

PMDA-ATC Pharmaceuticals Review Webinar 2025

Agenda
Date: December 9 - 11, 2025
Venue: On-line (Webex meeting)

as of 24 September 2025

Day 1 Tuesday, Dec.9	Day 2 Wednesday, Dec.10	Day 3 Thursday, Dec.11
14:00 - 14:10 Opening Remarks	14:00-15:20 Session 4 Generic Drug Review (Case study) - Lecture - Q&A	14:00-14:40 Session 7 Outline of Quasi-Drugs Review - Lecture - Q&A
14:10-15:00 Session 1 Overview of Pharmaceutical Review - Lecture - Q&A	Break (10 min)	14:40-15:30 Session 8 Review of Biosimilars - Lecture - Q&A
15:00-15:40 Session 2 Outline of OTC Drug Review - Lecture - Q&A	15:30-16:20 Session 5 Design and Evaluation of BE study for Orally Solid Dosage Form -M13 and Domestic Guideline- - Lecture - Q&A	
Break (10 min)	16:20-17:10 Session 6 BE Guidelines in Japan for Other Dosage Forms - Lecture - Q&A	15:30-15:40 Closing Remarks
15:50-16:50 Session 3 Country Introduction		15:40-15:50 Feedback of Day 3
16:50-17:00 Feedback of Day 1	17:10-17:20 Feedback of Day 2	