

APEC-LSIF-RHSC MRCT/GCP inspection Workshop



Date: January 26, 2017

Time: 13:30 – 17:30

Venue: The Hall at Zen-Nittsu Kasumigaseki Building 8F
3-3-3, Kasumigaseki, Chiyoda-ku, Tokyo

Agenda:

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| 13:30 – 13:45 | Greetings Mr. Kazuhiko MORI Director, Councilor for Pharmaceutical Affairs, MHLW |
| 13:45 – 15:25 | Review of Pilot Workshops |
| 13:45 – 14:05 | Report from Duke-NUS Medical School Dr. Silke VOGEL Associate Dean Duke-NUS Medical School |
| 14:05 – 14:25 | Report from Peking University Ms. Sandy ZHANG Peking University |
| 14:25 – 14:45 | Report from PMDA Dr. Yoshiaki UYAMA Office Director Office of Medical Informatics and Epidemiology PMDA |
| 14:45 – 15:25 | Panel Discussion |
| 15:25 – 15:45 | Break |
| 15:45 – 17:20 | Special Discussion Dr. Aloka CHAKRAVARTY Director, Division of Biometrics VII, U.S. FDA Mr. Jerry STEWART Deputy Vice President, PhRMA Dr. Hiromichi SHIRASAWA Vice President and Executive Officer, Head of Japan Development; MSD K.K., Japan Ms. Akanid WAPEEWUTTIKORN Head of Investigational Drug Section, Bureau of Drug Control, Food and Drug Administration, Thailand Dr. Rebecca LI Executive Director, |

Multi-Regional Clinical Trials Center of Harvard and Brigham
and Women's Hospital, USA

17:20 – 17:30 Closing Remarks
Dr. Tatsuya KONDO
Chief Executive, PMDA



Pharmaceuticals and Medical Devices Agency
Ministry of Health, Labour and Welfare

