4th Joint Conference of Taiwan and Japan on Medical Products Regulation

Day 1: 7th December 2016

Venue: Nihonbashi Life Science HUB (Joint session and pharmaceuticals/ Health Insurance session), Nihonbashi Life Science Bldg.10F (Medical devices session)

Joint Session	
08:30-09:00	**Registration**
09:00-09:30	**Opening Remarks** Mr. Hitoshi Funamachi, Senior Executive Director, Interchange Association, Japan Mr. Hou-Chun CHANG, Director, Economic Division, Taipei Economic and Cultural Representative Office in Japan Mr. Kazuhiko Mori, Councilor, MHLW Dr. Shiow-Ing Wu, Deputy Director-General, TFDA Mr. Tadaharu Goto, Director General, JPMA Mr. Tung-Mao Su, Standing Director, Taiwan Pharmaceutical Manufacturer's Association Mr. Koji Nakao, President, JFMDA Mr. Chi-Chung Huang, Chairman, Taiwan Medical and Biotech Industry Association
09:30-09:40	**Memorial Photo Taking**
09:40-10:40	**<u>Regulatory Updates for Medical Products in Japan and Taiwan</u>** **<u>(Moderator: Mr. Yoshihiko Sano (MHLW))</u>** (1). Currently regulation amendments and future prospects (2). Experience sharing on new medical product regulated 1. Dr. Toshiyosi Tominaga, Associate Executive Director for International Programs, PMDA (25min) 2. Ms. Chao-Yi Wang, Director, Division of Medicinal Products, TFDA (25min) 3. Q and A (10min)
10:40-10:55	**Coffee Break**

Parallel Session (Pharmaceuticals)	
10:55-11:55	**Moderator: Ms. Chao-Yi Wang (TFDA)** **WGs Progress Report** -New drugs Dr. Yi-Chu Lin, Section Chief, Division of Medicinal Products, TFDA (8min) -GCP Dr. Hideaki Ui, Division Director, Office of Non-clinical and Clinical Compliance, PMDA (8min) -OTC drugs Mr. Hung-Jung Lien, Section Chief, Division of Medicinal Products, TFDA (8min) -OTC drugs Mr. Fumihito Takanashi, Assistant Director, Office of International Regulatory Affairs, MHLW (8min) -Generic drugs Mr. Naoyuki Yasuda, Office Director, Office of International Programs, PMDA (8min) **Panel Discussion** (20min)
11:55-13:00	**Luncheon**
13:00-13:50	**Moderator: Mr. Naoyuki Yasuda (PMDA)** **1. New Strategies and Technologies** **(1) 3D printing** Prof. Jeng-Ywan Jeng, National Taiwan University of Science and Technology (20min) **(2) Electronic tools used in safety measures** Mr. Atsushi Noguchi, Coordinator, Office of Medical Informatics and Epidemiology, PMDA (20min) **Panel Discussion** (10min)
13: 50-15:05	**Moderator: Dr. Churn-Shiouh Gau (CDE)** **2. Experience Sharing on maintaining safety and quality of pharmaceuticals** **(1) Regulatory perspective** - API regulation and post-approval change: Current management in Taiwan

	Mr. Heng-Jung Lien, Section Chief, Division of Medicinal Products, TFDA (15min) - Description and comparison of the demanded document of API for the application of registration of generic medicine Mr. Ryosuke Kuribayashi, Chief Reviewer, Office of Generic Drugs, PMDA (15min) - Consideration point of post-approval change Mr. Gou Yamamoto, Deputy Director, Pharmaceutical Evaluation Division, MHLW (15min) **(2) Industry perspective** - Post-approval change application Dr. Alice Hsu, Standard Chemical & Pharmaceutical Co, TW (10min) - Post-approval change application Mr. Tomonori Nakagawa, Asia Project Leader, GMP Sub Committee, Quality & Technology Committee, JPMA (10min) **Panel Discussion** (10min)
15:05-15:20	**Coffee Break**
15:20-16:20	**Moderator: Mr. Yoshihiko Sano (MHLW)** **3. Post-marketing Management** (1) Safety information (including vaccine) report and research in Japan Dr. Daisaku Sato, Division Director, Safety Division, MHLW (15min) (2) **Adverse Event Reporting** - Current Status and policy direction on "Adverse Event Reporting" Ms. Wen-Wen Chen, CEO, Taiwan Drug Relief Foundation (15min) - Current Status and policy direction on "Adverse Event Reporting" Ms. Mariko Tsukuda, Reviewer, Office of Safety I, PMDA (15min) **Panel Discussion** (15min)
Parallel Session (Health Insurance)	
16:20-17:20	**Moderator: Mr. Yoshihiko Sano (MHLW)** **Update on regulations in NHI pricing and related policy** -Current update in NHI policy and future directions Mr. Hiroaki Mamiya, Section Chief, Pharmaceutical Affairs Division, MHLW (20min) -Current update in NHI policy and future directions Mr. Chang-Jr Chen, Specialist, Division of Medical Review and Pharmaceutical Benefits, NHIA (20min)

	Panel discussion (20min)
Pharmaceuticals &Health Insurance	
17:20-17:30	**Closing Remarks** - Ms. Chao-Yi Wang, Director, Division of Medicinal Products, TFDA - Dr. Toshiyoshi Tominaga, Associate Executive Director, PMDA
18:00-	**Welcome Reception (JPMA Bldg. 10F)**
Parallel Session (Medical Devices)	
11:15-12:25	**Moderator: Ms. Yumiko Aoyagi (both session 1&2) (MHLW)** **1. Progress of Product Registration WG** - Dr. Ta-Jen Wu, Technical Specialist, Division of Medical Devices and Cosmetics, TFDA (20min) **Panel Discussion** (15min)
	2. Progress of QSD/QMS WG - Mr. Katsuya Sawadaishi, Inspector, Division of Medical Devices, Office of Manufacturing/ Quality and Compliance, PMDA (15min) **Panel Discussion** (20min)
12:25-13:45	**Luncheon**
13:45-15: 30	**Moderator: Mr. Ming-Shin Lee, Director, Division of Risk Management, (Taiwan FDA)** **3. Information sharing on recent topics** - Software validation Mr. Tzu-Wei Li, Industrial Technology Research Institute of Taiwan (20min) Mr. Keiichiro Ozawa, FUJIFILM Corporation (20min) - In Vitro Companion Diagnostic Devices Mr. Tzu-Wei Li, Industrial Technology Research Institute of Taiwan (20min) Ms. Yumiko Aoyagi, Deputy Director, Medical Device Evaluation Division, MHLW (20min) **Panel Discussion** (25min)
15:30-15:40	**Closing Remarks** - Ms. Yu-Roo Chu, Deputy Director, Division of Medical Devices and Cosmetics, TFDA -Dr. Jun Kitahara, Division Director, Office of International Programs, PMDA

15:40-16:00	**Coffee Break**
16:00-17:30	**Closed Meeting** **1. Product Registration WG closed meeting** **2. QSD/ QMS WG closed meeting**
18:00~	**Welcome Reception (JPMA Bldg. 10F)**