

2026 APEC Good Registration Management (GRM) CoE Workshop

Full Agenda (Draft)

Day 1 – Aug. 26, 2026 (Wed.)

Time	Topic	Speaker	Room
08:40 – 09:10	Registration		1001
Opening Remarks			1001
09:10 – 09:25	Opening Remarks	<p>Speaker (TBD) Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare (MOHW), Chinese Taipei</p> <p>MD/GRM PWA Co-Champion: Speaker (TBD) Pharmaceuticals and Medical Devices Agency (PMDA), Japan</p> <p>GRM PWA Co-Organizer: Speaker (TBD) APAC Leader</p>	
09:25 – 09:35	Group Photo		
PWA Introduction & Special Topic 【Moderator】 TFDA			1001
09:35 – 09:50	Roadmap and Core Curriculum of GRM/MD PWA	<p>MD PWA: Speaker (TBD) PMDA, Japan</p> <p>GRM PWA: Speaker (TBD) PMDA or TFDA</p>	
09:50 – 10:40	<p>Special Keynote: Combination Products</p> <ul style="list-style-type: none"> - An Overview of Managing and Conducting the Review for Drug-Device Combination Products (Regulatory) - Industry Challenges in Preparing Combination Products for Regulatory Review (Industry) 	<p>TFDA/CDE, Chinese Taipei (TBD) Industry (TBD)</p>	
10:40 – 11:00	Break (GRM move to Room 801)		

Session 1: Core Competencies of Drug Applicants and Reviewers 【Moderator】 TFDA		801
11:00 – 11:40	Define the core competency of applicants & reviewers	USC (TBD)
11:40 – 12:00	Q & A	
12:00 – 13:30	Lunch	
Session 2: Managing and conducting the review Drugs Regulatory Strategies and Review Mechanisms for Generic Drugs 【Moderator】 TFDA		801
13:30 – 14:00	Insights from TFDA (TBD)	TFDA (TBD)
14:00 – 14:30	Insights from PMDA (TBD)	PMDA (TBD)
14:30 – 15:00	Insights from TGA (TBD)	TGA (TBD)
15:00 – 15:30	Insights from EMA (TBD)	EMA (TBD)
15:30 – 15:50	Panel discussion	All Speakers
15:50 – 16:10	Break	
Session 3: Updates on Drug Review Mechanisms Across Economies 【Moderator】 TFDA		801
16:10 – 16:20	Representative of Economy #1	Speaker (TBD)
16:20 – 16:30	Representative of Economy #2	Speaker (TBD)
16:30 – 16:40	Representative of Economy #3	Speaker (TBD)
16:40 – 16:50	Representative of Economy #4	Speaker (TBD)
16:50 – 17:00	Representative of Economy #5	Speaker (TBD)
17:00 – 17:10	Representative of Economy #6	Speaker (TBD)
17:10 – 17:20	Q&A	Representatives from each economy
17:20 – 17:30	Day 1 Questionnaire	
17:30 – 18:00	Break (move to Welcome Reception, B1F)	
18:00 – 20:00	Welcome Reception	B1

*Day 1, Opening, PWA Introduction, Special Keynote will be open to the public.

Day 2 – Aug. 27, 2026 (Thu.)

Time	Topic	Speaker	Room
08:30 – 09:00	Registration		803
Session 4: Planning of Application 【Moderator】 IRPMA			803
09:00 – 10:00	Lectures - Planning for a successful NDA submission to expedite early approval - Strategic Planning and Decision-Making in Generic Drug Registration: Leveraging Global Data and Reference Products	【Speaker】 IRPMA 【Facilitator】 TFDA/CDE/IRPMA	
10:00 – 10:10	Break		
10:10 – 11:00	Group Discussion		
11:00 – 11:55	Group Presentation		
11:55 – 12:00	Take Home Message		
12:00 – 13:00	Lunch		
Session 5: Preparation of Application Dossier 【Moderator】 Hiroko Kawaguchi Director, Regulatory Affairs Area Reg Strat & Liaison, Japan Development, MSD.K.K.			803
13:00 – 14:00	Lectures - Advancing for What's Next: Preparing Smarter Applications	【Speaker】 Toru Suzuki Kohei Koyama	
14:00 – 14:10	Break		
14:10 – 15:00	Group Discussion	【Facilitator】 TFDA/CDE/IRPMA	
15:00 – 15:55	Group Presentation		
15:55 – 16:00	Take Home Message		
16:00 – 16:10	Break		
Session 6: Communications			803
16:10 – 17:00	Lecture	【Speaker】 Min Chen	
17:00 – 17:30	Group Discussion	Former Acting Director of Division of Pharmacovigilance, Office of Surveillance and Epidemiology, CDER, US FDA	
17:30 – 18:00	Group Presentation		
18:00 – 18:05	Take Home Message		

		Jessica Tsai Sr. Regulatory Affairs Director, Asia North Cluster & Taiwan, Merck Sharp & Dohme (I.A.) LLC, Taiwan Branch 【Facilitator】 TFDA/CDE/IRPMA
18:05 – 18:10	Day 2 Questionnaire	

Day 3 – Aug. 28, 2026 (Fri.)			
Time	Topic	Speaker	Room
08:40 – 09:00	Registration		801
Session 7: Critical Thinking and Regulatory Decision-making Current Trends in AI for Regulatory Review and Decision-Making 【Moderator】 TFDA			801
09:00 – 09:30	Perspectives from TFDA	TFDA (TBD)	
09:30 – 10:00	Perspectives from PMDA	PMDA (TBD)	
10:00 – 10:30	Perspectives from US FDA (or EMA)	US FDA (or EMA) (TBD)	
10:30 – 10:40	Q & A	All Speakers	
10:40 – 10:45	Day 3 Questionnaire		
10:45 – 11:00	Break (move to Room 1001)		
Closing Remarks			1001
11:00 – 11:50	Certificate Award Ceremony	Speaker (TBD)	
11:50 – 12:00	Closing Remarks / Group Photo	TFDA, MOHW, Chinese Taipei	