第三屆台日醫藥交流會議議程
3rd Joint Conference of Taiwan and Japan on Medical Products Regulation

Open Session: 26th November 2015

Venue: Chang Yung-Fa Foundation International Conference Center

(1101 Room)

08:30-08:50	**Registration**
08:50-09:20	**Opening Remarks** - Mr. Jason Chou, Deputy Secretary-general, Association of East Asian Relations, Taiwan - Mr. Takashi Hamada, Secretary General, Interchange Association, Japan Taipei office, Japan - Ms. Yu-Mei Chiang, Director-General, Taiwan FDA - Dr. Toshiyoshi Tominaga, Associate Executive Director for International Programs, PMDA - Mr. Wei-Jen Chen, President, Taiwan Pharmaceutical Manufacturers Association (TPMA) - Mr. Kenichi Matsumoto, Vice Chairman, JFMDA - Mr. Kiyoshi Horie, Asia Subcommittee, JPMA
09:20-09:30	**Memorial Photo Taking**
09:30-10:10	**Keynote Speech** **Current status of medical products regulation in Taiwan and Japan** Moderator: Prof. Ming-Kung Yeh, Counselor, Ministry of Health and Welfare, Taiwan - Dr. Shiow-Ing Wu, Deputy Director-General, Taiwan FDA (20mins) - Dr. Kazuhiro Shigetoh, Executive Director, PMDA (20mins)
10:10-10:30	Coffee Break
Cooperation Accomplishments and Future Prospect for Japan-Taiwan Medical Products	
10:30-11:30	**Experience sharing on new product development in both Japan and Taiwan** Moderator: Ms. Li-Ling Liu, Director, Division of Medicinal Products, Taiwan FDA 1. Mr. Kouichi Tsuji, Terumo Corporation (20mins) 2. Prof. Chia-Chi Lin, International Center of Excellence in Cancer Research, Taiwan University (20mins) **Panel discussion** (20mins)
11:30-12:30	**How to exchange meaningful GCP information** Moderator: Dr. Junko Sato, Office Director, Office of International Cooperation, PMDA

	1. Mr. Yosuke Kobayashi, Office of Non-Clinical and Clinical Compliance, PMDA (20mins) 2. Dr. Paul-Lee Wu, Director, Division of Medical Devices, Center for Drug Evaluation (20mins) **Panel discussion** (20mins)
12:30-13:30	Luncheon

Parallel Session			
Pharmaceutical (1101 Room)		**Medical device (1001 Room)**	
13:30-14:30	**Collaboration between Taiwan and Japan for developing self-medication utilizing OTC** Moderator: Mr. Fumihito Takanashi, Deputy Director, Pharmaceutical Safety and Environmental Health Bureau, MHLW 1. Collaboration between Taiwan and Japan for Developing Non-prescription medicine Mr. Arthur Su, Board Member, Taiwan Pharmaceutical Marketing & Management Association (TPMMA) (20mins) 2. Mr. Motohito Nishizawa, Senior Advisor, Japan Self-Medication Industry, JSMI (20mins) **Panel discussion** (20mins)	13:30-14:20	**Currently regulation amendments and future prospects** 1. Dr. Yu-Wen, Ruby Huang, Section Chief, Division of Medical Devices and Cosmetics, Taiwan FDA (20mins) 2. Mr. Hideyuki Kondo, Deputy Director, Medical Device and Regenerative Medicine Product Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW (20mins) **Panel discussion** (10mins)
		14:20-14:40	Coffee Break
14:30-15:40	**Collaboration between Taiwan and Japan for faster approval for new drugs: "Current progress and next steps"** Moderator: Dr. Shih-Chih Tsai, Senior Technical Specialist, TFDA 1. Dr. Kanako Takatsuki, Office of International Cooperation, PMDA (15mins) 2. Regulation comparison of new drug review between Taiwan and Japan Mr. Po-Yu Wang, Section Chief, Taiwan FDA (15mins)	14:40-15:30	**Learning, assessments and proposal for the collaboration activities in the medical device field** 1. Mr. Makoto Yokote, JFMDA (15mins) 2. Mr. Karen Ho, Manager, Regulation & Document Management Department, United Orthopedic Corporation (15mins) **Panel discussion** (20mins)
		15:30-15:50	Coffee Break

<table>
<tr><td></td><td>3. Mr. Isao Sasaki, Astellas/ JPMA (10mins)
4. Ms. Carol Cheng, Chief Operating Officer, Taiwan Research- based Biopharmaceutical Manufacturers Association (TRPMA) (10mins)

Panel discussion for next step (20mins)</td><td>15:50-16:20</td><td colspan="2">Progress of WG activities

1. Product Registration WG: Dr. Madoka Murakami, Office of International Program, PMDA (10mins)
2. QSD/QMS WG: Ms. Yu-Hsuan Chen, Senior Technical Specialist, Division of Risk Management, Taiwan FDA (10mins)

Panel discussion (10mins)</td></tr>
<tr><td>15:40-16:10</td><td>Coffee Break</td><td>16:20-16:30</td><td colspan="2">Coffee Break</td></tr>
<tr><td>16:10-17:20</td><td>Collaboration between Taiwan and Japan for faster access to new drugs under NHI system

Opening remarks for NHI session
1. Ms. Ru-Liang Shih, Director, Medical Review and Pharmaceutical Benefits Division, NHIA (5mins)
2. Mr. Mimei Takahashi, Deputy Director, Economic Affairs Division, Health Policy Bureau, MHLW (5mins)

Presentation "Pricing effectiveness to realize faster access for NHI reimbursement"

1. Mr. Mimei Takahashi, Deputy Director, Economic Affairs Division, Health Policy Bureau, MHLW (20min)
2. Mr. Shang-Ping Chen, Medical Review and Pharmaceutical Benefits Division, Researcher, NHIA (20mins)

Panel discussion (20mins)</td><td>16:30-17:30</td><td>(1001 Room)

Product Registration WG closed meeting
1. Working plan discussion including
(1) Ask for Industry’s joining
(2) Case study process
(3) How to make benefits for both industries
2. Future collaboration possibility</td><td>(10F VIP Room)

QSD/ QMS WG closed meeting
1. Working plan discussion
2. Overseas inspection discussion
3. The mutual acceptance of inspection differences between Japan and Taiwan
4. Future collaboration possibility</td></tr>
<tr><td rowspan="3">17:20-17:40</td><td colspan="3">Closing Remarks (1101 Room)</td></tr>
<tr><td colspan="3">- Dr. Shiow-Ing Wu, Deputy Director-General, Taiwan FDA (10mins)</td></tr>
<tr><td colspan="3">- Dr. Kazuhiro Shigetoh, Executive Director, PMDA (10mins)</td></tr>
<tr><td>18:00</td><td colspan="3">Adjourn</td></tr>
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