2023 APEC Good Registration Management CoE Workshop Summary Report

1. Introduction

To promote regulatory harmonization and convergence, and enhance the efficiency and quality of evaluation, registration, and management of drugs and medical devices in the Asia-Pacific region, the Taiwan Food and Drug Administration (TFDA) hosted the '2023 APEC Good Registration Management (GRM) Center of Excellence (CoE) Workshop' from September 6th to September 8th. APEC is a multilateral official economic cooperation that Taiwan officially participates in. TFDA has engaged in the APEC RHSC activities to actively promote initiatives for regional regulatory harmonization. Since 2016 to date, TFDA has trained 70-110 trainees from APEC economies via regulatory training activities every year to not only contribute to promoting the concept of Good Registration Management but also improve the overall efficiency of drugs and medical devices review and submission.

2. Achievements

Due to the impact of COVID-19, the 2021 and 2022 APEC GRM Workshop were held via online. The 2023 APEC GRM Workshop was the first physical workshop after COVID-19. The workshop agenda focused on the core curriculum of GRM, Good Review Practice (GRevP) and Good Submission Practice (GSubP). Please refer to the agenda on the next page.

TFDA invited 21 experts from the US FDA, EMA, PMDA, International Center for Regulatory Science (University of Southern California), CDE and IRPMA, etc., as speakers to share their good registration management regulations and practical experiences.

In total, there were 81 trainees, including 22 trainees from regulatory authorities and 59 trainees from industries completed the GRM concept training. Trainees were from 5 APEC economies, including Taiwan, Malaysia, the Philippines, Singapore and Thailand and one non-APEC economy, Botswana, respectively.

3. Agenda

<table>
<tr><th colspan="3">September 6th 2023</th></tr>
<tr><th>Time</th><th>Topics</th><th>Affiliation/Economy</th></tr>
<tr><td>09:00-09:20</td><td>Opening Remarks</td><td>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</td></tr>
<tr><td>09:20-09:35</td><td colspan="2">GROUP PHOTO</td></tr>
<tr><td colspan="3">Keynote Speech 1
【Moderator】Yi-Chu Lin(林意筑專門委員), Senior Specialist, Division of Medicinal Product, TFDA</td></tr>
<tr><td>09:35-10:15</td><td>Good Review Practice and Regulatory Convergence in Accepting Global Clinical Data for Regulatory Approval</td><td rowspan="2">Herng-Der Chern (陳恆德醫師)
Standing Director, Taiwan Society of Regulatory Affairs for Medical Products</td></tr>
<tr><td>10:15-10:25</td><td>Q&A</td></tr>
<tr><td>10:25-10:40</td><td colspan="2">COFFEE BREAK</td></tr>
<tr><td colspan="3">Keynote Speech 2
【Moderator】Yi-Chu Lin(林意筑專門委員), Senior Specialist, Division of Medicinal Product, TFDA</td></tr>
<tr><td>10:40-11:20</td><td>Assessment of Global Clinical Data for Drug Approval in Europe</td><td rowspan="2">Aaron Sosa Mejia
Medical Oncologist, Chief Medical Officer, Danish Medicines Agency (DKMA), and Alternate CHMP member for Denmark, European Medicines Agency (EMA)</td></tr>
<tr><td>11:20-11:30</td><td>Q&A</td></tr>
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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	**Min Chen (李敏珠顧問)**

	- **Good communications: Fundamentals from Regulatory Perspectives**	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)	
12:00-13:00	**LUNCH**	
Keynote Speech 3 【**Moderator**】**Hwei-Fang Cheng(陳惠芳副署長)**, Deputy Director General, TFDA		
13:00-13:40	**Modernizing Clinical Trials:** **A Focus on Decentralized Clinical Trials**	**M. Khair ElZarrad** Director, Office of Medical Policy, Center for Drug Evaluation and Research, U.S. FDA
13:40-13:50	Q&A	
14:00-14:30	**Closing Remarks** • **Certificate Award Ceremony** • **Closing Remarks**	**Shou-Mei Wu (吳秀梅署長)** Director General, TFDA

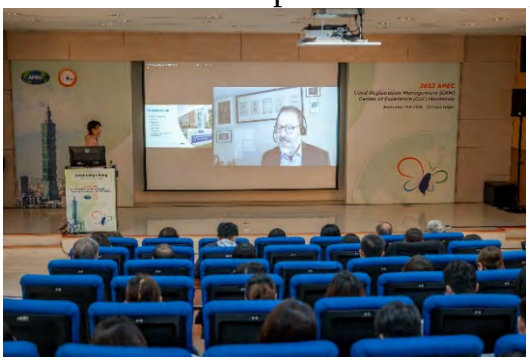
4. Photos

Group Photo

The speech from Dr. Aaron Sosa Mejia, the medical oncologist of Danish Medicines Agency (DKMA).

Regulatory authorities from Malaysia and Indonesia shared their experience of drug evaluation.


Group discussion and presentation: Cases studies



The video speech from Dr. M. Khair ElZarrad, the director of office of Medical Policy, Center for Drug Evaluation and Research, U.S. FDA

Dr. Wu presented certificates for trainees

Dr. Wu presented gifts for Ayumi Endo, the Office Director of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA and Shinji Hatakeyama, the leader of Regulations and Approvals Expert Working Group (RA-EWG), APAC.

5. Feedback from Trainees

The scores of each session were all above 4 and the general satisfaction reached 4.5 (Table 1). These results indicated trainees were satisfied with the workshop. Moreover, pre and post-surveys showed trainees' knowledge levels of the topic were improved after the workshop. Suggestions and feedback from trainees will be the reference for future workshop organizing. Please see the summarized suggestions in the following table 2 and 3.

Table 1: Workshop General Satisfaction

Workshop General Satisfaction	Average
Did the workshop strengthen your understanding of GRM concept?	4.5/ 5.0
Did the workshop meet your expectations?	4.5/ 5.0
Overall Satisfaction.	4.5/ 5.0

Table 2: The Topics that Trainees thought the Most Helpful

Topic
• Planning of Application: New Drugs
• Regulatory Competency Framework
• Bridging Study Evaluation
• Good Submission Practice
• Communication

Table 3: Trainees Suggested the Topics that Could be Involved in the Future Workshop

Topics
• Orphan Drugs and Rare Disease Therapeutic Area
• NDA Submission of Oncology)
• RWE Trend
• Regulation for Cell/Gene Therapy)
• Utilizing Digital Transformation to Apply Elements of Good Registration Management)