PMDA-ATC Pharmacovigilance Seminar 2019

Offered by Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

DATE: February 4-7, 2019. VENUE: PMDA Meeting Room #21-23 on 14th floor

Day 1 (February 4, 2019)

Time	Session
10:00 - 10:05	Opening Remarks
10:05 - 10:15	Overview of the Seminar etc.
10:15 - 10:55	1. Overview of Pharmacovigilance ➢ Purposes and significance of pharmacovigilance
10:55 - 11:10	Break
11:10 - 12:25	2. Pharmacovigilance in Japan, Europe, and the US ➢ Differences & similarities in key pharmacovigilance activities, and Safety reports harmonized by ICH and CIOMS
12:25 - 13:40	Lunch
13:40-16:10	3. Regulation on Labeling in Asia, Europe, and the US ➢ Labeling system and Company Core Data Sheet ➢ Labeling Regulatory System in Japan, Europe and the US ➢ e-Labeling
16:10-16:20	Break
16:20-18:00	4. Introduction of Pharmacovigilance in Each Country/Region ➢ Pharmacovigilance organization and regulation, labeling for HCPs/patients, and distribution system
18:00 – 18:15	Closing
18:15 -	Friendly Get Together

Day 2 (February 5, 2019)

Time	Session
10:00 - 11:00	5. US Pharmacovigilance Update ➢ The latest information on pharmacovigilance in the US
11:00 - 11:15	Break
11:15 - 12:15	6. Outline of Risk Management Plan ➢ Overview of risk management plan, e.g., purposes and concept
12:15 - 13:30	Lunch
13:30 - 14:30	7. Risk Management Plan – Practice at Industry and Regulatory ➢ Production and usage by Industry and Regulatory
14:30 - 14:40	Break
14:40 - 17:40	8. Group Work: RMP(Safety Specification) ➢ How to create RMP – Identification of Safety Specifications
17:40 - 17:55	Closing

Day 3 (February 6, 2019)

Time	Session
10:00 - 11:15	9. Pharmacovigilance and Pharmacoepidemiology ➢ Passive surveillance (Spontaneous reports system), Stimulated reporting, and Active surveillance (Post-marketing studies and registry)
11:15 - 11:30	Break
11:30 - 12:40	10. Pharmacoepidemiology – The New Tool for Drug Safety Assessment in PMDA ➢ MID-NET and Clinical Innovation Network, and Pharmacoepidemiological study design using database
12:40 - 13:55	Lunch
13:55 - 14:25	11. Benefit-Risk Assessment through Product Lifecycle ➢ Benefit-risk balance, and Effort for standardization of judgment, e.g., U.S. Framework
14:25 - 15:40	12. Group Work: RMP（Risk Minimization Activity） (1) ➢ How to create RMP – Planning Risk Minimization Activity
15:40 - 15:55	Closing

Day 4 (February 7, 2019)

Time	Session
10:00 - 12:00	13. Group Work: RMP（Risk Minimization Activity） (2) ➢ How to create RMP – Planning Risk Minimization Activity
12:00 - 13:15	Lunch
13:15 - 14:15	14. Risk Communication of Safety Information with Patients and Healthcare Professionals ➢ Goal, methods and tools of risk communication
14:15 - 14:35	15. Pharmacovigilance in Japan – Synergistic Collaboration in Risk Communication – ➢ Understanding and operation of risk communications at medical institutions
14:35 - 14:50	Break
14:50 - 15:50	16. Relief Services for Adverse Health Effects in Japan ➢ Relief services and operation
15:50 - 16:00	Break
16:00 - 16:30	Closing Ceremony