

PMDA-ATC GMP Inspection Seminar 2025

Agenda

Dates: 17-19 September 2025 Venue: Tokyo (PMDA office)

as of 8 September 2025

(JST)

Day 1 Wednesday, 17 September	Day 2 Thursday, 18 September	Day 3 Friday, 19 September
9:30-10:00 Registration	9:30-10:00 Registration	9:30-10:00 Registration
10:00-10:20 <u>Opening Ceremony</u>	10:00-10:50 <u>Session 5</u> Regulatory Reliance: PMDA Perspective	10:00-11:30 <u>Session 10</u> AT and Regulatory Reliance - Open discussion - Q&A, wrap up
10:20-10:35 <u>Seminar Orientation</u>	10:50-11:00 Break	11:30-11:45 <u>Closing Ceremony</u>
10:35-11:25 <u>Session 1</u> Advanced Technologies in Pharmaceutical Manufacturing: Industry Perspective	11:00-12:00 <u>Session 6</u> Reliance in Asia: Participants' Perspective - Participants' presentations, by country/region	11:45-12:00 Feedback - Day 3 and seminar overall
11:25-11:40 Break		
11:40-12:30 <u>Session 2</u> Advanced Technologies in Pharmaceutical Manufacturing: PMDA Perspective		
12:30-13:40 Lunch break	12:00-13:10 Lunch break	
13:40-15:00 <u>Session 3</u> Country Introduction - Participants' presentations, by country/region	13:10-14:00 <u>Session 6</u> (cont'd) - Participants' presentations, by country/region	
15:00-15:20 Break	14:00-14:20 Break	
15:20-16:10 <u>Session 4</u> Advanced Technologies in Pharmaceutical Manufacturing: WHO Perspective	14:20-15:10 <u>Session 7</u> Regulatory Reliance: Panel Discussion	
16:10-16:20 Feedback - Day 1	15:10-15:30 Break	
16:45-18:00 Get together	15:30-16:30 <u>Session 8</u> Advanced Technologies in Pharmaceutical Manufacturing (Annex 22)	
	16:30-16:40 Break	
	16:40-17:55 <u>Session 9</u> Advanced Technologies in Pharmaceutical Manufacturing (Revised Annex 11)	
	17:55-18:05 Feedback - Day 2	