正本

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受文者：台灣醫療暨生技器材工業同業公會

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主旨：敬邀參與本署於今(108)年10月22日至24日舉辦之「APEC醫療器材標準法規科學卓越訓練中心先期研討會」，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、今年度本署向APEC LSIF-RHSC爭取辦理「APEC醫療器材標準法規科學訓練卓越中心(Center of Excellence, CoE)」之先期計畫，並獲准執行CoE試辦訓練，現規劃於10月22日至24日假臺大醫院國際會議中心舉辦CoE先期研討會，以醫療器材標準為主題，邀請國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；另囿於名額限制，請依下列方式辦理：

(一)各受文單位以1人報名為原則，報名網址：http://tfdamdcoe.itri.org.tw/Registration.html。

(二)報名者必須完整參與10月22日至24日之所有課程，如任職於業界，建議為擔任法規事務相關工作之主管；如任職於學界，建議為現任教師。

(三)會議係以英文進行授課及討論，報名者應具備適當英文能力，並能全程以英文互動。

(四)如報名人數超出預期，本署保留篩選之權利。

四、本案委請工業技術研究院協助執行，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、台灣大學醫學工程研究所、國立陽明大學醫學工程研究所、國立成功大學生物醫學工程學系、中原大學生物醫學工程學系

副本：

署長吳秀梅

Regulatory Harmonization Steering Committee

APEC Life Sciences Innovation Forum

FDA

2019 APEC 醫療器材先期CoE研討會
Medical Devices Regulatory Science Center of Excellence Pilot Workshop

Date | Oct. 22-24, 2019
Venue | NTUH International Convention Center

- Address: No. 2, Xuzhou Road, Zhongzheng 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 been involved in international or national standard development activities
- Academic researchers or industry managers who have been involved in product development for products that require use of standards

Program Overview

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

Travel & Accommodation

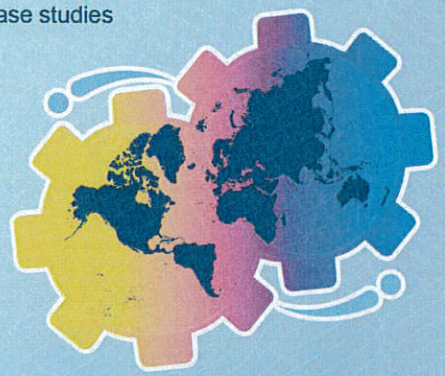
- Limited funding available for regulators from travel-eligible economies

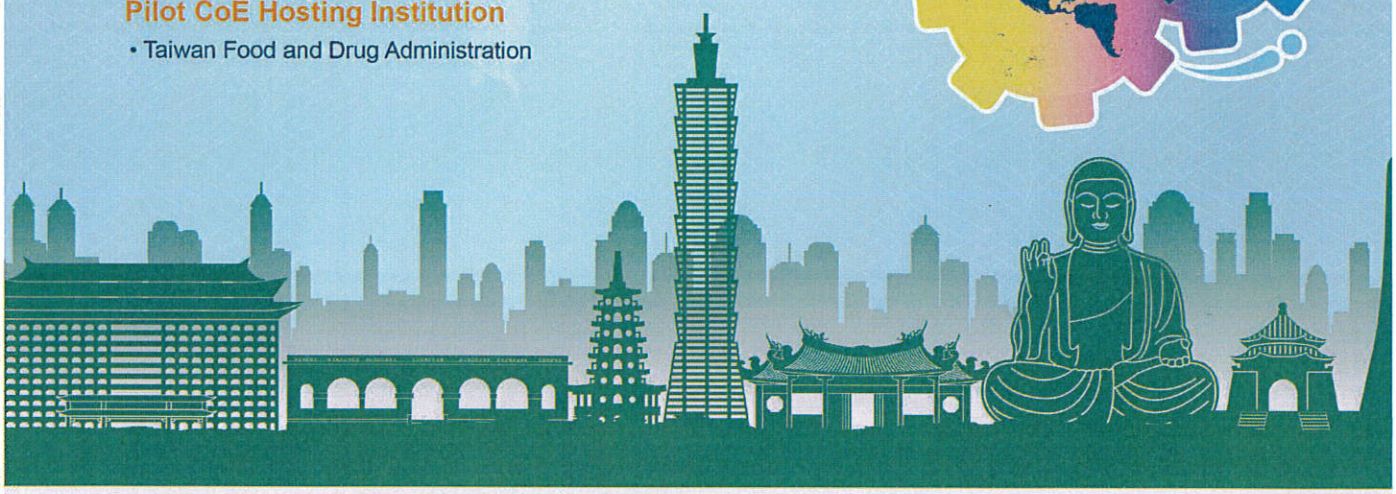
Contact Information

- ITRI Secretariat at TFDAMDCOE@gmail.com

Pilot CoE Hosting Institution

- Taiwan Food and Drug Administration





Co-Organizer

Regulatory Harmonization Steering Committee

APEC Life Sciences Innovation Forum

Pilot Planning Committee

pmda JIRA AdvaMed TMDIA 台灣醫療暨生技醫材工商同業公會 TAMTA 工業技術研究院 Industrial Technology Research Institute

The first day morning will be open to the public.

Time	Day 1	Day 2	Day 3
Morning	Registration	Registration	Registration

	Introduction of Workshop
	• Keynote speech
	  ◦ Role of standards in conformity assessment (GHTF/SG1/N44)
	  ◦ Role of Standards in the Assessment of Medical Devices (AHWP/WG2-WG8/F002:2014)
	• Introduction on Roadmap and Core-Curriculum of Medical Device PWA
	• Introduction of CoE pilot workshop
		Standards Recognition Process
		• Breakout group discussion
		• Group presentations
			• Case study: How to use the standards in conformity assessment
			• Group presentations
			• Panel discussion (Q&A)

	Coffee Break	Coffee Break	Coffee Break

	Special Section
	• Introduction of medical device registration in each economy
	• Panel discussion (Q&A)
		<u>Topic 2: Identify the Challenges in Standards for Regulatory Purposes</u>
		• Keynote speech
		  ◦ List of international standards recognized by IMDRF management committee members
		  ◦ Improving the quality of international standards for regulatory use
		  ◦ Optimizing standard for regulatory use (IMDRF/Standards WG/N51 FINAL:2018)
			Expectations from the Workshop and Next Steps
			• Stakeholder presentations
			• Certificate award ceremony

Noon	Lunch	Lunch	Lunch
Afternoon	**<u>Topic 1: Understand the Importance of the Use of Standards in the Assessment of Medical Devices</u>** • Basic scheme of conformity assessment procedure and classification (GHTF/SG1/N77&N78) • Summary of essential principles (IMDRF/GRRP WG/N47)	Common Challenges with Registration of Medical Devices • Breakout group discussion • Group presentations	Manufacturing Site Visit
	Coffee Break	Coffee Break	
	• Conformity assessment based on the standards • Standards recognition process in Japan • ISO/IEC standards recognition process	**<u>Topic 3: Optimizing Standards for Regulatory Use</u>** • Keynote speech: How Standards are improved by following IMDRF guidance • Case Study: 3rd Party Review based on EP	