Pharmaceuticals and Medical Devices Agency

with the support of PIC/S

Draft Program

PMDA-ATC GMP Inspection Seminar 2017, July 31st – August 4th, 2017

No.	*WG#*	*Ref*	*Title & Key Description*	*Time*
Day 1: 9:00am – 17:20pm				
Takeda Pharmaceutical Co., Ltd., Hikari-city, Yamaguchi, Japan				9:00am - 9:30am
1			**Plenary Presentation – Opening Remarks from Japan, Host Country** Dr. Junko Sato, Office Director, Office of International Cooperation, PMDA, Japan	9:30am - 9:40am (10mins)
2			**Plenary Presentation – Purpose of training and Introductory Remarks** Ms. Mami Yabuki, Principle Inspector of GMP Inspection, Office of Manufacturing/Quality and Compliance, PMDA, Japan	9:40am - 9:50am (10mins)
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 - 11:20pm (90mins)
Day 1: Lunch 11:20pm – 12:20pm				
4			**Presentation and Workshop – How to make a risk based inspection planning using SMF**	12:20pm - 15:20pm (180mins)
Break 15:20pm – 15:40pm				

5			**Workshop: Inspection planning**	15:40pm - 17:20pm (100mins)
End of Day 1 –Networking Event this Evening				
Day 2: 9:00am – 16:30pm				
6			**Basic Manner at Mock Inspection** Ms. Mami Yabuki, Principle Inspector of GMP Inspection, Office of Manufacturing/Quality Compliance, PMDA, Japan	9:00am - 9:30am (30mins)
7			**Mock Inspection**	9:30am - 12:30am (180mins)
Day 2: Lunch 12:30pm – 13:30pm				
8			**Mock Inspection**	13:30pm - 16:30pm (180mins)
End of Day 2				
Day 3: 9:00am – 17:00pm				
9			**Mock Inspection**	9:00am - 12:00am (180mins)
Day 3: Lunch 12:00 – 13:00pm				
10			**Group work:** Summarize concerns during plant tour and select documents to be confirm	13:00pm - 17:00pm (240mins) include 30mins break
End of Day 3				
Day 4: 9:00am – 17:00pm				
11			**Q&A session** Remaining Questions founded during Mock inspections	9:00am - 10:00pm (60mins)
12			**Group work: Document inspection**	10:00am - 13:00pm (180mins)
Day 4: Lunch 13:00pm – 14:00pm				
13			**Group work: Document inspection**	14:00pm - 17:00pm (180mins)
End of Day 4				
Day 5: 9:00am – 17:00pm				
14			**Group work: Document inspection**	9:00am - 12:00am (180mins)
Day 5: Lunch 12:00pm – 13:00pm				
15			**Group work:** Summarize findings	13:00pm - 15:00pm (120mins)
16			**Group work:** • Presentation of findings	15:00am - 16:00am (60mins)

17			**Summary** • Comment from Facilitator • Comment from Site	16:00pm - 16:30pm (30mins)
18			**Closing session** **Closing remarks** Dr. Shingou Sakurai, Office Director, Office of Manufacturing/Quality and Compliance, PMDA, Japan	16:30pm - 17:00pm (30mins)
End of training seminar				