As of 23 April 2018

The 5th Thailand – Japan Symposium

DATE: 26th April 2018

VENUE: Radisson Blu Plaza Bangkok, 489 Sukhumvit Road (Soi 27), Klongtoey Nua, Wattana, Bangkok 10110, Thailand

AGENDA:

8:00 – 8:30	Registration
8:30 – 9:00	Pharmaceutical and Medical Devices Booth & Exhibition
9:00 – 9:15	Opening Remarks Dr. Wanchai SATTAYAWUTHIPONG (Secretary-General, Thai FDA) Dr. Tatsuya KONDO (Chief Executive, PMDA) Mr. Noboru SEKIGUCHI (Minister, Embassy of Japan in Thailand)
9:15 – 9:20	MOC Celebration Ceremony Congratulation Speech by Dr.Surachoke TANGWIWAT (Deputy Secretary-General, Thai FDA)
9:20 – 9:30	Photo session
9:30 – 9:45	Introduction of Japanese Pharmaceutical Industry Mr. Tadaharu GOTO (Director General, Japan Pharmaceutical Manufacturers Association)
9:45 – 10:00	Introduction of Thai Pharmaceutical Industry Mr. Chernporn TENGAMNUAY (President, Thai Pharmaceutical Manufacturers Association)
10:00 – 10:30	Regulatory Update* 10:00—10:15

<table>
<tr><td></td><td colspan="3">- Dr. Surachoke TANGWIWAT (Deputy Secretary-General, Thai FDA)
10:15－10:30
- Dr. Nobumasa Nakashima (Director, Office of International Regulatory Affairs, Division of General Affairs, Pharmaceutical Safety and Environmental Health Bureau, MHLW)</td></tr>
<tr><td>10:30－11:00</td><td colspan="3">COFFEE BREAK and visit Pharmaceutical and Medical Devices Booth & Exhibition</td></tr>
<tr><td colspan="2">Pharmaceuticals Track</td><td colspan="2">Medical Devices Track</td></tr>
<tr><td>11:00－12:30</td><td>Best Practices for Pharmaceutical Post-Market Surveillance Maybe focus on high risk medical product and Antimicrobial medicines*
11:00－11:45 Post Marketing Surveillance in Thailand
- Mr. Pairoj OSATAPIRAT (Pharmacist, Practitioner Level, Bureau of Drug Control, Thai FDA)
11:45－12:30 Best Practice for Pharmaceutical Post-Marketing Surveillance on high risk medical products and Antimicrobial medicines
- Ms. Shohko SEKINE (Reviewer, Office of New Drug IV, PMDA)</td><td>11:00－12:30</td><td>Consultation for medical devices and SAKIGAKE system*
- Dr. Yutaka MATSUI (Reviewer, Office of Medical Devices III, PMDA)</td></tr>
<tr><td>12:30－13:30</td><td colspan="3">LUNCH BREAK</td></tr>
<tr><td colspan="2">Pharmaceuticals Track</td><td colspan="2">Medical Devices Track</td></tr>
<tr><td>13:30－15:00</td><td>GMP Inspection: building and strengthening GMP inspection of Regenerative Medicine*
13:30－14:00 GMP on Advanced Therapy Medicinal Product in Thailand
- Mrs. Achiraya PRAISUWAN (Pharmacist, Professional Level, Bureau of Drug Control, Thai</td><td>13:30－15:00</td><td>High risk medical devices (non-IVD) Regulation*
13:30－14:15 Contact Lens and Breast Implants CSDT Submission
- Mrs. Nutchnat KITIWOURANON (Pharmacist, Senior Professional Level, Medical Device Control Division, Thai FDA)</td></tr>
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	FDA) 14:00－14:30 Good Gene, Cellular, and Tissue-based Products Manufacturing Practice(GCTP): GMP for ATMPs in Japan - Mr. Taishi NAKASHIMA (Inspector, Office of Manufacturing/Quality and Compliance, PMDA) 14:30 － 15:00 Development and Manufacturing of Regenerative Medicine using Cell Sheet Engineering - Dr. Setsuko HASHIMOTO (President and CEO, CellSeed Inc.)		14:15 － 15:00 Review and approval of coronary stents and orthopedic implants - Dr. I KAKU (Review director, Office of Medical Devices I, PMDA)
15:00－15:15	COFFEE BREAK		
15:15－16:00	GDP and GSP in Japan* - Mr. Katsuaki Ura (Deputy Director, Office of International Regulatory Affairs, Division of General Affairs, Pharmaceutical Safety and Environmental Health Bureau, MHLW)	15:15－16:00	Global harmonized standard vs Local standard 15:15－15:35 Global harmonized Standard vs Local Standard - Mr. Takuya ITO (Reviewer, Office of Medical Devices III, PMDA) 15:35－15:55 Regulatory Review Using Essential Principles - Dr. Katsuhisa IDE (Director for Standards and Guidelines Coordination, Office of Standards and Guidelines Development, PMDA) 15:55－16:00 Q&A

16:00－17:00	Pharmacovigilance* 16:00－16:30 New dimension of Pharmacovigilance in Thailand - Ms. Yaowares OPPAMAYUN (Head of Health Product Vigilance Center, Technical and Planning Division , Thai FDA) 16:30－17:00 Pharmacovigilance in Japan - Mr. Shinji HIRASAWA (Reviewer, Office of Safety II, PMDA)	16:00－17:00	Post – marketing Alert System* 16:00－16:30 - Ms. Yuwadee PATANAWONG (Acting Senior Advisor in Safety and Effectiveness and Advisory in Safety and Efficacy of Health Products, Thai FDA) 16:30 － 17:00 Post-Market Safety Measures for Medical Devices - Mr. Kensei TANAKA (Reviewer, Office of Safety I, PMDA)

*Q&A is included in each presentation