PMDA-ATC Pharmaceuticals Review Webinar 2020

Date: Pre-live Self-learning : Dec 7-11

Live sessions : Dec 15-17, 2020

Offered by Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)

1. Pre-Live Self-learning

	E-learning open-site contents	
Dec. 7-11	#3.1. Review Team #3.2 Application Dossier #3.3 Review Process #3.4 Achievement	12 min
	Recorded Lectures	
	1_Start of Clinical Trial to NDA/MAA	20 min
	2_Review of New Drugs	20 min
	3_Toxicology studies, Good Laboratory Practice (GLP), First in Human (FIH) studies	20 min
	4_Clinical Trials, Good Clinical Practice (GCP), Inspections	20 min
	5_Review of Biosimilars	20 min
	6_Innovative review pathways	20 min
	7_Review of Chemistry, Manufacturing and Control (CMC)	20 min
	8_Review Process and Consultation for Generic Drugs	20 min
Dec. 11	Mini test / Questionnaire Due: 9:00 a.m. JST (UTC+9)	

2. Live Sessions

Time (JST)	Day 1 (Dec 15)	Day 2 (Dec 16)	Day 3 (Dec 17)
13:00	13:00-13:10 Opening Remarks	13:00-13:30 Q&A for Session 5	13:00-13:30 Q&A for Session 7
	13:10-13:30 Q&A for Session 1		
	13:30-14:00 Q&A for Session 2	13:30-14:00 Q&A for Session 6	13:30-14:00 Q&A for Session 8
14:00	14:00-14:30 Q&A for Session 3	14:00-16:00 Session 9 Case Study (Review of New Drugs) Introduction (15min) Group Discussion (60min) Group Presentation (30min) Commentary and Q&A (15min)	14:00-16:00 Sesson 10 Case Study (Review of Generic Drugs) Interactive Lecture
	14:30-15:00 Q&A for Session 4		
15:00	15:00-15:30 Ice breaking for Group work		
16:00			16:10-16:20 Closing Remarks
17:00	Evaluation Form (Day 1) Due	Evaluation Form (Day 2) Due	Evaluation Form (Day 3) Due