

研討會成果報告

2021 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

2021 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/2021CoE/>

前言

衛生福利部食品藥物管理署（以下簡稱食藥署）於 2021 年 8/24 ~ 9/16 期間成功辦理「2021 年 APEC 優良查驗登記管理法規科學卓越中心研討會（2021 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

由於 COVID-19 疫情嚴重影響全球差旅安排，「2021 年 APEC 優良查驗登記管理法規科學卓越中心研討會」首度轉換成以視訊方式辦理。2021 年 APEC 優良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 8/24 ~ 9/16 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 9/14 ~ 9/16 三天台北下午時間舉行三場線上會議，研討會學員於線上會議接受案例分組討論、經濟體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「促進國際審查合作」，「RWE/RWD 於法規科學決策的應用」及「COVID-19 疫情對藥品管理法規科學的挑戰」。議程請詳閱下頁研討會議程。

大會共邀請 17 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、歐洲藥品主管機關 EMA、日本藥品主管機關 PMDA、澳洲藥品主管機關 EMA、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。

總計共有 69 人次學員，包含 28 名審查人員及 41 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 APEC 會員經濟體，除我國外，包括香港、印尼、日本、韓國、馬來西亞、秘魯、菲律賓、俄羅斯、新加坡、泰國及越南。

2021 APEC GRM CoE Workshop Agenda

PART 1 : Self-Learning Lecture (Pre-Recorded)

Open from August 24th 09h00 to September 16th 24h00 (GMT+8 Time)

	TOPICS	TIME	AFFILIATION/ECONOMY
GRM Core-Curriculum Sessions			
Content 1	Opening Remarks	5 Mins	Shih-Chung Chen Minister, Ministry of Health and Welfare (MOHW)
			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 in the past decade ◆ Objective of the training	30 Mins	Chyn-Liang (Cindy) Huang Senior Technical Specialist, Division of Medicinal Products, Taiwan Food and Drug Administration (TFDA)
Session 2	Planning of Application ◆ Planning of New Drug Application ◆ Planning of Generic Drug Application	50 Mins	Finny Liu APAC Regional Regulatory Policy Lead Roche Singapore
			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)	25 Mins	Kumiko Hikida Manager Global Regulatory Affairs Department Mitsubishi Tanabe Pharma Cooperation
			Hiroko Kawaguchi Prin. Scientist Regulatory Affairs Area MSD. K. K
	TOPICS	TIME ¹	AFFILIATION/ECONOMY
Session 4	Managing and Conducting the Review ◆ An introductory overview of managing the review based on the WHO GRevP Guidelines for regulatory authorities	20 Mins	Shu-Ping Huang Technical Specialist, Division of Medicinal Products, Taiwan Food and Drug Administration (TFDA)

Session 5	Bringing Consistency and Efficiency to Regulatory Decision-Making ◆ Guidelines provide the building blocks for the construction of a fit-for-purpose dossier ◆ Communicating the agency's expectations for the dossier-pre-submission advice ◆ Communicating the agency's assessment decision	25 Mins	Lawrence Liberti Adjunct Research Professor Reg Affairs and Quality Assurance Graduate Program Temple University School of Pharmacy
Session 6	Communication ◆ Overview of Communication mechanisms – Review authorities' Aspects - Communication cycle management - Timing of Communication - Communication pathways ◆ Overview of Communication mechanisms - Industry Aspects	15 Mins	(Regulator's Aspect) Yu-Ju Lin Project Manager Center for Drug Evaluation (CDE) (Industry's Aspect) Shinji Hatakeyama Leader Regulations and Approvals Expert Working Group (RA-EWG), Asia Partnership Conference of Pharmaceutical Associations (APAC)
Topic of Special Interest I: Promoting Regulatory Cooperation			
	TOPICS	TIME	AFFILIATION/ECONOMY
Session 7	The Access Consortium New Active Substance working-sharing procedure – An Australian perspective ◆ Overview of TGA's reliance pathways and principles-where does Access fit? ◆ What is Access ◆ Key features of the work-sharing procedure ◆ TGA perspectives	30 Mins	Michael Shum Director Application and Advisory Management Prescription Medicines Authorisation Branch Medicines Regulation Division Health Products Regulation Group Australian Government Department of Health
Topic of Special Interest II: The Application of RWD/RWE in Regulatory Decision-Making			
	TOPICS	TIME	AFFILIATION/ECONOMY
Session 8	Considerations of the Application of RWD/RWE in Regulatory Decision-Making ◆ Introduction of RWD/RWE ◆ Examples ◆ Regulatory Perspective	15 Mins	Chi-Hsun Chen Senior Clinical Section Chief Center for Drug Evaluation (CDE)

2021 APEC GRM CoE Workshop Agenda

PART 2: Live Videoconference (via Webex)

DAY 1: September 14th 14h00-16h30 (GMT+8 Time)

TOPICS	TIME	MODERATOR/FACILITATOR
Group Discussion 1: Case Study: Planning of Submission and Preparation of Application Dossier		
Overview of the session	1400-1410	【 Moderator 】 Rosa Fu Associate Director Regulatory Affairs Eli Lilly and Company IRPMA
Discussion on generic drugs & new drugs cases (7 groups)	1410-1510	【 Speaker 】 Finny Liu APAC Regional Regulatory Policy Lead Roche Singapore Jocelyn Lee Senior Regulatory Manager Project & Regulatory Affairs Division TTY Biopharm Co., Ltd. 【 Facilitator 】 Industry experts from IRPMA
Break Time	1510-1525	
Group Presentation (7groups, around 8 min/group)	1525-1615	【 Speaker 】 Finny Liu APAC Regional Regulatory Policy Lead Roche Singapore Jocelyn Lee Senior Regulatory Manager Project & Regulatory Affairs Division TTY Biopharm Co., Ltd.
Wrap Up & Take Home Messages	1615-1630	【 Moderator 】 Rosa Fu Associate Director Regulatory Affairs Eli Lilly and Company IRPMA 【 Speaker 】 Finny Liu APAC Regional Regulatory Policy Lead Roche Singapore Jocelyn Lee Senior Regulatory Manager Project & Regulatory Affairs Division TTY Biopharm Co., Ltd.

DAY 2: September 15th, 14h00-17h05 (GMT+8 Time)

TOPICS	TIME	MODERATOR/FACILITATOR
Group Discussion II: Case Study: Managing and Conducting the Review- Fixed Dose Combination Products		
Overview of the session	1400-1410	Chi-Hsun Chen Senior Clinical Section Chief Center for Drug Evaluation (CDE)
Presentation by Each Economic (I) (6 economies, 8-15 min/economy)	1410-1520	Representatives of APEC member economies
Break Time	1520-1530	
Presentation by Each Economic (II) (6 economies, 8-15 min/economy)	1530-1640	Representatives of APEC member economies
Break Time	1640-1650	
Wrap Up & Take Home Messages	1650-1705	Chi-Hsun Chen Senior Clinical Section Chief Center for Drug Evaluation (CDE)

DAY 3: September 16th, 14h00-16h20 (GMT+8 Time)

TOPICS	TIME	MODERATOR/SPEAKER
1st Videoconference		
Brief Opening +Virtual Photo Time	1400-1410	Shou-Mei Wu Director General, Taiwan Food and Drug Administration (TFDA)
Regulatory Measure in Response to COVID-19 in Taiwan	1410-1430	Shou-Mei Wu Director General, Taiwan Food and Drug Administration (TFDA)
Brief Q&A Session	1430-1435	
International Collaboration in time of COVID-19: The Need for Regulatory Agility	1435-1505	Agnès Saint-Raymond Head of Division International Affairs EMA
Brief Q&A Session	1505-1510	
Regulatory Challenges Against COVID-19: Experience Sharing of Japan	1510-1530	Yuriko Takemura Coordinator, Division of Asia II, Office of International Programs, PMDA
Brief Q&A Session	1530-1535	
Break Time	1535-1550	
2nd Videoconference		
Expectations from the workshop	1550-1605	Daisuke Koga Division Director, Division of Asia II, Office of International Programs, PMDA
		Shinji Hatakeyama Leader RA-EWG, APAC
		Ping-Chiang Lyu Chairman RAPS Taiwan Chapter
Closing Remarks	1605-1615	Shou-Mei Wu Director General, Taiwan Food and Drug Administration (TFDA)
Virtual Photo time with all workshop participants		

研討會第一部分：線上學習課程



衛生福利部陳時中部長開幕致詞



食品藥物管理署吳秀梅署長開幕致詞



課程 1 邀請講者:食品藥物管理署黃琴嘓簡任技正



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)及台灣東洋藥品李函育資深法規經理(右).



課程 3 邀請講者 Kumiko Hikida, the manager of Mitsubishi Tanabe Pharma Cooperation (左), 以及 Ms. Hiroko Kawaguchi, the Prin. Scientist of MSD. K. K. (右).



課程 4 邀請講者食品藥物管理署黃淑萍技正



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林鈺儒專案經理 (左)與亞洲生技製藥聯盟(APAC)負責人 Dr. Shinji Hatakeyama (右).



課程 7 邀請講者澳洲藥品主管機關(TGA) 主管 Dr. Michael Shum

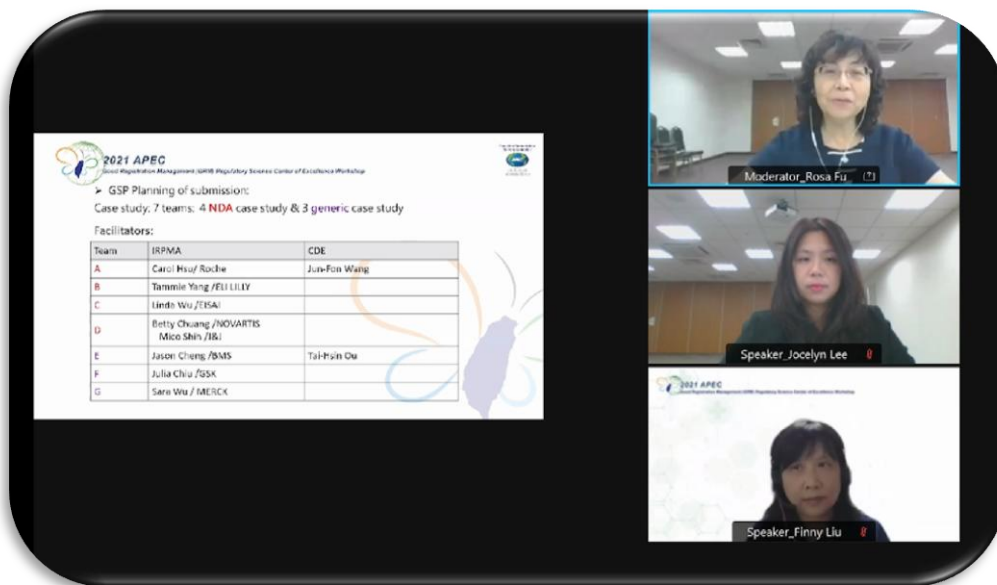


課程 8 邀請講者醫藥品查驗中心陳紀勳醫師/臨床資深小組長

研討會第二部分：第一場線上會議

第一場線上會議 (9 月 14 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



2021 APEC
Joint Registration Managers (JRM) Regulatory Science Center of Excellence Workshop

➤ GSP Planning of submission:
Case study, 7 teams: 4 NDA case study & 3 generic case study

Facilitators:

Team	IRPMA	CDE
A	Carol Hsu/ Roche	Jane-Fon Wang
B	Tammiie Yang /Eli Lilly	
C	Linda Wu /TCSA	
D	Betty Chuang /NOVARTIS Mico Shin /B&L	
E	Jason Cheng /BMS	Tai-Pin Ou
F	Julia Chiu /DSK	
G	Sara Wu / MERCK	

Moderator_Rosa Fu (*)

Speaker_Jocelyn Lee 0

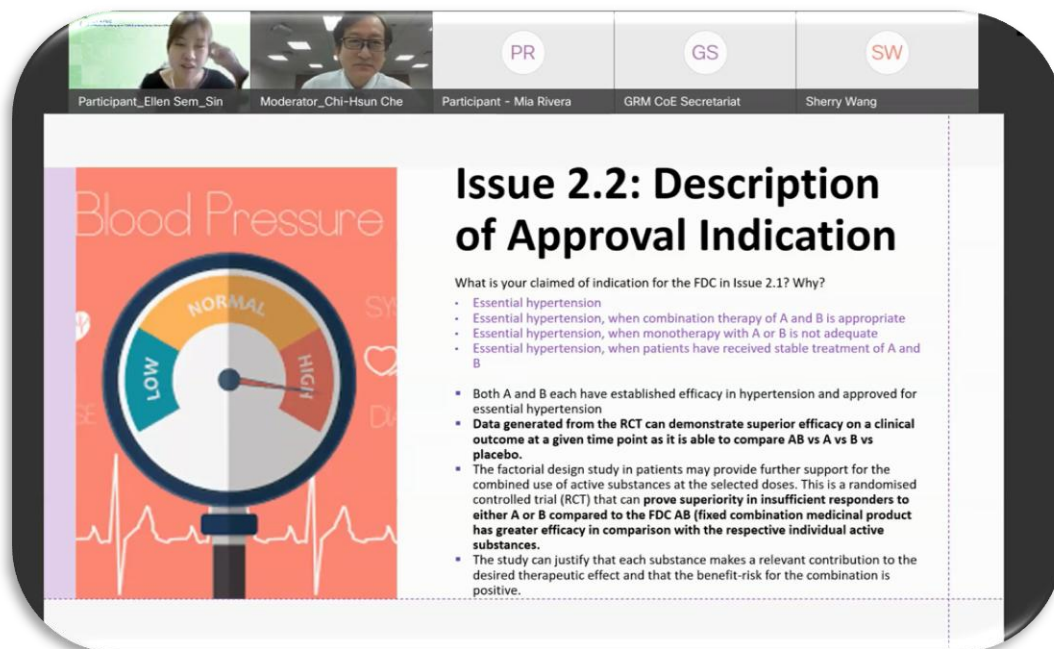
Speaker_Finny Liu 0

共同主持人台灣禮來醫藥學術處副處長傅玉萱(上)、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(下)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 15 日)

研討會學員依據不同經濟體分組進行案例討論，並有 9 位亞太經濟體代表分享案例討論結果。案例討論議題: Managing and Conducting the Review - Fixed Dose Combination Products。



The screenshot shows a Zoom meeting window. At the top, there are five video thumbnails: Participant_Ellen Sem_Sin, Moderator_Chi-Hsun Che, Participant - Mia Rivera, GRM CoE Secretariat, and Sherry Wang. The main content area displays a presentation slide titled "Issue 2.2: Description of Approval Indication". The slide features a graphic of a blood pressure gauge on the left, with the needle pointing to the "HIGH" section. The gauge is labeled "Blood Pressure" and has "LOW", "NORMAL", and "HIGH" markings. The text on the slide includes:

Issue 2.2: Description of Approval Indication

What is your claimed indication for the FDC in Issue 2.1? Why?

- Essential hypertension
- Essential hypertension, when combination therapy of A and B is appropriate
- Essential hypertension, when monotherapy with A or B is not adequate
- Essential hypertension, when patients have received stable treatment of A and B

- Both A and B each have established efficacy in hypertension and approved for essential hypertension.
- Data generated from the RCT can demonstrate superior efficacy on a clinical outcome at a given time point as it is able to compare AB vs A vs B vs placebo.
- The factorial design study in patients may provide further support for the combined use of active substances at the selected doses. This is a randomised controlled trial (RCT) that can prove superiority in insufficient responders to either A or B compared to the FDC AB (fixed combination medicinal product has greater efficacy in comparison with the respective individual active substances.
- The study can justify that each substance makes a relevant contribution to the desired therapeutic effect and that the benefit-risk for the combination is positive.

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: Fixed Dose Combination Products.

研討會第二部分：第三場線上會議

第三場線上會議 (9 月 16 日):上半場會議

三位藥政主管機關代表於上半場會議中發表 COVID-19 對藥政單位所帶來的挑戰專題之精闢演講。



食品藥物管理署吳秀梅署長發表演說 “Regulatory Measure in Response to COVID-19 in Taiwan”
議題



歐洲藥品主管機關代表 Dr. Agnès Saint-Raymond, Head of Division of European Medicines Agency (EMA)發表演說 “International Collaboration in time of COVID-19: the Need for Regulatory Agility”



日本藥品主管機關代表 Yuriko Takemura, Coordinator of Pharmaceuticals and Medical Devices Agency (PMDA)發表演說 “Regulatory Challenges Against COVID-19: Experience Sharing of Japan”.

第三場線上會議 (9 月 16 日):下半場會議

研討會協辦單位代表分享致詞：

三位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。

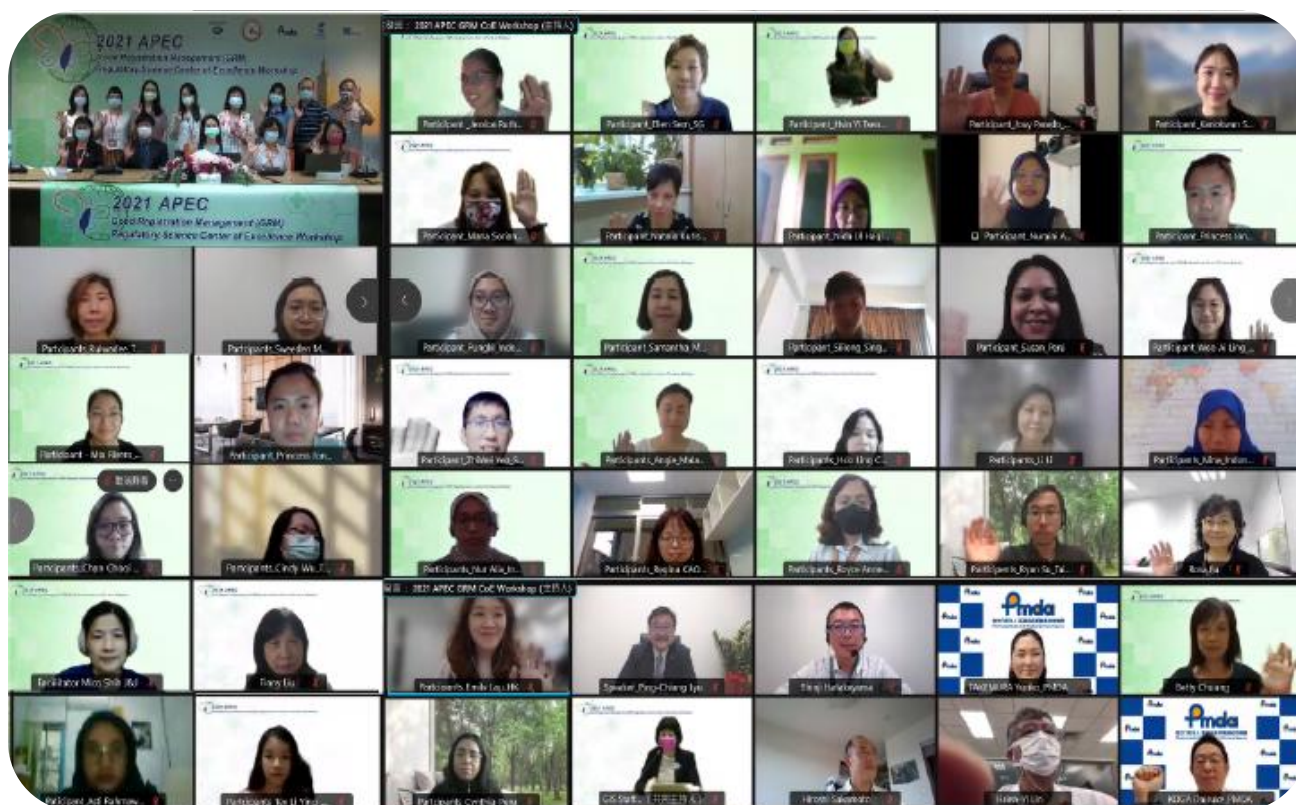


日本藥品主管機關主管 Mr. Daisuke Koga (左)、亞洲生技製藥聯盟 (APAC)負責人 Dr. Shinji Hatakeyama (中)、美國醫療法規學會台灣分會理事長呂平江教授(右) 於大會結束前分享致詞

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?	4.2/5.0
本次研討會課程是否有達到您原來的期望?	4.1/5.0
研討會整體評價 (是否有完善辦理).	4.3/5.0

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
- 2021 年研討會所有課程
- COVID-19 課題 (重大流行病對藥品管理法規科學之挑戰)
- 新藥及學名藥查驗登記申請規劃
- 藥品查驗登記申請文件之準備原則及技巧
- 案例討論：Fixed Dose Combination Products (FDC)
- 審查技巧及管理
- RWE/RWD 於查驗登記之應用
- ACCESS initiatives、國際合作藥品查驗登記之審查
- 各經濟體代表分享案例

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
- 2021 年研討會所有課題
- COVID-19 課題 (國際審查合作、對藥政機關的挑戰、新藥緊急核准)
- 新藥及學名藥查驗登記申請規劃、申請文件之準備原則及技巧 (CTD)

variation)
- GRM 理念導入之實例分享
- 審查決策的效率與一致性
- 審查機制、審查流程 SOP、加速審查機制、Reliance Pathway
- 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
- 醫藥產品案例討論: Orphan Drugs, non-prescription drugs, Biosimilar
- Guidelines/Practices: ICH guideline, GCP, Good Revision Practices, specific quality control of sterile products