

Day 1: October 22nd (初日：10月22日)

			Name and affiliation	Presentation Title
9:00	10:00	Reception		
10:00	10:05	Opening Remarks	Rumiko Shimazawa President, PDA Japan Chapter	
10:05	10:20	Opening Remarks	Yoshiki Sawa President, Organization for Advanced Healthcare Innovation	Introduction to Nakanoshima Qross
10:20	10:55	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 Moderator:Kentarō Hara, Ph.D., Office Director, Office of Manufacturing Quality for Drugs, Pharmaceutical and medical Devices Agency (PMDA)		
10:55	11:40	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	Lunch	Luncheon Seminar 11:40-11:55 Korber、12:00-12:15 Lonza) & Corporate Exhibition	
13:10	13:45	Presentation 2	Mitsuo Mori Vice President, Manufacturing/SCM DX Promotion Unit, Manufacturing Kyowa Kirin Co., Ltd.	Commentary on the Japanese Pharmacopoeia, 19th Edition: General Information “Rapid Microbial Methods <G4-6-190>”
13:45	14:20	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	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	Coffee Break		
15:25	17:45	Category : Contamination Control Strategy Moderator: Mitsuo Mori, Vice President, Manufacturing/SCM DX Promotion Unit, Manufacturing		
15:25	16:00	Presentation 5	Yuichi Minato Kyowa Kirin Co., Ltd. (RG-3, The Aseptic Products GMP Committee, PDA Japan Chapter)	Development, Documentation, and Implementation of a Contamination Control Strategy (CCS)
16:00	16:35	Presentation 6	Takashi Miyamoto Takeda Pharmaceutical Limited (RG-5, The Aseptic Products GMP Committee, PDA Japan Chapter)	Key Considerations for the Practical Implementation of Aseptic Process Simulation (APS) under PIC/S GMP Annex 1
16:35	17:10	Presentation 7	Saori Shikama, Ph.D. Associate Director, Analytical Development, Pharmaceutical Sciences, Takeda	Implementing Contamination Control Strategy Through Continuous Improvement
17:10	17:45	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 23rd (2日目：10月23日)

			Name and affiliation	Presentation Title
8:30	9:00	Reception		
9:00	11:30	Category : Aseptic Manufacturing Moderator: Manabu Mizutani, Ph.D., Associate Professor, Graduate School of Engineering, Osaka University		
9:00	9:35	Presentation 9	Sebastian Scheler Innerspace Co-Founder and Managing Director	AI and aseptic manufacturing simulation technology
9:35	10:10	Presentation 10	Chikako Yabuki Merck Ltd. (RG-4, The Aseptic Products GMP Committee, PDA Japan Chapter)	Major Revision Points in PDA Technical Report No. 26, “Sterilizing Filtration of Liquids” (Revised 2025)
10:10	10:20	Rest		
10:20	10:55	Presentation 11	Brent Lieffers Cytiva Sr. Director, Innovation Advocacy - Aseptic Filling	PDA / ANSI Standard 03-2025 Standard Practice for Quality Risk Management of Aseptic Processes A Holistic Approach to Quality Risk Management for Aseptic Manufacturing
10:55	11:30	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	Lunch	Luncheon Seminar (11:30-11:45 AICosmo) & Corporate Exhibition	
12:30	14:50	Category : QC&QA Moderator: Yuto Arima, Takeda Pharmaceutical Limited, Sterility Assurance Operation G-Head		
12:30	13:05	Presentation 13	Kenji Kimura Daiichi Sankyo Co., Ltd. (RG-2, The Aseptic Products GMP Committee, PDA Japan Chapter)	Advanced Implementation of PIC/S GMP Annex 1: Leveraging Rapid Microbial Methods in Pharmaceutical Water Quality Control
13:05	13:40	Presentation 14	Kenta Yoshii Santen Pharmaceutical Co., Ltd. (RG-2, The Aseptic Products GMP Committee, PDA Japan Chapter)	Application of Rapid Microbial Methods for Gowning Training under PIC/S GMP Annex 1
13:40	14:15	Presentation 15	Yuki Kaneko Takeda Pharmaceutical Limited (RG-1, The Aseptic Products GMP Committee, PDA Japan Chapter)	Establishment of a Japan-Initiated Program for Visual Inspection of Visible Particulates in Sterile Injectable Products and Prospects for Global Standardization
14:15	14:50	Presentation 16	Masakazu Tsuchiya, PhD Senior Research Scientist Microbial Solutions division, Charles River Laboratories Japan, Inc.	Recognition of Biases and Errors in Bacterial Endotoxins Test
14:50	15:20	Coffee Break		
15:20	16:05	Presentation 17	Special Invited Lecture Tracy Moore Senior Director, Lachman Consultants (United Kingdom) President, PDA UK Chapter Board Former MHRA Inspector and was involved in the revision of Annex 1	Safeguarding the Critical Zone Material Transfer, Barrier Technology, Glove Strategy and First Air
16:05	16:10	Short Break		
16:10	16:40	Panel Discussion	Moderator: Yoji Sato Panelist: Ying-Hua(Ellen) Chen, Kentaro Hara, Tracy Moore, Rumiko Shimazawa	Advancement and Future Directions of PIC/S GMP Annex 1 (Regulatory matters)
16:40	16:50	Summary & Closing remarks	Richard Denk DACH (Germany, Austria, Switzerland) President elect SKAN, Senior Consultant Aseptic Processing & Containment	