15 October 2020

8th Joint Conference of Taiwan and Japan on Medical Products Regulation

Date: October 15, 2020

Location: Virtual　我方會場：國家生技園區 C 棟 201 國際會議廳

*Simultaneous interpretation (Chinese - Japanese) provided

Registration: 11:30-11:50　Photo session: 11:50-12:00

Joint Session *MC:FUKUDA Eriko, International Coordination Officer, PMDA*		
Opening Remarks ***5min each**		
12:00-12:10	1. HANAKI Izuru, Senior Executive Director, Japan-Taiwan Exchange Association 2. Ching-Hung Lin, Deputy Secretary General, Taiwan-Japan Relations Association	
Keynote speeches		
12:10-12:25	Regulatory updates in Japan	UZU Shinobu, Senior Executive Director, Pharmaceuticals and Medical Devices Agency (PMDA)
12:25-12:40	Regulatory updates in Taiwan	Hwei-Fang Cheng, Deputy Director-General, Taiwan Food and Drug Administration (TFDA)
12:40-12:50	Q&A	

Pharmaceuticals *MC:FUKUDA Eriko, International Coordination Officer, PMDA*		
Regulatory challenge against COVID-19 Moderator: Chien-Liang Lin, Director, Division of Medicinal Products, TFDA		
12:50-13:05	Regulatory Challenge against COVID-19	MATSUKURA Yuji, Deputy Director, Office of International Regulatory Affairs, MHLW
13:05-13:20	Measures for accelerating vaccine development and challenges of clinical trials	Mei-Chen Huang, Section Chief, Division of Medicinal Products, TFDA
13:20-13:35	Q&A	
Health Insurance Moderator: NAGAOKA Akihiro, Chairman, Asia Committee International Affairs, Japan Pharmaceutical Manufacturers Association (JPMA)		
13:35-13:50	Drug Pricing System in Japan	MIYASHITA Masaya, Section Chief of New Drug Pricing Section in Economic Affairs Division

		Health Policy Bureau, MHLW
13:50-14:05	Updates on Drug Reimbursement Model of Taiwan's NHI System	Hsueh-Yung Tai, Director, Division of Medical Review and Pharmaceutical Benefits, the National Health Insurance Administration (NHIA)
14:05-14:20	Q&A	

Medical Devices *MC:FUKUDA Eriko, International Coordination Officer, PMDA*		
Recent Regulatory Challenge in Medical Devices Moderator: Pei-Weng Tu, Director, Division of Medical Devices and Cosmetics, TFDA		
14:20-14:35	The regulatory perspective of reviewing COVID-19 diagnostic test kits	YABANA Naoyuki, Director, Office of In Vitro Diagnostics, PMDA
14:35-14:50	The Principle of Reviewing Medical Device Cybersecurity	Chun-Jen Chien, Technical Specialist, Division of Medical Devices and Cosmetics, TFDA
14:50-15:05	Q&A	
QMS -Utilization of MOC- Moderator: KUSAKABE Tetsuya, International Coordination Officer, PMDA		
15:05-15:20	Current Situation of Utilizing MOC	FUJISAWA Hiroshi, Inspector, Office of Manufacturing Quality and Vigilance for Medical Devices, PMDA
15:20-15:35	QSD Review and Utilization of MOC	Szu-Yu Lee, Section Chief, Division of Quality Compliance and Management, TFDA
15:35-15:50	Q&A	

Joint Session *MC:FUKUDA Eriko, International Coordination Officer, PMDA*	
Closing Remarks ***5min each**	
15:50-16:00	1. UZU Shinobu, Senior Executive Director, PMDA 2. Hwei-Fang Cheng, Deputy Director-General, TFDA