3rd Malaysia - Japan Symposium on Pharmaceutical Regulatory System

DATE: 31st July 2025

Time	Item
8:30 - 9:00	**Networking Session**
9:00 - 9:10 (10 min)	**Opening Remarks / Keynote** • **Dr. Azuana Ramli,** Deputy Director General of Health (Pharmaceutical Services) (5min) • **Dr. Kondo Emiko,** Senior Executive Director, PMDA (5 min)
9:10 - 10:20 (70 min)	**Regulatory Review & Updates** • **Mdm. Rosliza Lajis,** Deputy Director of NPRA (20 min) • **Mr. OKUBO Takayuki,** Director, Office of International Regulatory Affairs, MHLW (20 min) • Q&A (30 min)
10:20 - 10:30	**Photo Session, 10 min**
10:30 – 10:50	**BREAK, 20 min**
10:50 - 12:00 (70 min)	**Session 1: Real World Data** <u>Chair</u> **Ms. ENDO Ayumi,** Office of Asia Training Center and International Cooperation (OAIC) <u>Topic & Speaker</u> 1. *Real-World Evidence for Pre-Market Approval : Malaysian Perspective* (20min) **Ms. Hu Suk Kwan**, New Drug Product Section, NPRA 2. *Utilization of Real World Data in Applications for Approval and its Expectations in Japan* (20min) **Ms. Matsuzaki Yu,** Office of Non-Clinical and Clinical Compliance I, PMDA

	Panel discussion and Q&A (30 min) Panelists 1. Ms. Hu Suk Kwan, New Drug Product Section, NPRA 2. Ms. Matsuzaki Yu, Office of Non-Clinical and Clinical Compliance I, PMDA 3. Ms. Soo Li Ping, Head of Regulatory Affairs, AstraZeneca Malaysia (PhAMA) 4. Mr. Takayuki Imaeda, Vice Chairperson, Drug Evaluation Committee, JPMA
12:00 - 13:10 (70 min)	**Session 2: Risk Management Plan (RMP)** Chair **Dr. Kitahara Jun,** Head of PMDA Asia Office Topic & Speaker *1. Post-registration Risk Management Plan: An insight into the Malaysia-Specific Annex (MSA)* (20min) **Dr. Vidhya Hariraj,** Pharmacovigilance Section, NPRA *2. Overview of Japanese Risk Management Plan* (20min) **Ms. Kobayashi Ayano,** Office of Pharmacovigilance II, PMDA Panel discussion and Q&A (30 min) Panelists 1. Dr. Vidhya Hariraj, Pharmacovigilance Section, NPRA 2. Ms. Kobayashi Ayano, Office of Pharmacovigilance II, PMDA 3. Dr. Evelyn Loh Yun Xi, Biologics Section, NPRA 4. Dr. Maeda Daisuke, Director Office of Pharmacovigilance II, PMDA 5. Dr. Matsumoto Jun, Coordination Director, Office of Asia Training Center and International Cooperation (OAIC)
13:10 - 14:10	**Lunch, 60 min**
14:10 - 15:20 (70 min)	**Session 3: Facilitated Registration Pathway** Chair

	Mdm. Rosliza Lajis, Deputy Director Centre of Product & Cosmetic Evaluation, NPRA <u>Topic & Speaker</u> 1. *Advancing Regulatory Efficiency: Updates on Malaysia's FRP Implementation* (20min) **Dr. Noraisyah Mohd Sani,** Head of New Drug Product Section, NPRA 2. *Utilization of Japanese review report for Malaysia's Facilitated Registration* (20min) **Mr. Shimizu Kaito,** Office of International Programs, PMDA Panel discussion and Q&A (30 min) <u>Panelists</u> 1. Dr. Noraisyah Mohd Sani, Head of New Drug Product Section, NPRA 2. Mr. Shimizu Kaito, Office of International Programs, PMDA 3. Ms. Long Siew Mei, Regulatory Affairs Director, Merck Sharp & Dohme Malaysia (PhAMA) 4. Ms. Ayaha Watanabe, Singapore & Malaysia Group Leader, Asian Division, International Affairs Committee, JPMA
15:20 - 15:40	**(BREAK, 20 min)**
15:40 - 16:50 (70 min)	**Session 4: Clinical Trial** <u>Chair</u> 1. **Dr. Khairulanwar Burhanuddin** Head of BE Centre & Ethics Committee Section, NPRA 2. **Dr. Kitahara Jun** Head of PMDA Asia Office <u>Topic & Speaker</u> 1. *From policy to practice : Implementing Clinical Trial Regulations in Malaysia (NPRA)* (20min) **Dr. Zaril Harza Zakaria,** Head of Investigational Product Evaluation and Safety Section, NPRA

	2. *Shaping Asia's Clinical Trial Landscape – Insights from the ATLAS Initiative and its Regulatory Collaborations* (20min) **Dr. Mitsumi Terada**, Section Head, Asian Partnerships Section, Department of International Clinical Development/ National Cancer Centre Hospital, Japan Panel discussion and Q&A (30 min) <u>Panelists</u> 3. Dr. Zaril Harza Zakaria, Head of Investigational Product Evaluation and Safety Section, NPRA 4. Dr. Mitsumi Terada, Section Head, Asian Partnerships Section, Department of International Clinical Development/ National Cancer Centre Hospital, Japan 5. Dr. Akhmal Yusof, CEO of Clinical Research Malaysia (CRM) 6. Dr. Kitahara Jun, Head of PMDA Asia Office
16:50 - 17:00 (10 min)	**Closing Remarks** • **Mr. OKUBO Takayuki,** Director, Office of International Regulatory Affairs, MHLW (5 min) • **Mdm. Rosliza Lajis,** Deputy Director of NPRA (5min)

As of 23rd July 2025