

PMDA-ATC GMP Inspection Webinar 2024

Agenda

Date: February 6 - 7, 2024

Style: On-line (Webex meeting)

Day 1 Tuesday, Feb.6	Day 2 Wednesday, Feb.7
14:00 - 14:20 (JST, UTC+9) Opening Remarks	14:00-14:20 (JST, UTC+9) Session 4 PMDA's efforts on pharmaceutical quality issues - Lecture (20 min)
14:20-14:50 Session 1 GMP regulation in Japan Part 1 - Lecture (30 min)	14:20-14:50 Session 5 Case study on GMP Inspection Part 1 - Group discussion (30 min)
14:50-15:10 Session 2 GMP regulation in Japan Part 2 - Lecture (20 min)	14:50-15:20 Session 6 Case study Case study on GMP Inspection Part 2 - Group discussion (30 min)
15:10-15:40 Q&A (30 min)	15:20-15:50 Q&A (30 min)
15:40-15:50 Break (10 min)	15:50-16:00 Break (10 min)
15:50-17:00 Session 3 Introduction of International Reliance in each country by participants - Participant's presentation (70 min)	16:00-16:45 Session 7 Industries' efforts on pharmaceutical quality issues - Lecture (30 min) - Q&A (15 min)
17:00-17:15 Evaluation of Day 1 / Guidance for Day 2	16:45 - 17:00 Closing Remarks / Evaluation of Day 2 and Overall