PMDA-ATC Medical Devices Webinar 2022 (November 28-30) - Implementation and Adaptation of IMDRF documents in the Japanese Medical Device Regulations -

Session Program (Webex) (all time in JST; UTC + 9)

Preliminary Session Monday, Nov. 21	Day 1 Monday, Nov. 28	Day 2 Tuesday, Nov. 29	Day 3 Wednesday, Nov. 30
14:00 - 15:00 General Guidance - Participants self-introduction - Connectivity check - General information - Breakout session trial	14:00 - 14:10Opening Remarks14:10 - 14:45Live Lecture 1: Regulations of IVDsand IVD Medical Devices- Lecture: 25 min- Q&A: 10 min14:45 - 15:20Live Lecture 2: Expedited ReviewPathways- Lecture: 25 min- Q&A: 10 min15:20 - 15:55Live Lecture 3: Regulation for Al-based Medical Devices- Lecture: 25 min- Q&A: 10 min15:55 - 16:30Live Lecture 4: Development andPractical Application- Lecture: 25 min- Q&A: 10 min	14:00 - 16:30 Group Work Case Study 1: Review of High Risk Medical Devices - Introduction: 15 min - Group Discussion: 70 min - Group Presentation: 30 min - Discussion: 15 min - Q&A: 10 min - Wrap Up: 10 min	14:00 - 14:35 Live Lecture 5: Regulatory Approach for Device Software Functions - Lecture: 25 min - Q&A: 10 min 14:35 - 16:40 Group Work Case Study 2: Review of Software as a Medical Device (SaMD) - Introduction: 15 min - Group Discussion: 60 min - Group Presentation: 20 min - Discussion: 10 min - Q&A: 10 min - Wrap Up: 10 min
	16:30 - 16:40 Group Work Guidance for Day 2 & 3 Evaluation of Day 1	16:30 - 16:40 Evaluation of Day 2	
	16:40-17:40 (optional) Free Study Room for Group Work	16:40-17:40 (optional) Free Study Room for Group Work	16:40 - 16:50 Closing Remarks
as of August 22, 2022			16:50 - 17:00 Evaluation of Day 3 and Overall