PMDA-ATC Pharmacovigilance Seminar 2017

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

Date: February 6 - 9, 2017　　Venue: PMDA Meeting rooms #21-25 (14th floor)

	Day 1 February 6 (Mon)	Day 2 February 7 (Tue)	Day 3 February 8 (Wed)	Day 4 February 9 (Thu)
AM	10:00 - 10:15 Opening Remarks, Oberview of the Seminar	10:00 - 11:30 (6) Pharmacovigilance Method (Passive Surveillance (AE assessment, ICSR, Reporting system etc.), Stimulated Reporting, Active Surveillance (Utilization Study, All case Surveillance, registry etc.) etc.)	10:00 - 12:00 (9) Workshop: Risk Management Plan	10:00 - 11:00 (11) Global Data Collection (Industry/Utilization of Foreign Data)
	10:15 - 11:15 (1) Overview of Pharmacovigilance (Basic of PhV, ICH, CIOMS etc.)			11:00 - 12:00 (12) New Challenge on Pharmacovigilance in Japan ・MID-NET, Clinical Innovation Network ・Study design of Post-Marketing Data Collection
	11:15 - 12:15 (2) Pharmacovigilance regulatory systems in each region (EU, US, Japan etc.)	11:30 - 12:30 (7) Safety Specification/Pharmacovigilance Plan		
Lunch				
PM	13:30 - 15:30 (3) Regulation on Labeling in Asia/EU/US	13:45 - 16:30 (8) Workshop: Safety Specification	13:15 - 15:15 (9) Workshop: Risk Management Plan (continued)	13:15 - 13:55 (13) Benefit-Risk Assessment through Product Lifecycle
				13:55 - 14:15 (14) Future Direction on Pharmacovigilance
				14:15 - 14:30 Break
				14:30 - 15:30 (15) Risk Communication For Patients and
	15:30 - 15:45 Break		15:15 - 17:15 (10) Risk Management Plan (Regulator's/Industry's View Point)	15:30 - 16:30 (16) Relief Services for Adverse Health Effects
	15:45 - 16:45 (4) Introduction of Pharmacovigilance in Each Countries/Regions (Each Trainee)			
	16:45 - 17:45 (5) Global Data Collection (Industry/Utilization of Foreign Data)			16:30 - 16:45 Wrap Up
	17:45 - 18:00 Wrap Up	16:30 - 16:45 Wrap Up	17:15 - 17:30 Wrap Up	16:45 - 16:55 Closing Remarks
	18:00 - Friendly Get Together			