2nd Joint Conference of Taiwan and Japan on Medical Products Regulation

- Open Session on October 31, 2014
  Venue: Sunsky Room (Joint Session), Tokyo
  JPMA Meeting Room (Pharmaceutical Regulation Session)

10 月 31 日(五)Open session	
08:20 – 08:25	Memorial photo taking
08:30 – 08:40	Opening remarks 交流協會、台北駐日經濟文化代表處
08:40 – 10:00	Keynote lecture
	Opening remarks & short presentation: JPMA、JFDMA、TPMA、TMBIA、TFMDCA
	Lecture: Masatoshi Narita, Counselor, Minister's Secretariat, MHLW Ms. Li-Ling Liu, Director, Division of Medicinal Products, TFDA Dr. Tatsuya Kondo, Chief Executive, PMDA Dr. San-Kuei Huang, Director General, NHIA
10:00 – 11:00	Time allowance + Coffee break 中場休息及換場
11:00 – 12:30	**醫材議題(Pharmaceuticals Regulatory)**
11:00 – 11:10	PMS WG reporting
11:10 – 11:20	GCP WG reporting
11:20 – 11:35	Product Registration WG reporting
11:35 – 11:50	QSD/QMS WG reporting
11:50 – 12:00	Short Break
12:00 – 12:30	QA & Wrap up session
14:00-18:00	Health Authority Closed Meeting (此部分不公開)
11:00 – 17:45	**藥品議題(Pharmaceuticals Regulatory)**
議題一：MRCT 及新藥審查(MRCT and New drug review)	

Chair：Mr. Kaoru Misawa, PMDA	
11:00 – 11:30	Regulatory experiences and challenges toward international harmonization on MRCTs Speaker: Yoshiaki Uyama, Director, Division of Epidemiology, Office of Safety I, PMDA
11:30 – 12:00	Clinical Trial Capacity and New Drug Reiew Related to MRCT in Taiwan Speaker: Dr. Chi-Hsun Chen, Team Leader, Center for Drug Evaluation (CDE)
12:00 – 12:30	Q&A
12:30 – 14:00	Lunch
議題二：再生醫療(Regenerative products) **Chair：Ms. Li-Ling Liu, Director, Division of Medicinal Products, TFDA**	
14:00 – 14:20	New Development of regenerative medical product regulation Speaker: Daisaku Sato, Director, Office of Cellular and Tissue-based Products, PMDA
14:20 – 14:40	Regulation of Cell therapy products in Taiwan Speaker: Dr. Yi-Chu Lin, Associate Researcher, Division of Medicinal Products, TFDA
14:40 – 15:00	Q&A
議題三：奈米醫學(Nano technology and products) **Chair：Dr. Churn-Shiouh Gau, Executive-Director, Center for Drug Evaluation**	
15:00 – 15:20	Evaluation of nanotechnology-based medicines Speaker: Dr. Naomi Nagai, PMDA
15:20 – 15:40	Regulatory Considerations for Nanotechnology-Related Drug Products in Taiwan Speaker: Dr Lin-Chau Chang, CDE
15:40 – 16:00	Q&A
16:00 – 16:30	Coffee break
議題四：OTC 藥物(OTC session) **Chair: Mr. Teruyoshi Ehara, Director, Office of International Programs (OIP), PMDA**	
16:30 – 16:50	Regulation of OTC Drugs in Japan

	Speaker: Dr.Takatoshi Nakamura, PMDA
16:50 – 17:10	Introduction of OTC Regulations in Taiwan Speaker: Mr Heng-Jung Lein, TFDA
17:10 – 17:30	Q&A
17:30 – 17:45	**Summary and Closing** Mr. Naoyuki Yasuda, PMDA Ms. Li-Ling Liu. TFDA