



PMDA-ATC GMP Inspection Seminar 2017

with the support of 

Program

July 31st – August 4th, 2017

No.	WG#	Ref	Title & Key Description	Time
Day 1: 9:00am – 17:20pm				
Registration Takeda Pharmaceutical Co., Ltd., Hikari-city, Yamaguchi, Japan				9:00am - 9:30am
1			Plenary presentation – Opening remarks from Japan, the host country	9:30am - 9:40am
2			Plenary presentation – purpose of training and introductory remarks	9:40am - 9:50am
3			Plenary presentation – overview of manufacturing site Takeda Pharmaceutical Co., Ltd. 1. Outline of drug manufacturing site 2. Layout of the manufacturing site 3. QRM 4. Plan of structures and facilities of the manufacturing site 5. GMP organization chart and quality assurance system 6. List of GMP documents 7. Outline of HVAC, processed water, 8. Outline of cleaning validation, preventive maintenance of facilities 9. Documents concerning the manufacturing process 10. Summary of process validation 11. History of deviation and change control 12. History of recall and claim	9:50am - 11:20am
Lunch 11:20am – 12:20pm				
4			Presentation and workshop – how to make a risk based inspection plan using SMF	12:20pm - 15:20pm
Break 15:20pm – 15:40pm				
5			Workshop: inspection planning	15:40pm - 17:20pm
End of Day 1 –Networking Event this Evening				

No.	WG#	Ref	Title & Key Description	Time
Day 2: 9:00am – 16:30pm				
6			Basic manner at mock inspection	9:00am - 9:30am
7			Mock inspection	9:30am - 12:30pm
Lunch 12:30pm – 13:30pm				
8			Mock inspection	13:30pm - 16:30pm
End of Day 2				
Day 3: 9:00am – 17:00pm				
9			Mock inspection	9:00am - 12:00am
Lunch 12:00am – 13:00pm				
10			Group work: Summarizing of concerns during plant tour and select documents to be confirm	13:00pm - 17:00pm
End of Day 3				
Day 4: 9:00am – 17:00pm				
11			Q&A session Remaining questions founded during mock inspections	9:00am - 10:00pm
12			Group work: Document inspection	10:00am - 13:00pm
Lunch 13:00pm – 14:00pm				
13			Group work: Document inspection	14:00pm - 17:00pm
End of Day 4				
Day 5: 9:00am – 17:00pm				
14			Group work: Document inspection	9:00am - 12:00am
Lunch 12:00am – 13:00pm				
15			Group work:	13:00pm - 15:00pm

No.	WG#	Ref	Title & Key Description	Time
			Summarizing of findings	
16			Group work: Presentation of findings	15:00pm - 16:00pm
17			Summary <ul style="list-style-type: none"> • Comment from facilitators • Comment from the site 	16:00pm - 16:30pm
18			Closing session Closing remarks	16:30pm - 17:00pm
End of training seminar				