

Day 1: October 22th（初日：10月22日）

		Lecture Time	Q&A		Name and affiliation	Presentation Title
9:00	10:00	60min	0min	Reception		
10:00	10:05	5min	0min	Opening Remarks	Yasuhito Ikematsu Director, PDA Japan Chapter	
10:05	10:20	15min	0min	Opening Remarks	Yoshiki Sawa President, Organization for Advanced Healthcare Innovation	Introduction to Nakanoshima Qross
10:20	10:55	30min	5min	Keynote Presentation	Hirokazu Sugiyama Professor, Dept. of Chemical System Engineering School of Engineering, The University of Tokyo	Digital design of pharmaceutical manufacturing processes and modality expansion:New approach in the Annex 1 Era
10:55	14:55			Category : Regulatory Perspective & Trends		
10:55	11:40	40min	5min	Presentation 1	WASHIO Atsushi, MBA Associate Senior Scientist （for Inspection） Kansai Branch Office of Manufacturing/Quality and Compliance Pharmaceuticals and Medical Devices Agency (PMDA)	Annex1 Implementation in Japan: Insights from PMDA's Inspections and Future Perspectives
11:40	13:10	90min		Lunch	Luncheon Seminar (Platinum Sponsor: 15 minutes per company) & Corporate Exhibition	
13:10	13:45	30min	5min	Presentation 2	Yasuhito Ikematsu Specially Appointed Associate Professor, Graduate School of Engineering,The University of Osaka	Commentary on the Japanese Pharmacopoeia, 19th Edition: “Rapid Microbiological Methods <G4-6-190>”
13:45	14:20	30min	5min	Presentation 3	Takao Ashikaga Head, 4th Section, Division of Genomic Safety Science, National Institute of Health Sciences	JP19 General Information, Recent Progress of Monocyte Activation Test （MAT） Method <G4-13-190>
14:20	14:55	30min	5min	Presentation 4	Ying-Hua(Ellen) Chen Director, Division Quality Compliance and Management, Taiwan Food & Drug Administration(TFDA) , Ministry of Health and Welfare	Navigating Annex 1 Implementation in Taiwan: TFDA’s Regulatory Perspectives and PIC/S Collaboration
14:55	15:25	30min		Coffee Break		
15:25	17:45			Category : Contamination Control Strategy		
15:25	16:00	30min	5min	Presentation 5	Yuichi Minato Kyowa Kirin Co., Ltd. （J-PDA Sterile Products GMP Committee RG-3）	Development, Documentation, and Implementation of a Contamination Control Strategy （CCS）
16:00	16:35	30min	5min	Presentation 6	Takashi Miyamoto Takeda Pharmaceutical Limited （J-PDA Sterile Products GMP Committee RG-5）	Key Considerations for the Practical Implementation of Aseptic Process Simulation （APS） under PIC/S GMP Annex 1
16:35	17:10	30min	5min	Presentation 7	Saori Shikama, Ph.D. Analtical Development Associate Director, Takeda	Implementing Contamination Control Strategy Through Continuous Improvement
17:10	17:45	30min	5min	Presentation 8	Alberto González Takeda （España） Global Sterility Assurance and Microbiology Associate Director	APS Challenges and Proposed Solutions
18:00	19:30			Social gathering (standing)		

Day 2: October 23th (2日目：10月23日)

		Lecture Time	Q&A		Name and affiliation	Presentation Title
8:30	9:00	30min	0min	Reception		
9:00	11:30			Category : Aseptic Manufacturing		
9:00	9:35	30min	5min	Presentation 9	Sebastian Scheler Innerspace Co-Founder and Managing Director	AI and aseptic manufacturing simulation technology
9:35	10:10	30min	5min	Presentation 10	Chikako Yabuki Merck Ltd. (J-PDA Sterile Products GMP Committee RG-4)	Major Revision Points in PDA Technical Report No. 26, “Sterilizing Filtration of Liquids” (Revised 2025)
10:10	10:20	10min		Rest		
10:20	10:55	30min	5min	Presentation 11	Brent Loeffers Cytiva Senior Director, Innovation Advocacy	Gloveless isolator - Recent Progress on Isolator Technology (Negotiations are currently underway through Shirokizawa-san)
10:55	11:30	30min	5min	Presentation 12	Richard Denk DACH (Germany, Austria, Switzerland) President elect SKAN, Senior Consultant Aseptic Processing & Containment	does and don`t about Robotics in Aseptic Manufacturing
11:30	12:30	60min		Lunch	Luncheon Seminar (Platinum Sponsor: 15 minutes per company) & Corporate Exhibition	
12:30	14:50			Category : QC&QA		
12:30	13:05	30min	5min	Presentation 13	Kenji Kimura Daiichi Sankyo Co., Ltd. (J-PDA Sterile Products GMP Committee RG-2)	Advanced Implementation of PIC/S GMP Annex 1: Leveraging Rapid Microbiological Methods in Pharmaceutical Water Quality Control
13:05	13:40	30min	5min	Presentation 14	Kenta Yoshii Santen Pharmaceutical Co., Ltd. (J-PDA Sterile Products GMP Committee RG-2)	Advanced Practical Application of Rapid Microbiological Methods in Gowning Training Based on PIC/S GMP Annex 1
13:40	14:15	30min	5min	Presentation 15	Yuki Kaneko Takeda Pharmaceutical Limited (J-PDA Sterile Products GMP Committee RG-1)	Japan-Originated Establishment of Visual Inspection Program for Insoluble Particulate Matter in Injections and Prospects toward Global Standardization
14:15	14:50	30min	5min	Presentation 16		
14:50	15:20			Coffee Break		
15:20	15:55	30min	5min	Presentation 17	Masakazu Tsuchiya, PhD Senior Research Scientist Microbial Solutions division, Charles River Laboratories Japan, Inc.	Recent Trends in Endotoxin Testing
15:55	16:40	40min	5min	Presentation 18	Special Invited Lecture Tracy Moore Senior Director, Lackman Consultants (United Kingdom) President, PDA UK Chapter Board	
16:40	16:50			Summary & Closing remarks	Richard Denk DACH (Germany, Austria, Switzerland) President elect SKAN, Senior Consultant Aseptic Processing & Containment	