PMDA-ATC Pediatric Review Seminar 2025

Agenda

(JST) **Dates: 9-12 June 2025 Venue: Tokyo (PMDA office)** As of 2 June 2025

Day 1 Monday, 9 June	Day 2 Tuesday, 10 June	Day 3 Wednesday, 11 June	Day 4 Thursday, 12 June
9:30-10:00 **Registration**	9:30-10:00 **Registration**	9:30-10:00 **Registration**	9:00-09:30 **Registration**
10:00-10:20 **Opening Ceremony**	10:00-10:30 **Case studies guidance**	10:00-10:50 **Session 8** **Pediatric Extrapolation including ICH E11A**	09:30-10:00 **Session 12** **QA session with U.S. FDA**
10:20-11:00 **Session 1** **Introduction for Pediatric Drug Development**	10:30-12:00 **Session 5** **Case study / Group work** **Practical Applications** - Introduction - Group Discussion	Break	**< Advanced Session >** 10:00-11:30 **Session 13** - 13-1 **Pediatric Clinical Pharmacology** - 13-2 **Modeling/Simulation**
11:00-12:20 **Session 2** **- PMDA Pediatric Regulation in Japan** **- U.S. FDA New Drug Regulation and Pediatrics (recorded lecture)**		11:00-12:00 **Session 9** **Pediatric Medicines: Pharmacist's Perspective**	11:30-12:15 **Session 14** **Practical considerations for using existing knowledge in pediatric review: From PMDA experience**
Lunch break	Lunch break	Lunch break	Break
13:30-14:50 **Session 3** **Round Table Discussion 1** - Introduction of Pediatric Regulations by participants	13:10-14:20 **Session 5** (continued) - Group presentations - Q&A, Wrap up	13:10-14:20 **Session 10** **Pharmaceutical Industry Initiatives for Pediatric Drug Development** - 10-1 - 10-2	12:30-12:45 **Closing Ceremony**
	14:20-15:10 **Session 6** **Round Table Discussion 2** - Introduction of Pediatric Regulations by participants		12:45-12:55 Feedback - Day 4, Seminar overall
		Break	
Break	Break	14:30-15:30 **Session 11** **Pediatric Medicines: Child's Perspective - Insights from a Child Life Specialist**	
15:00-16:00 **Session 4** **ICH E11 and the use of existing knowledge in pediatric drug development**	15:20-16:00 **Session 7 (EMA)** **EU Paediatric Regulation**		
16:00-16:15 Feedback - Day 1	16:00-16:10 Feedback - Day 2	15:30-15:40 Feedback - Day 3	
16:45-18:00 **Get together**			