

# PMDA-ATC Medical Devices Seminar 2023

## Agenda

Date: December 5 - 7 2023

Venue: Tokyo (PMDA office)

as of Nov 22, 2023

JST	Day 1 Tuesday, Dec.5	Day 2 Wednesday, Dec.6	Day 3 Thursday, Dec.7
10:00	10:00 - 10:20 <b>Opening Remarks</b> 10:20 - 11:05 <b>Session 1: Regulations of IVDs and IVD Medical Devices</b> - Lecture: 30 min - Q&A: 15 min Break (10m)	10:00 - 10:45 <b>Session 5: Regulation for AI-based Medical Devices</b> - Lecture: 30 min - Q&A: 15 min Break (10m)	10:00 - 12:15 <b>Session 8</b> <b>Case Study 2: Review of Software as a Medical Device (SaMD)</b> - Introduction: 15 min - Group Discussion: 60 min - Group Presentation: 30 min - Discussion: 10 min - Q&A, Wrap Up: 20 min
11:00	11:15 - 12:00 <b>Session 2: Expedited Review Pathways</b> - Lecture: 30 min - Q&A: 15 min	10:55- 11:40 <b>Session 6: Regulatory Approach for Device Software Functions</b> - Lecture: 30 min - Q&A: 15 min	
12:00-13:30	Lunch break (90m)	Lunch break (90m)	12:15 - 12:30 <b>Closing Remarks</b>
13:30	13:30-14:50 <b>Session 3</b> <b>Round Table Discussion</b> - Introduction of Medical Device Regulations by participants Break (10m)	13:30 - 17:10 <b>Session 7</b> <b>Case Study 1: Review of High Risk Medical Devices</b> - Introduction: 30 min - Group Discussion: 90 min Break (10m)	12:30 - 12:40 <b>Evaluation of Day 3 and Overall</b>
15:00	15:00 - 15:45 <b>Session 4: Development and Practical Application</b> - Lecture: 30 min - Q&A: 15 min 15:45 -16:00 <b>Evaluation of Day 1</b> 16:15-17:45 <b>Get together</b>	- Group Presentation: 40 min - Discussion: 30 min - Q&A, Wrap Up: 20 min 17:10 - 17:20 <b>Evaluation of Day 2</b>	