PMDA-ATC Pharmaceuticals Review Seminar 2018

Date: June 18-22, 2018

Venue: PMDA office in Tokyo and Manufacturing site in Toyama

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-1	10:00-10:20 Opening ceremony, group photo	9:00-9:10 Opening		9:00-9:10 Opening	9:00-9:10 Opening
	10:20-10:30 Seminar outline	9:10-10:00 Toxicology studies, Good Laboratory Practice (GLP), First in Human (FIH) studies		9:10-10:10 Review of Generic Drugs	9:10-10:10 Relief Sevices for Adverse Health Effects
Break		10:00-10:20 Break		10:10-10:30 Break	10:10-10:30 Break
AM-2	10:30-12:00 Outline of PMDA	10:20-12:00 Clinical Trials, Good Clinical Practice (GCP), Inspections		10:30-12:30 Case Study (Review of Generic Drugs) Explanation, Group Discussion, Presentation and PMDA comment	10:30-12:00 Current Effort by PMDA
Lunch	12:00-13:30 Lunch	12:00-13:30 Lunch		12:30-14:00 Lunch	12:00-13:30 Lunch
PM-1	13:30-14:30 Start of Clinical Trial to NDA/MAA	13:30-15:00 Review of New Drugs		14:00-15:00 Review of Biosimilars	13:30-15:20 Current Effort on Chemistry, Manufacturing and Control (CMC)
Break	14:30-14:50 Break	15:00-15:20 Closing		15:00-15:20 Break	15:20-15:30 Break
PM-2	14:50-17:50 Introduction of pharmaceutical regulations by participants			15:20-16:50 Post-marketing Pharmacovigilance	15:30-16:00 Closing Ceremony
	17:50-18:15 Closing			16:50-17:10 Closing	
	18:15- Friendly get together				

Manufacturing site visit and lecture by Toyama Prefecture