2025 APEC GRM CoE Workshop Agenda (draft)

Tuesday, August 26 (DAY 1)			
TIME	**TOPICS**	**AFFILIATION**	**Room**
Opening Remarks			401
08:50-09:30	Welcome Remarks & Opening Remarks & Group Photo & PWA Introduction	**TFDA/PMDA/APAC**	
09:30-09:45 GRM Relocate to Room 402CD			
Session 1: ***Define the core competency of applicants & reviewers*** **【Moderator】TFDA**			402CD
09:45-10:30	Define the core competency of applicants & reviewers	**Apurva Uniyal** Regulatory Innovation Research Scientist, The D. K. Kim International Center for Regulatory Science, Department of Regulatory and Quality of Southern Sciences, University of Southern California (USC)	
Session 2-1: ***Managing and conducting the review*** Focusing on implementation of pathways for approval of drugs for unmet medical needs and its outcomes **【Moderator】TFDA**			402CD
10:30-11:15	Experience sharing for accelerated approval in US	**Former US FDA officer** (TBC)	
11:15-12:00	Experience sharing for Conditional Marketing Authorisation by EMA	**Margaux PHILIPPE** Scientific Specialist, Oncology & Radiopharmaceuticals Office, Human Medicines Division, European Medicines Agency (EMA)	
12:00-13:00 Lunch Time			
Session 2-2: ***Managing and conducting the review*** Focusing on implementation of pathways for approval of drugs for unmet medical needs and its outcomes **【Moderator】Apurva Uniyal** Regulatory Innovation Research Scientist, The D. K. Kim International Center for Regulatory Science, Department of Regulatory and Quality of Southern Sciences, University of Southern California (USC)			402CD

13:00-13:20	Principles of accelerated approval by TFDA	**TFDA**
13:20-13:40	Experience sharing for conditional early approval by PMDA	**PMDA**
13:40-14:00	Panel Discussion	**TBD**
14:00-14:15 Coffee Break		
Session 3: *Planning of Application* **【Moderator】IRPMA**		402CD
14:15-15:15	*Introductory Lectures* ─ Planning for Submission for NDA with unmet medical needs ─ Planning for Submission for LEX, biosimilar with unmet medical needs	**【Speaker】** **IRPMA** **【Facilitator】** **TFDA/CDE/APAC/IRPMA**
15:15-16:15	Group Discussion	
16:15-17:15	Group Presentation	
17:15-17:20	Take Home Message	
1720-1730 Relocate to 1F (LIYAN international banquet restaurant)		1F
17:30-19:30	**Welcome Reception**	

<table>
<tr><th colspan="3">Wednesday, August 27 (DAY 2) - Room 402CD</th></tr>
<tr><th>TIME</th><th>TOPICS</th><th>AFFILIATION</th></tr>
<tr><td colspan="3">Session 4: Preparation of Application Dossier
Innovating for the Future: Preparing Your Applications
【Moderator】JPMA</td></tr>
<tr><td>09:00-10:00</td><td>Introductory Lectures
– Current Environment
– Preparation of Application Dossier based on GsubP</td><td rowspan="5">【Speaker】
JPMA

【Facilitator】
TFDA/CDE/APAC/IRPMA</td></tr>
<tr><td colspan="2">10:00-10:15 Coffee Break</td></tr>
<tr><td>10:15-11:00</td><td>Group Discussion</td></tr>
<tr><td>11:00-11:55</td><td>Group Presentation</td></tr>
<tr><td>11:55-12:00</td><td>Take Home Message</td></tr>
<tr><td colspan="3">12:00-13:00 Lunch Time</td></tr>
<tr><td colspan="3">Session 5: Experience sharing for implementation of pathways for approval of drugs for unmet medical needs in 3 Economies
【Moderator】 TFDA</td></tr>
<tr><td>13:00-13:20</td><td>Economies 1</td><td>TBD</td></tr>
<tr><td>13:20-13:40</td><td>Economies 2</td><td>TBD</td></tr>
<tr><td>13:40-14:00</td><td>Economies 3</td><td>TBD</td></tr>
<tr><td>14:00-14:20</td><td>Q&A</td><td>TBD</td></tr>
<tr><td colspan="3">14:20-14:35 Coffee Break</td></tr>
<tr><td colspan="3">Session 6: Communications
【Moderator】Min Chen Former Acting Director of Division of Pharmacovigilance, Office of Surveillance and Epidemiology, CDER, US FDA</td></tr>
<tr><td>14:35-15:35</td><td>Communications for submission and review of drugs for unmet medical needs</td><td>【Speaker】
Min Chen
Former Acting Director of Division of</td></tr>
</table>

15:35-16:35	Group Discussion	Pharmacovigilance, Office of Surveillance and Epidemiology, CDER, US FDA **JPMA** **【Facilitator】** **TFDA/CDE/APAC/IRPMA**
16:35-17:35	Group Presentation	
17:35-17:40	Take Home Message	

Thursday, August 28 (DAY 3) - Room 402CD		
TIME	**TOPICS**	**AFFILIATION**
Session 7: *Critical Thinking and Regulatory Decision-making* **【Moderator】TFDA**		
09:00-10:00	An overview of regulatory strategies for products with unmet medical needs & Cases demonstration	**Chi-Hsun Chen** Senior Clinical Section Chief, Center for Drug Evaluation
Session 8: *Special Lecture* **【Moderator】TFDA**		
10:00-10:30	An overview of managing and conducting the review for drug-device combination products (Regulator)	**PMDA**
10:30-11:00	Experience sharing for success in regulatory approval of drug-device combination products (Industry)	**Christian Andreas Emmendörffer** (TBC) Principal Regulatory Program Director, Roche Pharma LTD
11:00-11:30 Coffee Break		
Closing Remarks		
11:30-12:15	Certificate Award Ceremony	**TFDA**
12:15-12:30	Closing Remarks	