

PMDA-ATC Pharmaceuticals Review Webinar 2025

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

as of 26 November 2025

Day 1 Tuesday, December 9	Day 2 Wednesday, December 10	Day 3 Thursday, December 11
14:00 - 14:10 Opening Remarks	14:00-15:20 Session 4 Generic Drug Reviews (Case study) - Lecture - Q&A	14:00-14:40 Session 7 Outline of Quasi-Drugs Review in Japan - 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 Regulatory Framework and Review Practice for OTC Drugs in Japan - Lecture - Q&A	15:30-16:20 Session 5 Design and Evaluation of BE Studies for Solid Oral Dosage Forms –ICH M13 and the Japanese 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 Roundtable on Pharmaceutical Reviews – Country/Region Snapshots		15:40-15:50 Feedback of Day 3
16:50-17:00 Feedback of Day 1	17:10-17:20 Feedback of Day 2	