Update: September 1

2022 APEC Good Registration Management (GRM)_Agenda

PART 1: Online Self-Learning Lecture (Pre-recorded) from August 29th to September 11th

	TOPICS	TIME	AFFILIATION/ECONOMY
Content 1	**Welcome Letter**	N/A	**Shou-Mei Wu** Director General Taiwan Food and Drug Administration (TFDA)
Session 1	**Introduction of GRM** ◆ Concept of GRM ◆ Achievements of APEC Roadmap to promote GRM ◆ Objectives of this year's workshop	17 Mins	**Chia-Ping Liu** Section Chief Division of Medicinal Products Taiwan Food and Drug Administration (TFDA)
Session 2	**Planning of Application** ◆ Planning of New Drug Application & Example of Registration ◆ Planning of Generic Drug Application & Example of Registration	30 Mins	**Finny Liu** APAC Regional Regulatory Policy Lead Roche Singapore
		33 Mins	**Jocelyn Lee** Senior Regulatory Manager Project & Regulatory Affairs Division TTY Biopharm Co., Ltd
Session 3	**Preparation of Application Dossier** ◆ Standard process of application dossier preparation ◆ Support tools (template, glossary, checklist & timeline table)	23 Mins	**Kumiko Hikida** Manager Global Regulatory Affairs Department Mitsubishi Tanabe Pharma Corporation

			APAC
Session 4	**Managing and Conducting the Review** ◆ An introductory overview of managing the review ◆ Example of implementing GRevP in the review process	20 Mins	**Wan-Yu Chao** Specialist Division of Medicinal Products Taiwan Food and Drug Administration (TFDA)
Session 5	**Using Facilitated Regulatory Pathways (FRPs) for Special Case Authorizations** ◆ Understanding FRP and work sharing models as they apply to special authorizations ◆ Practical cases: How these pathways have been used for • COVID-19 authorizations • Orphan Drugs • Advanced Therapeutic Medicinal products ◆ Barriers and promotors	50 Mins	**Lawrence Liberti** Adjunct Research Professor Reg Affairs and Quality Assurance Graduate Program Temple University School of Pharmacy
Session 6	**Communication with Applicants-Regulator's Aspects** ◆ Effective Communication ◆ Communication with Applicants in Taiwan ◆ Case Scenario-Consultation	10 Mins	**Ting-Yao Wang** Project Manager Division of Regulatory Affairs and Compliance Center for Drug Evaluation
	Communication ~Industries' Aspects~ ◆ Sharing importance of effective communication based on APEC	10 Mins	**Shinji Hatakeyama** Leader Regulations and Approvals Expert Working Group (RA-EWG)

	RHSC Good Submission Practice Guideline for Applicants		APAC
Topic of Special Interest I: Orphan Drug Regulations			
Session 7	**Regulatory Perspective of Orphan Drug Development for Rare Diseases**	12 Mins	**Yen-Hui Wu** Deputy Director Division of New Drugs Center for Drug Evaluation
	An Overview of the European Orphan Regulation ◆ Procedure for orphan designation ◆ Marketing authorisations of orphan drugs ◆ International Collaboration ◆ Tips and tricks (i.e., lessons learned over the years)	28 Mins	**Kristina Larsson** Head of Office Orphan Medicines Human Medicines EMA
Topic of Special Interest II: RWD/RWE for regulatory decision-making			
Session 8	**The Challenges of the application of RWD/RWE in regulatory decision making from PMDA's perspective**	18 Mins	**Atsushi Noguchi** Deputy Review Director Office of New Drug V PMDA
	Evolving Role of Real-Word Data (RWD) & Evidence (RWE) in Drug Development	30 Mins	**Alexander Liede** Senior Director Head of Evidence and Partnerships Global Epidemiology, Pharmacovigilance and Patient Safety (PPS) AbbVie

Part 2: Webinar

DAY 1: September 13th 14h00-17h00 (GMT+8 Time)

TOPICS	TIME	MODERATOR/FACILITATOR
Group Discussion 1: Case Study: Planning of Submission and Preparation of Application Dossier		
Overview on New Drugs & Generic Drugs Cases	14h00-14h15	【**Moderator**】 **Rosa Fu** Associate Director Regulatory Affairs Eli Lilly and Company (Taiwan) IRPMA 【**Speaker**】 **Finny Liu** APAC Regional Regulatory Policy Lead Roche Singapore **Jocelyn Lee** Senior Regulatory Manager Project & Regulatory Affairs Division TTY Biopharm Co., Ltd. 【**Facilitator**】 IRPMA & TFDA/CDE Members
Discussion on New Drugs & Generic Drugs Cases (4 groups of New Drugs/ 3 groups of Generic Drugs)	14h15-15h15	
Break Time	15h15-15h25	
Group Presentation I (4 groups of New Drugs, around 8 mins/group)	15h25-16h10	
Group Presentation II (3 groups of Generic Drugs, around 8 mins/group)	16h10-16h50	
Q&A / Wrap Up	16h50-17h00	

Day 2: September 14th 14h00-16h40 (GMT+8 Time)

TOPICS	TIME	MODERATOR/FACILITATOR
Group Discussion II: Review of Biosimilar Products: Basic Principles		
Overview of the session	10 Mins	**【Moderator】** **Chi-Hsun Chen** Senior Clinical Section Chief Center for Drug Evaluation **【Speaker】** **Participants** **【Facilitator】** CDE Members
Case discussions (7 groups)	60 Mins	
Presentations (7groups, around 8 mins/group)	60 Mins	
Break Time	10 Mins	
Q&A	10 Mins	
Wrap Up & Take Home Messages	10 Mins	

[LIVE] Day 3: September 15th 08h30-11h10 (GMT+8 Time)

TOPICS	TIME	SPEAKER
Brief Opening	08h30-08h40	**Shou-Mei Wu** Director General Taiwan Food and Drug Administration (TFDA)
COVID-19 Vaccine Pharmacovigilance: TFDA's experience	08h40-08h50	**Jo-Feng Chi** Researcher Division of Medicinal Products Taiwan Food and Drug Administration (TFDA)
Key components of a vaccine safety program in the evolving COVID-19 vaccine campaign	08h50-09h15	**Daina Esposito** Senior Director, Global Safety Epidemiologist Clinical Safety and Risk Management Moderna
Q& A Time	09h15-09h20	
US FDA Pilots: Project Orbis, Real Time Oncology Review (RTOR), Assessment Aid **- BMS's Experience** ◆ Provide an overview of FDA pilot programs ◆ Share BMS learnings on FDA pilots of Project Orbis, RTOR, Assessment Aid ◆ Offer insight on considerations needed when submissions occur via these innovative processes	09h20-09h45	**Heidi Wang** Vice President Head of Oncology Global Regulatory Strategy & Policy BMS
Q& A Time	09h45-09h50	

Virtual Photo Time (With All Speakers and Guests)	09h50-09h55	
ACCESS Work-sharing model	09h55-10h20	**John Skerritt** Adjunct Professor Deputy Secretary for Health Products Regulation Australian Department of Health and Aged Care
Q& A Time	10h20-10h25	
Gulf Health Council, experience in Reliance (Pre-recorded)	10h25-10h50	**Hajed M. H. Hashan** Deputy of General Manager Gulf Health Council
Brief Announcement	10h50-10h55	
Closing Remarks I (Pre-recorded)	10h55-11h00	**Junko Sato** Office Director Office of International Program Pharmaceuticals and Medical Devices Agency (PMDA)
Closing Remarks II	11h00-11h05	**Shinji Hatakeyama** Leader Regulations and Approvals Expert Working Group (RA-EWG) Asia Partnership Conference of Pharmaceutical Associations (APAC)
Closing Remarks III+ Virtual Photo Time (With All Participants)	11h05-11h10	**Shou-Mei Wu** Director General Taiwan Food and Drug Administration (TFDA)

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