2021 台灣醫療器材單一識別系統國際論壇
2021 Taiwan FDA Medical Device UDI International Virtual Workshop
November 2nd, 2021

Workshop Agenda

November 2nd, 2021 (Tue.) Taipei Time

Time	Topic	Speaker
19:00 – 19:10	Opening remarks 長官致詞	Dr. Shou-Mei Wu Director General Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare (MOHW)
19:10 – 19:25	Taiwan UDI regulations and recent updates 台灣 UDI 法規更新動態	Mr. Hsiu-Te Lin Section Chief Division of Medical Devices and Cosmetics, TFDA, MOHW
19:25 – 19:40	US UDI regulations and recent updates 美國 UDI 法規更新動態	Ms. Erin Cutts International Policy Analyst Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration (FDA)
19:40 – 19:55	EU UDI regulations and recent updates 歐盟 UDI 法規更新動態	Mr. Jay Crowley Vice President Medical Device Solutions and Services, USDM Life Sciences
19:55 – 20:10	Australia UDI regulations and recent updates 澳洲 UDI 法規更新動態	Ms. Michelle van Wijk Advisor Post Market Reforms and Reviews, Medical Devices Surveillance Branch, Therapeutic Goods Administration (TGA)
20:10 – 20:30	Panel Discussion綜合座談： UDI implementation and harmonization UDI法規推動與國際法規調和	All speakers
20:30 – 20:40	Closing remarks 閉幕致詞	Dr. Shou-Mei Wu Director General Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare (MOHW)

Panel Discussion Topics 綜合座談

Topic	Description	Panel
UDI implementation and harmonization 綜合座談：UDI 法規推動與國際法規調和	As more and more countries develop UDI regulations, the importance of global harmonization and standardization of UDI regulations cannot be overly addressed. This panel will discuss the visions and activities to promote globally harmonized UDI regulations and accelerate UDI adoption across the healthcare field. 隨著各國陸續開始訂定與實施 UDI 法規，如何進行 UDI 法規調和是相當重要的議題。本座談會邀請與會專家分享如何確保各國 UDI 法規調和與推動 UDI 臨床應用。 1. In practice, what are the most difficult challenges in promoting UDI? 實務上 UDI 法規推動最大的困難? 2. What is the most urgent aspect of UDI for international regulatory harmonization? 各國 UDI 法規哪一個面向最迫切須要進行國際調和?	**Moderator** Grace Huang, GIS Taiwan **Panelists** • **Ms. Cheng-Ning Wu,** Senior Technical Specialist Division of Medical Devices and Cosmetics, TFDA, MOHW • **Ms. Erin Cutts** International Policy Analyst CDRH, U.S. FDA • **Mr. Jay Crowley** Vice President Medical Device Solutions and Services, USDM Life Sciences • **Ms. Michelle van Wijk** Advisor Post Market Reforms and Reviews, Medical Devices Surveillance Branch, TGA

Audience

- Regulatory authority employees
- Industry managers (or equivalent position) who have experience in medical device regulatory affairs
- Academic researchers or industry managers who have experience in medical device development

Language

- English

Venue

- Time：2021/11/2 (Tue.) 07:00 – 08:40 (ET) or 19:00-20:40 (Taipei Time, UTC/GMT+8)
- The workshop will be held virtually by online videoconference through Cisco Webex system.

Enrollment

- Sign up for the meeting
  - Virtual workshop registration：https://reurl.cc/ZjZD5M

Hosting Institution

Taiwan Food and Drug Administration, MOHW

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