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台灣醫療暨生技器材工業同業公會
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主旨：敬邀參加本署於今(113)年8月28日至30日舉辦之「2024 APEC醫療器材法規科學卓越中心研討會」，請查照轉知。

說明：

一、為促進國際法規協和，增進醫療器材標準之採用，本署以國際醫療器材主管機關論壇(IMDRF)之符合性評鑑文件為主軸，規劃於113年8月28日至30日假台北漢來大飯店辦理旨揭研討會，邀請國內外專業人士擔任課程講師，分享醫療器材分類分級、上市前審查採用國際標準之經驗。此外，將安排以案例研究之方式針對醫療器材分類分級、安全性與功效性之基本規範及其應用進行討論。

二、檢附該研討會之廣宣及議程資料，為利強化我國產官學研各界與各國學員之交流互動，敬邀派員參與。

三、本會議係以英文進行授課及分組討論，報名者應具備適當英文能力，如報名人數超出預期，本署保留篩選之權力。

四、本研討會委請財團法人工業技術研究院協助執行，報名網址：https://tfdamdcoe.itri.org.tw/Registration.html。聯絡人及電話：工業技術研究院量測技術發展中心許爾婷博士(03)574-3924。

正本：台灣醫療暨生技器材工業同業公會、中華民國醫療器材商業同業公會全國聯合會、台北市美國商會醫療器材委員會、歐洲在台商務協會醫療器材委員會、台北市日僑工商醫藥品部會醫療器材委員會、中華民國生物醫學工程學會

副本：

署長吳秀梅

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 Technical Specialist, 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 Technical Specialist, 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

Short Agenda of 2024 APEC Medical Devices CoE Workshop

Time	Day 1: 8/28 (Wed.)	Day 2: 8/29 (Thu.)	Day 3: 8/30 (Fri.)
Morning (3-hr)	Registration		
	Introduction of Workshop: (1) APEC MD PWA (2) CoE	Lecture #3: Review of (1) Essential Principles of Medical Device Safety & Performance and (2) Principles of Conformity Assessment	Lecture #4: Clinical Evaluation
	Lecture #1: Current Harmonization Status of Pre-Market Regulation in Each Economy Q&A	Group Practice #2: IVD Case Study (1 case) (1) Case Study Intro (2) Group Discussion (3) Group Presentation	Expectations from the Workshop and Next Steps Certificate Award Ceremony
Noon	Lunch		
Afternoon (3-hr)	Icebreaker Activities	Group Practice #3: MD Case Study (2 cases) (1) Case Study Intro (2) Group Discussion (3) Group Presentation	Manufacturing Site Visit (optional – only for regulators)
	Lecture #2: Medical Device and IVD Definition and Classification		
	Group Practice #1: Definition and Classification Practice		
Evening	Welcome Reception		

衛生福利部
食品藥物管理署
Taiwan Food and Drug Administration

Asia-Pacific Economic Cooperation

2024 APEC 醫療器材法規科學卓越中心研討會
Medical Devices Regulatory Science Center of Excellence Workshop

Date | August 28 – 30, 2024
Venue | Grand Hilai Taipei

- Address: No. 168, Jingmao 1st Road, Nangang District, Taipei City

Target Audience

- Regulators from APEC member economies and non-member economies
- Industry managers (or equivalent position) who have experience in product application submission
- Academic researchers or industry managers who have experience in product development

Program Overview

- Online and self-paced learning to develop knowledge base in advance of training
- 3-day training designed with lectures, group discussions, and case studies
- Manufacturing site visit for regulators

Travel & Accommodation

- Limited funding available for regulators from travel-eligible economies

Contact Information

- ITRI Secretariat at TFDAMDCOE@gmail.com

CoE Hosting Institution

- Taiwan Food and Drug Administration

Co-Organizer

Asia-Pacific Economic Cooperation

Program Committee

Pmda JIRA AdvaMed TMBIA 台灣醫療器材工業同業公會 TAMTA 財團法人醫藥品查驗中心 Center for Drug Evaluation, Taiwan 工業技術研究院 Industrial Technology Research Institute