

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 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)	9:10-10:00 Post-marketing safety measures	
Break		10:00-10:20 Break	*Break during session	10:00-10:20 Break	
AM-2	10:00-11:40 Outline of PMDA	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)	13:30-15:10 Recent challenge to accerelate drug development in Japan	
Break	14:40-15:00 Break	15:00-15:20 Break	14:50-15:10 Break	15:10-15:30 Break	
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	15:30-16:20 Wrap-up	
	16:00-16:20 Break	16:20-16:40 Wrap-up	16:30-16:50 Wrap-up		
	16:20-17:40 Self-introduction by participants				
	17:40-18:00 Wrap-up				
	18:15- Friendly Get-together				

as of Apr. 10, 2017