第四屆台日醫藥交流會議議程
4th Joint Conference of Taiwan and Japan on Medical Products Regulation
(tentative only)

Day 1: Open Session: 7th December 2016

Venue:

Nihonbashi Life Science HUB (Joint session and pharmaceuticals session)

Room at JPMA (Medical devices session)

08:30-09:00	**Registration**
09:00-09:20	**Opening Remarks**
	Interchange Association, Japan Taipei office, Japan
	Association of East Asian Relations, Taiwan
	MHLW/PMDA
	TFDA
	Industry Association from Japan side (TBD)
	Industry Association from Taiwan side (TBD)
09:20-09:30	**Memorial Photo Taking**
09:30-10:30	**Regulatory Updates for Medical Products in Japan and Taiwan** (1).Currently regulation amendments and future prospects (2).Experience sharing on new medical product regulated Moderator: MHLW/PMDA 1. MHLW/PMDA (30mins) 2. Taiwan FDA (30mins)
10:30-11:00	**Coffee Break**

	Parallel Session	
	Pharmaceuticals	**Medical Devices**
11:00-12:00	**WGs Progress Report** -New drugs (Yi-Chu Lin, TW) (10mins) -GCP (TW) (10mins) -OTC drugs (JP) (10mins) -Generic drugs (JP) (10mins) **Panel Discussion (20mins)**	**1. Progress of Product Registration WG** -(TW or JP) (TBD) (20mins) **Panel Discussion** (15mins) **2. Progress of QSD/QMS WG** -(TW or JP) (TBD) (20mins) **Panel Discussion** (15mins)
12:00-13:15	**Luncheon**	
13:15-14:30	**1. Experience Sharing on maintaining safety and quality of pharmaceuticals** **(1).Regulatory perspective** **-API regulation and post-approval change:** Current management in Taiwan (Hung-Jung Lien,TW) (15mins) -Description and comparison of the demanded document of API for the application of registration of OTC or prescription medicine (JP) (15mins) -Consideration point of post-approval change (JP) (15mins) **(2).Industry perspective** - Post-approval change application (TW) (10mins) - Post-approval change application (JP) (10mins) **Panel Discussion** (10mins)	**3. Discussion on the variety of Software Validation** -TBD (TW) (15mins) -TBD (JP) (15mins) **Panel Discussion** (20mins)
14:30-15:20	**2. Post-marketing Management** **(1).Post-market Surveillance:** -Safety information (including vaccine) report and research in Japan (JP) (15mins) **(2).Electronic tools used in safety measures** (JP) (15mins) **(3).Adverse Event Reporting** - Current Status and policy direction on "Adverse Event Reporting" (Wen-Wen Chen, TW and JP) (10mins each) **Panel Discussion** (10mins)	**4. Trends in Molecular Diagnostics and Precision Medicine** -TBD(TW) (15mins) -TBD (JP) (15mins) **Panel Discussion** (20mins)
15:20-15:40	**Coffee Break**	
15:40-16:25	3. **New Strategies and Technologies** (1).Green channel: new way to accelerate market approval (Yi-Chu Lin, TW) (15mins) (2).3D printing (TW) (15min) **Panel Discussion** (15mins)	**Close Meeting** **1.Product Registration WG closed meeting** **2.QSD/ QMS WG closed meeting**
16:25-17:30	**4. Update on regulations in NHI pricing and related policy** -Current update in NHI policy and future directions (JP) (25min) -Current update in NHI policy and future directions (TW) (25min) **Panel discussion** (15min)	
17:30-17:50	**Panel Discussion**	**Panel Discussion**
17:50-18:00	**Closing Remarks**	
18:00	**Adjourn**	
18:00~	**Welcome Reception**	

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