PMDA-ATC Pharmacovigilance Seminar 2025

Agenda
Date: February 26 - 28, 2025
Venue: Vision Center Tokyo Toranomon, Tokyo, Japan

(JST)

As of February 21, 2025

Day 1 Wednesday, Feb. 26	Day 2 Thursday, Feb. 27	Day 3 Friday, Feb. 28
9:30-10:00 Registration	9:00-9:30 Registration	9:00-9:30 Registration
10:00-10:20 **Opening Ceremony**	9:30-12:20 **Session 6 (Group Work 1)** **ADR Case Evaluation/Identification of safety specification**	9:30-12:10 **Session 10 (Group Work 2)** **Risk Management Plan**
10:20-11:10 **Session 1** **Overview of post-marketing drug safety in Japan**		
11:10-12:00 **Session 2** **Outline of RMP**		
12:00-13:00 **Lunch time**	12:20-13:40 **Lunch time**	12:10-13:30 **Lunch time**
13:00-13:50 **Session 3** **Country Introduction**	13:40-14:30 **Session 7** **Communication of Safety Risk Information to Patients and Healthcare Professionals**	13:30-15:00 **Session 11 (Case study)** **Pharmacovigilance Methods (signal detection)**
13:50-14:20 **Introduction of Case studies**		
14:20-15:15 **Session 4** **4-1. Development and update of RMP** **4-2. Evaluation of RMP** **Q&A for 4-1 and 4-2**	14:30-15:10 **Session 8** **End-to-end Labeling including CCDS Labeling Principles, electronic Labeling initiatives, patient centric labeling/health literacy**	15:00-15:50 **Session 12** **Utilization of Real world Data for post-marketing drug safety in PMDA**
15:15-15:30 **Break**	15:10-15:25 **Break**	15:50-16:00 **Break**
15:30-16:20 **Session 5** **Overview of post-marketing drug safety, RMP in EU**	15:25-16:15 **Session 9** **Use of published safety information at clinical site**	16:00-16:10 **Closing Ceremony**
16:20-16:30 **Feedback for Day 1**	16:20-16:30 **Feedback for Day 2**	16:10-16:20 **Feedback for Day 3**
16:45-18:00 **Friendly Get Together**		

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