

## PMDA-ATC Pharmaceuticals Review Seminar for JICA trainees 2023

Period : 20-26, July 2023

As of July 6th,2023

### Program in Tokyo

JST	Day1 Thursday, July 20	Day2 Friday, July 21
10:00-11:00	10:00-10:30 <u>Opening ceremony</u> Self-introduction/ Group photo	10:00-11:00 <u>Session 5</u> Approval Review of New drug
	10:30-10:50 <u>Session 1</u> History of PMDA	
	<u>Break (10 min)</u>	
11:00-12:00	11:00-12:00 <u>Session 2</u> Outline of PMDA	11:00-12:00 <u>Session 6</u> GCP Inspection Conducted by PMDA/ GLP Compliance Monitoring in PMDA
12:00-13:30	<u>Lunch (90 min)</u>	<u>Lunch (90 min)</u>
13:30-14:30	13:30-14:30 <u>Session 3</u> Collection of Safety Information and Dissemination of Risk Communication During the Post-marketing Phase	13:30-14:30 <u>Session 7</u> Review of Generic Drugs
14:30-15:00	<u>Break (30 min)</u>	<u>Break (30 min)</u>
15:00-16:00	15:00-16:00 <u>Session 4</u> Safety Measures for Drugs and Evaluation of Safety Information	15:00-16:00 <u>Session 8</u> Regulatory framework and review practice for OTC products/ Quasi-Drugs in

### Program in Toyama

JST	Day3 Monday, July 24	Day4 Tuesday, July 25	Day5 Wednesday, July 26
9:15-12:00	9:15-9:45 <u>Greeting from Toyama prefectural government</u>	9:30-10:00 Travel (from Toyama Prefectural government to a Manufacturing site)	9:15-10:00 Travel (from Toyama Prefectural government to Toyama Prefectural Institute for Pharmaceutical Research)
	9:45-10:15 Travel (from Toyama Prefectural government to a meeting site)	10:00-12:00 <u>Site tour 1</u> Manufacturing site 1	10:00-12:00 <u>Site tour 3</u> Toyama Prefectural Institute for Pharmaceutical Research
	10:15-12:00 <u>Session 9</u> Pharmaceutical administration in Toyama Prefecture		
12:00-13:00	<u>Lunch (90min)</u>	<u>Lunch (60 min)</u>	<u>Lunch (60 min)</u>
13:00-16:00		13:00-13:45 Travel (from the Manufacturing site1 to the site 2)	13:00-14:00 Travel (from Toyama Prefectural Institute for Pharmaceutical Research to a Center for Medicinal Plant Resources)
	13:30-15:00 <u>Session 10</u> 1. GMP regulation in Japan 2. Basic Knowledge of Active substances	13:45-15:45 <u>Site tour 2</u> Manufacturing site 2	14:00-16:00 <u>Site tour 4</u> Center for Medicinal Plant Resources
		15:45-16:15 Travel (Manufacturing site 2 to Toyama Prefectural government)	16:00-16:15 <u>Closing</u>
			16:15-17:00 Travel (from a Center for Medicinal Plant Resources to Toyama Prefectural government)