

PMDA-ATC Pharmacovigilance Seminar 2018

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

Date: February 5-8, 2018 Venue: PMDA Meeting Room #1-5 on 6th floor

Day 1 (February 5, 2017)

Time	Session
10:00 - 10:05	Opening
10:05 - 10:15	Overview of the Seminar etc.
10:15 - 11:15	1. Overview of Pharmacovigilance
11:15 - 12:15	2. Pharmacovigilance in Japan, Europe, and the US
12:15 - 13:30	Lunch
13:30 - 15:30	3. Regulation on Labeling in Asia/EU/US <ul style="list-style-type: none"> ➤ Labeling Regulatory System in Japan vs US vs EU ➤ Drug-Drug Interaction
15:30 - 15:45	Break
15:45 - 16:45	4. REMS/ETASU
16:45 - 18:00	5. Introduction of Pharmacovigilance in Each Countries/Regions (Each Trainee)
18:00 - 18:15	Closing
18:15 -	Friendly Get Together

Day 2 (February 6, 2017)

Time	Session
9:50 - 10:00	Q&A on Day1 sessions
10:00 - 11:00	6. Safety Specification and Pharmacovigilance Plan
11:00 - 12:00	7. Risk Management Plan (RMPs) from Industry Perspective
12:00 - 13:15	Lunch
13:15 - 16:00	8. Workshop: Identification of Safety Specification <ul style="list-style-type: none"> ➤ How to identify risk based on available data?
16:00 - 16:15	Closing

Day 3 (February 7, 2017)

Time	Session
9:50-10:00	Q&A on Day2 sessions
10:00 - 12:00	9. Workshop: Risk Management Plan ➤ How to create appropriate RMP?
12:00 - 13:15	Lunch
13:15 - 15:15	10. Workshop: Risk Management Plan (continued)
15:15-15:45	11. Feedback on the Group work & RMP (Regulator's View Point)
15:45 – 16:00	Break
16:00 - 17:00	12. International Safety Data Collection
17:00 - 17:15	Closing

Day 4 (February 8, 2017)

Time	Session
9:50 – 10:00	Q&A on Day3 sessions
10:00 - 11:15	13. Pharmacovigilance and Pharmacoepidemiology
11:15 - 12:15	14. Pharmacoepidemiology - The New Tool for Drug Safety Assessment - in PMDA
12:15 - 13:30	Lunch
13:30 – 14:10	15. Benefit-Risk Assessment through Product Lifecycle
14:10 - 15:10	16. Risk Communication of Safety Information with Patients and Healthcare Professionals
15:10 – 15:25	Break
15:25 – 15:45	17. Future Direction on Pharmacovigilance in Japan - Urgent Need Synergistic Collaboration -
15:45 - 16:45	18. Relief System for Adverse Health Effects in Japan
16:45 – 17:10	Closing Ceremony