PMDA-ATC Medical Devices Seminar 2019 (Draft)

Date：November 25-29, 2019　　Venue：PMDA

	Day 1, Nov. 25（Mon）	Day 2, Nov. 26（Tue）	Day 3, Nov. 27（Wed）	Day 4, Nov. 28（Thu）	Day 5, Nov. 29（Fri）
AM	9:30 - 9:45 Opening Ceremony	9:30 - 10:15 6. Consultation - from developing medical devices to getting marketing approval -	9:30 - 10:30 13. Good Clinical Practice(GCP)/Good Laboratory Practice(GLP) Inspection and Inspection Based on Standards of Reliability for Medical Devices		9:30 - 11:45 18. Group Work on Review of Medical Devices 2 (Review cases where preparation of academic guidelines and/or training was required as conditions for approval, etc.)
	9:45 - 10:00 Seminar Outline				
	10:00 - 10:45 1. Outline of PMDA	10:15 - 11:00 7. Review of Software (Categorization of Software as a “Medical Device” or not, etc.)			
	10:45 - 11:45 2. International Harmonization (International Medical Device Regulators Forum (IMDRF), Asia Pacific Economic Cooperation-Life Science Innovation Forum-Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC), etc.）	11:00 - 11:45 8. Review of Reprocessed Single-Use Device	10:30 - 11:45 14. Quality Management System (QMS) for Medical Devices/Outline of Medical Device Single Audit Program (MDSAP)		
Lunch	11：45-13：00	11：45-13：00	11：45-13：00		11：45-13：00
PM 1	13:00 - 14:00 3. Review and Approval of Medical Devices (Definition, classification, essential principle, review process, approval process, etc.)	13：00-13：45 9. Standards for Medical Devices (Utilization of international standards, etc.)	13:00 - 15:00 15. Group Work on Review of Medical Devices 1 (Review cases requiring discussion on clinical data, etc.)	9:00-18:00 17. Site Visit to Manufacturing Facilities	13:00 - 15:00 19. Post-market Safety Measures for Medical Devices
	14:00 - 15:30 4. Regulations, Legislative Systems and Current Effort for Medical Devices in Japan. (Approval system, certification system, early conditional approval system, sakigake system, etc.)	13：45-14：30 10. Review Conducted by Registered Certification Bodies			
Break	15：30-15：45	14：30-15：00	15：00-15：30		15：00-15：30
PM 2	15:45 - 17:45 5. Introduction of Medical Device Regulations by Participants	15：00-15：45 11. Selection and Supervision of Registered Certification Bodies	15:30 - 17:30 16. Review and Approval of In Vitro Diagnostics (IVDs)		15:30 - 17:30 20. Development, Practical Application and International Deployment
		15：45-16：30 12. Manufacturer's Expectation toward Third Party Certification System			
	18:15-　Friendly Get Together				17:30 - 18:00 Closing Ceremony