# 3rd Malaysia - Japan Symposium on Pharmaceutical Regulatory System

**DATE: 31st July 2025**

| Time | Item |
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| 8:30 - 9:00 | **Networking Session** |
| 9:00 - 9:10<br>(10 min) | **Opening Remarks / Keynote**<br>• **Dr. Azuana Ramli,** Deputy Director General of Health (Pharmaceutical Services) (5min)<br>• **Dr. Kondo Emiko,** Senior Executive Director, PMDA (5 min) |
| 9:10 - 10:20<br>(70 min) | **Regulatory Review & Updates**<br>• Director of NPRA (20 min)<br>• **Mr. OKUBO Takayuki,** Director, Office of International Regulatory Affairs, MHLW (20 min)<br>• Q&A (30 min) |
| 10:20 - 10:30 | **Photo Session (10 min)** |
| 10:30 - 11:40<br>(70 min) | **Session 1: Real World Data**<br><br><u>Chair</u><br>**Ms. ENDO Ayumi,** Office of Asia Training Center and International Cooperation (OAIC)<br><br><u>Topic & Speaker</u><br>1. *Current progress, opportunities and challenges in adopting Real World Data/Evidence for regulatory submissions in Malaysia* (20min)<br>**Ms. Hu Suk Kwan**, New Drug Product Section, NPRA<br><br>2. *Utilization of Real World Data in Applications for Approval and its Expectations in Japan* (20min)<br>**Ms. Matsuzaki Yu,** Office of Non-Clinical and Clinical Compliance I, PMDA<br><br>Panel discussion and Q&A (30 min)<br><u>Panelists</u><br>1. Ms. Hu Suk Kwan, New Drug Product Section, NPRA |

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| | 2. Ms. Matsuzaki Yu, Office of Non-Clinical and Clinical Compliance I, PMDA<br>3. Ms. Soo Li Ping, Head of Regulatory Affairs, AstraZeneca Malaysia (PhAMA)<br>4. Mr. Takayuki Imaeda, Vice Chairperson, Drug Evaluation Committee, JPMA |
| 11:40 - 12:00 | **BREAK, 20 min** |
| 12:00 - 13:10<br>(70 min) | **Session 2: Risk Management Plan (RMP)**<br><br><u>Chair</u><br>**Dr. Kitahara Jun,** Head of PMDA Asia Office<br><br><u>Topic & Speaker</u><br>*1. Post-registration Risk Management Plan: An insight into the Malaysia-Specific Annex (MSA)* (20min)<br>**Dr. Vidhya Hariraj,** Pharmacovigilance Section, NPRA<br><br>*2. Overview of Japanese Risk Management Plan* (20min)<br>**Ms. Kobayashi Ayano,** Office of Pharmacovigilance II, PMDA<br><br>Panel discussion and Q&A (30 min)<br><u>Panelists</u><br>1. Dr. Vidhya Hariraj, Pharmacovigilance Section, NPRA<br>2. Ms. Kobayashi Ayano, Office of Pharmacovigilance II, PMDA<br>3. Dr. Evelyn Loh Yun Xi, Biologics Section, NPRA<br>4. Dr. Maeda Daisuke, Director Office of Pharmacovigilance II, PMDA<br>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<br>(70 min) | **Session 3: Facilitated Registration Pathway**<br><br><u>Chair</u><br>**Mdm. Rosliza Lajis,** |

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| | Deputy Director Centre of Product & Cosmetic Evaluation, NPRA<br><br><u>Topic & Speaker</u><br>1. *Updates on the implementation of Malaysia's FRP, highlighting key achievements and challenges* (20min)<br>**Dr. Noraisyah Mohd Sani,** Head of New Drug Product Section, NPRA<br><br>2. *Utilization of Japanese review report for Malaysia's Facilitated Registration* (20min)<br>**Mr. Shimizu Kaito,** Office of International Programs, PMDA<br><br>Panel discussion and Q&A (30 min)<br><u>Panelists</u><br>1. Dr. Noraisyah Mohd Sani, Head of New Drug Product Section, NPRA<br>2. Mr. Shimizu Kaito, Office of International Programs, PMDA<br>3. Ms. Long Siew Mei, Regulatory Affairs Director, Merck Sharp & Dohme Malaysia (PhAMA)<br>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<br>(70 min) | **Session 4: Clinical Trial**<br><br><u>Chair</u><br>**Dr. Khairulanwar Burhanuddin**<br>Head of BE Centre & Ethics Committee Section, NPRA<br><br><u>Topic & Speaker</u><br>1. *From policy to practice : Implementing Clinical Trial Regulations in Malaysia (NPRA)* (20min)<br>**Dr. Zaril Harza Zakaria,** Head of Investigational Product Evaluation and Safety Section, NPRA<br><br>2. *Recent NCC efforts to promote clinical trials in Asian region – ATLAS* (20min) |

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| | **Dr. Mitsumi Terada**, Section Head, Asian Partnerships Section, Department of International Clinical Development/ National Cancer Centre Hospital, Japan<br><br>Panel discussion and Q&A (30 min)<br><u>Panelists</u><br>1. Dr. Zaril Harza Zakaria, Head of Investigational Product Evaluation and Safety Section, NPRA<br>2. Dr. Mitsumi Terada, Section Head, Asian Partnerships Section, Department of International Clinical Development/ National Cancer Centre Hospital, Japan<br>3. Dr. Akhmal Yusof, CEO of Clinical Research Malaysia (CRM)<br>4. Dr. Kitahara Jun, Head of PMDA Asia Office |
| 16:50 - 17:00<br>(10 min) | **Closing Remarks**<br>• Director of NPRA (5min)<br>• **Mr. OKUBO Takayuki,** Director, Office of International Regulatory Affairs, MHLW (5 min) |

As of 20th June 2025