

PMDA-ATC GMP Inspection Seminar 2024

Agenda Date: October 8-10, 2024 Venue: Toyama prefecture

(UTC+9)

As of August 26, 2024

Day 1 Tuesday, Oct. 8	Day 2 Wednesday, Oct. 9	Day 3 Thursday, Oct. 10
8:00-9:00 Travel (From the hotel to the manufacturing site)	8:00-9:00 Travel (From the hotel to the manufacturing site)	8:00-9:00 Travel (From the hotel to the manufacturing site)
9:00-9:15 Opening Ceremony	Session 5 Group work on on-site GMP inspection 9:00-9:30 (Lecture 30m) - Lecture - Plant tour at 3 areas	Session 6 Group work on document-based GMP inspection 9:00-12:00 (Lecture m + Q&A m)
9:15-9:45 (Lecture 30m) Session 1 Overview -GMP regulation in Japan	①9:30-11:20	
9:45-10:45 (Lecture 60m) Session 2 The point of inspection on the drug substance manufacturing		
10:45-11:00 (Q&A 15m) Session 1,2 Q&A		
11:00-11:10 Break (10m)		
11:10-12:10 (Lecture 30m+ Q&A 30m) Session 3 Overview of manufacturing site and products	②12:20-14:10	13:00-13:45 13:45-15:15 (90m) Group Work for presentation
12:10-13:10 Lunch break (60m)		
13:10-15:00 (110 m) Session 4 Group Work on GMP inspection planning -Introduction -discussion	14:10-14:25 Break	15:15-15:30 Break
15:00-15:15 Break	③14:25-16:15 16:15-16:45 Group Work	15:30-16:15 (45m) Presentation, Q&A
15:15-16:15 -Presentation -Feedback		16:15-16:45 (30m) Wrap-up, Feedback
16:15-16:30 Feedback for Day 1	16:45-17:00 Feedback for Day 2	16:45-17:00 Closing Ceremony
16:30-17:30 Travel (From the venue to the hotel)	17:00-18:00 Travel (From the venue to the hotel)	17:00-18:00 Travel (From the venue to the hotel)