

The 6th Thailand – Japan Symposium

DATE: 15th May 2019

VENUE: Grande Centre Point Terminal 21 Bangkok

AGENDA:

9:00 – 9:30	Registration
09:30 – 09:45	Opening Remarks Dr. Tares Krassanairawiwong (Secretary-General, Thai FDA) Dr. Yasuhiro Fujiwara (Chief Executive, PMDA)
09:45 – 09:50	VTR to kick start the symposium by Dr. Tares Krassanairawiwong (Secretary-General, Thai FDA) Dr. Yasuhiro Fujiwara (Chief Executive, PMDA)
09:50 – 10:05	Keynote Speech Dr. Yasuhiro Fujiwara (Chief Executive, PMDA)
10:05 – 10:20	Expectation from Japanese Pharmaceutical Industry Mr. Tadaharu Goto (Director General, Japan Pharmaceutical Manufacturers Association)
10:20 – 10:30	PHOTO Session
10:30 – 10:50	COFFEE BREAK
10:50 – 12:00	Regulatory Update* 10:50-11:25 Dr. Surachoke Tangwiwat (Deputy Secretary-General, Thai FDA) 11:25-12:00 Dr. Nobumasa Nakashima (Senior Director for International Programs, PMDA)
12:00 – 13:00	LUNCH BREAK

*Q&A is included in each presentation

Pharmaceuticals Track		Medical Devices Track	
13:00– 14:10	<p>Good Registration Management</p> <p>13:00-13:30 About Good Submission Practice (Thai FDA)</p> <p>13:30-14:00 About Good Review Practice (PMDA)</p> <p>14:00-14:10 Q&A</p>	13:00– 13:50	<p>Efficient review of medical devices</p> <p>13:00 - 13:20 (Thai FDA)</p> <p>13:20- 13:40 (MHLW)</p> <p>13:40-13:50 Q&A</p>
14:10– 15:20	<p>Risk communication (Labeling, Patient information leaflet, etc.)</p> <p>14:10-14:40 (Thai FDA)</p> <p>14:40-15:10 (PMDA)</p> <p>15:10-15:20 Q&A</p>	13:50– 14:00	<p>New Regulations for Certain Medical Devices in 2019</p> <p>(Thai FDA)</p>
		14:00– 14:45	<p>14:00-14:35</p> <p>Best practice for high risk medical devices review (Automated external Defibrillator (AED))</p> <p>(PMDA)</p> <p>14:35-14:45 Q&A</p>

Pharmaceuticals Track		Medical Devices Track	
		14:45 – 15:20	14:45-15:10 Best practice for high risk medical devices review (Software as Medical Device (SaMD)) (PMDA) 15:10-15:20 Q&A
15:20 – 15:40	COFFEE BREAK	15:20 – 15:40	COFFEE BREAK
15:40 – 16:50	Challenges for accelerating access to innovative medical products 15:40-16:10 (Thai FDA) 16:10-16:40 (PMDA) 16:40-16:50 Q&A	15:40 – 16:50	Introduce in vitro diagnostics products 15:40 - 16:10 (Thai FDA) 16:10 - 16:40 (PMDA) 16:40-16:50 Q&A