

## PMDA-ATC Medical Devices Seminar 2016

Offered by Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)

Date: November 7-11, 2016      Venue: PMDA Meeting rooms #1-3 (6th floor)

	DAY 1 Nov 7 (Mon)	DAY 2 Nov 8 (Tues)	DAY 3 Nov 9 (Wed)	DAY 4 Nov 10 (Thurs)	DAY 5 Nov 11 (Fri)	
<b>AM</b>	9:00 - 10:00 Registration			16. Manufacturing Site Visit  <b>MEET AT 8:00 on the lobby floor of PMDA</b>  <b>MAKE SURE TO BRING YOUR LUNCH!</b>		
	10:00 - 10:15 Opening Ceremony, Photo Session	10:00 - 11:00 7. GCP/GLP Inspection for Medical Devices	10:00 - 12:00 11. Group Work on Review of Medical Devices (Review cases where preparation of guidelines and/or training was required as a condition for approval)			17. Group Work on Review of Medical Devices (Review cases requiring discussion on necessity of clinical data / Review cases of me-too products, etc)
	10:15 - 10:30 1. Seminar Outline					
	10:30 - 11:00 2. Outline of PMDA	11:00 - 12:00 8. Quality Management System for Medical Devices				
11:00 - 12:00 3. Regulations and Ordinance for Medical Device in Japan						
<b>Lunch</b>						
<b>PM(1)</b>	13:00 - 15:00 4. Review and Approval of Medical Devices (definition, classification, review process, bio-products, combination products, etc)	13:00 - 15:00 9. Post-Marketing Safety Measures for Medical Devices, Medical Safety Measures, Package Inserts	13:00 - 14:00 12. Patient registration system (outline of Japanese registry for Mechanically Assisted Circulatory Support, J-MACS)	<b>MAKE SURE TO BRING YOUR LUNCH!</b>	13:00 - 14:00 18. International Activities on Medical Device Regulations (IMDRF guidelines, etc)	
			14:00 - 15:00 13. Standards for Medical Devices (utilization of international standards, etc)		14:00 - 14:30 19. Wrap-up	
<b>Break</b>						
<b>PM(2)</b>	15:30 - 16:30 5. Consultation for Medical Devices	15:30 - 17:30 10. Introduction of Regulations by participants	15:30 - 16:30 14. Review of IVD	<b>MAKE SURE TO BRING YOUR LUNCH!</b>	14:30 - 15:00 Closing Ceremony	
	16:30 - 17:30 6. Clinical Trial for Medical Devices		16:30 - 17:30 15. People Development (significance and approach)			
	18:00- Friendly Get-together					