PMDA-ATC Pharmaceuticals Review Seminar 2017

Date: June 26-30, 2017　Venue: PMDA and Toyama prefecture

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	9:30-9:50 Opening ceremony, group photo	9:00-9:10　Opening	9:00-9:10　Opening	9:00-9:10　Opening	Manufacturing site visit and lecture in Toyama prefecture
	9:50-10:00 Seminar outline	9:10-10:00 Toxicology studies･Good Laboratory Practice (GLP)･First In Human (FIH) trials	9:10-12:00 Case study (review) *Break during session	9:10-10:00 Post-marketing safety measures	
Break	10:00-11:40 Outline of PMDA	10:00-10:20　Break		10:00-10:20　Break	
AM-2		10:20-12:00 Clinical trials･Good Clinical Practice (GCP) inspections		10:20-12:00 Risk Management Plan	
Lunch	11:40-13:10　Lunch	12:00-13:30　Lunch	12:00-13:30　Lunch	12:00-13:30　Lunch	
PM-1	13:10-14:40 From clinical trial notification to drug review / approval in Japan	13:30-15:00 Review of new drugs	13:30-14:50 Case study (cont'd)	13:30-15:00 Recent challenge to accelerate drug development in Japan	
Break	14:40-15:00　Break	15:00-15:20　Break	14:50-15:10　Break	15:00-15:50 New Drug Development –Target Product Profile & Decision Making Process –	
PM-2	15:00-16:00 Relief services	15:20-16:20 Review of generic drugs	15:10-16:30 Introduction of pharmaceutical regulations by participants		
				15:50-16:00　Break	
	16:00-16:20　Break	16:20-16:40　Wrap-up	16:30-16:50　Wrap-up	16:00-16:30 Closing ceremony	
	16:20-17:40 Self-introduction by participants				
	17:40-18:00　Wrap-up				
	18:15-　Friendly Get-together				