

PMDA-ATC Pharmaceuticals Review Webinar 2021  
Session Program (Webex) (all time in JST; UTC+9)

(as of Aug. 30)

Preliminary Session Monday, Nov.29	Day 1 Monday, Dec.6	Day 2 Tuesday, Dec.7	Day 3 Wednesday, Dec8
14:00 - 15:00 <b>General Guidance</b> - Participants self-introduction - Connectivity check - General information - Breakout session trial	14:00 - 14:10 <b>Opening Remarks</b>	14:00-16:45 <b>Session 4</b> <b>Case Study (Review of New Drugs)</b> - Introduction (30min) - Group Discussion (60min) - Presentation (30min) - Commentary and Q&A (45min)	14:00-14:50 <b>Session 5</b> <b>Review of Chemistry, Manufacturing and Control (CMC)</b> - Lecture (20min) - Q&A (30min)
	14:10-14:40 <b>Session 1</b> <b>New drug approval review</b> - Lecture(20min) - Q&A (10min)		14:50-15:50 <b>Session 6</b> <b>Case Study (Review of Generic Drugs)</b> Interactive Lecture
	14:40-15:10 <b>Session 2</b> <b>Consultation meetings</b> - Lecture (20min) - Q&A (10min)		
	15:10-15:40 <b>Session 3</b> <b>Regulatory Challenge against COVID-19</b> - Lecture (15min) - Q&A (15min)		15:50 - 16:00 <b>Closing Remarks</b>
	15:40-15:50 <b>Evaluation of Day 1</b>	16:45 - 16:55 <b>Evaluation of Day 2</b>	16:00 - 16:10 <b>Evaluation of Day 3</b>