Draft PMDA-ATC Pharmacovigilance Seminar 2020

Offered by Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)
Date: February 3 - 6, 2020　　Venue: PMDA Meeting rooms #21-23 (14th floor)

	Day 1 February 3 (Mon)	Day 2 February 4 (Tue)	Day 3 February 5 (Wed)	Day 4 February 6 (Thu)
AM	9:15-9:45 Registration	9:10-9:20 Opening	9:20-9:30 Opening	9:20-9:30 Opening
	9:45 - 10:00 Opening Ceremony, Overview of the Seminar	9:20 - 12:10 (5) Risk minimization measures: Labeling management - End-to-End Labeling process: CCDS/CCSI Labeling system, Management of Labeling in Asia, electronic labeling initiatives - Management of USPI and Medication guide - Management of EUSmPC and package leaflet - Management of Japan Package Insert, patient medication guide	9:30-10:30 (8)Evaluation of Benefit/Risk Balance throughout Product Lifecycle, Assessment of effectiveness of risk minimization activities	9:30-10:45 (11) Pharmacovigilance and Pharmacoepidemiology
	10:00 - 10:45 (1) Outline of PMDA		10:30-10:40 Break	10:45-11:00 Break
	10:45 - 12:15 (2) Comparison of Pharmacovigilance systems among the US, Europe and Japan and International Cooperation		10:40-11:40 (9) Communication of Safety Risk Information to Patients and Healthcare Professioals involvement	11:00 - 12:00 (12) Pharmacoepidemiology - The New Tool for Drug Safety Assessment in PMDA -
Lunch	**(1 hour 30min. Starting time varies.)**			
PM	13:45 - 14:45 (3) Pharmacovigilance in the US	13:40 - 15:10 (6) Risk Management Plan - Practice at Industry and Regulatory ・Overview (PMDA) ・Industory ・Regulatory	13:10 - 16:30 (10) Group Work:RMP (Risk Minimization Activity) - How to Create RMP – Planning Risk Minimization Activity	13:30 - 14:40 (13) Healthcare Professionals involvement ・ADR reporting by Healthcare Professionals ・The use of safety information by Healthcare Professionals
	14:45 - 15:00 Break	15:10 - 15:25 Break		14:40 - 14:50 Break
	15:00 - 17:15 (4) Introduction of Pharmacovigilance in Each Country/Region	15:25 - 17:45 (7) Group Work: RMP (Safety Specification) - How to create RMP – Identification of Safety Specifications		14:50 - 15:50 (14) Relief System for Adverse Drug Reactions
				15:50 - 16:00 Break
			16:30 - 16:45 Closing	16:00 - 16:30 Closing Ceremony
	17:15 - 17:30 Closing	17:45 - 18:00 Closing		
	17:30 - Friendly Get Together			