

PMDA-ATC Medical Devices Webinar 2021, APEC Center of Excellence Workshop
 Session Program (Webex) (all time in JST; UTC+9)

(as of Aug. 18)

Preliminary Session Monday, Nov.8	Day 1 Monday, Nov.15	Day 2 Tuesday, Nov.16	Day 3 Wednesday, Nov.17
14:00 - 15:00 General Guidance - Participants self-introduction - Connectivity check - General information - Breakout session trial	14:00 - 14:10 Opening Remarks 14:10 - 14:55 Live Lecture 1: International Harmonization of Medical Device Regulations - Lecture: 30 min - Q&A: 15 min 14:55 - 15:40 Live Lecture 2: International Standardization of Medical Device - Lecture: 30 min - Q&A: 15 min 15:40 - 16:25 Live Lecture 3: Medical Device Single Audit Program (MDSAP) - Lecture: 30 min - Q&A: 15 min 16:25 - 16:35 Group Work Guidance for Day 2 & 3 Evaluation of Day 1	14:00 - 16:15 Group Work Case Study 1: Clinical Evaluation of Medical Devices - Introduction: 15 min - Group Discussion: 60 min - Group Presentation: 30 min - Discussion: 10 min - Q&A: 10 min - Wrap Up: 10 min 16:15 - 16:25 Evaluation of Day 2	14:00 - 16:15 Group Work Case Study 2: Post-market Safety Measures for Medical Devices - Introduction: 15 min - Group Discussion: 60 min - Group Presentation: 30 min - Discussion: 10 min - Q&A: 10 min - Wrap Up: 10 min 16:15 - 16:25 Closing Remarks 16:25 - 16:35 Evaluation of Day 3