$The \ 3^{rd} \ Thail and - Japan \ Symposium$

DATE: 24 March 2016

VENUE: Hotel Windsor Suites & Convention, Sukhumvit Soi 20 Bangkok Thailand

AGENDA:

9:00 - 9:30	Registration	
9:30 – 10:00	Opening Remarks	Praphon ANGTRAKOOL
		Deputy Secretary-General, Thai FDA
		Tatsuya KONDO, M.D., Ph.D.
		Chief Executive, PMDA
		Akihiko UCHIKAWA
		Minister of Economics,
		Embassy of Japan in Thailand
10:00 - 10:25	Updates from Thailand	Chapon RATANAPAN
		Director Technical and Policy
		Administration Division, Thai FDA
10:25 - 10:50	Updates from Japan	Toshiyoshi TOMINAGA, Ph.D.
		Associate Executive Director,
		PMDA
10:50 – 11:10	Coffee Break	

<Pharmaceuticals Track>

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11:10 – 12:00	Registration in Japan	Yuki SAKURAGI		
	 Biological products 	Office of International Cooperation,		
	 Regenerative medicines 	PMDA		
	• Quasi – drugs			
12:00 – 13:30	LUNCH BREAK			
13:30 – 14:20	Registration in Thailand			
	 Biological products 	Pramote AKARAPANON		
		Head of Biological product		
		sub-division, Bureau of Drug		
		Control, Thai FDA		
	 Abridged New Drug 	Tharnkamol CHANPRAPAPH, Ph.D.		
	Evaluation	Chief of Pre-Marketing Control		
		Division, Bureau of Drug Control,		
		Thai FDA		
	 Regenerative medicines 	Morakot PAPASSIRIPAN		
		Pharmacist, Professional level		
		Biological product sub-division		
		Bureau of Drug Control, Thai FDA		

14:20 – 15:20	eCTD Submission in Japan	Taku WATANABE
		Principal IT Expert
		Office of Review Management,
		PMDA
15:30 – 16:30	e Submission in Thailand	Kritsada LIMPANANONT
		Head of Drug Information and
		Technology Group,
		System Development Division,
		Bureau of Drug Control, Thai FDA
16:30 – 17:00	Q&A	

<Medical Devices Track>

11:10 – 11:35	Update of Japanese Regulation on Medical Devices (e.g. Pharmaceutical Affairs Law	Madoka MURAKAMI, Ph.D. Unit Chief Division of International Regulatory
	Amendment)	Coordination Office of International Programs, PMDA
11:35 – 12:00	Update of Thailand Regulation on Medical Devices	Yuwadee PATANAWONG Senior Expert in Safety of Medical Devices and Acting Director, Medical Device Control Division, Thai FDA
12:00 – 13:30 13:30 – 14:00	LUNCH BREAK Classification of Medical Devices and utilization of international standards in Japan	Katsuhisa IDE, Ph.D.DDS Principal Officer Division of Standards for Medical
	- Especially for certification standards and approval standards -	Devices Office of Standards and Guidelines Development, PMDA
14:00 – 14:30	Definition and Classification of Medical Devices and List of Medical Devices in each medical devices class and AMDD in Thailand	Yuwadee PATANAWONG Senior Expert in Safety of Medical Devices and Acting Director, Medical Device Control Division, Thai FDA
14:30 – 15:00	Post-market Safety Measures for Medical Devices in Japan	Takako NIWA Officer Medical Device Safety Division Office of Safety 1, PMDA
15:00 – 15:30	Post-market surveillance and vigilance system in Thailand	Chanchai WASUTHALAINUN Head of Post-Marketing Group, Pharmacist Senior Professional Level, Medical Device Control Division, Thai FDA

15:30 – 16:00	QMS (Quality Management System)	Taishi NAKASHIMA
	for Medical Device in Japan	Inspector (QMS Audit)
		Office of Manufacturing/Quality and
		Compliance Division of Medical
		Devices, PMDA
16:00 – 16:30 16:30 – 16:50	QMS (Quality Management System) for Medical Device/GMP in Thailand Expectation from Industry Japan	Nakorn TANGWANCHAROENCHAI Head of Standard Development Group, Pharmacist Senior Professional Level, Medical Device Control Division, Thai FDA Hiroshi MISAWA
	Japan	Chair, Council for Industrial Policy The Japan Federation of Medical Devices Associations (JFMDA)
	• Thailand	Preecha BHANDTIVEJ President of Thai Medical Device Technology Industry Association /THAIMED Chairman of ASEAN Federation of Medical Device Industry/ ASEANMed
16:50 - 17:00	Q&A	