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, Pharmaceuticals and Medical Devices Agency (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**	**Herng-Der Chern（陳恆德醫師）** Standing Director, Taiwan Society of Regulatory Affairs for

	Approval	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	
17:30-	WELCOME BANQUET (桂華軒)	

<table>
<tr><th colspan="3">September 7th 2023</th></tr>
<tr><th>Time</th><th>Topics</th><th>Affiliation/Economy</th></tr>
<tr><td colspan="3">Session 4: Planning of Application
【Moderator】Rosa Fu Associate Director, Regulatory Affairs, Eli Lilly and Company(Taiwan), IRPMA</td></tr>
<tr><td>08:30-08:35</td><td>Ice Breaker</td><td rowspan="5">【Speaker】
Finny Liu
APAC Regional Regulatory Policy Lead, Roche Singapore
Jocelyn Lee
Director of Regulatory Affair, Senhwa Biosciences
【Facilitator】
IRPMA & TFDA/CDE Members</td></tr>
<tr><td>08:35-09:25</td><td>Introductory Lectures
- Planning of New Drug application
- Planning of Generic Drug applications</td></tr>
<tr><td>09:25-10:15</td><td>Group Discussion
Case Studies:
New Drugs & Generic Drugs</td></tr>
<tr><td>10:15-10:30</td><td>COFFEE BREAK</td></tr>
<tr><td>10:30-11:20</td><td>Group Presentation
Case Studies:
New Drugs & Generic Drugs</td></tr>
<tr><td colspan="3">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)</td></tr>
<tr><td>11:30-11:35</td><td>Ice Breaker</td><td>Yukiko Noguchi
Associated Director, Regulatory Affairs, Astellas Pharma Inc. RA-EWG APAC (Japan)</td></tr>
<tr><td>11:35-12:15</td><td>Lectures
- Standard process of application dossier preparation</td><td>Kumiko Hikida
Manager, Global Regulatory Affairs Department, Mitsubishi Tanabe Pharma Corporation,</td></tr>
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		JAPAN, RA-EWG APAC (Japan)
	- **Support tools**	**Masaaki Kanno** SP Team Lead, Overseas Regulatory Office Regulatory Affairs Department, Otsuka Pharmaceutical Co., Ltd. RA-EWG APAC (Japan)
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)	

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