

PMDA-ATC Pharmaceuticals Review Seminar 2019 in Jakarta, Indonesia

Date: January 28-31, 2019 Venue: Grand Mercure Jakarta Kemayoran Hotel, Jakarta, Indonesia

Offered by Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) with Japan International Cooperation Agency (JICA)

	Day 1	Day 2	Day 3	Day 4
	9:30-9:50 Registration	9:30-9:40 Opening	9:30-9:40 Opening	9:30-9:40 Opening
AM-1	10:00-10:20 Opening Ceremony, Group Photo	9:40-10:30 Toxicology Studies · Good Laboratory Practice (GLP) · First In Human (FIH) Trials	9:40-10:40 Review of Biosimilars	9:40-11:30 Current Effort on Chemistry, Manufacturing and Control (CMC)
	10:20-10:30 Seminar Outline			
Break		10:30-10:50 Break	10:40-11:00 Break	
	10:30-12:00 Outline of PMDA	10:50-11:05 Bridging session by BPOM speaker	11:00-11:15 Bridging session by BPOM speaker	
AM-2		11:05-12:45 Clinical Trials · Good Clinical Practice (GCP) Inspections	11:15-12:15 Review of Generic Drugs	
Lunch	12:00-13:30 Lunch	12:45-14:15 Lunch	12:15-13:45 Lunch	
PM-1	13:30-14:30 From Clinical Trial Notification to Drug Review / Approval in Japan	14:15-14:30 Bridging session by BPOM speaker	13:45-15:45 Case Study (Review of Generic Drugs)	13:00-13:15 Bridging session by BPOM speaker
Break	14:30-14:50 Break	14:30-16:00 Review of New Drugs		14:45-15:05 Break
PM-2	14:50-15:50 Relief Services		15:45-16:05 Closing	15:05-16:35 Recent Challenge to Accelerate Drug Development in Japan
	15:50-16:10 Closing	16:00-16:20 Closing		16:35-16:45 Break
				16:45-17:15 Closing Ceremony