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

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| 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 | | | 1. Pharmacovigilance in Japan, Europe, and the US | | | |
| 12:15 - 13:30 | | | Lunch | | | |
| 13:30 - 15:30 | | | 1. Regulation on Labeling in Asia/EU/US  * Labeling Regulatory System in Japan vs US vs EU * Drug-Drug Interaction | | | |
| 15:30 - 15:45 | | | Break | | | |
| 15:45 – 16:45 | | | 1. REMS/ETASU | | | |
| 16:45 – 18:00 | | | 1. 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 | | | 1. Safety Specification and Pharmacovigilance Plan | |
| 11:00 - 12:00 | | | 1. Risk Management Plan (RMPs) from Industry Perspective | |
| 12:00 - 13:15 | | | Lunch | |
| 13:15 - 16:00 | | | 1. Workshop: Identification of Safety Specification  * 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 | | | 1. Workshop: Risk Management Plan  * How to create appropriate RMP? | |
| 12:00 - 13:15 | | | Lunch | |
| 13:15 - 15:15 | | | 1. Workshop: Risk Management Plan (continued) | |
| 15:15-15:45 | | | 1. Feedback on the Group work & RMP (Regulator’s View Point) | |
| 15:45 – 16:00 | | | Break | |
| 16:00 - 17:00 | | | 1. 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 | | | 1. Pharmacovigilance and Pharmacoepidemiology | | |
| 11:15 - 12:15 | | | 1. Pharmacoepidemiology - The New Tool for Drug Safety Assessment - in PMDA | | |
| 12:15 - 13:30 | | | Lunch | | |
| 13:30 – 14:10 | | | 1. Benefit-Risk Assessment through Product Lifecycle | | |
| 14:10 - 15:10 | | | 1. Risk Communication of Safety Information with Patients and Healthcare Professionals | | |
| 15:10 – 15:25 | | | Break | | |
| 15:25 – 15:45 | | | 1. Future Direction on Pharmacovigilance in Japan - Urgent Need Synergistic Collaboration - | | |
| 15:45 - 16:45 | | | 1. Relief System for Adverse Health Effects in Japan | | |
| 16:45 – 17:10 | | | Closing Ceremony | | |