



PMDA-ATC GMP Inspection Webinar 2021

1. Preliminary session (Webex Meeting)

As of Sep.22.2021

Date	Session	Title	Duration
Thursday Nov.18	Preliminary	14:00-15:00 General Guidance -Participants self-introduction -Connectivity check -General information -Breakout sessio trial	60 min

2. Live Sessions (Webex Meeting)

JST (UTC)	Day 1 Thursday, Nov. 25	Day 2 Friday, Nov. 26
14:00 - (5:00 -)	14:00-14:20 Opening Remarks	14:00-14:50 (Lecture 30m.+ Q&A20m.) Session 3 Basic concept and current topics of QRM (Quality Risk Management)
	14:20-15:20 (Lecture 40m.+ Q&A20m.) Session 1 Japan's GMP regulation ▪Japan's GMP regulation ▪Recent topics of GMP inspection	14:50-15:00 Break (10m.)
	15:00 - (6:00 -)	15:00-16:30 (Group work 90m.) Session 4 QRM case study - Introduction - Group Discussion - Group presentation
	15:20-15:40 Break (20m.)	
	15:40-16:50 (Presentation 70m.) Session 2 Introduction of GMP regulations by participants	16:30-16:50 (20m.) ▪QRM case study Q&A ▪Day 2 Wrap-up
17:00 - (7:00 -)	16:50-17:00 (10m.) ▪Day 1 Wrap-up ▪Day 2 Introduction Evaluation form for Day 1	16:50-17:00 (10m.) Closing Remarks Evaluation form for Day 2 and Overall