

APEC CoE Workshop

PMDA-ATC MRCT/GCP Inspection Seminar 2027

Agenda

Dates: January 26 - 29, 2027 Venue: Tokyo

as of 21 August 2026

Day 1 Tuesday, January 26	Day 2 Wednesday, January 27	Day 3 Thursday, January 28	Day 4 Friday, January 29
9:30-10:00 Registration	9:30-10:00 Registration	9:30-10:00 Registration	9:30-10:00 Registration
10:00-10:20 Opening ceremony	10:00-10:40 Session 4	10:00-10:40 Session 7	10:00-10:40 Session 9
10:20-10:40 Introduction of case studies	Industry experience in GCP inspections	AI-assisted clinical trial operations	Designing of MRCT - sponsor's perspective
10:40-11:30 Session 1 GCP Inspections in Japan: Latest Perspectives on ICH E6(R3)	10:40-11:30 Session 5 GCP inspections - NCC experience	10:40-11:40 Session 8-1 Points to consider when evaluating results	10:40-11:30 Session 10 Clinical trials in Asia
11:30-12:00 Session 2 Focused GCP Inspection Case Study	Break 11:30-11:40 11:40-12:40 Session 6-1	11:40-12:10 Session 8-2 (case study)	11:30-11:45 Closing ceremony
Lunch 12:00-13:00	Points to consider when planning & designing MRCT	Lunch 12:10-13:10	11:45-12:00
13:00-15:10 Session 2 (cont'd) - group discussions - break - group presentations - wrap up + QA	Lunch 12:40-13:40 13:40-14:10 Session 6-2 (case study)	13:10-14:30 Session 8-2 (cont'd) - group discussion	Feedback - Day 4 + seminar overall
Break 15:10-15:20	14:10-15:30 Session 6-2 (cont'd) - group discussion	Break 14:30-14:40	
15:20-16:30 Session 3 (Round Table Discussion) Considerations for MRCT/GCP Operations - participants' presentations (by country)	Break 15:30-15:40	14:40-15:40 Session 8-2 (cont'd) - group presentations - QA, wrap up	
16:30-16:40 Feedback - Day 1	15:40-16:40 Session 6-2 (cont'd) - group presentations - QA, wrap up	15:40-15:50 Feedback - Day 3	
17:15-18:30 Get-together	16:40-16:50 Feedback - Day 2		