

2025 Annual Meeting Program (Japan Affiliate)

May 29 Annual General Meeting 9:30-10:20

5F Hall	9:30-10:20	50	Welcome				
			Nomination and Election of AGM chairman				
			2024 Activity Report				
			2024 Financial Report				
			2024 Internal Audit Report				
			2025 Action Plan				
			2025 Budget Proposal				
			2025 Election Results of Board & Officers				
			Bylaw Revision				

May 29 Annual Conference 10:30-17:45

Venue	Time	minutes	Title		Speaker	Affiliation	Moderator	Affiliation
5F Hall	10:30-10:35	5	Orientation					
	10:35-10:45	10	Opening Remarks		Hirokazu Kisaka	ISPE Japan Affiliate, Chair		
	10:45-11:05	20	ISPE HQ Update	ISPE HQ Update (*)Video	Vivianne J. Arencibia	ISPE HQ, Chair		
	11:05-11:55	50	Keynote Speech 1			経済産業省 生物化学産業課		
2F Event Hall	11:55-13:00	65	Lunch (Luncheon Seminar)					
5F Hall	13:00-13:50	50	Keynote Speech 2	厚生省アップデート（仮）	Tsuyoshi Yamamoto	厚生労働省 医薬局 監視指導・麻薬対策課 室長		
	13:50-14:40	40	Special Lecture 1	DX/AIのトレンド（仮）	Masahiro Teranabe	中外製薬株式会社		
	14:40-15:20	40	FDA Update	FDA Oversight of Drug Quality (Updated) (*)Video	Jeinifer Maguire	CDER/FDA		
2F Event Hall	15:20-16:00	40	Coffee Break					
5F Hall	16:00-16:50	50	Special Lecture 2	創薬スクリーニングへのAIの活用（仮）	Ryuji Kato	名古屋大学 創薬科学研究科 基盤創薬学専攻 創薬生物化学		
	16:50-17:40	50	Keynote Speech 3	AIの全般的な話題（仮）	Yoshihiro Matsuda	PMDA		
	17:40-17:45	5	Closing Remark for Day 1		Tetsuro Noguchi	大会実行委員長		
2F Event Hal	18:10-20:10	120	交流会					

May 30 Workshops 9:30-17:00

Venue	Time	minutes		Title	Speaker	Affiliation	Moderator	Affiliation
2 F Zuiun	9:30-12:45 Workshop 1-1 : BIO & ATMP COP							
	Theme : Paving the Future: Leading the World in Advanced Therapies and Biopharmaceuticals! Teams ATMP & BIO!!				MC :			
	9:30-9:45	15	Intro	COP activities and lecture content	Tsutomu Igarashi Takashi Kaminagayoshi	ATMP COP Leader, Takeda Pharmaceuticals BIO COP Leader, Takeda Pharmaceuticals	N/A	
	9:45-10:25	40	Keynote Speech	Aiming to be a thriving drug discovery ecosystem open to the world	Toshio Fujimoto	Chief Executive Officer, iPark Institute Co., Ltd.	Tsutomu Igarashi	Takeda Pharmaceuticals
	10:25-11:05	40	Special Lecture1	ISPE ATMP CoP: Global Collaboration, Local Impact, and Regulatory Alignment	Liu Shanshan	No Deviation Pte Ltd/ISPE International Board of Director		
	11:05-11:20	20	Coffee Break					
	11:20-12:00	40	Special Lecture2	Frontiers in ATMPs	Zhang Peiqing	Cytiva/ISPE Singapore Affiliate President	Tsutomu Igarashi	Takeda Pharmaceuticals
	12:00-12:25	25	Program1	2025 ATMP CoP Activity Report – Capturing Emerging Trends in Cell Therapy ① Autologous vs. Allogeneic Cell Therapies: Insights into Regulatory, Manufacturing, and Quality Considerations	Kenichi Tahara	Takara Bio Inc.		
	12:25-12:45	20	Program2	2025 ATMP CoP Activity Report – Capturing Emerging Trends in Cell Therapy ② Supply chain and transportation technology for ATMPs: Quality strategies for different temperature zones.	Tetsuro Hatsuoka	Kajima Corporation		
	12:45-13:45	60	Lunch	(Mini-Luncheon Seminar)				
	13:45-17:00 Workshop 1-2 : BIO & ATMP COP							
	Theme : Evolving Manufacturing Technologies and New Risk-Based Management Strategies: With an eye on Sustainability				MC : Takashi Kaminagayoshi	Takeda Pharmaceutical Company Limited.		
	13:45-13:50	5	Intro		Takashi Kaminagayoshi	Takeda Pharmaceutical Company Limited.	—	
	13:50-14:40	50	Program1	Revolutionizing Bioprocess Development: How to evaluate your green design?	Yuki Abe	Biopharm Services Ltd	Shuji Ninomiya	JGC HOLDINGS CORPORATION
	14:40-14:50	10	Coffee Break					
	14:50-16:00	70	Program2	"ISPE Baseline Guide : Biopharmaceutical Manufacturing Facilities 3rd Edition" lead the new world for biopharmaceutical manufacturing	Keisuke Shibuya Yu Kamine Tomohiro Sakogawa	Hitachi, Ltd Biopharmaceutical Facility Engineering & Cosulting KANEKA CORPORATION	Yutaro Niitsuma Kentaro Nagatomo	Hubnet Co.,Ltd DAIICHI SANKYO COMPANY, LIMITED
	16:00-16:20	20	Coffee Break					
	16:20-17:00	40	Panel discussion	ATMP & BIO Joint Event Panel Discussion	Liu Shanshan Zhang Peiqing Yuki Abe Takashi Kaminagayoshi Sei Murakami Kenichi Tahara	No Deviation Pte Ltd/ISPE International Board of Director Cytiva/ISPE Singapore President Biopharm Services Ltd Takeda Pharmaceutical Company Limited. Hitachi, Ltd Takara Bio Inc.	Osamu Shirakisawa	Life Scientia Limited

Venue	Time	minutes		Title	Speaker	Affiliation	Moderator	Affiliation
2 F Heian	9:30-12:45 Workshop 2-1 : SPP & Packaging							
	Theme : Invitation to a profound, aseptic processing world				MC : Yuri Enomoto	MORIMURA BROS., INC.		
	9:30-9:50	20		COP activities and lecture content	Kentaro Nakamura Mao Hirata	SPP COP Leader, JGC JAPAN CORPORATION Packaging COP Leader, FUKUDA CO., LTD.	N/A	
	9:50-10:40	50		Key Points of Smoke Studies learned from FDA Form 483 Case Studies	Takeshi Ono Takashi Yoneyama	DAIICHI SANKYO CO., LTD. MORIMURA BROS., INC.	Takeshi Ono	DAIICHI SANKYO CO., LTD.
	10:40-10:55	15	Coffee Break					
	10:55-11:45	50		Working positions for measuring airflow velocity. ～Observations on actual measurements～ How to test recovery characteristics in clean rooms. ～Observations on actual measurements～	Yuta Yamada Katsuya Inoue	AIREX Co., Ltd. ASAHI KOGYOSHA CO., LTD.	Kodai Chiba	AIREX Co., Ltd.
	11:45-12:45	60		Lessons learned from the development of sterile dosage forms	Dr. Armin Wilfinger	Team Lead Technology & Process Transfer Vetter Pharma-Fertigung GmbH & Co. KG	Kentaro Nakamura	JGC JAPAN CORPORATION
	12:45-13:45	60	Lunch	(Mini-Luncheon Seminar)				
	13:45-17:00 Workshop 2-2 : SPP & Packaging							
	Theme : Invitation to a profound, aseptic processing world				MC : Yuri Enomoto	MORIMURA BROS., INC.		
	13:45-14:45	60		Theory, verification, and challenges in implementing packaging integrity evaluation	Mao Hirata Yoshihiro Akimoto Taku Hatakeyama	FUKUDA CO.,LTD Eisai CO.,LTD NIPRO CORPORATION	Minoru Mikawa	Chiyoda Corporation
	14:45-15:40	55		Conformity to Annex 1 for existing manufacturing facilities	Koichi Kishimoto Masaru Fujita	Chugai Pharma Manufacturing Co., Ltd. Kyowa Kirin Co., Ltd.	Hironobu Sunayama	SHIBUYA CORPORATION
	15:40-15:55	15	Coffee Break					
	15:55-16:55	60		Challenges and Recommendations for Single-Use System (SUS) ～ Challenges Identified by Working Group Members through the ISPE Good Practice Guide: "Single-Use Technology" ～ 1. Consideration of the scope, timing, and risk of testing for SUS 2. Suggestions for the sustainable utilization of SUS	Kohei Yamamoto Shigeru Okumura	IBP Inc. TEC Project Services Corporation	Seiji Shimura	Global Life Sciences Technologies Japan K.K
	16:55-17:00	5		Closing remarks	Yuri Enomoto	MORIMURA BROS., INC.		

Venue	Time	minutes		Title	Speaker	Affiliation	Moderator	Affiliation
2 F Fukuju	9:30-12:45 Workshop 3 : FOF							
	Theme : Next Generation Drug Manufacturing: Efficiency and Innovation through DX				MC :			
	09:30～09:35	5	Opening Remarks	Contact information, notes, etc.	Emiko Yamada	Mitsubishi Chemical Engineering		
	09:35～10:00	25	Lecture 1	ISPE Pharma4.0 Overview and Outlook for Japan	Hiroyuki Miyazaki	Takeda	Emiko Yamada	Mitsubishi Chemical Engineering
	10:00～10:30	30	Lecture 2	Next Generation Drug Manufacturing: Introduction of AI Use Case Study	Mitsunobu Kobayashi	Dalton	Emiko Yamada	Mitsubishi Chemical Engineering
	10:30～11:10	40	Lecture 3	Next Generation Pharmaceutical Manufacturing: Vision System Use Case Study Introduction	Masaoki Ohya	Daiichi Sankyo	Emiko Yamada	Mitsubishi Chemical Engineering
	11:10～11:50	40	Lecture 4	Validation 4.0: Status of the AI Validation Maturity Model	Daichi Takahashi	Pharma Planning	Emiko Yamada	Mitsubishi Chemical Engineering
	11:50～12:00	10	Coffee Break					
	12:00～12:40	40	Panel Discussion	Panel Discussion on Pharma4.0 Use Cases & DX Initiatives	Kenta Goto Masaoki Ohya Hideaki Hosaka Naoki Sakamoto Shuhei Wakamatsu	Takeda Daiichi Sankyo Chugai Pharmaceutical Industry Taisei Corporation Chiyoda Corporation	Hiroyuki Miyazaki	Takeda
	12:45-13:45	60	Lunch	(Mini-Luncheon Seminar)				
	13:45-17:00 Workshop 6 : Pharma PSE							
	Theme : Make, use, and judge models - towards more efficient process development				MC : Yasuaki Yabuki	AstraZeneca		
	13:45-14:05	20	Lecture 1	Make models - from academic perspectives	Hirokazu Sugiyama / Junu	UTokyo / Auxilart	Daisuke Yamakawa	Cytiva
	14:05-14:25	20	Lecture 2	Use models - from industrial perspectives	Keita Yaginuma	Daiichi Sankyo		
	14:25-14:45	20	Lecture 3	Judge models - from regulatory perspectives	Tomoki Yokomizo	PMDA		
	14:45-15:15	30	Panel discussion		Presenters			
	15:15-15:30	15	Coffee Break					
	15:30-16:30	60		Exercise of modeling and simulation	Junu Kim	Auxilart	Tomoyuki Taguchi	Chiyoda Corporation

Venue	Time	minutes		Title	Speaker	Affiliation	Moderator	Affiliation
2 F Togen	9:30-12:45 Workshop 4 : EM				MC : Shigeki Moriuchi			
	Theme : 「Risk Management Seminar for Pharmaceutical Manufacturing Facility Construction Projects ～Use risk management tools to ensure smooth project execution !! ～」							
	9:30～9:40	10	Introduction of EM COP Activities	Introduction to Today's Agenda and EM COP Activities	Yasuyuki Suga	CM plus Corporation		
	9:40～10:05	25	Lecture①	Introduction to Risk Management	Akitomo Nagahama	TEC Project Services Corporation		
	10:05～10:30	25	Lecture②	The stages and key activities of a construction project	Itaru Kimura	JGC CORPORATION		
	10:30～10:55	25	Lecture③	What are the major risks in a project	Ken Teratani	KYOWA HAKKO KIRIN CO.,LTD.		
	10:55～11:20	25	Lecture④	Considerations of major risks in the project	Tsuneki Harada	JGC CORPORATION		
	11:20～11:30	10	Coffee Break					
	11:30～11:55	25	Lecture⑤	Introduction to case studies that have occurred as a result of inadequate risk management	Shingo Goto	Chugai Pharma Manufacturing CO.,LTD.		
	11:55～12:10	15	Lecture⑥	Summary of this Workshop	Sei Murakami	Hitachi, Ltd.		
	12:10～12:45	35	Q & A Session Panel Discussion	Panel Discussion: "Sharing Case Studies Occurring as a Result of Inadequate Risk Management			Yasuyuki Suga	
	12:45-13:30	45	Lunch					
	13:45-17:00 Workshop 7 : Containment & EHS				MC : Shunta Hashimoto	KIT Co,ltd		
	13:45～14:15	30	COP Activities	Containment COP and EHS COP Initiatives Related to Sustainability	Ayumi Hasegawa	ONO Pharmaceutical Co.,Ltd		
	14:15～14:35	20	Lecture①	Derivation of Occupational Exposure Limits (OEL)	Akiko Nakazawa	Sumika Chemical Analysis Service ,Ltd	Morihiko Takeda	Pharma Solutions Co.,Ltd
	14:35～14:55	20	Lecture②	Q&A on Health-Based Exposure Limits	Takao Kuroka	EA Pharma Co., Ltd	Morihiko Takeda	Pharma Solutions Co.,Ltd
	14:55～15:10	15	Coffee Break					
	15:10～16:00	50	Special Lecture	Introduction for Operation of Containment Equipment for Oral Solid dosage form and Case Studies for Improvement of Issues.	Tetsuo Takiguchi	Nisshin Pharmaceutical Co.,Ltd	Masahiro Yamamoto	Takeda Pharmaceutical Co., Ltd.
	16:00～17:00	60	EHS COP	Considering pharmaceuticals and the environment: APIs in wastewater and their environmental impact	Ayumi Hasegawa Mitsuhiro Kimura Satsuki Sugawara	ONO Pharmaceutical Co.,Ltd TAKATA Pharmaceutical Co., Ltd. Chugai Pharma Manufacturing Co., Ltd	Tomoyuki Hasegawa	ONO Pharmaceutical Co.,Ltd

Venue	Time	minutes		Title	Speaker	Affiliation	Moderator	Affiliation
2 F Horai	9:30-12:45 Workshop 5 : IP COP							
	Theme : Patient Centricity							
	9:40-10:10		IRT WG	Providing Educational Materials for IRT Utilization - Handling of Unblind Information in Double-blind	Tomoyuki YAMASHITA	Suvoda Software G.K.	Hirofumi Shigeta	Kissei Pharmaceutical Co., Ltd
	10:10-10:40		TBD					
	10:40-11:00		Coffee Break					
	11:00-11:30		DTP DFP	DTP/DFP for DCT (Decentralized Clinical Trial) penetration	Minoru Mihara	Marken Japan KK	Teruyuki Furuya	Otsuka Pharma Co., Ltd
	11:30-12:00		TBD					
	12:00-12:30		Digital Display Label	Let's Experience the World of Digital Display Label	Sawada Yoshihiro	AstraZeneca K.K.	Minami Atsushi	Novartis Pharma K.K.
	12:45-13:45		Lunch					
	13:45-17:00 Workshop 8 : WiP & EL							
	Theme : Shaping Your Future Career ~Chance Management Using LinkedIn and the Cutting Edge of Global Career Development ~							
	13:45~13:50	5	orientation	Activities for Emerging Leaders	Mayuko Shimokawa	Taiyo Pharmatech		
	13:50~14:35☒	45	Lecture 1	Linkdin Utilization Seminar "How to Accelerate Your Career with LinkedIn"	Toshiya Magara	Kyowa Kirin	Daichi Takahashi	Pharma Planning
	14:35~14:50	15	Coffee Break					
	14:50~14:55	5	orientation	Activities for Women in Pharma				
	14:55~15:40	45	Lecture 2	Cutting Edge of Global Career Development Build each relationship with care. ~Asian Perspective Building Trust and Global Success~.	Vivien Santillan	NOVATEK INTERNATIONAL	Wakako Kawada	Paseon
	15:40~15:55	15	Coffee Break					
	15:55~17:00	60		Cutting Edge of Global Career Development Panel Discussion (bilingual session with interpretation)	Vivien Santillan Vivianne Arencibia Wakako Kawada Emiko Yamada	NOVATEK INTERNATIONAL Moderna Paseon Mitsubishi Chemical Engineering	Emiko Yamada	Mitsubishi Chemical Engineering