2024 APEC GRM CoE Workshop Agenda_Draft

September 3rd (day 1)			
SESSION	**TOPICS**	**TIME**	**AFFILIATION**
Guided Reading	Introduction of GRM (Video, Free Participation)	0830-0850	TFDA
Opening	**Opening Remarks & Group Photo**	**0900-0920**	TFDA, PMDA, APAC
Session 1	***Critical thinking and regulatory decision-making:*** **Benefit-Risk Assessment in Regulatory Decision-Making for Market Authorization of Medicinal Products**		
	Regulatory: — An overview of ICH M4E(R2) — Experience sharing from perspectives of a clinical reviewer	0920-1000	**Chi-Hsun Chen** Senior Clinical Section Chief, Center for Drug Evaluation
	Academic: (Online) — Structured frameworks to increase the transparency of the assessment of benefits and risks of medicines: Current status and possible future directions	1000-1050	**Lawrence Liberti** Director, The D. K. Kim International Center for Regulatory Science, University of Southern California (USC)
	Break time		
	EMA: Current Practices for Benefit-Risk Assessment of Medicinal Products in EMA	1105-1200	**Andreas Kouroumalis** Scientific Officer, Human Medicines Division Advanced Therapies and Haematological Diseases Office
1200-1300 Lunch Time			
Session 1 (continue)	**PMDA:** Current Practices for Benefit-Risk Assessment of New Drugs in PMDA	1300-1330	**PMDA**
	Industry: Industry perspectives on benefit-risk assessment	1330-1400	**TBD**
	Panel Discussion	1405-1435	**CDE/Academic/EMA/PMDA/Industry**

<table>
<tr><td colspan="4">Break time & Relocated to 3F classroom</td></tr>
<tr><td rowspan="5">Session 2</td><td colspan="2">Communication:
Communication of benefit and risk for pre-market approval and post-market surveillance</td><td>【Moderator】
Min Chen
Former Acting Director of Division of Pharmacovigilance, Office of Surveillance and Epidemiology, CDER, US FDA</td></tr>
<tr><td>• Introductory Lectures: Overview of Communication Mechanisms
- Regulators' Aspects
- Industry Aspects</td><td>1455-1535</td><td rowspan="4">【Speaker】
Min Chen
APAC RA-EWG</td></tr>
<tr><td>• Group Discussion</td><td>1535-1635</td></tr>
<tr><td>• Group Presentation</td><td>1635-1735</td></tr>
<tr><td>• Take Home Message</td><td>1735-1740</td></tr>
<tr><td colspan="4">Break Time</td></tr>
<tr><td></td><td>Welcome Reception</td><td>1830-2030</td><td></td></tr>
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＊ The program may be subjected to change.

September 4th (day 2)			
SESSION	**TOPICS**	**TIME**	**AFFILIATION**
Session 3	**Status of Implementation of GRM in the Economies**	**0900-0930**	Representatives from 3 economies
Session 4	***Planning of Application***		**【Moderator】** IRPMA
	• Ice breaker • Introductory Lectures - Planning for a successful submission to expedite early approval - How to develop a good Generic registration plan?	0930-1030	**【Speaker】** IRPMA
	• Group Discussion	1045-1135	
	• Group Presentation	1135-1225	
	• Take Home Message	1225-1230	
1230-1330 Lunch Time			
Session 5	***Preparation of Application Dossier***		**【Moderator】** APAC
	• Ice breaker • Introductory Lectures - Think about preparing your current and future applications (tentative) - Standard process of application dossier preparation - Support tools	1330-1430	**【Speaker】** APAC
	• Group Discussion	1430-1520	
	• Group Presentation	1535-1635	
	• Take Home Message	1635-1640	
Special Thanks	**Certificate of Appreciation & Group Photo**	**1640-1650**	

∗ The program may be subjected to change.

2024/05/14

September 5th (day 3)			
SESSION	**TOPICS**	**TIME**	**AFFILIATION**
Session 6	**Conducting the Review in Regenerative Medicine**	**0900-1130**	PMDA
	Regulatory Updates for Regenerative Medicine in Taiwan	0900-0920	TFDA
	Regulatory Updates for Regenerative Medicine in Japan	0920-0940	PMDA
	GRevP of Quality part regarding CMC consideration	0940-1000	PMDA
	Break Time		
	GRevP of Quality part regarding Clinical consideration	1015-1035	PMDA
	Industry	1035-1055	PMDA
	Q & A	1055-1115	PMDA
Break Time			
Closing Remarks	**Certificate Award Ceremony**	**1130-1145**	
	Closing Remarks	**1145-1200**	

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