PMDA-ATC Medical Devices Seminar 2017

Date: November 6-10, 2017　　Venue: PMDA

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

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