Full Agenda of 2025 APEC Medical Devices CoE Workshop

Day 1 – Aug. 26, 2025 (Tue.)

Time	Topic	Speaker
08:30 – 08:50	Registration	
08:50 – 09:05	Opening Remarks	**TFDA:** **TBD** 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
09:05 – 09:15	Group Photo	
09:15 – 09:30	Roadmap and Core Curriculum of GRM/MD PWA	**GRM PWA:** **Ms. Tomoko Tanaka** Coordinator, OAIC, PMDA, Japan **MD PWA:** **Mr. Kazuyoshi Takatori** Special Appointed Staff, OAIC, PMDA, Japan

09:30 – 09:50	Coffee Break	
09:50 – 10:00	Introduction of TFDA MD CoE Training Program	**Mr. Hsiu-Te Lin** Section Chief, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei
10:00 – 12:00	Lecture #1: Current Harmonization Status of Pre- and Post-Market Regulation in Each Economy	20 min per economy
12:00 – 13:30	Lunch	
13:30 – 14:30	Lecture #1: Current Harmonization Status of Pre- and Post-Market Regulation in Each Economy	20 min per economy
14:30 – 14:50	Lecture #1: Current Harmonization Status of Pre- and Post-Market Regulation in Each Economy (Q&A)	Representatives from each economy
14:50 – 15:10	Coffee Break	
15:10 – 15:40	Icebreaker Activities	Moderator
15:40 – 17:00	Lecture #2: Medical Device Definition and Classification • Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device' (GHTF/SG1/N071:2012) • Principles of Medical Device Classification (GHTF/SG1/N77:2012) • Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (IMDRF/IVD WG/N64FINAL:2021) Group Practice	**Dr. Sheng-Hui Liao** Senior Engineer, Office of Medical Device Evaluation, Center for Measurement Standards, ITRI, Chinese Taipei
17:30 – 19:30	Welcome Reception	

*Day 1, Lecture #1 will be open to the public.

Day 2 – Aug. 27, 2025 (Wed.)

Time	Topic	Speaker
09:00 – 09:30	Registration	
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)	**Mr. Naoki Morooka** Senior Manager, Quality Assurance Dept., Medical Systems Division, Shimadzu Corporation, Japan
10:00 – 12:00	Group Practice: MD Case Study (1 case) Case Study Introduction (10 min) Group Discussion (50 min) Coffee Break (15 min) Group Presentation (30 min) Q&A (15 min)	**Ms. Pei-Ting Sarah Chou** Supervisor & Consultant / Founding Board of Director, Regulatory Affairs Professionals Society (RAPS) Taiwan Chapter, Chinese Taipei
12:00 – 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:2025 Updated Annexes)	**Ms. Yu-Hsuan Yang** Specialist, Taiwan Drug Relief Foundation (TDRF), Chinese Taipei
14:30 – 14:50	Coffee 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, TDRF, Chinese Taipei

Day 3 – Aug. 28, 2025 (Thu.)

Time	Topic	Speaker
09:00 – 09:40	Registration	
09:40 – 10:40	Lecture #5: Clinical Evaluation • 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
10:40 – 11:00	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)	**TFDA:** **TBD** Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei **MD PWA Co-Champion:** **Mr. Kazuyoshi Takatori** Special Appointed Staff, OAIC, PMDA, Japan
11:00 – 11:30	Coffee Break	
11:30 – 12:15	Certificate Award Ceremony	**TBD** TFDA, MOHW, Chinese Taipei
12:15 – 12:30	Closing Remarks	**TBD** TFDA, MOHW, Chinese Taipei
12:30 – 12:40	Group Photo	
12:40 – 13:30	Lunch	
13:30 – 16:00	Manufacturing Site Visit	Regulators Only