

PMDA-ATC GMP Inspection Seminar 2026

Agenda

Dates: 15 - 17 September 2026 Venue: Tokyo

(JST)

As of 04 September 2026

Day 1 Tuesday, 15 September	Day 2 Wednesday, 16 September	Day 3 Thursday, 17 September
9:30-10:00 Registration		
10:00-10:20 <u>Opening Ceremony</u>	10:00-10:30 Registration	10:00-10:30 Registration
10:20-10:35 <u>Seminar Orientation</u>	10:30-11:00 <u>Session 5</u> Regulatory reliance in Asia: PMDA perspective	10:30-11:30 <u>Session 10</u> Advanced Technologies and Regulatory Reliance: - Shared understanding paper - Q&A, Wrap Up
10:35-11:25 <u>Session 1</u> Credibility Assessment of an AI Model in an Automated Visual Inspection (AVI) System	11:00-12:30 <u>Session 6</u> Regulatory Reliance in the EEA and the role of the EEA GMDP Inspectors' Working Group (GMDP IWG) - Workshop	11:30-11:45 <u>Closing Ceremony</u>
11:25-11:40 Break	12:30-13:40 Lunch Break	11:45-12:00 Feedback - Day 3 and seminar overall
11:40-12:30 <u>Session 2</u> PMDA's Perspective on AI System Inspections ~ A Use Case-Based Proposal ~	13:40-14:40 <u>Session 7</u> Regulatory reliance in Asia - Interactive discussion	
12:30-13:40 Lunch break	14:40-15:00 break	
13:40-14:30 <u>Session 3</u> Advanced technologies in pharmaceutical manufacturing: Taiwan FDA Perspective	15:00-16:00 <u>Session 8</u> AI in GMP Operations: Case Studies from Manufacturing and Quality Management -Adaptive Airflow HVAC Technology -Use of GenAI for Quality System Tasks	
14:30-15:00 Break	16:00-16:20 Break	
15:00-16:10 <u>Session 4</u> AI in Pharmaceutical Manufacturing -Turning Potential in Compliance	16:20-17:50 <u>Session 9</u> Interactive Discussion on How to Inspect AI-enabled GMP Systems	
16:10-16:20 Feedback - Day 1	17:50-18:00 Feedback - Day 2	
16:45-18:00 Get together		