PMDA-ATC Medical Devices Seminar 2018

Date: November 12-16, 2018　　Venue: PMDA

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

	Day 1 11/12 (Mon)	Day 2 11/13 (Tues)	Day 3 11/14 (Wed)	Day 4 11/15 (Thurs)	Day 5 11/16 (Fri)
AM	9:30 - 10:00 Registration 10:00 - 10:15 Opening ceremony, Photo session 10:15 - 10:30 Seminar outline 10:30 - 11:00 Outline of PMDA	10:00 - 11:00 Review of reprocessing system for single-use device	10:00 - 12:00 Review and approval of IVD	9:00-18:00 Site visit to manufacturing facilities	10:00 - 12:00 Group work on review of medical devices 2 (Review cases where preparation of guidelines and/or training was required as a condition for approval)
	11:00 - 12:00 Regulations, ordinance and current effort for medical devices in Japan. (certification system, early conditional approval system, reprocessing system for single-use device, sakigake-system, and so on)	11:00 - 12:00 Overview of reviewing for additive manufacturing technology, included three-dimensional printing, and customized patient specific devices.			
Lunch	12:00-13:00 Lunch				12:00-13:00 Lunch
PM-1	13:00 - 14:00 Review and approval of medical devices (definition, classsification, essenntial principle, review process, approval process, and so on)	13:00 - 14:00 Consultation -from developing medical devices to getting marketing approval-	13:00 - 15:00 Group work on review of medical devices 1 (review cases requiring discussion on clinical data, and so on)		13:00 - 14:00 Supervise and guidance of registered certification bodies
	14:00 - 15:00 Review of software, categorization of software as “Medical devices” or not, etc.	14:00 - 15:00 GCP/GLP inspection for medical devices - GCP inspections - GLP inspections			14:00 - 15:00 Medical device innovation - Global Market Strategy - Difficulties of Regulatory Application for Global Expansion
Break	15:00-15:30 Break				15:00-15:30 Break
PM-2	15:30 - 17:30 Introduction of regulations by participants	15:30 - 16:30 Quality management system for medical devices	15:30 - 16:30 Registry system for medical devices - Registry system for post-market surveillance - Consideration for registry system (International Medical Device Regulators Forum (IMDRF) registry working group, Clinical Innovation Network (CIN), and so on)		15:30 - 17:30 Post-market safety measures for medical devices
		16:30 - 17:30 Standards for medical devices (utilization of international standards, etc.)	16:30 - 17:30 Introduction of Harmonization By Doing (HBD) activities -Collaboration with Food and Drug Administration (FDA) in the U.S. , MAHs and Academic parties-		
	18:15- Friendly get-together				17:30 - 18:00 Closing ceremony
					18:00 Close