

PMDA-ATC GCP case study seminar 2023 in Bangkok, Thailand

Facilitator: Kaori OGAWA, PMDA

Time	Session Title
13:30-14:00 30min	GCP on-site inspection - Overview - (Lecture) Mr. Hironori SETO, Senior Scientist for GCP, Office of Non-clinical and Clinical Compliance, PMDA (15min) Dr. Hideki UENO, Clinical Trial Coordination (& Support) Office, Clinical Research Support Office, NCC (15min)
14:00-14:25 25min	Instruction (25min) Ms. Misato OKAZAKI, Inspector, Office of Non-clinical and Clinical Compliance, PMDA
14:25-15:25 60min	GCP case study Facilitators: <ul style="list-style-type: none"> • Mr. Hironori SETO, Senior Scientist for GCP, Office of Non-clinical and Clinical Compliance, PMDA • Ms. Misato OKAZAKI, Inspector, Office of Non-clinical and Clinical Compliance, PMDA • Dr. Chiharu MIZOGUCHI, Department of International Clinical Development, NCC • Dr. Mitsumi TERADA, General Manager, Asian Partnerships Office, Department of International Clinical Development, NCC • Dr. Kenichi NAKAMURA, Director, Department of International Clinical Development, NCC
15:25-15:55 30min	Participants' presentation (5min*5groups)
15:55-16:15 20min	Feedback by facilitators
16:15-16:30 15min	Wrap up/Closing remarks Dr. Kenichi NAKAMURA, Director, Department of International Clinical Development, NCC Dr. Junko SATO, Office Director, Office of International Programs, PMDA

PMDA: Pharmaceuticals and Medical Devices Agency

NCC: National Cancer Center Japan