PMDA-ATC GMP Inspection Seminar 2025

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

(JST)

as of 4 August 2025

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