



PMDA-ATC Medical Devices Webinar 2020 Program



Pre-live Self-learning: Nov. 5 to 13, Live Sessions: Nov. 16 to 20

1. Self-Learning (Viewing of pre-recorded videos)

Updated: Oct. 23, 2020

Period	Type	Session	Duration
Nov. 5 to Nov. 13	e-learning (open to public)	#3.4. Achievement #6.1. The PMDA International Strategic Plan, #6.2. International Activities (#3.4, #6.1, #6.2: available now) #8.1. Medical Device and IVD Regulations, #8.2. Medical Device Unit, #8.3. Review of Medical Devices #8.4. Review of IVD, #8.5. Third Party Certification, #8.6. QMS, Safety Measures (#8.1 thru #8.6: available in November)	40 min
	Pre-recorded Lectures	1. Review of Medical Devices and International Harmonization (Definitions, Classifications, Essential Principles, Review, IMDRF, APEC-LSIF-RHSC, etc.)	30 min
		2. Biological Safety	30 min
		3. Quality Management System (QMS) for Medical Devices/Outline of Medical Device Single Audit Program (MDSAP)	30 min
		4. International Standardization for Medical Devices (Utilization of International Standards, Certification Criteria, etc.)	30 min
		5. Selection and Supervision of Registered Certification Bodies	30 min
		6. Development and Practical Application -Viewpoint of Medical Front-	30 min
	Group Work Preparation	7. Case Study 1: Review and Approval of Medical Devices	30 min
		8. Case Study 2: Review and Approval of In Vitro Diagnostics (IVDs)	30 min
		9. Case Study 3: Post-market Safety Measures for Medical Devices	30 min

2. Live Sessions (Webex)

JST (UTC)	Day 1 Monday, Nov.16	Day 2 Tuesday, Nov.17	Day 3 Wednesday, Nov.18	Day 4 Thursday, Nov.19	Day 5 Friday, Nov.20
13:50 - (4:50 -)	13:50 - 14:00 Opening Remarks				
14:00 - (5:00 -)	14:00 - 14:30 Q&A for Session 1	14:00 - 14:30 Q&A for Session 4	Session 7: Case Study 1 14:00 - 14:15 - Brief Introduction 14:20 - 15:20 - Group Discussion 15:25 - 15:55 - Group Presentation	Session 8: Case Study 2 14:00 - 14:15 - Brief Introduction 14:20 - 15:20 - Group Discussion 15:25 - 15:55 - Group Presentation	Session 9: Case Study 3 14:00 - 14:15 - Brief Introduction 14:20 - 15:20 - Group Discussion 15:25 - 15:55 - Group Presentation
	14:30 - 15:00 Q&A for Session 2	14:30 - 15:00 Q&A for Session 5			
15:00 - (6:00 -)	15:00 - 15:30 Q&A for Session 3	15:00 - 15:30 Q&A for Session 6			
	15:30 - 16:00 Ice Breaking for Group Work	15:30 - 16:00 Ice Breaking for Group Work			
16:00 - (7:00 -)			16:00 - 16:30 - Comments - Q&A, Wrap up	16:00 - 16:30 - Comments - Q&A, Wrap up	16:00 - 16:30 - Comments - Q&A, Wrap up 16:40 - 16:50 Closing Remarks