

APEC Center of Excellence Workshop

PMDA-ATC Pharmacovigilance Seminar 2026

Agenda

Dates: February 25 - 27, 2026 Venue: Tokyo

as of 2025.12.25

(JST)

Day 1 Wednesday, Feb. 25	Day 2 Thursday, Feb. 26	Day 3 Friday, Feb. 27
9:30 - 10:00 Registration	9:00 - 9:30 Registration	9:00 - 9:30 Registration
10:00-10:20 Opening Ceremony	9:30-10:20 Session 6 Signal detection and use of AI in pharmacovigilance	9:30-10:20 Session 11 Communication of Safety Risk Information to Patients and Healthcare Professionals
10:20 - 11:10 Session 1 Overview of post-marketing drug safety in Japan	10:20-12:00 Session 7 (Group Work 1) ADR Case Evaluation/Identification of safety specification - Introduction - Group Discussion	10:20-11:10 Session 12 Use of published safety information at clinical site
11:10-12:00 Session 2 Outline of RMP in Japan		11:10-11:20 Break
12:00-12:20 Introduction of Case studies		11:20-11:40 Session 13 (Group Work 2) Risk Management Plan - Introduction
12:20-13:20 Lunch time	12:00-13:00 Lunch time	11:40-12:40 Lunch time
13:20 - 14:10 Session 3 Development and update of RMP	13:00-14:00 - Group Presentation - Q&A / Wrap up	12:40-14:50 - Group Discussion - Group Presentation - Q&A / Wrap up
14:10 - 15:50 Session 4 (Round Table Discussion) Country introduction	14:00-14:50 Session 8 End-to-end Labeling including CCDS Labeling Principles, electronic Labeling initiatives, patient centric labeling/health literacy	
	14:50-15:00 Break	14:50-15:00 Break
	15:00-15:50 Session 9 GVP in Japan	15:00-15:50 Session 14 Pharmacovigilance Methods
15:50-16:40 Session 5 Overview of post-marketing drug safety including REMS in US	15:50-16:40 Session 10 Global PV initiatives	15:50-16:40 Session 15 Utilization of Real world Data for post-marketing drug safety in PMDA
		16:40-16:50 Break
16:40 - 16:50 Feedback for Day 1	16:40 - 16:50 Feedback for Day 2	16:50 - 17:00 Closing Ceremony
17:15 - 18:30 Friendly Get Together		17:00 - 17:10 Feedback for Day 3