# APEC Center of Excellence Workshop
# PMDA-ATC Pharmacovigilance Seminar 2026

## Agenda

**Dates: February 25 - 27, 2026** **Venue: Tokyo**

(JST) as of 2025.9.4

| Day 1<br>Wednesday, Feb. 25 | Day 2<br>Thursday, Feb. 26 | Day 3<br>Friday, Feb. 27 |
|---|---|---|
| 9:30 - 10:00<br>Registration | 9:00 - 9:30<br>Registration | 9:00 - 9:30<br>Registration |
| 10:00-10:20<br>**Opening Ceremony** | 9:30-12:20<br>**Session 6 (Group Work 1)**<br>**ADR Case Evaluation/Identification of safety specification**<br>- Introduction<br>- Group Discussion<br>- Break<br>- Group Presentation<br>- Q&A / Wrap up | 9:30-10:20<br>**Session 11**<br>**Overview of post-marketing drug safety, REMS in US** |
| 10:20 - 11:10<br>**Session 1**<br>**Overview of post-marketing drug safety in Japan** | | 10:20-10:30 Break |
| 11:10-12:00<br>**Session 2**<br>**Outline of RMP in Japan** | | 10:30-12:00<br>**Session 12 (Group Work 2)**<br>**Risk Management Plan**<br>- Introduction<br>- Group Discussion |
| 12:00-13:00 Lunch time | 12:20-13:20 Lunch time | 12:00-13:00 Lunch time |
| 13:00 - 13:50<br>**Session 3**<br>**Development and update of RMP** | 13:20-14:10<br>**Session 7**<br>**Communication of Safety Risk Information to Patients and Healthcare Professionals** | - Group Presentation<br>- Q&A / Wrap up |
| | | 14:00-14:10 Break |
| 13:50 - 15:30<br>**Session 4**<br>**Country introduction** | 14:10-15:00<br>**Session 8**<br>**End-to-end Labeling including CCDS Labeling Principles, electronic Labeling initiatives, patient centric labeling/health literacy** | 14:10-15:00<br>**Session 13**<br>**GVP in Japan** |
| | 15:00-15:10 Break | 15:00-15:50<br>**Session 14**<br>**Pharmacovigilance Methods** |
| | 15:10-16:00<br>**Session 9**<br>**Use of published safety information at clinical site** | |
| 15:30-16:20<br>**Session 5**<br>**Overview of post-marketing drug safety, RMP in EU** | 16:00-16:50<br>**Session 10**<br>**Global PV initiatives** | 15:50-16:40<br>**Session 15**<br>**Utilization of Real world Data for post-marketing drug safety in PMDA** |
| | | 16:40-16:50 Break |
| 16:20 - 16:30<br>Feedback for Day 1 | 16:50 - 17:00<br>Feedback for Day 2 | 16:50 - 17:00<br>**Closing Ceremony** |
| 16:45 - 18:00<br>Friendly Get Together | | 17:00 - 17:10<br>Feedback for Day 3 |