

PMDA-ATC Pharmacovigilance Seminar 2019

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

Date: February 4 - 7, 2019 Venue: PMDA Meeting rooms #21-23 (14th floor)

	Day 1 February 4 (Mon)	Day 2 February 5 (Tue)	Day 3 February 6 (Wed)	Day 4 February 7 (Thu)
AM	9:15-10:00 Registration	9:50-10:00 Opening	9:50-10:00 Opening	9:50-10:00 Opening
	10:00 - 10:15 Opening Ceremony, Overview of the Seminar	10:00 - 11:00 (5) Pharmacovigilance in the US	10:00 - 11:15 (9) Pharmacovigilance and Pharmacoepidemiology	10:00 - 12:00 (13) Group Work:RMP (Risk Minimization Activity) (2) - How to Create RMP – Planning Risk Minimization Activity
	10:15 - 10:55 (1) Overview of Pharmacovigilance			
	1055 - 11:10 Break	11:00 - 11:15 Break	11:15-11:30 Break	
	11:10 - 12:25 (2) Pharmacovigilance in the US, Europe and Japan and International Cooperation	11:15 - 12:15 (6) Safety Specification & Pharmacovigilance Plan	11:30 - 12:40 (10) Pharmacoepidemiology - The New Tool for Drug Safety Assessment in PMDA -	
	(1 hour 15 min. Starting time varies.)			
PM	13:40 - 16:10 (3) End-to-End Labeling Process - Labeling Regulations, Asia including Japan, US and EU - Labeling system and Company Core Data Sheet - Labeling regulating system in Japan vs US vs EU - e-Labeling	13:30 - 14:30 (7) Risk Management Plan - Practice at Industry and Regulatory	13:55 - 14:25 (11) Evaluation of Benefit/Risk Balance throughout Product Lifecycle	13:15 - 14:15 (14) Communication of Safety Risk Information to Patients and Healthcare Professionals
	16:10 - 16:20 Break	14:30 - 14:40 Break	14:25-15:40 (12) Group Work:RMP (Risk Minimization Activity) (1) - How to Create RMP – Planning Risk Minimization Activity	14:15 - 14:35 (15) Pharmacovigilance in Japan - Possible utilization of RMP for patient safety–
	16:20 - 18:00 (4) Introduction of Pharmacovigilance in Each Country/Region	14:40 - 17:40 (8) Group Work: RMP (Safety Specification) - How to create RMP – Identification of Safety Specifications		14:35 - 14:50 Break
				14:50 - 15:50 (16) Relief System for Adverse Drug Reactions
				15:50 - 16:00 Break
	18:00 - 18:15 Closing	17:40 - 17:55 Closing	15:40 - 15:55 Closing	16:00 - 16:30 Closing Ceremony
	18:15 - Friendly Get Together			