2026 APEC 優良查驗登記管理法規科學卓越中心研討會

2026 APEC Good Registration Management (GRM) Center of Excellence (CoE) Workshop

活動主旨：

衛生福利部食品藥物管理署持續辦理 APEC 優良查驗登記（Good Registration Management，GRM）管理研討會之培訓課程，致力於亞太地區推行藥品 GRM 管理理念。本年度將於 8 月 26 日至 28 日舉辦「2026 年 APEC 優良查驗登記管理法規科學卓越中心研討會」，強化亞太地區醫藥品法規審查人員與送審人員的查驗登記專業知能，並交流最新藥品法規發展。同時，期望藉由本次研討會協助國內業者掌握國際最新藥品法規趨勢，提升送審資料品質及查驗登記實務能力，進一步強化我國醫藥整體量能。研討會特別開放 8 月 26 日及 28 日課程場次（僅開放講座課程），供國內外相關人員線上參加。

活動資訊：

主辦單位：衛生福利部食品藥物管理署

承辦單位：工業技術研究院量測技術發展中心

活動時間：2026 年 8 月 26 日（星期三）上午 9 時 10 分至下午 5 時
2026 年 8 月 28 日（星期五）上午 9 時至 10 時 40 分

辦理方式：線上與會（本次開放 8/26 及 8/28 講座課程報名）

參加人士：政府相關單位人員、製藥業者及學術研究機構人員（含大專院校）

參加費用：免費

報名日期：即日起至 2026 年 8 月 17 日（星期一）中午 12 時或額滿為止

報名方式：網路報名，報名連結：

https://reurl.cc/Z8j6qW

聯絡人：工業技術研究院　量測技術發展中心

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研討會議程 Agenda

Aug. 26, 2026 (Wed.)			
Time	Topic	Speaker	Room
08:40 – 09:10	Registration		1001
Opening Remarks			1001
09:10 – 09:25	Opening Remarks	**Speaker (TBD)** Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare (MOHW), Chinese Taipei **MD/GRM PWA Co-Champion:** **Ayumi Endo** Office Director, Office of Asia Training Center and International Cooperation, Pharmaceuticals and Medical Devices Agency (PMDA), Japan **GRM PWA Co-Organizer:** **Masaaki Kanno** Leader, Regulations and Approvals Expert Working Group (RA-EWG), APAC, and SP Team Lead, Overseas Regulatory Office, Regulatory Affairs Department, Otsuka Pharmaceutical Co., Ltd., Japan	
09:25 – 09:35	Group Photo		
PWA Introduction & Special Topic			1001
09:35 – 09:50	Roadmap and Core Curriculum of GRM & MD PWA	**MD PWA:** **Kazuyoshi Takatori** Special Appointed Staff, OAIC, PMDA, Japan **GRM PWA:** **Ayumi Endo** Office Director, OAIC, PMDA, Japan	

09:50 – 10:40	**Special Keynote: Combination Products** - An Overview of Managing and Conducting the Review for Drug-Device Combination Products (Regulatory) - Industry Challenges in Preparing Combination Products for Regulatory Review (Industry)	**Huai-Yao Chuang** Reviewer, Division of Medical Devices, Center for Drug Evaluation (CDE), Chinese Taipei **Andreas Emmendoerffer** Principal Regulatory Program Director, Pharma Technical Regulatory – Devices and Combination products, Roche Pharma Ltd, Switzerland
10:40 – 11:00	Break (GRM move to Room 801)	
Session 1: *Core Competencies of Drug Applicants and Reviewers*		801
11:00 – 11:40	Define the core competency of applicants & reviewers	**Lawrence Liberti** Director, The D. K. Kim International Center for Regulatory Science, University of Southern California (USC)
11:40 – 12:00	Q & A	
Session 2: *Managing and conducting the review*		801
13:30 – 14:00	TFDA's Strategies for Regulatory Resilience and Efficient Regulation of APIs and Generic Drugs (TBD)	**Chi Chung** Section Chief, Division of Medicinal Product, TFDA
14:00 – 14:30	Drugs Regulatory Strategies and Review Mechanisms for Generic Drugs: Insights from PMDA (TBD)	**Mayu Nozawa** Reviewer, Office of Generic Drugs, PMDA
14:30 – 15:00	Authorisation and lifecycle management of Generic Drugs: Insights from EMA	**Brian Dooley (Virtual)** Pharmaceutical Quality Senior Specialist, European Medicines Agency (EMA)
15:00 – 15:20	Panel discussion	【Moderator】 **Mei-Chen Huang** Senior Technical Specialist, Division of Medicinal Product, TFDA 【Panelists】 **Chi Chung** Section Chief, Division of Medicinal Product, TFDA **Hiroshi Takeda** Review Director, Office of Generic Drugs, PMDA **Mayu Nozawa** Reviewer, Office of Generic Drugs, PMDA **Brian Dooley (Virtual)** Pharmaceutical Quality Senior Specialist, European Medicines Agency (EMA)
15:20 – 15:40	Break	

Session 3: ***Updates on Drug Review Mechanisms Across Economies***		801
15:40 – 15:50	Representative of Chile	**Cristina Troncoso** CMC Reviewer, Biological Register Department, Public Health Institute of Chile (ISP)
15:50 – 16:00	Representative of India	**Harish Gautam** Drugs Inspector, Central Drugs Standard Control Organisation (CDSCO)
16:00 – 16:10	Representative of Malaysia	**Thanu Radha Maiyauen** Senior Principal Assistant Director, Generic Medicines Section, Centre of Product and Cosmetic Evaluation, National Pharmacy Regulatory Agency (NPRA)
16:10 – 16:20	Representative of Peru	**Erik Adrian Cotera Yactayo** Pharmaceutical Chemist, Biological Products Team, Directorate of Pharmaceutical Products, General Directorate of Medicines, Supplies and Drugs (DIGEMID)
16:20 – 16:30	Representative of Philippines	**Michael Galang** Food-Drug Regulation Officer IV, Center for Drug Regulation and Research, FDA Philippines
16:30 – 16:40	Representative of Thailand	**Piyaporn Chootikul** Pharmacist Professional, Pharmaceutical Substance Promotion Subdivision, Medicine Regulation Division, Thai FDA
16:40 – 17:00	Q&A	**Representatives from each economy**

Aug. 28, 2026 (Fri.)			
Time	Topic	Speaker	Room
08:40 – 09:00	Registration		801
Session 7: *Critical Thinking and Regulatory Decision-making*			801
09:00 – 09:30	TFDA Intelligent Review for Pharmaceutical Regulatory Assessment (TBD)	**Po-Wen Yang** Senior Technical Specialist, Division of Medicinal Product, TFDA	
09:30 – 10:00	Current Trends in AI for Regulatory Review and Decision-Making: Insights from PMDA (TBD)	**Sakurana Fukuda** Coordinator, Review Planning Division, Office of Review Management, PMDA	
10:00 – 10:30	Current Trends in AI for Regulatory Review and Decision-Making: Insights from EMA	**David Filipovic (Virtual)** Digital Portfolio Lead, EMA **Paul Zabbal (Virtual)** Innovation Manager, EMA	
10:30 – 10:40	Q & A	**All Speakers**	

*承辦單位保留變更議程、講題及主講人之權利。若有任何未盡事宜，承辦單位亦保有隨時補充、說明、修改之權利。

注意事項：

- 本次研討會不提供紙本講義，將於活動當天提供電子講義下載連結。
- 本次研討會僅接受線上報名，名額有限，承辦單位保留受理報名之權利。
- 報名成功者，承辦單位將於活動前 7 日，以 e-mail 方式寄發「報到通知」。如未收到，請主動來電洽詢。