **Chia-Hsun Tsai (蔡佳洵)** **Jun-Fon Wang (王竣鋒)**
Case discussions (7 groups)	14h10-15h10	
Presentations (Groups A to C, around 8 mins/group), 3 groups	15h10-15h35	
Break Time	15h35-15h45	
Presentations (Groups D to G, around 8 mins/group), 4 groups	15h45-16h20	
Q&A	16h20-16h30	
Wrap Up & Take Home Messages	16h30-16h40	

[LIVE] Day 3: September 15th 08h30-11h10 (GMT+8 Time)

TOPICS	TIME	SPEAKER
Brief Opening	08h30-08h40	**Shou-Mei Wu** Director General Taiwan Food and Drug Administration (TFDA)
COVID-19 Vaccine Pharmacovigilance: TFDA's experience	08h40-08h50	**Jo-Feng Chi** Researcher Division of Medicinal Products Taiwan Food and Drug Administration (TFDA)
Modular study design within a vaccine safety program	08h50-09h15	**Daina Esposito** Senior Director, Global Safety Epidemiologist Clinical Safety and Risk Management Moderna
Q& A Time	09h15-09h20	
US FDA Pilots: Project Orbis, Real Time Oncology Review (RTOR), Assessment Aid **- BMS's Experience** ◆ Provide an overview of FDA pilot programs ◆ Share BMS learnings on FDA pilots of Project Orbis, RTOR, Assessment Aid ◆ Offer insight on considerations needed when submissions occur via these innovative processes	09h20-09h45	**Heidi Wang** Vice President Head of Oncology Global Regulatory Strategy & Policy BMS

Q& A Time	09h45-09h50	
Virtual Photo Time (With All Speakers and Guests)	09h50-09h55	
ACCESS Work-sharing model	09h55-10h20	**John Skerritt** Adjunct Professor Deputy Secretary for Health Products Regulation Australian Department of Health and Aged Care
Q& A Time	10h20-10h25	
Gulf Health Council, experience in Reliance (Pre-recorded)	10h25-10h50	**Hajed M. H. Hashan** Deputy of General Manager Gulf Health Council
Brief Announcement	10h50-10h55	
Closing Remarks I (Pre-recorded)	10h55-11h00	**Junko Sato** Office Director Office of International Program Pharmaceuticals and Medical Devices Agency (PMDA)
Closing Remarks II	11h00-11h05	**Shinji Hatakeyama** Leader Regulations and Approvals Expert Working Group (RA-EWG) Asia Partnership Conference of Pharmaceutical Associations (APAC)
Closing Remarks III+ Virtual Photo Time (With All Participants)	11h05-11h10	**Shou-Mei Wu** Director General Taiwan Food and Drug Administration (TFDA)

研討會第一部分：線上學習課程

課程 1 邀請講者:食品藥物管理署劉佳萍科長

課程 2 邀請講者羅氏大藥廠亞太地區藥事法規政策負責人劉瑞芬 (左)及台灣東洋藥品李涵育資深法規經理 (右).

課程 3 邀請講者 Kumiko Hikida, the manager of Mitsubishi Tanabe Pharma Cooperation.

課程 4 邀請講者食品藥物管理署趙婉妤技士

課程 5 邀請講者美國 Temple University School of Pharmacy 教授 Dr. Lawrence Liberti


課程 6 邀請講者醫藥品查驗中心汪廷耀專案經理 (左)與亞洲生技製藥聯盟(APAC)負責人 Dr. Shinji Hatakeyama (右).


課程 7 邀請講者醫藥品查驗中心主管吳彥慧醫師(左)及 Ms. Kristina Larsson, the Head of Office of EMA(右)


課程 8 邀請講者 Dr. Atsushi Noguchi, the Deputy Review Director of PMDA (左) and Dr. Alexander Liede, the senior Director of AbbVie(右)

研討會第二部分：第一場線上會議

第一場線上會議 (9 月 13 日)

研討會學員共分成 7 個小組並進行分組案例討論，案例討論議題:
Planning of Submission and Preparation of Application Dossier



共同主持人台灣禮來醫藥學術處副處長傅玉萱 (左)、台灣東洋藥品李函育資深法規經理 (中)與羅氏大藥廠亞太地區藥事法規政策負責人劉瑞芬(右)引導與會學員討論新藥 (共 4 組)及學名藥(共 3 組)案例分組討論

研討會第二部分：第二場線上會議

第二場線上會議 (9 月 14 日)

研討會學員分成 7 組進行案例討論，案例討論議題: Review of Biosimilar Products: Basic Principles。

主持人醫藥品查驗中心陳紀勳醫師/臨床資深小組長引導經濟體代表討論案例: Review of Biosimilar Products.

研討會第二部分：第三場線上會議

第三場線上會議 (9 月 15 日)

食品藥物管理署吳秀梅署長於會議開始時發表開幕致詞

五位藥政主管機關及業界法規專家於會議中發表精闢演講。

TFDA 主管機關代表 Dr. Jo-Feng Chi, the Researcher of TFDA 發表演說 “COVID-19: Vaccine Pharmacovigillance: TFDA’s experience”

業界法規專家 Dr. Daina Esposito, the Senior Director of Moderna 發表演說 “Modular study design within a vaccine safety program”.

業界法規專家 Dr. Heidi Wang, the Vice President and the Head of Oncology of BMS 發表演說 “US FDA Pilots: Project Orbis, Real Time Oncology Review (RTOR), Assessment Aid - BMS’s Experience”.

澳洲主管機關代表 Professor John Skerritt, the Deputy Secretary for Health Products Regulation of Australian Department of Health and Aged Care 發表演說 “ACCESS Work-sharing Model”.

沙烏地阿拉伯主管機關代表 Dr. Hajed M. H. Hashan, the Deputy of General Manager of Gulf Health Council 以預錄影片方式發表演說 “Gulf Health Council, experience in Reliance”.

第三場線上會議 (9 月 15 日)

研討會協辦單位代表分享致詞:
大會邀請研討會協辦單位代表於下半場會議中發表此次研討會的感想致詞。

日本藥品主管機關主管 Dr. Junko Sato (左)及亞洲生技製藥聯盟 (APAC)負責人 Dr. Shinji Hatakeyama (右)於大會結束前分享致詞

研討會第三場線上會議之大合影截圖

研討會與會貴賓合照

研討會參與人員大合照

研討會學員反饋

此次研討會參與學員給予研討會所有分項課程之平均評分為 4 以上之評分（1=差，5=優），可見與會者對此次研討會是相當滿意的 (表 1)。課題認知程度分析結果顯示，學員們在課後對該課題認知程度有普遍提升。大會另彙整學員反饋意見，值得注意的是本次研討會各課程獲得學員一致好評。茲將有助於未來研討會改進的意見羅列如下(表 2 及表 3)

表 1: 研討會整體滿意度

研討會整體滿意度	學員平均滿意度
此次研討會課程是否有增進您對 GRM 理念的認知?	4.3/5.0
本次研討會課程是否有達到您原來的期望?	4.3/5.0
研討會整體評價 (是否有完善辦理).	4.4/5.0

表 2:本次研討會最受用課程之學員反饋

本次研討會最受用課程
- 2022 年研討會所有課程
- 生物相似藥相關議題
- 新藥及學名藥查驗登記申請規劃
- 審查技巧及管理
- 國際合作藥品查驗登記之審查
- 研討會 Part 2 Day 線上會議演講議題

表 2: 本次研討會學員反饋之未來建議課題

未來研討會建議課題
- 2022 年研討會所有課題
- 生物相似藥相關議題
- Be 生物相似性議題
- 罕藥議題
- RWE/RWD 於查驗登記之應用
- 國際合作藥品查驗登記之審查、Work sharing

- 上市後變更查驗登記申請、申請文件之準備原則及技巧 (validation variation)
- 全球查驗登記議題
- 臨床試驗 議題
- 優良查驗登記管理議題