



# PMDA-ATC GMP Inspection Webinar 2022

## 1. Preliminary session (Webex Meeting)

As of October 24, 2022

Date	Session	Title	Duration
Oct.18	Preliminary	14:00-15:00 General Guidance -Connectivity check -Participants self-introduction  -General information -Breakout sessio trial (team building)	60 min

## 2. Live Sessions (Webex Meeting)

JST (UTC)	Day 1 Tuesday, Oct. 25	Day 2 Wednesday, Oct. 26
14:00 - (5:00 -)	14:00-14:20 Opening Session	14:00-16:35 (Group work 140m.+ Break 15m.)  <b>Session 4</b> Case study GMP Inspection focusing on Data Integrity - Introduction (10m.) - Group discussion (60m.)  - Break (15min.)  - Group presentation (40m.) - Q&A and wrap-up (30m.)
	14:20-14:35 (Lecture 10~15m.) <u>Special lecture by PIC/S</u> Data Integrity (DI)	
	14:35-14:55 (Lecture 20m.) <b>Session 1</b> Basic Knowledge of Data Integrity and Related Observations by Pmda	
	14:55-15:25 (Lecture 30m.) <b>Session 2</b> Risk-Based DI Inspections 1. The importance of Risk-Based DI inspections 2. Introduction of the inspection process to find DI deficiencies	
	15:25-15:55 Q&A (30m.)	
	15:55-16:05 Break (10m.)	
	16:05-17:15 (Participant presentation 70m.) <b>Session 3</b> Introduction of Data Integrity in each country by participants	
15:00 - (6:00 -)		16:35-16:50 (15m.) Closing Session
17:00 - (7:00 -)	17:15-17:20 (5m.) Evaluation for Day 1	16:50-17:00 (10m.) Evaluation for Day 2 & overall