

On-line

PMDA-ATC Pharmaceuticals Review Webinar 2025



Dates:

December 9-11, 2025

14:00 to 17:00 JST (UTC+9)

On-line: **Beginner to Intermediate level**

Regulators only

Application Due:

October 31, 2025

<https://www.pmda.go.jp/english/symposia/0336.html>



Program topics:

- Assessment of biosimilars and generic drugs
- Assessment of OTC drugs and quasi drugs
- Design and evaluation of bioequivalence (BE) studies
- Outline of ICH M13A Guideline