

PMDA-ATC Pharmaceuticals Review Webinar 2024

Agenda
Date: December 10 - 12, 2024
Venue: On-line (Webex meeting)

Day 1 Tuesday, Dec.10	Day 2 Wednesday, Dec.11	Day 3 Thursday, Dec.12
14:00 - 14:10 Opening Remarks	14:00-15:00 Session 4 BE guideline in Japan	14:00-14:50 Session 7 Review of biosimilars
14:10-15:00 Session 1 Outline of Drug Review and Review Report	15:00-15:50 Session 5 Design and evaluation of BE study	Break (10 min)
15:00-15:50 Session 2 CMC review of Generic drug		15:00-16:50 Session 8 Case Study (Generic drug review)
Break (10 min)	Break (10 min)	
16:00-16:50 Session 3 Review of Drugs using Drug Delivery System	16:00-16:50 Session 6 Regulatory framework and review practice of OTC/Quasi-Drugs	16:50-17:00 Closing Remarks
16:50-17:00 Feedback of Day 1	16:50-17:00 Feedback of Day 2	17:00-17:15 Feedback of Day 3
	17:00-17:30 Start up meeting for Group Work	

as of Aug. 29, 2024