

PMDA-ATC Pharmacovigilance Webinar 2021 Program

Pre-live Self-learning: Jan. 21 to 29, Live Sessions: Feb. 1 to 4

1. Self-Learning (Viewing of pre-recorded video)

Period	Type	Session	Title	Duration	
Jan. 21 to Jan. 29	PMDA-ATC e-learning	PMDA Overview (contents 1)	#3.3 Review Process, #4 Safety Measures, #5.1 The Relief System, #5.3 Relief System for ADR, #5.4 Judgment on the Relief System	21 min	
		PV (contents 2)	#1. Overview of PV, #2.1 What is the RMP?, #2.2 Pharmacovigilance Activity, #2.3 Risk Minimization Activity	20 min	
	Lecture	Session 1	Considerations on Pharmacovigilance		30 min
		Session 2	2.1 Pharmacovigilance System in Japan (incl. labeling process) 2.2 Pharmacovigilance Systems in the US and Europe 2.3 Recent Pharmacovigilance Activities in the US		60 min (20/20/20)
		Session 3	Evaluation of Benefit/Risk Balance throughout Product Lifecycle, Assessment of Effectiveness of Risk Minimization Activities		30 min
		Session 4	4.1 Pharmacoepidemiology 4.2 New Tool for Drug Safety Assessment in PMDA		50 min (30/20)
		Session 5	End-to-End Labeling process: CCDS/CCSI Labeling System, Electronic Labeling Initiatives		30 min
		Session 6	Communication of Safety Risk Information to Patients and Healthcare Professionals Involvement		30 min
	Group Work Preparation	Session 7	Instruction for Group Work 1: RMP (Safety Specifications) - How to Create RMP – Identification of Safety Specifications		10 min
		Session 8	Instruction for Group Work 2: RMP (Risk Minimization Activity) - How to Create RMP – Planning Risk Minimization Activity		10 min
Session 7 & 8		Introduction of Group Work Material - Hypothetical Drug Case - Self-study of Hypothetical Drug Data Sheet (pdf file to be sent separately)		10 min 20 min	

2. Live Sessions (Webex Meetings)

JST (UTC)	Day 1 Monday, Feb.1	Day 2 Tuesday, Feb.2	Day 3 Wednesday, Feb.3	Day 4 Thursday, Feb.4
11:00 - (2:00 -)		11:00 -11:30 Q&A for Session 2.3		
14:00 - (5:00 -)	14:00 - 14:10 Opening Ceremony	14:00 - 14:30 Q&A for Session 3	Session 7 14:00 - 14:10 - Brief Introduction	Session 8 14:00 - 14:10 - Brief Introduction
	14:10 - 14:40 Q&A for Session 5		14:10 - 15:10 - Group Discussion	14:10 - 15:10 - Group Discussion
	14:40 - 15:10 Q&A for Session 2.1	14:30 - 15:00 Q&A for Session 1	15:20 -15:50 - Group Presentation	15:20 -15:50 - Group Presentation
	15:10 - 15:40 Q&A for Session 2.2	15:00 - 15:30 Q&A for Session 4.1		
16:00 - (7:00 -)	15:40 - 16:10 Q&A for Session 6	15:30 - 16:00 Q&A for Session 4.2	16:00 - 16:30 - Q&A / Wrap up	16:00 - 16:30 - Q&A / Wrap up
	16:10 - 16:40 Ice Breaking for Group Work			16:40 - 16:50 Closing Ceremony