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 - 14:10 **Opening Remarks**	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
	14:10 - 14:45 **Live Lecture 1: Regulations of IVDs and IVD Medical Devices** - 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
	14:45 - 15:20 **Live Lecture 2: Expedited Review Pathways** - Lecture: 25 min - Q&A: 10 min		
	15:20 - 15:55 **Live Lecture 3: Regulation for AI-based Medical Devices** - Lecture: 25 min - Q&A: 10 min		
	15:55 - 16:30 **Live Lecture 4: Development and Practical Application** **- Lecture: 25 min** **- Q&A: 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**
			16:50 - 17:00 **Evaluation of Day 3 and Overall**

as of August 22, 2022