

PMDA-ATC GMP Seminar 2019

Date: November 12-15, 2019

Venue: Toyama Prefectural Civic Center, ANA CROWNE PLAZA TOYAMA

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

	Day 1 (Nov 12)	Day 2 (Nov 13)	Day 3 (Nov 14)	Day 4 (Nov 15)
	Toyama Prefectural Civic Center	ANA CROWNE PLAZA TOYAMA	ANA CROWNE PLAZA TOYAMA	AM: ANA CROWNE PLAZA TOYAMA PM: Toyama Prefectural Civic Center (TBD)
AM-1		9:00-9:15 4_Opening Remarks of PIC/S Seminar	09:00-10:00 11_Risk-management for sterile products	9:00-10:00 16_Examples of observations for Sterile Products
		9:15-10:00 5_Summary of revised Annex1		
AM-2		10:00-10:45 6_Discussed points during revision	10:00-11:00 12_Single use (SU) System	10:00-11:00 17_Rapid Microbiological Methods
Break		10:45-11:10 Break	11:00-11:30 Break	11:00-11:30 Break
AM-3		11:10-11:55 7_Process Simulation Test (PST)	11:30-12:30 13_Management of WFI	11:30-12:10 18_Summary of Workshop by Speaker and panel discussion
AM-4		11:55-12:40 8_Clean room management for sterile products		12:10-12:40 19_2020 Seminar Address 20_Closing remarks of PIC/S Seminar
Lunch		12:40-13:40 Lunch	12:30-13:30 Lunch	12:40-14:00 Lunch
PM-1	14:30-15:00 Opening Ceremony, Orientation of the Seminar Group Photo	13:40-15:10 9_Workshop W1: Process Simulation Test (PST) W2: Clean room qualification and Environmental Monitoring	13:30-15:00 14_Workshop W3: Single Use W4: Restricted Access Barriers technology (RABS) and Isolators	14:00-15:30 21_Re-cap of the Seminar
	15:00-15:30 1_Outline of PMDA			
	15:30-16:00 2_GMP Compliance Inspection by the Toyama Prefectural Government			
Break	16:00-16:30 Break	15:10-15:40 Break	15:00-15:30 Break	15:30-15:40 Break
PM-2	16:30-17:20 3_Introduction of PIC/S activity (include Q&A)	15:40-17:10 10_Workshop W1: Process Simulation Test (PST) W2: Clean room qualification and Environmental Monitoring	15:30-17:00 15_Workshop W3: Single Use W4: Restricted Access Barriers technology (RABS) and Isolators	15:40-16:10 Closing Ceremony
	End of Day1	End of Day2	End of Day3	
	18:00-20:00 PIC/S Seminar Welcome Reception	18:30-20:30 Networking Event		