

The 3rd Thailand – 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>

11:10 – 12:00	Registration in Japan <ul style="list-style-type: none"> • Biological products • Regenerative medicines • Quasi – drugs 	Yuki SAKURAGI Office of International Cooperation, PMDA
12:00 – 13:30	LUNCH BREAK	
13:30 – 14:20	Registration in Thailand <ul style="list-style-type: none"> • Biological products • Abridged New Drug Evaluation • Regenerative medicines 	Pramote AKARAPANON Head of Biological product sub-division, Bureau of Drug Control, Thai FDA Tharnkamol CHANPRAPAPH, Ph.D. Chief of Pre-Marketing Control Division, Bureau of Drug Control, Thai FDA 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 Amendment)	Madoka MURAKAMI, Ph.D. Unit Chief Division of International Regulatory 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	LUNCH BREAK	
13:30 – 14:00	Classification of Medical Devices and utilization of international standards in Japan - Especially for certification standards and approval standards -	Katsuhisa IDE, Ph.D.DDS Principal Officer Division of Standards for Medical 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

