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
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| 11:15 - 12:15 | 1. Pharmacovigilance in Japan, Europe, and the US
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| 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
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| 16:45 – 18:00 | 1. Introduction of Pharmacovigilance in Each Countries/Regions (Each Trainee)
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| 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
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| 11:00 - 12:00 | 1. Risk Management Plan (RMPs) from Industry Perspective
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| 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)
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| 15:15-15:45 | 1. Feedback on the Group work & RMP (Regulator’s View Point)
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| 15:45 – 16:00 | Break |
| 16:00 - 17:00 | 1. International Safety Data Collection
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| 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
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| 11:15 - 12:15 | 1. Pharmacoepidemiology - The New Tool for Drug Safety Assessment - in PMDA
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| 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
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| 16:45 – 17:10 | Closing Ceremony |