

# PMDA-ATC Pharmaceuticals Review Seminar 2024

## for PPWG member states

### Agenda

Date: June 11 - 14, 2024 Venue: Tokyo (PMDA office)

(JST)

As of March 25, 2024

Day 1 Tuesday, June 11	Day 2 Wednesday, June 12	Day 3 Thursday, June 13	Day 4 Friday, June 14
		9:00-9:30 <b>Registration</b>	9:00-9:30 <b>Registration</b>
9:30-10:00 <b>Registration</b>	9:30-10:00 <b>Registration</b>	9:30-11:10 <b>Case study 2: Toxicology part</b> <b>Toxicology data evaluation of the product</b> - Introduction (20m) - Group Discussion(30m) - Group presentation (20m) - Q&A, Wrap up (30m)	9:30-12:00 <b>Case study 5: Clinical part 1</b> <b>Efficacy and safety data evaluation of the product</b> - Introduction (45m)
10:00-10:20 <b>Opening Ceremony</b>	10:00-11:00 <b>Session 4</b> <b>Structure and content of PMDA review report</b>		
10:20-11:10 <b>Session 1</b> <b>Overview of new drug review in Japan</b> - Regulations, review process, review system			
Break (10m)	Break (10m)	Break (10m)	Break (15m)
11:20-12:30 <b>Session 2</b> <b>Points to consider in evaluation of new drug</b>	11:10-11:50 <b>Session 5</b> <b>Structure and content of PMDA Risk Management Plan (RMP)</b>	11:20-12:10 <b>Case study 3: Pharmacology part</b> <b>Pharmacology data evaluation of the product</b> - Introduction (20m) - Group Discussion(30m)	- Group Discussion(90m)
	11:50-12:20 (30m) <b>Introduction of case studies</b>		
12:30-14:00 <b>Lunch break</b>	12:20-14:00 <b>Lunch break</b>	12:10-13:30 <b>Lunch break</b>	12:00-13:30 <b>Lunch break</b>
14:00-16:00 <b>Session 3 (Participants)</b> <b>Round table discussion on review issues in ASEAN JA and national assessment</b>	14:00-16:40 <b>Case study 1: quality part</b> <b>Quality data evaluation of the product</b> - Introduction (30m) - Group Discussion(60m)	13:30-14:20 <b>Case study 3: Pharmacology part</b> - Group presentation (20m) - Q&A, Wrap up (30m)	13:30-15:30 <b>Case study 5: Clinical part 2</b> - Group presentation (80m) - Q&A, Wrap up (40m)
	Break (10m) - Group presentation (30m) - Q&A, Wrap up (30m)	Break (10m)	Break (10m)
		14:30-17:10 <b>Case study 4: ADME part</b> <b>ADME data evaluation of the product</b> - Introduction (30m) - Group Discussion(60m) - Group presentation (30m) - Q&A, Wrap up (40m)	15:40-15:50 <b>Closing ceremony</b>
16:00-16:10 <b>Evaluation for Day 1</b>	16:40-16:50 <b>Evaluation for Day 2</b>	17:10-17:20 <b>Evaluation for Day 3</b>	15:50-16:00 <b>Evaluation for Day 4 &amp; Overall</b>
16:30-18:00 <b>Get together</b>			