

PMDA-ATC MRCT Seminar 2017

Offered by Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)

Date: January 23-26, 2017 Venue: PMDA Meeting rooms #21-25 (14th floor)

	Day 1 Jan 23 (Mon)	Day 2 Jan 24 (Tue)	Day 3 Jan 25 (Wed)	Day 4 Jan 26 (Thu)
AM (1)	9:00 - 9:20 Opening Ceremony			
	9:20 - 9:50 Key Note Speech (1): Regulatory Science and Global Cooperation			
	9:50 - 10:00 Message from JPMA President: Expectation for Regulatory Authorities in Globalization Era	9:00 - 10:30 Session 2: Considerations for MRCT Operations	9:00 - 10:15 Session 4: International Cooperation and Alignment	9:00 - 10:20 Session 6: Post-market Safety Evaluation of Approved Drugs Based on MRCT
	10:00 - 10:30 Key Note Speech (2): Strategies and Challenges for Drug Development - Future Movements and Backgrounds of Development Strategies -			
Break				
AM (2)	11:00 - 11:30 History of Drug Evaluation Using Overseas Data in Japan	11:00 - 12:30 Session 2 Case Study (group discussion)	10:30 - 11:30 Session 4 Panel Discussion	10:45 - 12:15 Session 6 Case Study (group discussion)
	11:30 - 12:00 Scientific Insights about Ethnic Factors			12:15 - 12:40 Overall Discussion, Closing Ceremony
Lunch				
PM (1)	13:30 - 15:00 Session 1: Points to Consider When Planning and Designing MRCT (when consulting about clinical trials)	14:00 - 15:30 Session 3: Points to Consider When Evaluating Results (Evaluation overall population in efficacy and safety and consistency evaluation)	13:00 - 14:30 Session 5: GCP Inspection of Global Study	13:30 - 17:30 APEC-LSIF-RHSC MRCT/GCP Inspection Workshop
Break				
PM (2)	15:30 - 17:30 Session 1 Case Study (group discussion)	16:00 - 18:00 Session 3 Case Study (group discussion)	15:00 - 17:00 Session 5 Case Study (group discussion)	Venue: The Hall at Zen-Nittsu Kasumigaseki Building 8F
			17:00 - 17:30 PMDA Tour	
	18:00 - Friendly Get Together			