正本

檔　　號：
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台灣醫療暨生技器材工業同業公會
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附件：廣宣及議程資料各1份。

主旨：敬邀參與本署於今(110)年8月28日至9月11日舉辦之「APEC醫療器材法規科學卓越中心線上研討會」，請查照轉知。

說明：

一、為促進亞太經濟合作(APEC)區域法規協和，增進醫療器材標準之採用，本署積極參與APEC生命科學創新論壇(LSIF)法規協和指導委員會(RHSC)所倡議推動之醫療器材工作領域事務，期透過此工作參與，可更進一步探討國際間之典範實務，提升各國主管機關之互信、合作及法規調和，嘉惠亞太地區之人民健康及福祉。

二、本署於108年向APEC LSIF-RHSC爭取辦理「APEC醫療器材標準法規科學卓越中心(Center of Excellence, CoE)」之先期計畫，獲准執行CoE試辦訓練，並於109年6月獲認可成為正式卓越中心，持續辦理相關會議，今年因受疫情影響，旨揭會議將採線上課程方式舉辦，以醫療器材標準為主題，邀請國內外專業人士擔任課程講師，分享上市前審查採用國際標準之經驗。

三、檢附前揭研討會之廣宣及議程資料，為利強化我國產官學研各界與APEC會員國間之交流互動，敬邀派員參與。

四、會議係以英文進行授課，報名者應具備適當英文能力，如報名人數超出預期，本署保留篩選之權利。

五、本案委請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：量測技術發展中心郭乃瑋博士 (03)574-3807。

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：

1101608008

署長吳秀梅

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Regulatory Harmonization Steering Committee

APEC Life Sciences Innovation Forum

2021 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 to September 11, 2021

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

- Five online courses about the training program, principles of conformity assessment and classification, essential principles of medical devices and in vitro diagnostic devices, and clinical evaluation will be open for access beginning on August 28, 2021.

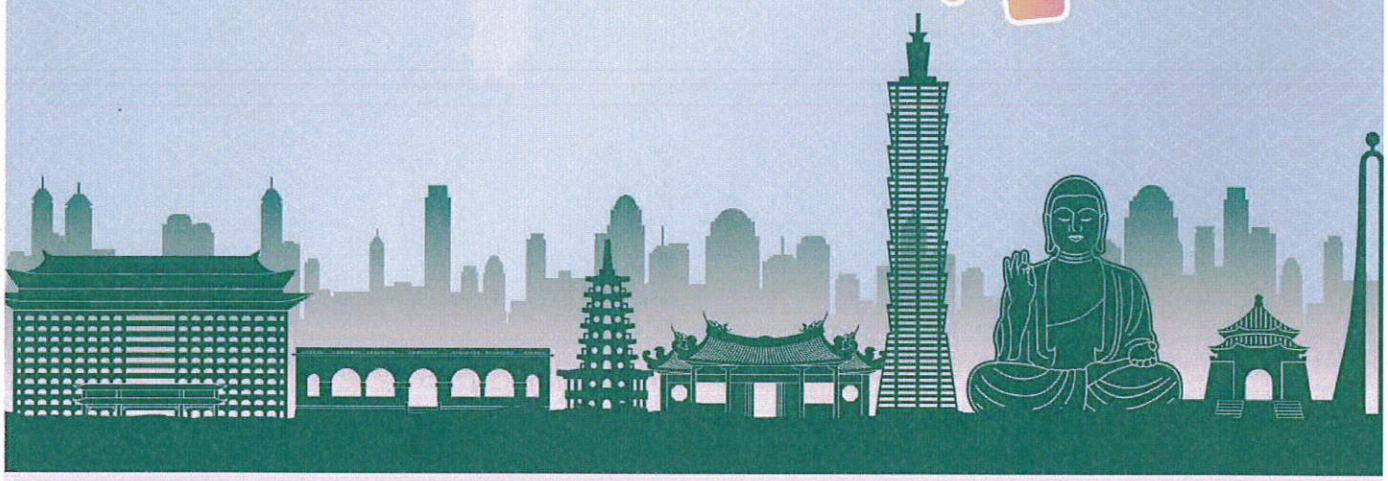
For more information, please visit https://tfdamdcoe.itri.org.tw.

Contact Information

ITRI Secretariat at TFDAMDCOE@gmail.com

CoE Hosting Institution

Taiwan Food and Drug Administration



Co-Organizer

Regulatory Harmonization Steering Committee

APEC Life Sciences Innovation Forum

Program Committee

Pmda JIRA AdvaMed TMDIA 台灣醫療器材工業同業公會 TAMTA 工業技術研究院 Industrial Technology Research Institute

Agenda of 2021 APEC Medical Devices CoE Workshop

Version of June 9, 2021

August 28 to September 11
Online Course 1 • Opening Remarks • Roadmap and Core Curriculum of Medical Device PWA • CoE Training Program
Online Course 2 • Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device' (GHTF/SG1/N071:2012) • Basic Scheme of Conformity Assessment Procedure and Classification for Medical Devices (GHTF/SG1/N77&N78) • Summary of Essential Principles for Medical Devices (IMDRF/GRRP WG/N47) • Introduction of Case Study: MD Session
Online Course 3 • Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device' (GHTF/SG1/N071:2012) • Basic Scheme of Conformity Assessment Procedure and Classification for In Vitro Diagnostic (IVD) Medical Devices (GHTF/SG1/N045&N046) • Summary of Essential Principles for In Vitro Diagnostic (IVD) Medical Devices (IMDRF/GRRP WG/N47) • Introduction of Case Study: IVD Session
Online Course 4 • Introduction of Clinical Evaluation (IMDRF/MDCE WG/N55&N56&N57 FINAL:2019)
Online Course 5 Current harmonization status of pre-market regulation in APEC member economies

Course	Time length	Topic	Speaker
Introduction Session (Online Course)			
1	N/A	Introductory Remarks	Letter from MOH Minister
	5 minutes	Opening Remarks	TFDA Director General
	10 minutes	Roadmap and Core Curriculum of Medical Device PWA	APEC LSIF RHSC MD PWA Co-Champion: Dr. Maeda Yuta Coordinator, Office of International Cooperation, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
	10 minutes	CoE Training Program	Ms. Cheng-Ning Wu, Section Chief, Division of Medical Devices and Cosmetics, TFDA, MOHW
Medical Device Session (Online Course)			
2	40 minutes	• Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device' (GHTF/SG1/N071:2012) • Basic Scheme of Conformity Assessment Procedure and Classification for Medical Devices (GHTF/SG1/N77&N78) • Summary of Essential Principles for Medical Devices (IMDRF/GRRP WG/N47) • Introduction of Case Study: MD Session Product: Soft Contact Lens	Dr. Jai-Yen Chen Senior Reviewer, Division of Medical Devices, Center for Drug Evaluation (CDE)
In Vitro Diagnostic Medical Device Session (Online Course)			

3	40 minutes	• Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device' (GHTF/SG1/N071:2012) • Basic Scheme of Conformity Assessment Procedure and Classification for Medical Devices (GHTF/SG1/N77&N78) • Summary of Essential Principles for Medical Devices (IMDRF/GRRP WG/N47) • Introduction of Case Study: IVD Session Product: Pregnancy Rapid Test	Dr. Te-Hsuen Chen Senior Reviewer, Division of Medical Devices and Cosmetics, TFDA, MOHW
Clinical Evaluation Session (Online Course)			
4	40 minutes	• Clinical Investigation (IMDRF/MDCE WG/N57FINAL:2019) • Clinical Evaluation (IMDRF/MDCE WG/N56FINAL:2019) • Clinical Evidence (IMDRF/MDCE WG/N55FINAL:2019)	Dr. Mami Ho Senior Scientist for Clinical Medicine, Medical Device Unit, Office of Medical Devices I, PMDA, Japan
Current harmonization status of pre-market regulation in APEC member economies (Online Course)			
5	10 minutes/each	The sharing of current harmonization status of pre-market regulation in APEC member economies will be pre-recorded. Regulators who participate in the workshop will be invited to pre-record their presentation.	Representatives from regulatory authorities of each participating member economy
Digital Health (Optional Online Course)			
6	40 minutes	Cybersecurity Case Sharing of Korea	Ms. Eun-Hee Cho RA Director, Abbott Medical Devices, Korea