

## Draft The 5<sup>th</sup> Thailand – Japan Symposium

**DATE:** 26<sup>th</sup> April 2018

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

**AGENDA:**

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

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|                       | <ul style="list-style-type: none"> <li>- Thai FDA</li> </ul> <p>10:15 – 10:30</p> <ul style="list-style-type: none"> <li>- MHLW</li> </ul>   |                       |  |
| 10:30 – 11:00         | COFFEE BREAK and visit Pharmaceutical and Medical Devices Booth & Exhibition   |                       |  |
| Pharmaceuticals Track |  | Medical Devices Track |  |
| 11:00 – 12:30         | <p>Best Practices for Pharmaceutical Post-Market Surveillance</p> <p>Maybe focus on high risk medical product and Antimicrobial medicines*</p> <p>11:00 – 11:45</p> <ul style="list-style-type: none"> <li>- Thai FDA</li> </ul> <p>11:45 – 12:30</p> <ul style="list-style-type: none"> <li>- PMDA</li> </ul>   | 11:00 – 12:30         | <p>Consultation for medical devices and SAKIGAKE system*</p> <ul style="list-style-type: none"> <li>- PMDA</li> </ul>  |
| 12:30 – 13:30         | LUNCH BREAK  |                       |  |
| Pharmaceuticals Track |  | Medical Devices Track |  |
| 13:30 – 15:00         | <p>GMP Inspection : building and strengthening GMP inspection of Regenerative Medicine*</p> <p>13:30 – 14:00</p> <ul style="list-style-type: none"> <li>- Thai FDA</li> </ul> <p>14:00 – 14:30</p> <ul style="list-style-type: none"> <li>- PMDA</li> </ul> <p>14:30 – 15:00</p> <ul style="list-style-type: none"> <li>- Japanese industry</li> </ul> | 13:30 – 15:00         | <p>High risk medical devices (non-IVD) Regulation*</p> <p>13:30 – 14:15</p> <ul style="list-style-type: none"> <li>- Thai FDA</li> </ul> <p>14:15 – 15:00</p> <ul style="list-style-type: none"> <li>- PMDA</li> </ul> |
| 15:00 – 15:15         | COFFEE BREAK   |                       |  |
| 15:15 – 16:00         | <p>GDP and GSP in Japan*</p> <ul style="list-style-type: none"> <li>- MHLW</li> </ul>  | 15:15 – 16:00         | <p>Global harmonized standard vs Local standard</p> <p>15:15 – 15:35</p>   |

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|               |   |               | <ul style="list-style-type: none"> <li>- PMDA</li> </ul> 15:35 – 15:55 <ul style="list-style-type: none"> <li>- PMDA</li> </ul> 15:55 – 16:00 Q&A                                   |
| 16:00 – 17:00 | Pharmacovigilance*<br>16:00 – 16:30 <ul style="list-style-type: none"> <li>- Thai FDA</li> </ul> 16:30 – 17:00 <ul style="list-style-type: none"> <li>- PMDA</li> </ul> | 16:00 – 17:00 | Post – marketing Alert System*<br>16:00 – 16:30 <ul style="list-style-type: none"> <li>- Thai FDA</li> </ul> 16:30 – 17:00 <ul style="list-style-type: none"> <li>- PMDA</li> </ul> |

\*Q&A is included in each presentation