

## PMDA-ATC & WHO Pharmaceuticals Review Seminar 2019

Date: July 22-26, 2019

Venue: PMDA office in Tokyo and Manufacturing site in Toyama

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

	Day 1 (July 22)	Day 2 (July 23)	Day 3 (July 24)	Day 4 (July 25)	Day 5 (July 26)
	Meeting Room 21-23@PMDA	Meeting Room 21-23@PMDA	Meeting Room 21-23@PMDA	Yomiuri-Hall	Toyama
AM-1	10:00-10:15 • Opening ceremony, • Opening Remarks from PMDA and WHO • Photo session  • Seminar outline	9:00-9:10 Opening  9:10-10:10 4_Review of New Drugs	9:00-9:10 Opening  9:10-10:10 8_Innovative review pathways	10:00-15:00 13_Seminar for ICH E8 (R1)  10:00-10:10 Opening Remarks	9:30-11:30 14_Manufacturing site visit (Nishihongo Plant, TOA Pharmaceuticals Co., Ltd.)  9:30-10:00 Overview of the Nishihongo Plant
Break		10:10-10:30 Break	10:10-10:30 Break	<Session 1> 10:10-11:55 • ICH Updates including GCP Renovation • Updates on MHLW/PMDA international activities • Current status of ICH E topics	10:00-11:00 Manufacturing Line Tour
AM-2	10:15-11:45 1_Outline of PMDA	10:30-11:30 5_Review of Chemistry, Manufacturing and Control (CMC)	10:30-11:15 9_WHO Efforts to Promote Reliance  11:15-12:00 10_FDA Recent activities		11:00-11:30 Q&A  11:30 Depart Nishihongo Plant
Lunch	11:45-13:15 Lunch	11:30-13:00 Lunch	12:00-13:30 Lunch	11:55-13:00 Lunch	12:00-13:00 Lunch
PM-1	13:15-14:15 2_WHO Recent activities	13:00-14:00 6_Review Process and Consultation for Generic Drugs	13:30-15:20 11_Case Study (Review of Generic Drugs)	<Session 2> 13:00-15:00 • E8 (R1) (Draft): Background, Concept of revised guideline (draft), Regulatory perspective	13:00-14:30 (Room 702, Toyama Prefectural Civic Center) 15_Drugs Approved by the Toyama Prefectural Government
Break	14:15-14:35 Break	14:00-14:20 Break	15:20-15:40 Break		14:30-14:45 Break
PM-2	14:35-17:35 3_Introduction of pharmaceutical regulations by participants	14:20-15:50 7_Review of Biosimilars	15:40-16:40 12_Post-marketing Pharmacovigilance	15:00- Travel to Toyama	14:45-15:30 Closing Ceremony • Closing Remarks from PMDA
	17:35-17:40 Closing	15:50-16:10 Closing	16:40-17:00 Closing		
	17:40-18:15 Break				
	18:15- Friendly get together				