

PMDA-ATC Pharmaceuticals Review Seminar 2026 for PPWG

Agenda

Dates: 6 - 9 Oct 2026 Venue: PMDA (Meeting room 21 - 25)

(JST)

As of Jun 17, 2026

Day 1 Tuesday, October 6	Day 2 Wednesday, October 7	Day 3 Thursday, October 8	Day 4 Friday, October 9
	9:00-9:30 Registration	8:00 Assembly	9:00-9:30 Registration
9:30-10:00 Registration	9:30-10:00 (30m) <u>Guidance for case studies</u>	8:00-12:00 <u>Plant visit to an active pharmaceutical ingredient (API) manufacturing facility</u> - Transportation to the plant (180m) - Classroom training (60m) Astellas Pharma Inc. Takahagi Technology Center	9:30-10:20 (50m) <u>Session 7</u> Structure of Risk Management Plan (RMP)
10:00-10:20 Opening Ceremony			
10:20-11:10 (50m) <u>Session 1</u> Overview of new drug review in Japan - Regulations, review process, review system	10:00-12:50 <u>Session 5</u> <u>Case study 1: Quality part</u> - Introduction (30m) - Group discussion (70m) - Group presentations (40m) - Q&A, Wrap up (30m)		10:20-12:40 <u>Session 8</u> <u>Case study 3: Clinical part</u> Efficacy and safety data evaluation of the product - Introduction (50m) - Group discussion (90m)
11:10-12:00 (50m) <u>Session 2</u> Points to consider in evaluation of new drugs			
12:00-13:10 Lunch break		12:00-13:00 Lunch break	
13:10-14:00 (50m) <u>Session 3</u> Structure of PMDA Review Report	12:50-14:00 Lunch break	13:00-19:00 <u>Plant visit to an active pharmaceutical ingredient (API) manufacturing facility</u> (cont'd) - Plant visit (150m) - Q&A, Wrap up (30m) - Transportation to the Hotel (180m) Astellas Pharma Inc. Takahagi Technology Center	12:40-14:00 Lunch break
Break (20m)	14:00-15:30 <u>Session 6</u> <u>Case study 2: Toxicology part</u> Toxicology data evaluation of the product - Introduction (30m) - Group Discussion(60m)		14:00-16:00 <u>Session 8</u> <u>Case study 3: Clinical part</u> (cont'd) Toxicology data evaluation of the product - Group presentations (80m) - Q&A, Wrap up (40m)
14:20-16:20 (120m) <u>Session 4</u> (participants) Round table discussion on review issues in ASEAN JA and national assessment	Break (10m)		Break (10m)
	15:40-16:50 <u>Session 6</u> (cont'd) - Group presentations (40m) - Q&A, Wrap up (30m)		16:10-16:20 Closing ceremony
16:20-16:30 Feedback - Day 1	16:50-17:00 Feedback - Day 2		16:20-16:30 Feedback - Day 4, seminar overall
16:45-18:00 Get-together			