Pharmaceuticals and Medical Devices Agency

with the support of PIC/S

Program

PMDA-ATC GMP Inspection Seminar 2016, December 5th – 9th, 2016

No.	*WG#*	*Ref*	*Title & Key Description*	*Time*
Day 1: 9:30am – 17:30pm				
			Registration: Toyama Prefectural Civic Center, Shinsogawa 4-18, Toyama-city, Toyama 930-0006, Japan	9:30am – 10:00am
1			**Plenary Presentation - Welcome Presentation from Japan, Host Country**	10:00am - 10:10am (10mins)
2			**Plenary Presentation –Purpose of training and Introductory Remarks** Mr. Masatoshi Morisue, Director of GMP Inspection, Office of Manufacturing/Quality Compliance, PMDA, Japan	10:10am - 10:30am (20mins)
3			***Presentation – Latest information of PIC/S*** Mr. Meow Hoe Boon, HSA, Singapore	10:30am – 12:00pm (90mins)
Day 1: Lunch 12:00pm-13:00pm				
4			**Presentation and Workshop – Where and what will be a potential risk for manufacturing solid dosage form** Dr. Kevin O'Donnell, HPRA, Ireland	13:00pm – 15:00pm Include Workshop (75mins)
Break 15:00pm – 15:20pm				
5			**Presentation – Interpretation of "Data Integrity considerations for electronic-based systems"** Mr. David Churchward, MHRA, United Kingdom	15:20pm – 17:00pm (100mins)

6			**Basic Manner at Mock Inspection** Mr. Masatoshi Morisue, Director of GMP Inspection, Office of Manufacturing/Quality Compliance, PMDA, Japan	17:00pm – 17:30pm (30mins)
End of Day 1 –Networking Event this Evening				
Day 2: 9:00am to 17:00pm Astellas Pharma Tech Co., Ltd.,				
7			**Plenary 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:** • 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:** • Summarize findings	9:00am - 10:00am (60mins)
16			**Group work:** • Presentation of findings	10:00am - 11:00am (60mins)
17			**Summary** • Comment form PIC/S Speaker • Comment form Site	11:00am - 12:00pm (60mins)
18			**Closing session** **Closing remarks**	12:00pm - 12:30pm (30mins)
End of training seminar				