




PMDA-ATC GMP Inspection Seminar 2016

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

with the support of 

Program

December 5th – 9th, 2016

No.	Title & Key Description	Time
Day 1: 9:30am to 17:30pm		
	Registration: Toyama Prefectural Civic Center, Shinsogawa 4-18, Toyama-city, Toyama 930-0006, Japan	9:30am – 10:00am
1	Opening ceremony	10:00am - 10:05am (5mins)
2	Presentation –Purpose of training and Introductory Remarks	10:05am - 10:15am (10mins)
3	Presentation – Latest information of PIC/S	10:15am – 11:45pm (90mins)
Day 1: Lunch 11:45pm-12:30pm Greetings 12:30pm-13:00pm		
4	Presentation and Workshop – Where and what will be a potential risk for manufacturing solid dosage form	13:00pm – 15:00pm Include Workshop (75mins)
Break 15:00pm – 15:20pm		
5	Basic Manner at Mock Inspection	15:20pm – 15:50pm (30mins)
6	Presentation – Interpretation of “Data Integrity considerations for electronic-based systems”	16:00pm – 17:10pm (70mins)
End of Day 1 –Networking Event this Evening		

Day 2: 9:00am to 17:00pm		
7	Presentation - Overview of Manufacturing Site 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	9:00am – 12:00am (180mins) Include 10min break
Day 2: Lunch 12:00pm – 13:00pm		
8	Workshop: Inspection planning	13:00pm – 17:00pm Workshop(240mins) Include 45min break
End of Day 2		

Day 3: 9:00am to 17:00pm		
9	Point to notice for Mock inspection	9:00am-9:30am (30mins)
10	Mock Inspection	9:30am-11:30am (120mins)
Day 3: Lunch 11:30 – 12:30pm		
11	Mock Inspection contd.	12:30pm-14:30pm (120mins)
Break 14:30pm-15:00pm (30mins)		
12	Mock Inspection contd.	15:00pm-17:00pm (120mins)
End of Day 3		

Day 4: 9:00am to 17:00pm		
13	Group work: <ul style="list-style-type: none"> Summarize concerns during plant tour and select documents to be confirm 	9:00am - 12:00pm (120mins)
Day 4: Lunch 12:00pm – 13:00pm		
14	Group work: Document inspection	13:00pm - 17:00pm (240mins)
End of Day 4		

Day 5: 9:00am to 13:00pm		
Mock Inspection contd.		
15	Group work: <ul style="list-style-type: none"> Summarize findings 	9:00am - 10:00am (60mins)
16	Group work: <ul style="list-style-type: none"> Presentation of findings 	10:00am - 11:00am (60mins)
17	Summary <ul style="list-style-type: none"> Comment form lecturers Comment form manufacturing site 	11:00am - 12:00pm (60mins)
18	Closing ceremony	12:00pm - 12:30pm (30mins)
End of seminar		