

## PMDA-ATC Pharmaceuticals Review Seminar 2016

### DRAFT AGENDA

Date: July 25-29, 2016 Venue: PMDA (6th floor, Meeting rooms #1-5)

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

	Day 1 (July 25, Mon)	Day 2 (July 26, Tues)	Day 3 (July 27, Wed)	Day 4 (July 28, Thurs)	Day 5 (July 29, Fri)
	Session Title	Session Title	Session Title	Session Title	Session Title
10:00-12:00		10:00 - 11:00 ⑤Clinical Trial	10:00 - 12:00 ⑨Product Review	10:00 - 12:00 ⑭Product Review (case study)	10:00 - 11:00 ⑱People Development
		11:00 - 12:00 ⑥Consultation			11:00 - 11:30 Wrap-up 11:30 - 12:30 Closing ceremony Photo session
Lunch					
13:00-15:00	13:00 - 14:00 Registration	13:00 - 14:00 ⑦Consultation (cont'd)	13:00 - 14:00 ⑩Product Review (cont'd)	13:00 - 14:00 ⑭Product Review (case study)	
	14:00 - 14:15 Opening Ceremony				
	14:15 - 14:30 ①Seminar outline	14:00 - 15:00 ⑧Consultation (case study)	14:00 - 15:00 ⑪Package Insert	14:00 - 15:00 ⑮Relief Services	
	14:30 - 15:00 ②Outline of PMDA				
Break					
15:15-17:30	15:15 - 16:30 ③Outline of PMDA (cont'd)	15:15 - 17:15 ⑧Consultation (case study)	15:15 - 16:15 ⑫Post-Market Safety	15:15 - 16:15 ⑯Product Life Cycle Management	
	16:30 - 17:15 ④Introduction of regulations by participants		16:15 - 17:15 ⑬Risk Management Plan	16:15 - 17:15 ⑰Utilization of the learnings (discussion among participants)	
	17:15 - 17:30 Wrap-up	17:15 - 17:30 Wrap-up	17:15 - 17:30 Wrap-up	17:15 - 17:30 Wrap-up	
18:00-	Friendly Get-together				