正本

檔　　號：
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受文者：台灣醫療暨生技器材工業同業公會

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：敬邀參加本署於今(111)年8月26日至9月11日舉辦之「TFDA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5堂數位課程及4場視訊會議，並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。此外，在視訊會議中，將安排以案例研究之方式針對醫療器材安全性與功效性之基本規範及其應用進行討論。

二、檢附旨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：

署長吳秀梅

2022 TFDA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 26 to September 11, 2022

Target Audiences

- Regulators from competent authorities
- Industrial managers (or equivalent position) who have experience in product application submission
- Academic researchers or industrial managers who have experience in product development

Program Overview

- Five online courses about principles of conformity assessment and classification, essential principles of safety and performance of medical devices and in vitro diagnostic devices, optimizing standards for regulatory use, trends & challenges of AI technology in digital health, and manufacturing video on continuous positive airway pressure (CPAP) ventilators will be open for access beginning on August 26, 2022.
- Four videoconferences for medical device regulations, case studies and presentation, and Q&A will be held on September 2, September 6, and September 8, 2022.

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

Certificate Requirements

Each trainee is expected to complete 5 online courses and attend 3 videoconferences (including 1 videoconference on case study). The case study to attend will be assigned by CoE hosting institution. Certificates of participation will be mailed to qualified trainees that have met the following minimum requirements:

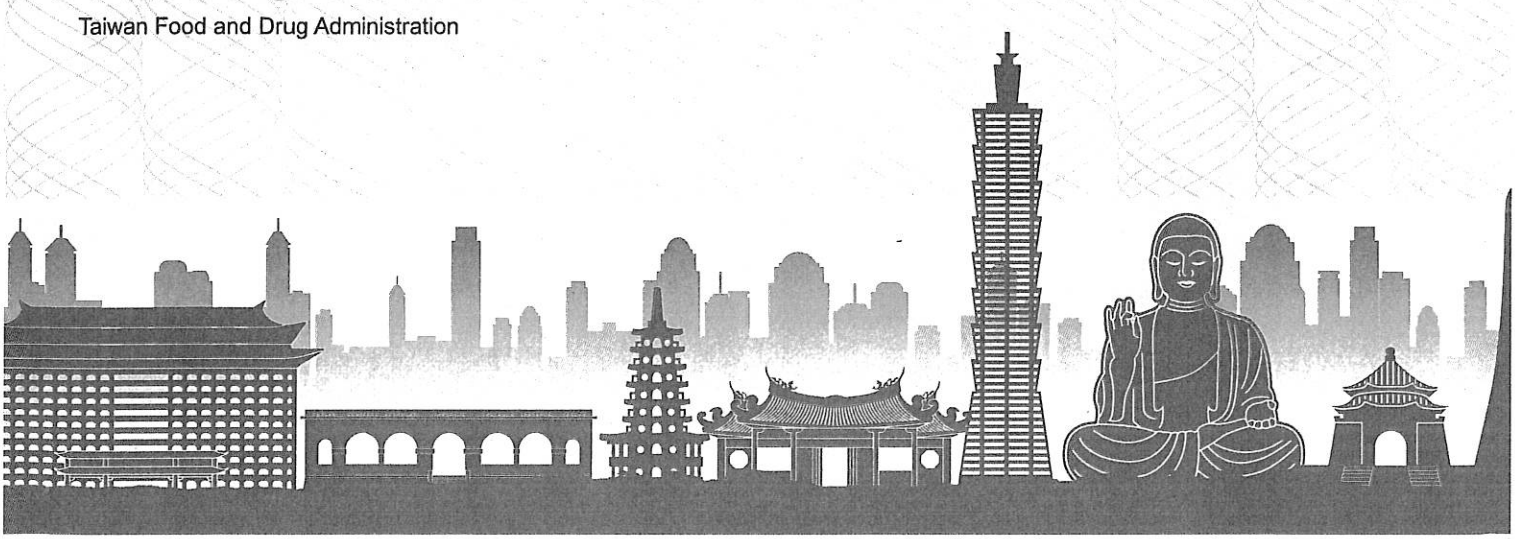
- Completion of 90% of the total hours of all 5 online courses
- Attendance of at least 2 videoconferences (including 1 on case study)

Contact Information

ITRI Secretariat at **TFDAMDCOE@gmail.com**

CoE Hosting Institution

Taiwan Food and Drug Administration



Full Agenda of 2022 TFDA Medical Devices Regulatory Science Center of Excellence Workshop

1st Part (August 26 to September 11)

Item	Time length	Topic	Speaker
Online Learning Session			
Medical Device Session			
1	30 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: Fingertip Pulse Oximeter	Dr. Shang-Lung Dong Reviewer, Division of Medical Devices and Cosmetics, TFDA, MOHW
In Vitro Diagnostic Medical Device Session			
2	30 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 In Vitro Diagnostic Medical Devices (GHTF/SG1/N45&N46) • Summary of Essential Principles for Medical Devices (IMDRF/GRRP WG/N47) • Introduction of Case Study: Dengue Virus Antigen Assay	Dr. Shang-Ching Lin Assistant Technical Specialist, Division of Medical Devices and Cosmetics, TFDA, MOHW
Optimizing Standards Session			