

PMDA-ATC Pharmaceuticals Review Webinar 2023

Agenda

Date: September 26 - 28 2023

Style: Live Sessions (Webex meeting)

Day 1 Tuesday, Sep.26	Day 2 Wednesday, Sep.27	Day 3 Thursday, Sep.28
14:00 - 14:10 (JST) Opening Remarks	14:00-16:00 (JST) Session 4 Case Study (New drug review) - Introductory Lecture (20 min) - Group Discussion (60 min) - Group Presentation, Sum up (40 min)	14:00-14:40 (JST) Session 6 Review of Chemistry, Manufacturing and Control (CMC) - Lecture (20 min) - Q&A (20 min)
14:10-14:50 Session 1 New drug approval review - Lecture (30 min) - Q&A (10 min)		14:40-15:50 Session 7 Case Study (Generic drug review) - Interactive Lecture (50 min) - Q&A (20 min)
14:50-15:10 Session 2 Global clinical trials - Lecture (15 min) - Q&A (5 min)		
15:10-15:40 Session 3 Digital transformation for approval review - Lecture (20 min) - Q&A (10 min)	16:00-16:30 Session 5 Review of biosimilars - Lecture (20 min) - Q&A (10 min)	15:50-16:00 Closing Remarks
15:40-15:50 Evaluation of Day 1	16:30-17:00 Country introduction	16:00-16:10 Evaluation of Day 3
15:50-16:20 (Optional) Free Study Room	17:00-17:10 Evaluation of Day 2	

as of Sep. 12, 2023