

The 4th Thailand – Japan Symposium

DATE: 2nd February 2017

VENUE: Holiday Inn Bangkok Sukhumvit, Sukhumvit 22, Bangkok, Thailand

AGENDA:

9:00–9:30	Registration			
9:30–9:45	Opening Remarks Mr. Haruo AKAGAWA (Senior Executive Director, PMDA)			
9:45–10:30	Keynote Lecture Dr. Wanchai SATTAYAWUTHIPONG (Secretary-General, Thai FDA)			
10:30–10:50	COFFEE BREAK			
	Pharmaceuticals Track		Medical Devices Track	
10:50–12:00	Update of Pharmaceuticals - Thai FDA - PMDA		10:50–12:00	Update New Regulations of Medical device - Thai FDA - PMDA
12:00–13:00	LUNCH BREAK			

Pharmaceuticals Track		Medical Devices Track	
13:00–14:00	Pharmacopoeia - Thai FDA - PMDA	13:00–13:40	Adverse Event / Device Defect & Field Safety Corrective Action Reporting Requirements and Implementation - Thai FDA
14:00–15:00	Pharmacovigilance - Thai FDA (about high quality and reliable reports) - PMDA (about RMP) - PMDA (about MID-NET)	13:40–14:20	Standards for Medical Devices - PMDA (about Classification of Medical Devices and utilization of international standards in Japan)
		14:20–15:00	Requirement of GMP-MD Japan - PMDA (about QMS for Medical Device in Japan)
15:00–15:15	COFFEE BREAK	15:00–15:20	COFFEE BREAK
15:15–16:00	Supportive measure for industry - PMDA (about Scientific Consultations including Pharmaceutical Affairs Consultation on R&D Strategy) - Thai FDA	15:20–16:00	SaMD. Software as Medical Device Control - PMDA
16:00–16:45	Capacity building for regulator and industry - PMDA (about Asia Training Center) - Thai FDA	16:00–16:40	Control System on Advertisement of Medical Devices in Thailand - Thai FDA