2023 年 APEC 優良查驗登記管理(GRM)國際研討會成果報告

一、前言

為增進 APEC 亞太區域法規協和，同時提升醫藥品查驗登記管理品質和效率，衛生福利部食品藥物管理署(以下簡稱食藥署)於 112 年 9 月 6 至 9 月 8 日舉辦為期 3 天之「2023 APEC 優良查驗登記管理國際研討會(2023 APEC Good Registration Management CoE Workshop)」。

APEC 是我國正式參與的多邊官方經濟合作論壇，食藥署長期參與 APEC RHSC 活動，積極推動倡議區域法規協和，自 2016 年至今每年藉由法規培訓活動培訓 70~110 位不等之 APEC 經濟體種子師資，藉此落實及推廣亞太區域優良查驗登記管理(GRM)理念，提升整體醫藥品審查和送件效率。

二、研討會議程、邀請講師及參與學員

由於 COVID-19 疫情影響，2021-2022 年之優良查驗登記管理(GRM)法規科學卓越中心(CoE)國際研討會皆以視訊方式辦理，2023 年 APEC 優良查驗登記管理國際研討會於 COVID-19 疫情後首度恢復實體辦理。研討會議程內容以 GRM 核心課綱(優良審查及優良送審規範)為主要培訓議題內容，議程請詳閱下頁研討會議程。

邀請美國 FDA、歐盟 EMA、日本 PMDA、美國南加州大學(USC)法規科學國際中心(International Center for Regulatory Science, University of Southern California)、財團法人醫藥品查驗中心(CDE)及中華民國開發性製藥研究協會(IRPMA)等產官學專家共 21 位擔任講師，分享優良查驗登記管理規範和實務經驗。

本次研討會共有 81 位學員(22 名審查人員及 59 名業界人士)完成此次推廣 GRM 理念的教育訓練，分別來自 5 個 APEC 經濟體(馬來西亞、菲律賓、新加坡、泰國及我國)及 1 個非 APEC 經濟體(波札那)之產官學界醫藥品法規人員。

2023 APEC Good Registration Management (GRM) CoE Workshop Agenda

September 6th 2023		
Time	**Topics**	**Affiliation/Economy**
09:00-09:20	**Opening Remarks**	**Shou-Mei Wu (吳秀梅署長)** Director General, Taiwan Food and Drug Administration (TFDA) **Ayumi Endo** Office Director, Office of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, (PMDA) **Shinji Hatakeyama** Leader, Regulations and Approvals Expert Working Group (RA-EWG), APAC, and Director, Japan/Asia Regulatory & Asia Clinical Operations Department, Medicine Development Center, Eisai Co., Ltd, Japan
09:20-09:35	**GROUP PHOTO**	
Keynote Speech 1 **【Moderator】Yi-Chu Lin(林意筑專門委員)**, Senior Specialist, Division of Medicinal Product, TFDA		
09:35-10:15	**Good Review Practice and Regulatory Convergence in Accepting Global Clinical Data for Regulatory Approval**	**Herng-Der Chern（陳恆德醫師）** Standing Director, Taiwan Society of Regulatory Affairs for Medical Products

10:15-10:25	Q&A	
10:25-10:40	**COFFEE BREAK**	
Keynote Speech 2 **【Moderator】Yi-Chu Lin(林意筑專門委員)**, Senior Specialist, Division of Medicinal Product, TFDA		
10:40-11:20	**Assessment of Global Clinical Data for Drug Approval in Europe**	**Aaron Sosa Mejia** Medical Oncologist, Chief Medical Officer, Danish Medicines Agency (DKMA), and Alternate CHMP member for Denmark, European Medicines Agency (EMA)
11:20-11:30	Q&A	
Session 1: Introduction of GRM **【Moderator】Mei-Chen Huang(黃玫甄簡任技正)**, Senior Technical Specialist, Division of Medicinal Product, TFDA		
11:40-12:00	**- Concept of GRM** **- Objective of the training**	**Kuo-Teng Hung (洪國登科長)** Section Chief, Division of Medicinal Product, TFDA
12:00-13:00	**LUNCH TIME**	
Session 2: Managing and Conducting the Review **【Moderator】Mei-Chen Huang(黃玫甄簡任技正)**, Senior Technical Specialist, Division of Medicinal Product, TFDA		
13:00-13:40	**An introductory overview of Managing and Conducting the Review**	**Yueh-Tung Tsai (蔡岳橦技正)** Technical Specialist, Division of Medicinal Product, TFDA
13:40-14:20	**Global Clinical Data Evaluation for Drug Approval in Japan**	**Kanae Ohara** Coordinator, Office of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA

14:20-15:20	**Current Practices for Managing and Conducting the Review of New Drug Applications in 3 Economies**	**Representatives from 3 economies**
15:20-15:35	**Panel Discussion**	**Yueh-Tung Tsai (蔡岳橦技正)** Technical Specialist, Division of Medicinal Product, TFDA **Ayumi Endo** Office Director Office of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA **Representatives from 3 economies**
15:35-15:50	**COFFEE BREAK**	
Session 3: Regulatory Competency Framework **【Moderator】Ming-Mei Wu(吳明美副組長)**, Deputy Director, Division of Medicinal Product, TFDA		
15:50-16:20	**Regulatory Competency Framework: A Tool to Help Planning Professional Development and Training**	**Lawrence Liberti** Director, The D. K. Kim International Center for Regulatory Science, University of Southern California (USC)
16:20-16:50	**Rolling Out the GRM Training Program in Each Economy: Trainer's Manual**	**Hiroko Kawaguchi** Prin. Scientist, MSD. K. K RA-EWG APAC (Japan)
16:50-17:00	Q&A	

September 7th 2023		
Time	**Topics**	**Affiliation/Economy**
Session 4: Planning of Application 【**Moderator**】**Rosa Fu**, Director, Regulatory Affairs, Eli Lilly and Company(Taiwan), IRPMA		
08:30-08:35	Ice Breaker	【**Speaker**】 **Finny Liu** APAC Regional Regulatory Policy Lead, Roche Singapore **Jocelyn Lee** Director of Regulatory Affair, Senhwa Biosciences 【**Facilitator**】 IRPMA & TFDA/CDE Members
08:35-09:25	Introductory Lectures - **Planning of New Drug application** - **Planning of Generic Drug applications**	
09:25-10:15	Group Discussion **Case Studies:** **New Drugs & Generic Drugs**	
10:15-10:30	**COFFEE BREAK**	
10:30-11:20	Group Presentation **Case Studies:** **New Drugs & Generic Drugs**	
Session 5-1: Preparation of Application Dossier /Practice: How to Prepare Application Dossier 【**Moderator**】**Yukiko Noguchi**, Associated Director, Regulatory Affairs, Astellas Pharma Inc. RA-EWG APAC (Japan)		
11:30-11:35	Ice Breaker	**Yukiko Noguchi** Associated Director, Regulatory Affairs, Astellas Pharma Inc. RA-EWG APAC (Japan)
11:35-12:15	Lectures - **Standard process of application dossier preparation**	**Kumiko Hikida** Manager, Global Regulatory Affairs Department, Mitsubishi Tanabe Pharma Corporation,

		JAPAN, RA-EWG APAC (Japan)
	- **Support tools**	**Masaaki Kanno** SP Team Lead Overseas Regulatory Office Regulatory Affairs Department Otsuka Pharmaceutical Co., Ltd.
12:15-13:10	**LUNCH TIME**	
Session 5-2: Preparation of Application Dossier /Practice: How to Prepare Application Dossier **【Moderator】Shinji Hatakeyama** Leader, Regulations and Approvals Expert Working Group (RA-EWG), APAC, and Director, Japan/Asia Regulatory & Asia Clinical Operations Department, Medicine Development Center, Eisai Co., Ltd, Japan		
13:10-14:00	Group Discussion **Practice: How to prepare application dossier**	**【Moderator】** **Shinji Hatakeyama** Leader, Regulations and Approvals Expert Working Group (RA-EWG), APAC, and Director, Japan/Asia Regulatory & Asia Clinical Operations Department, Medicine Development Center, Eisai Co., Ltd, Japan **【Facilitator】** IRPMA&TFDA/CDE Members
14:00-14:50	Group Presentation **Practice: How to prepare application dossier**	
14:50-15:00	**COFFEE BREAK**	
Session 6: Communications **【Moderator】Min Chen(李敏珠顧問)** Principal of US Pharmacovigilance LLC, and Consultant, Division of Medicinal Products, TFDA, and Former Acting Director of Division of Pharmacovigilance, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research (CDER), US FDA		

15:00-15:20	Lectures - **Good communications: Fundamentals from Regulatory Perspectives**	**Min Chen (李敏珠顧問)** Principal of US Pharmacovigilance LLC, and Consultant**,** Division of Medicinal Products, TFDA, and Former Acting Director of Division of Pharmacovigilance, Office of Surveillance and Epidemiology, CDER, US FDA
15:20-15:40	Lectures - **Overview of Communication mechanisms: Industry Aspects**	**Wimolsiri Punjatanasak** Regulatory Affairs Director, MSD (Thailand) Ltd., RA-EWG APAC (Thailand)
15:40-16:35	Group Discussion	**【Moderator】** **Min Chen(李敏珠顧問)** Principal of US Pharmacovigilance LLC, and Consultant, Division of Medicinal Products, TFDA, and Former Acting Director of Division of Pharmacovigilance, Office of Surveillance and Epidemiology, CDER, US FDA **Wimolsiri Punjatanasak** Regulatory Affairs Director, MSD (Thailand) Ltd., RA-EWG APAC (Thailand) **【Facilitator】** IRPMA&TFDA/CDE Members
16:35-17:30	Group Presentation	

September 8th 2023		
Time	**Topics**	**Affiliation/Economy**
Session 7: Critical thinking and regulatory decision-making **【Moderator】Jo-Feng Chi (祁若鳳研究員)**, Researcher, Division of Medicinal Product, TFDA		
09:00-09:30	Lectures - **The Elements of Quality Regulatory Decision Making**	**Lawrence Liberti** Director, The D. K. Kim International Center for Regulatory Science, University of Southern California (USC)
09:30-09:50	Lectures - **Bridging Study Evaluation (How to accept foreign data): An Overview**	**Chi-Hsun Chen（陳紀勳醫師）** Senior Clinical Section Chief, Center for Drug Evaluation
09:50-10:05	**COFFEE BREAK**	
10:05-11:00	Case Studies (1/2)	**【Moderator】** **Chi-Hsun Chen（陳紀勳醫師）** Senior Clinical Section Chief, Center for Drug Evaluation **Wei-Lun Peng（彭偉倫醫師）** Senior Medical Reviewer, Division of New Drugs, Center for Drug Evaluation **Yi-Lin, Wang（王藝琳資深審查員）** Senior Reviewer, Division of Pharmaceutical Science, Center for Drug Evaluation **【Facilitator】** IRPMA&TFDA/CDE Members
11:00-12:00	Case Studies (2/2)	

<table>
<tr><td>12:00-13:00</td><td colspan="2">LUNCH</td></tr>
<tr><td colspan="3">Keynote Speech 3
【Moderator】Hwei-Fang Cheng(陳惠芳副署長), Deputy Director General, TFDA</td></tr>
<tr><td>13:00-13:40</td><td>Modernizing Clinical Trials: A Focus on Decentralized Clinical Trials</td><td rowspan="2">M. Khair ElZarrad
Director, Office of Medical Policy, Center for Drug Evaluation and Research, U.S. FDA</td></tr>
<tr><td>13:40-13:50</td><td>Q&A</td></tr>
<tr><td>14:00-14:30</td><td>Closing Remarks
• Certificate Award Ceremony
• Closing Remarks</td><td>Shou-Mei Wu (吳秀梅署長)
Director General, TFDA</td></tr>
</table>

三、研討會照片

大合照

丹麥藥品管理局首席醫療官 Dr. Aaron Sosa Mejia 受邀演講

馬來西亞及印尼審查人員分享該國藥品審查經驗

審查案例分組討論

美 FDA 醫藥政策辦公室主任 Dr. M. Khair ElZarrad 受邀視訊演講

吳秀梅署長頒發學員與會證書

吳秀梅署長頒發紀念品予 PMDA 亞洲訓練中心辦公室主任 Ayumi Endo 及 APAC 專家工作組主席 Shinji Hatakeyama

四、 研討會學員回饋

學員對於本次研討會的各項課程評分皆高於 4 分，對於研討會整體的滿意度評分達 4.5 分(表 1)，顯示學員對於本次研討會辦理十分滿意。此外會前、會後測驗結果亦顯示學員們於課後對議題之認知皆有顯著提升，學員回饋意見將作為未來研討會辦理之參考，摘要學員回饋意見於表 2、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?	4.5/ 5.0
本次研討會課程是否有達到您的期望?	4.5/ 5.0
研討會整體評價	4.5/ 5.0

表 2：學員認為本次研討會最有幫助的課程

學員認為本次研討會最有幫助的課程
• 新藥申請規劃(Planning of Application: New Drugs)
• 審查人員能力架構(Regulatory competency Framework)
• 銜接性試驗評估(Bridging Study Evaluation)
• 優良送審規範(Good submission practice)
• 查驗登記管理溝通機制(communication)

表 3：學員建議未來研討會之課題

建議未來研討會之課題
• 孤兒藥(Orphan drugs)及罕見疾病治療(Rare disease therapeutic area)相關議題
• 腫瘤藥品之新藥送審規劃(NDA submission of oncology)
• 真實世界證據之趨勢(RWE trend)
• 細胞/基因治療之相關藥品法規(Regulation for cell/gene therapy)
• 數位轉型應用於實踐 GRM 之要件 (Utilizing digital transformation to apply elements of good registration management)