

# PMDA-ATC Generic Drugs Review Seminar 2026

## Agenda

Dates: 14 - 17 July 2026 Venue: Toyama

as of 2026.4.1

Day 1 Tuesday, July 14	Day 2 Wednesday, July 15	Day 3 Thursday, July 16	Day 4 Friday, July 17
9:00-9:30 Registration	8:30-9:00 Registration	8:30-9:00 Registration	8:30-9:00 Registration
9:30-10:00 <b>Opening Ceremony</b>	9:00-10:00 <b>Session 3</b> <b>Design and Evaluation of BE studies for Solid Oral Dosage Forms -M13 and Domestic Guideline-</b> - Lecture - Q&A	9:00-9:20 Case study orientation	9:00-10:00 <b>Session 8</b> <b>Regulatory Framework and Review Practice for OTC Products in Japan</b> - Lecture - Q&A
10:00-10:50 <b>Session 1</b> <b>Outline of Pharmaceutical Review</b> - Lecture - Q&A	10:00-11:00 <b>Session 4</b> <b>BE Guidelines in Japan for Other Dosage Forms</b> - Lecture - Q&A	9:20-12:00 <b>Session 6</b> <b>Generic Drug Review (Case study)</b> - Introduction - Discussion - Presentation - Wrap-up	10:00-11:00 <b>Session 9</b> <b>Quasi-Drugs Review in Japan</b> - Lecture - Q&A
Break		11:00-11:30 Site tour briefing	
11:00-12:30 <b>Session 2</b> <b>Round Table Discussion</b> - Introduction of Regulations, by participants	11:00-11:30 Site tour briefing		Break
12:30-13:30 Lunch break	11:30-12:30 Lunch break	12:00-13:00 Lunch break	11:10-11:20 <b>Closing Ceremony</b>
13:30-13:40 Feedback - Day 1			
transfer (seminar - symposium site)	transfer (seminar - manufacturing site)	transfer (seminar - manufacturing site)	11:20-11:30 Feedback - Day 4 and overall
14:00-19:00 <b>PMDA Hokuriku Branch 10th Anniversary Symposium &amp; Reception</b>	13:30-16:00 <b>Session 5</b> (Manufacturing site lecture and tour) <b>TBD</b>	14:00-16:00 <b>Session 7</b> (Manufacturing site lecture and tour) <b>TBD</b>	
	transfer (from manufacturing site) Feedback for Day 2	transfer (manufacturing site - hotel) Feedback for Day 3	
	17:30-19:00 Get-together		