

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