

APEC Center of Excellence Workshop
PMDA-ATC Medical Devices Workshop 2022
Session Program (Webex) (all time in JST; UTC + 9)

Preliminary Session Monday, Nov. 7	Day 1 Monday, Nov.14	Day 2 Tuesday, Nov.15	Day 3 Wednesday, Nov.16
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	14:00 - 16:30 Group Work
	14:10 - 14:45 Live Lecture 1: International Harmonization of Medical Device Regulations - Lecture: 25 min - Q&A: 10 min	Case Study 1: Clinical Evaluation of Medical Devices - Introduction: 15 min - Group Discussion: 70 min - Group Presentation: 30 min - Discussion: 15 min - Q&A: 10 min - Wrap Up: 10 min	Case Study 2: Post-market Safety Measures for Medical Devices - Introduction: 15 min - Group Discussion: 70 min - Group Presentation: 30 min - Discussion: 15 min - Q&A: 10 min - Wrap Up: 10 min
	14:45 - 15:20 Live Lecture 2: Review of Medical Devices - Lecture: 25 min - Q&A: 10 min		
	15:20 - 15:55 Live Lecture 3: QMS Inspection for Medical Devices - Lecture: 25 min - Q&A: 10 min		
	15:55 - 16:30 Live Lecture 4: Post-market Safety Measures for Medical Devices - 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	16:30 - 16:40 Closing Remarks
	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 Evaluation of Day 3 & Overall CoE WS