Short Agenda of 2024 APEC Medical Devices CoE Workshop

<table>
<tr><th>Time</th><th>Day 1: 8/28 (Wed.)</th><th>Day 2: 8/29 (Thu.)</th><th>Day 3: 8/30 (Fri.)</th></tr>
<tr><td rowspan="3">Morning
(3-hr)</td><td colspan="3">Registration</td></tr>
<tr><td>Introduction of Workshop:
(1) APEC MD PWA
(2) CoE</td><td>Lecture #3: Review of
(1) Essential Principles of Medical Device Safety & Performance and
(2) Principles of Conformity Assessment</td><td>Lecture #4:
Clinical Evaluation</td></tr>
<tr><td>Lecture #1:
Current Harmonization Status of Pre-Market Regulation in Each Economy
Q&A</td><td>Group Practice #2:
IVD Case Study (1 case)
(1) Case Study Intro
(2) Group Discussion
(3) Group Presentation</td><td>Expectations from the Workshop and Next Steps

Certificate Award Ceremony</td></tr>
<tr><td>Noon</td><td colspan="3">Lunch</td></tr>
<tr><td rowspan="3">Afternoon
(3-hr)</td><td>Icebreaker Activities</td><td rowspan="3">Group Practice #3:
MD Case Study (2 cases)
(1) Case Study Intro
(2) Group Discussion
(3) Group Presentation</td><td rowspan="3">Manufacturing Site Visit
(optional – only for regulators)</td></tr>
<tr><td>Lecture #2:
Medical Device and IVD Definition and Classification</td></tr>
<tr><td>Group Practice #1:
Definition and Classification Practice</td></tr>
<tr><td>Evening</td><td>Welcome Reception</td><td colspan="2"></td></tr>
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Full Agenda of 2024 APEC Medical Devices CoE Workshop

Day 1 – Aug. 28, 2024 (Wed.)

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 **MD PWA Co-Champion:** **Ms. Miwa Kanematsu** Principal Coordinator, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
09:40 – 09:50	Group Photo	
09:50 – 10:00	Roadmap and Core Curriculum of MD PWA	**MD PWA Co-Champion:** **Ms. Kanae Ohara** Coordinator, Office of International Programs, PMDA, Japan
10:00 – 10:10	Introduction of TFDA CoE Training Program	**Mr. Ching-Wei Chang** Section Chief, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei
10:10 – 12:00	Lecture #1: Current Harmonization Status of Pre-Market Regulation in Each Economy Presentation (30 min) Coffee Break (20 min) Presentation (45 min) Q&A (15 min)	15 min per economy
12:00 – 13:20	Lunch	
13:20 – 14:20	Icebreaker Activities	Moderator

14:20 – 14:50	Lecture #2: Medical Device and IVD 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)	**Dr. Sheng-Hui Liao** Senior Engineer, Office of Medical Device Evaluation, Center for Measurement Standards, Industrial Technology Research Institute (ITRI), Chinese Taipei
14:50 – 15:00	Coffee Break	
15:00 – 16:00	Group Practice #1: Definition and Classification Practice (40 min) Group Presentation (15 min) Q&A (5 min)	**Dr. Sheng-Hui Liao** Senior Engineer, Office of Medical Device Evaluation, Center for Measurement Standards, Industrial Technology Research Institute (ITRI), Chinese Taipei
17:30 – 19:30	Welcome Reception	

*The morning session will be open to the public.

Day 2 – Aug. 29, 2024 (Thu.)

Time	Topic	Speaker
09:00 – 09:30	Registration	
09:30 – 10:00	Lecture #3: Review of (1) Essential Principles of Medical Device Safety & Performance and (2) Principles of Conformity Assessment • Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2018) • Principles of Conformity Assessment for Medical Devices (GHTF/SG1/N78:2012) • Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices (GHTF/SG1/N046:2008)	**Mr. Shang-Ching Lin** Associate Researcher, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei
10:00 – 12:00	Group Practice #2: IVD Case Study Case Study Introduction (10 min) (1 case) Group Discussion (50 min) Coffee Break (15 min) Group Presentation (30 min) Q&A (15 min)	**Mr. Shang-Ching Lin** Associate Researcher, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei
12:00 – 13:30	Lunch	
13:30 – 16:00	Group Practice #3: Medical Device Case Study Case Study Introduction (15 min) (2 cases) Group Discussion (60 min) Coffee Break (15 min) Group Presentation (45 min) Q&A (15 min)	**Ms. Yu-Hui Huang** Specialist, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei **Mr. You-Lin Lee** Associate Reviewer, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei

Day 3 – Aug. 30, 2024 (Fri.)

Time	Topic	Speaker
09:00 – 09:30	Registration	
09:30 – 10:10	Lecture #4: Clinical Evaluation • Clinical Investigation (IMDRF/MDCE WG/N57FINAL: 2019) • Clinical Evaluation (IMDRF/MDCE WG/N56FINAL:2019) • Clinical Evidence (IMDRF/MDCE WG/N55FINAL:2019) Q&A	**Dr. Daisuke Fujisawa** Principal Reviewer Office of Medical Device II, PMDA, Japan
10:10 – 10:20	Group Photo	
10:20 – 10:40	Coffee Break	
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 the planning committee or participants (2 mins each)	**TFDA:** **Ms. Pei-Weng Tu** Director, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei **MD PWA Co-Champion:** **Ms. Miwa Kanematsu** Principal Coordinator, Office of International Programs, PMDA, Japan
11:00 – 11:20	Certificate Award Ceremony	**Dr. Der-Yuan Wang** Deputy Director-General, TFDA, MOHW, Chinese Taipei
11:20 – 11:30	Closing Remarks	**Dr. Der-Yuan Wang** Deputy Director-General, TFDA, MOHW, Chinese Taipei
11:30 – 13:00	Lunch	
13:00 – 17:00	Manufacturing Site Visit	Regulators Only