1st Malaysia – Japan Symposium on Pharmaceutical Regulatory System

Day 1 (10 March 2015)	
8:30-9:00	Registration of Participants **Symposium Narration: (NPCB)**
9:00-10:00	**Welcoming Remarks/Officiating Speech** ➢ ***YBhg. Dato' Eisah* A. Rahman** Senior Director of Pharmaceutical Services, Ministry of Health, Malaysia (20 min) **Updates/Keynote** ➢ NPCB ➢ "Role and Vision of PMDA -Promoting Global Public Health-" Taisuke Hojo, Senior Executive Director, PMDA (20 min) PHOTO SESSION (10 min)
10:00-10:30	**Morning Break**
10:30-12:30	**Session 1: Regulatory Review & Updates** Chair: (NPCB) ➢ "Japan regulatory system for pharmaceutical products and Active Pharmaceutical Ingredients "(tentative) Hiroaki Yamada, Office Director, Office of New Drug II, PMDA ➢ "Malaysia regulatory system for pharmaceutical products" (NPCB) **Discussion**
12:30-14:00	**Lunch**

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14:00-16:00	**Session 2: Guidelines & References** Chair: Teruyoshi Ehara, Office Director, Office of Int'l Programs, PMDA ➢ "MS 2424:2012 - Halal pharmaceuticals: General guidelines" (NPCB) ➢ "Malaysia herbal monograph" (NPCB) ➢ "Japanese Pharmacopoeia" (tentative) Seiko Miyazaki, Office Director, Office of Standards and Guidelines Development, PMDA
	Discussion
16:00-17:30	**Afternoon Break & Networking Session**
	End of Day 1

Day 2 (11 March 2015)	
9:00-10:15	**Session 3: NPCB Sessions** Chair: (NPCB) ➢ "Regulatory control for herbal/traditional medicines and health supplements" (NPCB) ➢ "Regulatory control for generics" (NPCB)
	Discussion
10:15-10:45	**Morning Break**
10:45-12:00	**Session 4: PMDA Sessions** Chair: Daisuke Koga, Deputy Director for Medical Devices, Office of Int'l Programs, PMDA ➢ "GMP Inspection (Risk Based Assessment & Product Recall)" (tentative)

Day 2 (11 March 2015)	
	Kentaro Hara, Principal Inspector, Office of Manufacturing/Quality and Compliance, PMDA ➢ "Regulatory framework for biotherapeutic products including similar biotherapeutic products" Yasuhiro Kishioka, Principal Reviewer, Office of Cellular and Tissue-based Products PMDA
	Discussion
12:00-12:30	**Closing Remarks** ➢ Teruyoshi Ehara, Office Director, Office of Int'l Programs, PMDA ***End of Symposium***
12:30-14:00	**Lunch**