PMDA-ATC Pharmaceuticals Review Webinar 2021

Date: Dec 6-8, 2021

1. Pre-live self-learning

Session	Duration
1. Review Team	2 min
2. Application Dossier	3 min
3. Review Process	3 min
4. Achievements	2.5 min
5. Toxicology studies	6 min
6. Good Laboratory Practice	2 min
7. First in Human studies	5.5 min
8. Good Clinical Practice	3 min
9. GCP inspection procedure in Japan	6.5 min
10. Review of Generic drugs	5.5 min
11. Review of Biosimilars	9.5 min
12. Expedited regulatory pathways	10 min
13. Start of Clinical Trial to NDA/MAA	20 min
14. Review of New Drugs	20 min
Total	98.5 min

2. Live sessions

Day 1 Monday, Dec. 6	Day 2 Tuesday, Dec. 7	Day 3 Wednesday, Dec. 8
14:00 - 14:10 Opening Remarks	14:00-16:45 Session 4 Case Study (Review of New Drugs) - Introduction (30min) - Group Discussion (70min) - Group Presentation and Commentary plus Q&A (65 min)	14:00-14:50 Session 5 Review of Chemistry, Manufacturing and Control (CMC) - Lecture (20min) - Q&A (30min)
14:10-14:40 Session 1 New drug approval review - Lecture(20min) - Q&A (10min)		
14:40-15:10 Session 2 Consultation meetings - Lecture (20min) - Q&A (10min)		14:50-15:50 Session 6 Case Study (Review of Generic Drugs) - Introduction (10min) - Group Discussion (30min) - 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