2026 APEC Medical Devices CoE Workshop
Full Agenda

- Date: August 26 – 28, 2026
- Venue: Chang Yung-Fa Foundation International Convention Center
- CoE Host Institution: Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare

Day 1 – Aug. 26, 2026 (Wed.)

Time	Topic	Speaker
08:40 – 09:10	Registration (meeting room 1001)	
09:10 – 09:25	Opening Remarks	**Dr. Der-Yuan Wang** Deputy Director-General, Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare (MOHW), Chinese Taipei **MD/GRM PWA Co-Champion:** **Ms. Ayumi Endo** Office Director, Office of Asia Training Center and International Cooperation (OAIC), Pharmaceuticals and Medical Devices Agency (PMDA), Japan **GRM PWA Co-Organizer:** **Mr. 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	

09:35 – 09:50	Roadmap and Core Curriculum of GRM/MD PWA	**MD PWA:** **Mr. Kazuyoshi Takatori** Special Appointed Staff, OAIC, PMDA, Japan **GRM PWA:** **Ms. Ayumi Endo** Office Director, OAIC, PMDA, Japan
09:50 – 10:40	Special Keynote: An Overview of Managing and Conducting the Review for Drug-Device Combination Products *(not endorsed as APEC MD CoE topic)*	**Dr. Huai-Yao Chuang** Reviewer, Division of Medical Devices, Center for Drug Evaluation (CDE), Chinese Taipei **Dr. Andreas Emmendoerffer** Principal Regulatory Program Director, Pharma Technical Regulatory – Devices and Combination products, Roche Pharma Ltd, Switzerland
10:40 – 10:50	Break	
10:50 – 11:00	Introduction of TFDA MD CoE Training Program	**Mr. Hsiu-Te Lin** Section Chief, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei
11:00 – 12:00	Lecture #1: Current Harmonization Status of Pre- and Post-Market Regulation in Each Economy *(Chile, Chinese Taipei, Egypt)*	20 min per economy
12:00 – 13:30	Lunch	
13:30 – 15:10	Lecture #1: Current Harmonization Status of Pre- and Post-Market Regulation in Each Economy (continued) *(Indonesia, Philippines, Tanzania, Thailand, and Vietnam)*	20 min per economy
15:10 – 15:40	Break	

15:40 – 16:00	Lecture #1: Current Harmonization Status of Pre- and Post-Market Regulation in Each Economy (Q&A)	Representatives from each economy
16:00 – 16:20	Break (move to closed-door meeting room 1002)	Moderator
16:20 – 16:50	Lecture #2-1: MDSAP Introduction • MDSAP Training Modules: Introduction to MDSAP	**Mr. Katsuhito Ono (Virtual)** Principal Assessor, Office of Compliance and Manufacturing Quality for Medical Devices, Division of Registered Certification Body Assessment, PMDA, Japan
16:50 – 17:30	Lecture #2-2: ISO13485:2016 Overview and Practical Implementation in Medical Device Quality Management + QA • ISO13485: 2016 Medical devices -- Quality management systems -- Requirements for Regulatory Purposes	**Mr. Naoki Morooka** Senior Manager, Quality Assurance Dept., Medical Systems Division, Shimadzu Corporation, Japan
17:30 – 17:40	Day 1 Questionnaire	
17:40 – 18:00	Break (move to Welcome Reception, B1F)	
18:00 – 20:00	Welcome Reception	

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

Day 2 – Aug. 27, 2026 (Thu.)

Time	Topic	Speaker
08:30 – 09:00	Registration (meeting room 1002)	
09:00 – 09:30	Icebreaker Session	Moderator
09:30 – 10:00	Lecture #3: Review of Essential Principles of Medical Device Safety & Performance and Principles of Conformity Assessment • Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2024 (Edition 2)) • Principles of Conformity Assessment for Medical Devices (GHTF/SG1/N78:2012)	**Dr. Pei-Chia Chan** Reviewer, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei
10:00 – 10:10	Break	
10:10 – 11:50	Group Practice: MD Case Study (1 case) Case Study Introduction (10 min) Group Discussion (50 min) Group Presentation (30 min) Q&A (10 min)	**Dr. Tai-Long Chen** Senior Reviewer, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei
11:50 – 13:30	Lunch	
13:30 – 14:30	Lecture #4: Adverse Event Reporting • Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices (GHTF/SG2/N54R8:2006) • IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes (IMDRF/AE WG/N43FINAL:2020 (Edition 4) and IMDRF/AE WG/N43FINAL:2026 Updated Annexes)	**Ms. Yu-Hsuan Yang** Specialist, Taiwan Drug Relief Foundation (TDRF), Chinese Taipei
14:30 – 14:50	Break	
14:50 – 16:00	Group Practice: IMDRF Terminologies for Medical Device Adverse Event Group Discussion (30 min) Group Presentation (30 min) Q&A (10 min)	**Ms. Yu-Hsuan Yang** Specialist, Taiwan Drug Relief Foundation (TDRF), Chinese Taipei
16:00 – 16:10	Day 2 Questionnaire	

Day 3 – Aug. 28, 2026 (Fri.)

Time	Topic	Speaker
08:30 – 09:00	Registration (meeting room 1002)	
09:00 – 10:10	Lecture #5: Clinical Evaluation + QA • Clinical Investigation (IMDRF/MDCE WG/N57FINAL: 2019) • Clinical Evaluation (IMDRF/MDCE WG/N56FINAL:2019) • Clinical Evidence (IMDRF/MDCE WG/N55FINAL:2019)	**Dr. Kevin Wei-I Lee** Clinical Reviewer, Division of Medical Devices, Center for Drug Evaluation (CDE), Chinese Taipei
10:10 – 10:20	Day 3 Questionnaire	
10:20 – 10:40	Expectations from the Workshop and Next Steps • TFDA (3 min) • APEC RHSC MD PWA Co-Champion (3 min) • APEC RHSC MD PWA Sub-Champions (3 min each) • Members of the program committee or participants (2 min each)	**Ms. Elma Chi-Wen Hsieh** Senior Technical Specialist, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei **MD PWA Co-Champion:** **Mr. Kazuyoshi Takatori** Special Appointed Staff, OAIC, PMDA, Japan **MD PWA Sub-Champion:** **Mr. Naoki Morooka** Vice Division Chairman, Japan Medical Imaging and Radiological Systems Industries Association (JIRA), Japan
10:40 – 11:00	Break (move to Ceremony meeting room 1001)	
11:00 – 11:50	Certificate Award Ceremony	**Dr. Chih-Kang Chiang** Director-General, TFDA, MOHW, Chinese Taipei
11:50 – 12:00	Closing Remarks/Group Photo	
12:00 – 13:30	Lunch	
13:30 – 16:00	Manufacturing Site Visit	Regulators Only