

10th Joint Conference of Taiwan and Japan on Medical Products Regulation

Date: Thursday, 20 October, 2022

Location: Hybrid (On-site & Virtual)

On-site: Nihonbashi Life Science Building, 2-3-11, Nihonbashi-honcho, Chuo-ku, Tokyo, Japan

Virtual: WebEx

*Simultaneous interpretation (Mandarin - Japanese) provided

MC: Dr. SATO Junko, PMDA

Joint Session		
Opening Remarks *5min each		
8:00-8:30 (TW) 9:00-9:30 (JP)	1. Japan-Taiwan Exchange Association 2. Taiwan-Japan Relations Association 3. PMDA by Mr. UZU Shinobu, Deputy Executive Director 4. TFDA by Shou-Mei Wu, Director General 5. JPMA 6. TPMA	
Photo session: Group Photo & Web Photo		
Keynote speeches		
8:30-8:50 (TW) 9:30-9:50 (JP)	Regulatory updates in Japan	Dr. NAKASHIMA Nobumasa, Associate Executive Director (International Programs), Pharmaceuticals and Medical Devices Agency (PMDA)
8:50-9:10 (TW) 9:50-10:10 (JP)	Regulatory updates in Taiwan	Taiwan Food and Drug Administration Shou-Mei Wu, Director General
9:10-9:30 (TW) 10:10-10:30 (JP)	Q&A	

10 th Anniversary session	
Moderators: Mr. YASUDA Naoyuki (MHLW) & Dr. Shyr-Yi Lin (CDE)	
9:30-11:00 (TW) 10:30-12:00 (JP)	Past, Present and Future of Medical Products Development – between Taiwan and Japan – (TBD) Speakers: JP Mr. UZU Shinobu, Deputy Executive Director, PMDA (as “current”) Dr. HAYASHI Yoshikazu, Kyoto Prefectural University of Medicine (as “past”) TBD (from JPMA)

	<p>TW Shou-Mei Wu, Director General, TFDA (as “current”)</p> <p>Dr. Ming-Hsun Liu, Counselor, Office of Science and Technology, MOHW (as “past”)</p> <p>TBD (from TPMA)</p> <p><u>Time course of the session:</u> (JST)</p> <p>10:30-10:35 Introduction Moderators</p> <ul style="list-style-type: none"> ➤ To explain the purpose of this session and introduce panelists <p>10:35-10:45 Presentation Shou-Mei Wu, Director-General, TFDA</p> <ul style="list-style-type: none"> ➤ To look back our 10 years history <p>10:45-11:40 Discussion Moderators and all panelists</p> <ul style="list-style-type: none"> ➤ Refer discussion points ➤ Moderators show discussion point one by one as a slide <p>11:40-11:50 Special comments From Taiwan-Japan Relations Association From Japan-Taiwan Exchange Association</p> <p>11:50-12:00 Wrap up and closing remarks By Moderators</p>
<p>11:00-12:00 (TW) 12:00-13:00 (JP)</p>	<p>Lunch</p>

Pharmaceuticals

Digital tools to facilitate clinical trials

Moderator: Japan (MHLW or PMDA)

<p>12:00-12:20 (TW) 13:00-13:20 (JP)</p>	<p>“Digital tools and methods to facilitate clinical trials in Japan” (TBD)</p>	<p>Dr. OGATA Akiko, Division Director, Division of Asia I, Office of International Programs, PMDA</p>
<p>12:20-12:40 (TW) 13:20-13:40 (JP)</p>	<p>Digital tools in clinical trials: current utilization situation and challenges in Taiwan (TBD)</p>	<p>Mr. Wei-Jeng Lin, Technical Specialist, Division of Medicinal Products, TFDA</p>
<p>12:40-13:00 (TW) 13:40-14:00 (JP)</p>	<p>Q&A</p>	

COVID-19 measures – Looking back from the present situation

Moderator: Dr. Jo-Feng Chi, Researcher, Division of Medicinal Products, TFDA		
13:00-13:20 (TW) 14:00-14:20 (JP)	“COVID-19 measures in Japan – looking back from the present situation” (TBD)	Ms. ISHIDA Kirie, Coordinator, Office of International Programs, PMDA
13:20-13:40 (TW) 14:20-13:40 (JP)	COVID-19 vaccine Pharmacovigilance: TFDA’s experiences (TBD)	Ms. Jhih-Yu Syu, Specialist, Division of Medicinal Products, TFDA
13:40-14:00 (TW) 14:40-15:00 (JP)	Q&A	
14:00-14:15 (TW) 15:00-15:15 (JP)	Break	
Health Insurance -> need discussion by separate route		
Moderator: Japan (JPMA)		
14:15-14:35 (TW) 15:15-15:35 (JP)	TBD	MHLW
14:35-14:55 (TW) 15:35-15:55 (JP)	TBD	NHIA
14:55-15:15 (TW) 15:55-16:15 (JP)	Q&A	
Medical Devices		
Moderator: Ying-Hua Chen, Deputy Director, Division of Medical Devices, TFDA		
15:15-15:35 (TW) 16:15-16:35 (JP)	“Utilization status and issues regarding QMS MOC” (P)	PMDA
15:35-15:55 (TW) 16:35-16:55 (JP)	“Latest status of the Medical Devices Act” (P)	Mr. Hsiu-Te Lin, Section Chief, Division of Medical Devices, TFDA
15:55-16:15 (TW) 16:55-17:15 (JP)	Q&A	
Joint Session		
16:15-16:35 (TW) 17:15-17:35 (JP)	Closing Remarks 1. JFMDA 2. TMBIA 3. PMDA 4. Shou-Mei Wu, Director General, TFDA	
Reception 18:00- (JP) (TBD)		