5th October 2023

11th Joint Conference of Taiwan and Japan on Medical Products Regulation

Date: Thursday, 5th October 2023

Location: Hybrid (On-site & Virtual)

On-site: 2F, 201 Conference room, Building C, National Biotechnology Research Park, No. 99, Ln. 130, Sec. 1, Academia Rd., Nangang Dist., Taipei City, Taiwan (R.O.C.)

Virtual: WebEx

*Simultaneous interpretation (Mandarin - Japanese) provided

Joint Session		
08:30-09:00 (TW) **09:30-10:00 (JP)**	Registration	
Opening Remarks		
09:00-09:30 (TW) **10:00-10:30 (JP)**	1. Mr. Ching-Hung Lin, Deputy Secretary General, Taiwan-Japan Relations Association 2. Mr. HATTORI Takashi, Deputy Representative, Taipei Office, Japan-Taiwan Exchange Association 3. Dr. Shou-Mei Wu, Director General, TFDA 4. Mr. YADA Shinji, Senior Executive Director, PMDA 5. Mr. Tung-Mao Su, President, TPMA 6. Dr. NAKAGAWA Sachiko, Managing Director, JPMA 7. Mr. ZC Chen, Executive Director, TMBIA 8. Mr.MATSUMOTO Kenichi, Vice-Chairman, JFMDA（On-line）	
	Photo session: Group Photo	
Keynote Speeches		
09:30-09:50 (TW) **10:30-10:50 (JP)**	Regulatory Updates in Taiwan	Dr. Shou-Mei Wu, Director General, TFDA
09:50-10:10 (TW) **10:50-11:10 (JP)**	Regulatory Updates in Japan	Dr. TANAKA Daisuke, Office Director, Office of International Programs, PMDA
10:10-10:30 (TW) **11:10-11:30 (JP)**	Q&A	

Pharmaceuticals		
RWD/RWE for Acceleration Clinical Development Moderator: Mr. Chien-Liang Lin, Director, Division of Medicinal Products, TFDA		
10:30-10:45 (TW) **11:30-11:45 (JP)**	Establishment of RWD/RWE from Biobank for Industrial Application in Taiwan: a Pilot Project	Dr. Shiu-Feng Huang, Investigator and Attending Physician, National Health Research Institutes

10:45-11:00 (TW) **11:45-12:00 (JP)**	Utilization RWD/RWE (for premarket review)	Mr. KOGA Daisuke, Director, Office of International Regulatory Affairs, MHLW
11:00-11:15 (TW) **12:00-12:15 (JP)**	Q&A	
New Drug Review Cooperation between Japan and Taiwan Moderator: Mr. KUROIWA Kenji, Deputy Director, Office of International Regulatory Affairs, MHLW		
11:15-11:30 (TW) **12:15-12:30 (JP)**	Current Progress on New Drug Review Cooperation between Taiwan and Japan	Dr. Wen-Yi Hung, Senior Reviewer, Division of Medicinal Products, TFDA
11:30-11:45 (TW) **12:30-12:45 (JP)**	New Drug Review Cooperation – Next Step	Mr. YASUDA Naoyuki, Associate Executive Director, PMDA
11:45-12:00 (TW) **12:45-13:00 (JP)**	Q&A	
12:00-13:00 (TW) **13:00-14:00 (JP)**	Lunch	
Regenerative Medicinal Products Regulation Moderator: Ms. Ming-Mei Wu, Deputy Director, Division of Medicinal Products, TFDA		
13:00-13:20 (TW) **14:00-14:20 (JP)**	Regulation of Regenerative Medicinal Products in Taiwan	Ms. Mei-Chen Huang, Senior Technical Specialist, Division of Medicinal Products, TFDA
13:20-13:40 (TW) **14:20-14:40 (JP)**	Regulation for Regenerative Medicinal Products	Dr. MARUYAMA Yoshiaki, Office of Cellular and Tissue-based Products, PMDA
13:40-14:00 (TW) **14:40-15:00 (JP)**	Q&A	
Health Insurance for Sustainable Universal Health Coverage Moderator: Mr. KAGAWA Osamu, Chair, Asia Committee International Affairs, JPMA		
14:00-14:20 (TW) **15:00-15:20 (JP)**	Strategies on New Drug Reimbursement of Taiwan's NHI System	Dr. Yu-Wen Huang, Director of Medical Review and Pharmaceutical Benefits Division, NHIA
14:20-14:40 (TW) **15:20-15:40 (JP)**	Japan's NHI Drug Price System	Mr. SAWADAISHI Katsuya, Deputy Director, Policy Planning division for Pharmaceutical Industry Promotion and Medical Information Management, Health Policy Bureau, MHLW
14:40-15:00 (TW) **15:40-16:00 (JP)**	Q&A	
15:00-15:15 (TW) **16:00-16:15 (JP)**	Break	

Medical Devices		
Cybersecurity for Medical Devices Moderator: Ms. Pei-Weng Tu, Director, Division of Medical Devices and Cosmetics, TFDA		
15:15-15:35 (TW) **16:15-16:35 (JP)**	Cybersecurity Evaluation Requirements for Medical Device Product Registration and Regulatory Update Product Registration and Regulatory Update	Mr. Shiu-Huei Yeh, Section Chief, Division of Medical Devices and Cosmetics, TFDA
15:35-15:55 (TW) **16:35-16:55 (JP)**	Cybersecurity Requirements for Medical Device Product Registration	Mr. IMAGAWA Kuniki, Deputy Division Director, Office of Standards and Compliance for Medical Devices/ Office of Software as a Medical Device, PMDA
15:55-16:15 (TW) **16:55-17:15 (JP)**	Q&A	
Sharing of Latest Medical Device Issues Moderator: Mr. MIYASAKA Tomoyuki, Deputy Director, Medical Device Evaluation Division, MHLW		
16:15-16:35 (TW) **17:15-17:35 (JP)**	UDI Regulations in Taiwan	Mr. Hsiu-Te Lin, Section Chief, Division of Medical Devices and Cosmetics, TFDA
16:35-16:55 (TW) **17:35-17:55 (JP)**	Remanufactured-Single Use Device in Japan	Mr. MIYAKE Manabu, Deputy Division Director, Office of Manufacturing Quality and Vigilance for Medical Devices, PMDA
16:55-17:15 (TW) **17:55-18:15 (JP)**	Q&A	

Joint Session	
Closing Remarks	
17:15-17:25 (TW) **18:15-18:25 (JP)**	1. Dr. Shou-Mei Wu, Director General, TFDA 2. Mr. YASUDA Naoyuki, Associate Executive Director, PMDA
Reception 18:30- (TW)	