



PMDA-ATC In-person Pharmaceutical Review Seminar 2026 for PPWG

Date: **October 6-9, 2026**

10:00 to 16:00 JST (UTC+9)

Location: **Tokyo**

Audience: **Regulators only**

Intermediate or higher level

Program overview:

- Overview of new drug review in Japan
- Points to consider in evaluation of new drug
- Structure of PMDA review report
- Case studies on new drug assessment (quality, non-clinical safety and clinical)
- Plant visit to an active pharmaceutical ingredient (API) manufacturing facility
- Structure of Risk Management Plan (RMP)