

APEC Center of Excellence Workshop PMDA-ATC Medical Devices Workshop 2023

Live Sessions (On-line, Webex meeting)

As of Aug 7, 2023

Day 1 Tuesday, Nov.14	Day 2 Wednesday, Nov.15	Day 3 Thursday, Nov.16
14:00 - 14:10 Opening Remarks	14:00 - 16:30 Session 5: Case Study 1: Clinical Evaluation of Medical Devices - Introduction: 15 min - Group Discussion: 70 min - Group Presentation: 30 min - Discussion: 15 min - Q&A, Wrap Up: 20 min	14:00 - 16:30 Session 6: 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, Wrap Up: 20 min
14:10 - 14:45 Session 1: International Harmonization of Medical Device Regulations - Lecture: 25 min - Q&A: 10 min		
14:45 - 15:20 Session 2: Review of Medical Devices - Lecture: 25 min - Q&A: 10 min		
Break (10m)		
15:30 - 16:05 Session 3: QMS Inspection for Medical Devices - Lecture: 25 min - Q&A: 10 min		
16:05 - 16:40 Session 4: Post-market Safety Measures for Medical Devices - Lecture: 25 min - Q&A: 10 min		
16:40 - 17:10 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
17:10-17:40 Start up meeting for Group Work	16:40-17:10 (optional) Free Study Room for Group Work	16:40 - 16:50 Evaluation of Day 3 & Overall