PMDA-ATC Pharmaceuticals Review Webinar 2022

Session Program (Webex) (all time in JST; UTC+9)

(as of Aug 30)

Preliminary Session Tuesday,, Nov.29	Day 1 Tuesday,, Dec.6	Day 2 Wednesday, Dec.7	Day 3 Thursday, Dec.8
14:00 - 15:00 **General Guidance** - Participants self-introduction - Connectivity check - General information - Breakout session trial	14:00 - 14:10 **Opening Remarks**	14:00-14:30 **Session 4** **Review of Orphan Drugs** - Lecture(20min) - Q&A (10min)	14:00-14:40 **Session 6** **Review of Chemistry, Manufacturing and Control (CMC)** - Lecture (20min) - Q&A (20min)
	14:10-14:40 **Session 1** **New drug approval review** - Lecture(20min) - Q&A (10min)		
	14:40-15:10 **Session 2** **Review using Foreign clinical data** - Lecture (20min) - Q&A (10min)	14:30-16:45 **Session 5** **Case Study (Review of Orphan Drugs)** - Introduction (10min) - Group Discussion (70min) - Group Presentation and Commentary plus Q&A (55 min)	14:40-15:50 **Session 7** **Case Study (Review of Generic Drugs)** - Introduction (10min) - Group Discussion (40min) - Commentary and Q&A (20 min)
	15:10-15:40 **Session 3** **Regulatory Challenge against COVID-19** - Lecture (15min) - Q&A (15min)		15:50 - 16:00 **Closing Remarks**
	15:40-15:50 **Evaluation of Day 1**	16:45 - 16:55 **Evaluation of Day 2**	16:00 - 16:10 **Evaluation of Day 3**