

# APEC Center of Excellence Workshop

## PMDA-ATC MRCT/GCP Inspection Seminar 2025

### Agenda

Date: January 21 - 24, 2025 Venue: Tokyo (PMDA office)

(JST)

as of December 13, 2024

DAY 1 Tuesday, January 21	DAY 2 Wednesday, January 22	DAY 3 Thursday, January 23	DAY 4 Friday, January 24
09:30-10:00 <b>Registration</b>	09:30-10:00 <b>Registration</b>	09:30-10:00 <b>Registration</b>	09:30-10:00 <b>Registration</b>
10:00-10:20 <b>Opening ceremony</b>	10:00-10:20 <b>Introduction of Case studies</b>	10:00-10:30 <b>Session 5</b> Recent trend of MRCT by industry	10:00-10:30 <b>Session 7</b> MRCT operation by sponsor
10:20-11:30 <b>Session 1</b> How to conduct GCP inspection in Japan	10:20-11:20 Points to consider when planning & designing MRCT <b>Session 4-1 (Lecture)</b>	10:30-11:30 Points to consider when evaluating results <b>Session 6-1 (Lecture)</b>	10:30-11:40 <b>Session 8-1</b> NCC experience in complying GCP and conducting clinical trials
	Break (10m)		
11:30-11:50 <b>Session 2</b> GCP inspection (Case study)	11:30-12:00 <b>Session 4-2 (Case study)</b>	11:30-12:00 <b>Session 6-2 (Case study)</b>	11:40-12:40 <b>Session 8-2</b> Clinical trials in Asia by NCC
11:50-13:00 <b>Lunch</b>	12:00-13:10 <b>Lunch</b>	12:00-13:10 <b>Lunch</b>	12:40-12:55 <b>Closing ceremony</b>
13:00-15:00 <b>Group discussion</b> <b>Group presentation</b> <b>Q&amp;A, Wrap up</b>	13:10-14:30 <b>Group discussion</b>	13:10-14:30 <b>Group discussion</b>	12:55-13:10 <b>Feedback of Day4</b>
Break (10m)	Break (10m)	Break (10m)	
15:10-16:20 <b>Session 3 (Round Table Discussion)</b> Considerations for MRCT/ GCP operation	14:40-15:40 <b>Group presentation</b> <b>Q&amp;A, Wrap up</b>	14:40-15:40 <b>Group presentation</b> <b>Q&amp;A, Wrap up</b>	
16:20-16:30 <b>Feedback of Day1</b>	15:40-15:50 <b>Feedback of Day2</b>	15:40-15:50 <b>Feedback of Day3</b>	
16:45-18:00 <b>Get together</b>			