The Third Indonesia - Japan Symposium

DATE: May 16, 2017
VENUE: Hotel Grand Mercure Jakarta Harmoni

AGENDA:

Time	Program
8:30-9:00	Registration
9:05-9:20	Indonesia National Anthem Opening remarks • Mr. Shinobu Uzu (Chief Safety Officer, PMDA) • Mr. F. Tirto Kusnadi (Ketua Umum, GPFI) • Mr. Akihiko Matsubara (Managing Director, JPMA) • Ir. Penny K. Lukito, MCP, PhD (Chairperson, BPOM)
9:20-9:40 9:40-10:00	Keynote speech: • Dr. Tatsuya Kondo (Chief Executive, PMDA) "Moving forward to strengthen regulatory science" • Ir. Penny K. Lukito, MCP, PhD (Chairperson, BPOM) "Revitalization of Drug and Food Control in Indonesia"
10:00-10:15	Photo Session & Break
	Door Stop
10:15-10:35	New drug review in Japan: Importation scheme Dr. Junko Sato (Office Director, Office of International Cooperation, PMDA)
10:35-11:05	Review of New drug in Indonesia, including review scheme Dra. Togi J. Hutadjulu, Apt, MHA (Director for Drug and Biological Product Evaluation, BPOM)
11:05-11:25	Conditional approval system in Japan Mr. Yu Sakamoto (Office of International Cooperation, PMDA)
11:25-11:45	Orphan drug system in Japan Mr. Yu Sakamoto (Office of International Cooperation, PMDA)
11:45-12:30	Panel discussion Chair: Dra. Ratna Irawati, Apt, M.Kes (BPOM) Panelists: All speakers from PMDA and BPOM
12:30-13:30	Lunch

Time	Program
13:30-13:50	Pharmacovigilance activities in Japan • Post-market safety • Punishment to MAH in PhV area (not report ISR etc.) • RMP Mr. Shinobu Uzu (Chief Safety Officer, PMDA)
13:50-14:10	Importance and utilization of RMP from manufacturer's perspective Mr. Shinya Takemoto (Chugai Pharmaceutical Co., Ltd.)
14:10-14:30	Pharmacovigilance activities in Indonesia Current Situation Ms. Siti Asfijah Abdoellah, S.Si, Apt, M.MedSc (BPOM)
14:30-14:50	Implementation of pharmacovigilance from manufacturer's perspective Ms. Evi Dwi Nofiarny, S.Si, Apt, M.Sc (PT. Dexa Medica)
14:50-15:20	Panel discussion Chair: Drs. H.G. Kakerissa, Apt (BPOM) Panelists: All speakers
15:20-15:35	Break
15:35-15:55	Bioequivalence evaluation in Japan Mr. Yu Sakamoto (Office of International Cooperation, PMDA)
15:55-16:55	Panel discussion with industry: Quality, safety, and efficacy in drug development Chair: Dr. Junko Sato (Office Director, Offfice of International Cooperation)
16:55-17:00	Closing • Dra. Nurma Hidayati, Apt, M.Epid (Deputy for Therapeutic Product and Narcotics, Psychotropic, and Addictive Subtance Control, BPOM) • Dr. Junko Sato (Office Director, Office of International Cooperation, PMDA)
End of Symposium	