5th Joint Conference of Taiwan and Japan on Medical Products Regulation

Date: December 1, 2017

Place: 10F, Chang Yung-Fa International Convention Center (No.11, Zhongshan S. Rd., Taipei)

*Simultaneous interpretation (Chinese - Japanese) provided

Joint Session (Room 1001) *MC: Keng-Che Chou, Project Manager, Administration Office II, CDE*	
8:30-9:00	**Registration**
9:00-9:40	**Opening remarks** (40 min) *5min each 1. Mr. Ching-Hung Lin, Deputy Secretary General, Taiwan-Japan Relations Association 2. Mr. Mitsuhiro Yokota, Deputy Representative, Taipei Office of the Japan-Taiwan Exchange Association 3. Dr. Shou-Mei Wu, Director-General, TFDA 4. Mr. Seiichi Inoue, Executive Director, PMDA 5. Mr. Wei-Jen Chen, President, TPMA 6. Mr. Akihiko Matsubara, Managing Director, JPMA 7. Mr. Francis Hong, President, TMBIA 8. Mr. Kenichi Matsumoto, Vice Chairman, JFMDA
9:40-11:00	**Keynote speeches** (80 min) -Regulatory updates in Taiwan, Dr. Shou-Mei Wu, Director-General, TFDA (30min) -Regulatory updates in Japan, Mr. Seiichi Inoue, Executive Director, PMDA (30min) Q&A (20min) Dr. Shou-Mei Wu, Director-General, TFDA, Ms. Chao-Yi Wang, Director, Division of Medicinal Products, TFDA, Ms. Pei-Weng Tu, Director, Division of Medical Devices & Cosmetics, TFDA Mr. Seiichi Inoue, Executive Director, PMDA, Mr. Naoyuki Yasuda, Office Director, Office of International Programs, PMDA
11:00-11:20	**Break/Memorial Photo Taking**

【Parallel session (Pharmaceutical)】

Pharmaceutical (Room 1001)	
11:20-12:15	**Impact of MRCT after ICH E17 fully implement** (55min) Moderator: Ms. Chyn-Liang Huang, Section Chief, Division of Medicinal Products, TFDA / Mr. Yoshihiko Sano, Office of International Programs, Deputy Director, MHLW - Regulatory perspective, Mr. Shuji Kamada, Reviewer, Office of New Drug V, PMDA (15min) - Academic perspective, Dr. James Chih-Hsin Yang, Director, Department of Oncology, NTUH (15min) - Industry perspective, Mr. Chikara Kikuchi, Sr. Director, Regulatory Affairs, Development Japan, Pfizer Japan Inc. (10min) Q&A (15min)

12:15-13:00	**Lunch Break**
13:00-13:40	*MC: Jessica H. Chou, Section Chief, Section of Project Management, CDE* **Generic drug** (40 min) Moderator: Ms. Chyn-Liang Huang, Section Chief, Division of Medicinal Products, TFDA / Mr. Naoyuki Yasuda, Office Director, Office of International Programs, PMDA - Introduction of review points of generic drugs and BE guideline in Japan, Mr. Yoshihiko Sano, Deputy Director, Office of International Regulatory Affairs, MHLW (15min) - Strength of Taiwan generic industry, Dr. Calvin Chen, President and CEO, TWi Biotechnology (10min) Q&A (15min)
13:40-14:30	Moderator: Ms. Chyn-Liang Huang, Section Chief, Division of Medicinal Products, TFDA / Mr. Yoshihiko Sano, Deputy Director, MHLW **1. Advanced approaches to assure pharmaceutical product quality - Lifecycle management** (50min) -Dr. Mei-Fang Chen, Senior Reviewer, Division of Medicinal Products, TFDA (25min) -Mr. Kazuhiro Okochi, Chairman of ICH Quality Group, JPMA and Hiroshi Fujie, GMP Expert Committee, JPMA (25min)
14:30-14:50	**Break**
14:50-16:00	**2. Cutting-edge technologies and strategies - Using real world data** (50min) -Dr. Kin-Wei Chan, Director, Clinical Trial Center, NTUH (25min) - Ms. Kaori Yamada, Pharmacoepidemiologist, Office of Medical Informatics and Epidemiology, PMDA (25min) Q&A (20min)
16:00-16:20	**Break**
Health Insurance	
16:20-17:20	**Drug price adjustment under health insurance system** (60min) - Mr. Jau-Jic Huang, Senior Executive Officer, Medical Review and pharmaceutical Benefits Division, National Health Insurance Administration (20mim) - Dr. Masanobu Yamate, Deputy Director, Economic Affairs Division, Health Policy Bureau, MHLW (20min) Q&A (20min)
17:20-17:30	**Closing Remarks (pharmaceuticals)** - Dr. Shiow-Ing Wu, Deputy Director-General, TFDA - Mr. Yoshihiko Sano, Deputy Director, Office of International Regulatory Affairs, MHLW

【**Parallel session (Medical Devices)**】

Medical Devices (Room 1002) *MC: Pei-Hua Chung, Project Manager, Section of Project Management, CDE*	
11:20-12:15	**WG report & future image** (55min) Moderator: Ms. Yumiko Aoyagi, Deputy Director, Medical Device Evaluation Division, MHLW 1. Product registration WG -Dr. Madoka Murakami, Unit Chief, Office of International Programs, PMDA (15min) 2. QMS WG -Ms. Szu-Yu Lee, Specialist, TFDA (15min) -Mr. Hideki Asai, JFMDA (10min) 3. Q&A (15min)
12:15-13:00	**Lunch**
13:00-14:50	Moderator: Ms. Cheng-Ning Wu, Section Chief, Division of Medical Devices & Cosmetics, TFDA **1. Postmarket evaluation techniques: Evaluation of postmarket clinical benefits and risks of medium-high risk medical devices** (50min) - Dr. Kin-Wei Chan, Clinical Trial Center, NTUH (20 min) - Ms. Yumiko Aoyagi, Deputy Director, Medical Device Evaluation Division, MHLW (20min) - Q&A (15min) 2. **International trend on medical device regulatory convergence** (50min) - Mr. Wen-Wei Tsai, Technical Specialist, Division of Medical Devices & Cosmetics, TFDA (20min) - Dr. Mari Shirotani, Division Director, Office of International Programs, PMDA (20min) - Q&A (15min)
14:50-15:00	**Closing Remarks (medical devices)** -Ms. Pei-Weng Tu, Director, Division of Medical Devices & Cosmetics, TFDA -Dr. Mari Shirotani, Division Director, Office of International Programs, PMDA