Full Agenda of 2023 APEC Medical Devices CoE Workshop (Day 1 – Aug. 29 Tue.)

2023.08.11 V3

Time	Topic	Speaker
09:00-09:30	Registration	
09:30-09:40	Opening Remarks	**TFDA:** **Dr. Shou-Mei Wu** Director General, Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare (MOHW), Chinese Taipei **APEC RHSC MD PWA Co-Champion:** **Dr. Kinue Nishioka** Division Director, Division of Asia II, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
09:40-09:50	Group Photo	
Introduction of Workshop		
09:50-10:00	Roadmap and Core Curriculum of Medical Device PWA	**APEC RHSC MD PWA Co-Champion:** **Ms. Miwa Kanematsu** Principal Coordinator, Division of Asia II, Office of International Programs, PMDA, Japan
10:00-10:10	Introduction of TFDA CoE Training Program	**Mr. Hsiu-Te Lin** Section Chief, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei
Current Harmonization Status of Pre-Market Regulation in Each Economy		
10:10-10:40	• Introduction of Medical Device Registration in Each Economy	• 10 mins per economy
10:40-10:55	Coffee Break	
10:55-11:55	• Introduction of Medical Device Registration in Each Economy	• 10 mins per economy
11:55-12:10	Panel Discussion (Q&A)	
12:10-13:30	Lunch	
13:30-14:20	● Icebreaker Activities	**Moderator (TBD)**
14:20-14:40	● **Medical Device & In Vitro Diagnostic Device Definition & Classification Session** • Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device’ (GHTF/SG1/N071:2012)	**Dr. Sheng-Hui Liao** Senior Engineer, Office of Medical Device Evaluation, Center for Measurement Standards, Industrial Technology Research Institute (ITRI), Chinese Taipei

	• Principles of Medical Device Classification (GHTF/SG1/N77:2012) • Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (IMDRF/IVD WG/N64FINAL:2021)	
14:40-15:00	Coffee Break	
15:00-16:20	• Definition and Classification Practice • Presentation (Q&A)	**Dr. Sheng-Hui Liao** Senior Engineer, Office of Medical Device Evaluation, Center for Measurement Standards, ITRI, Chinese Taipei
18:30-20:20	Welcome Reception	

***Morning sessions will be open to public**

Full Agenda of 2023 APEC Medical Devices CoE Workshop (Day 2– Aug. 30 Wed.)

Time	Topic	Speaker/Facilitator
Medical Device Session		
08:30-09:00	Registration	
09:00-09:30	● **Medical Device Session** • Principles of Conformity Assessment for Medical Devices (GHTF/SG1/N78:2012) • Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices(IMDRF/GRRP WG/N47FINAL:2018) • Case Study 1: Infusion set	**Dr. Hsi-Yi Yeh** Senior Reviewer, Division of Medical Devices, Center for Drug Evaluation (CDE), Chinese Taipei
09:30-10:40	• Group Discussion	
10:40-11:00	Coffee Break	
11:00-12:00	• Group Presentation (Q&A)	**Dr. Hsi-Yi Yeh** Senior Reviewer, Division of Medical Devices, CDE, Chinese Taipei
12:00-13:30	Lunch	
In Vitro Diagnostic Device Session		
13:30-14:00	● **In Vitro Diagnostic Device Session** • Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices (GHTF/SG1/N046:2008) • Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2018) • Case Study 2: Influenza Virus Antigen Detection Test System	**Mr. Shang-Ching Lin** Associate Technical Specialist, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei
14:00-15:10	• Group Discussion	
15:10-15:30	Coffee Break	
15:30-16:30	• Group Presentation (Q&A)	**Mr. Shang-Ching Lin** Associate Technical Specialist, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei
16:30	Adjourn	

Full Agenda of 2023 APEC Medical Devices CoE Workshop (Day 3 – Aug. 31 Thr.)

Time	Topic	Speaker/Facilitator
Optimizing Standards for Regulatory Use Session		
08:30-09:30	Registration	
09:30-10:10	• Optimizing Standards for Regulatory Use (IMDRF/Standards WG/N51FINAL:2018) • Q&A	**Mr. Naoki Morooka** Senior Manager, Quality Assurance Dept., Medical Systems Division, Shimadzu Corporation, Japan
10:10-10:25	Group Photo	
10:25-10:40	Coffee Break	
Expectations from the Workshop and Next Steps		
10:40-11:00	Expectations from the Workshop and Next Steps • TFDA (3 mins) • APEC RHSC MD PWA Co-Champion (3 mins) • APEC RHSC MD PWA Sub-Champions (3 mins each) • Members of planning committee or Participants (2 mins each)	**TFDA** **Dr. Hwei-Fang Cheng** Deputy Director General, TFDA, MOHW, Chinese Taipei **MD PWA Co-Champion** **Dr. Kinue Nishioka** Division Director, Division of Asia II, Office of International Programs, PMDA, Japan **MD PWA Sub-Champion**
11:00-11:15	Certificate Award Ceremony	**Dr. Hwei-Fang Cheng** Deputy Director General, TFDA, MOHW, Chinese Taipei
11:15-11:20	Closing Remarks	**Dr. Hwei-Fang Cheng** Deputy Director General, TFDA, MOHW, Chinese Taipei
11:20-13:30	Lunch	
13:30-17:00	• Manufacturing Site Visit	Regulators only