

ACCSQ PPWG - PMDA-ATC Pharmaceutical Review Seminar 2025

Agenda Dates: October 7 - 10, 2025 Venue: Tokyo

(JST)

as of 11 June 2025

Day 1 Tuesday, October 7	Day 2 Wednesday, October 8	Day 3 Thursday, October 9	Day 4 Friday, October 10
	9:00-9:30 Registration	9:00-9:30 Registration	9:00-9:30 Registration
9:30-10:00 Registration	9:30-10:00 <u>Guidance for case studies</u>	9:30-10:20 <u>Session 4</u> Structure of Risk Management Plan (RMP)	9:30-11:50 <u>Case study 5: Clinical part 1</u> Efficacy and safety data evaluation of the product
10:00-10:20 Opening Ceremony			- Introduction - Group Discussion
10:20-11:10 <u>Session 1</u> Overview of new drug review in Japan - Regulations, review process, review system	10:00-12:50 <u>Case study 1: Quality part</u> - Introduction - Group discussion 1 - Group discussion 2 - Group presentations - Q&A, Wrap up	10:20-11:50 <u>Case study 3: Toxicology part</u> Toxicology data evaluation of the product - Introduction - Group Discussion	
11:10-12:00 <u>Session 2</u> Points to consider in evaluation of new drugs		11:50-13:00 Lunch break	11:50-13:00 Lunch break
12:00-13:10 Lunch break	12:50-14:00 Lunch break	13:00-14:10 <u>Case study 3 (cont'd)</u> - Group presentations - Q&A, Wrap up	13:00-15:00 <u>Case study 5: Clinical part 2</u> - Group presentations - Q&A, Wrap up
13:10-14:00 <u>Session 3</u> Structure of PMDA Review Report	14:00-16:50 <u>Case study 2: Pharmacology part</u> - Introduction - Group Discussion	14:10-17:00 <u>Case study 4: ADME part</u> ADME data evaluation of the product - Introduction - Group Discussion	
Break	Break	Break	Break
14:10-16:20 <u>Session 4 (Participants)</u> Round table discussion on review issues in ASEAN JA and national assessment	<u>Case study 2 (cont'd)</u> - Group presentations - Q&A, Wrap up	- Group presentations - Q&A, Wrap up	15:10-15:20 Closing ceremony
16:20-16:30 Feedback - Day 1	16:50-17:00 Feedback - Day 2	17:00-17:10 Feedback - Day 3	15:20-15:30 Feedback - Day 4, seminar overall
16:45-18:00 Get together			