

2024 Annual Meeting Program (Japan Affiliate)

As of 2024/5/24

Tower Hall Funabori, Tokyo

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

5F Hall	9:30-10:20	50	Welcome	MC: Tetsuro Noguchi	Head of Secretariat	
			Nomination and Election of AGM chairman	Hirokazu Kisaka	Chairman	
			2023 Activity Report	Tetsuro Noguchi	Head of Secretariat	
			2023 Financial Report	Akihiro Matsuki	Treasurer	
			2023 Internal Audit Report	Fujio Isemoto	Japan Affiliate Auditor	
			2024 Action Plan	Tetsuro Noguchi	Head of Secretariat	
			2024 Budget Proposal	Akihiro Matsuki	Treasurer	
			2024 Election Results of Board & Officers	Toshiya Suzuki	2023 Head of Election Committee	

May 30 Annual Conference 10:30-17:40

Venue	Time	minutes	Title	Speaker	Affiliation	Moderator	Affiliation
5F Hall	10:30-10:40	10	Orientation Opening Remarks	MC: Tetsuro Noguchi Chair, Japan Affiliate	Treasurer, ISPE Japan Affiliate, Nobelpharma Co., Ltd. Chair, Japan Affiliate		
	10:40-11:30	50	Keynote Speech 1 Winning for Patients: Lessons Learned from the Pandemic and Opportunities to Reshape our Industry	Vivianne J. Arencibia	Treasurer of ISPE International Board of Directors Vice President, Global Quality Systems and Compliance Moderna	Wakako Kawada	ISPE Japan Affiliate Board of Director, Patheon by Thermo Fisher Scientific
	11:30-12:10	40	FDA ISPE 2023 Annual Meeting A Fireside Chat with Dr. Califf (USFDA) and Tom Hartman (ISPE CEO)	Robert M. Califf Tom Hartman	the 25th Commissioner of the US Food and Drug Administration CEO ISPE International		
2F Event Hall	12:10-13:20	70	Lunch (Luncheon Seminar) Tim, Vivianne and our COP Leaders will host a Japan COP meeting				
5F Hall	13:20-14:10	50	Keynote Speech 2 Recent Trends in Pharmaceutical Regulations	Yasunori Yoshida	Councilor for Pharmaceutical Affairs Minister, S Secretariat, MHLW	Junya Soma	Vice Chair, ISPE Japan Affiliate, GlaxoSmithKline K.K. Japan
	14:10-14:30	20	ISPE HQ Update ISPE Global Technical Communities	Tim Postlethwaite	ISPE Director, Technical Communities	Hirofumi Suzuki	ISPE International Board of Director, Bayer Yakuhin, Ltd.
	14:30-15:10	40	Keynote Speech 3 Breaking new ground beyond the "Wall of 0.05 µg/m3" -Honored as ISPE Facility of the Year Awards Category Winner	Daisuke Hiraswa	ISPE Japan Affiliate Board of Director, Chugai Pharma Manufacturing Co., Ltd.	Hirofumi Suzuki	ISPE International Board of Director, Bayer Yakuhin, Ltd.
	15:10-15:30	20	ISPE EL Update Shaping tomorrow of young professionals by Emerging Leaders	Hiroyuki Miyazaki	Takeda Pharmaceutical Company Limited		
2F Event Hall	15:30-15:55	25	Coffee Break				
5F Hall	15:55-16:45	50	Special Lecture 1 Contact Task in Automation	Kouhei Ohnishi	Professor, Keio University, Keio Frontier Research & Education Collaborative Square at Shin-Kawasaki	Akihiro Matsuki	Head of Secretariat, Japan Affiliate Mitsubishi Chemical Engineering Corporation
	16:45-17:35	50	Special Lecture 2 Our Vision of the Future of Healthcare	Naoki Okamura	Representative Director, President and CEO, Astellas Pharma Inc.	Hirokazu Kisaka	Chair, Japan Affiliate, Kyowakirin. Co., Ltd.
	17:35-17:40	5	Closing Remark for Day 1	Yukinobu Maruyama	Chairman, 2024 Annual Meeting Organizing Committee		
2F Event Hall	18:00-20:00	120	Networking Party				

May 31 Workshops 9:30-17:00

Venue	Time	minutes	Title		Speaker	Affiliation	Moderator	Affiliation	
2F Zuiun	9:30-12:45 Workshop 1-1 SPP & ATMP COP								
	Theme : Fast Alone, Far Together, Team SPP+ ATMP!					MC : Hironobu Sunayama	SHIBUYA CORPORATION		
	9:30-9:45	15		COP activities and lecture content	Kentaro Nakamura Tsutomu Igarashi	SPP COP Leader, JGC JAPAN CORPORATION ATMP COP Leader, Takeda Pharmaceuticals	N/A		
	9:45-10:40	55		The context of Annex 1 and CCS study regarding barrier system	Masato Hoshino Kimihiko Yatsu	Stäubli Kanto Chemical Co., Inc.	Kentaro Nakamura	JGC JAPAN CORPORATION	
	10:40-11:30	50		Explanation about revised JIS B 9927 and report on Questionnaire results of the revision JIS B 9927: 2022 "High-efficiency filters (EPA, HEPA and ULPA) and filter media for removing particles in air"	Teruaki Ariga Tatsuki Fujita	OSHITARI LABORATORY,INC. Toray Engineering Co., Ltd.	Tetsutoshi Yanagida	ASAHI KOGYOSHA CO., LTD.	
	11:30-11:45	15	Coffee Break						
	11:45-12:35	50		Lyophilization: Impact of Annex 1 and process development according to ICH Q8	Jörg Zimmermann	VP External Affairs, Vetter Pharma, Past-Chair of the International Board of Directors, ISPE	Kentaro Nakamura	JGC JAPAN CORPORATION	
	12:35-12:45	10		Progress report on Japanese translation of ATMP(Autologous) Guide, and introduction of latest published ATMP Guides	Ryo Ueda	Chiyoda Corporation	Tsutomu Igarashi	Takeda Pharmaceuticals	
	12:45-13:45	60	Lunch	(Mini-Luncheon Seminar)					
	13:45-17:00 Workshop 1-2 SPP & ATMP COP								
	Theme : Fast Alone, Far Together, Team SPP+ ATMP!					MC : Hironobu Sunayama	SHIBUYA CORPORATION		
	13:45-14:35	50		Advances in Multimodal ATMP Facilities	Robert Piccirillo	JACOBS Consultancy	Tsutomu Igarashi	Takeda Pharmaceuticals	
	14:35-15:20	45		Automation/closed manufacturing process for cell therapy and trends in facility expansion plan	Kenichi Tahara Tetsuro Hatsuoka	Takara Bio Inc. Kajima Corporation			
	15:20-15:35	15	Coffee Break						
	15:35-16:15	40		Smoke Study Practices from FDA Form 483 Case Studies	Shingo Takizawa Misaki Yamagishi	ROHTO Pharmaceutical Co., Ltd. DAIICHI SANKYO PROPHARMA CO., LTD.	Toshihide Takemoto	KANTO CHEMICAL CO.,INC.	
	16:15-16:55	40		Considerations for Implementing Single-Use Systems in LNP Formulations ~Differences in risks and countermeasures between low-molecular-weight injectable drugs and LNP formulations~	Ryo Nakamura Kaito Yamauchi	JGC JAPAN CORPORATION TEC Project Services Corporation	Seiji Shimura	Global Life Sciences Technologies Japan K.K	
16:55-17:00	5		Closing remarks	Hironobu Sunayama	SHIBUYA CORPORATION				

Venue	Time	minutes	Title		Speaker	Affiliation	Moderator	Affiliation	
2F Heian	9:30-12:45 Workshop 2 FoF								
	Theme : Pharma 4.0					MC : Yuki Kumanomido	Mitsubishi Chemical Engineering Corporation		
	09:30-09:35	5	Orientation	Opening Speech	Yuki Kumanomido	Mitsubishi Chemical Engineering Corporation	Yuki Kumanomido		
	09:35-09:55	20	Session 1	Application of AI and Robotics technology in Smartfactories	Prof. Yoshiyuki Yamashita	Tokyo University of Agriculture and Technology	Yuki Kumanomido		
	09:55-10:05	10	Session 2	Pharma4.0 overall activity overview	Hirokazu Kisaka	Kyowa Kirin Co., Ltd	Yuki Kumanomido		
	10:05-10:35	30	Session 3	Pharma4.0 translation activity introduction	Emiko Yamada	Mitsubishi Chemical Engineering Corporation	Yuki Kumanomido		
	10:35-10:45	10	Coffee Break						
	10:45-11:15	30	Session 4	Considering the application of AI in Pharma4.0	Nobumitsu Kobayashi	DALTON CORPORATION	Yuki Kumanomido		
	11:15-11:45	30	Session 5	Consideration of robotics technology in Pharma4.0	Hiroyuki Miyazaki	Takeda Pharmaceutical Company Limited	Yuki Kumanomido		
	11:45-11:50	5	Preparation	Preparation for panel discussion					
	11:50-12:45	55	Panel Discussion	Panel Discussion					
	12:45-13:45	60	Lunch	(Mini-Luncheon Seminar)					
	13:45-17:00 Workshop 6 Pharma PSE COP								
	Theme : The role and the opportunities of modeling for process development and operation					MC : TBD			
	13:45-14:05	20		Modeling research for small molecules, biologics, and stem cell manufacturing	Hirokazu Sugiyama	The University of Tokyo	Yasuaki Yabuki	AstraZeneca K.K.	
	14:05-14:25	20		Modeling of API flow synthesis and design space development	Junu Kim	The University of Tokyo / Auxilart	Yasuaki Yabuki	AstraZeneca K.K.	
14:25-14:45	20		Modeling of solid drug product manufacturing and PAT development	Koji Muteki	Pfizer	Yasuaki Yabuki	AstraZeneca K.K.		
14:45-15:00	15	Coffee Break							
15:00-15:20	20		Modeling of stem cell cultivation and design space development	Keita Hirono	The University of Tokyo	Tetsuhito Takarada	Pharma Planning Co., Ltd.		
15:20-15:40	20		Modeling of stem cell freezing and expansion to equipment design	Yusuke Hayashi	The University of Tokyo	Tetsuhito Takarada	Pharma Planning Co., Ltd.		
15:40-16:00	20		Modeling from the perspective of regulatory science	Yoshihiro Matsuda	PMDA	Tetsuhito Takarada	Pharma Planning Co., Ltd.		
16:00-16:30	30		Panel discussion	Hirokazu Sugiyama	The University of Tokyo	Hirokazu Sugiyama	The University of Tokyo		

Venue	Time	minutes	Title		Speaker	Affiliation	Moderator	Affiliation
2F Fukuju	9:30-12:45 Workshop 3 BIO COP							
	Theme : Latest trends in biomanufacturing technology ~ Focusing on sustainability ~				MC : Kaminagayoshi Takeshi	Takeda Pharmaceutical Company Limited.		
	09:30-09:35	5	Intro	—	Kaminagayoshi Takeshi	Takeda Pharmaceutical Company Limited.		
	09:35-10:10	35	Program1	Advancing Modalities: The Evolution of Drug Development	Nagatomo Kentaro Sugiyama Satoshi	Daiichi Sankyo, Inc. Chiyoda Corporation	Kaminagayoshi Takeshi	Takeda Pharmaceutical Company Limited.
	10:10-10:45	35	Program2	Sustainability for the Bio Pharmaceutical Processing	Terashima Iyo Ninomiya Shuji	Life Technologies Japan Ltd. JGC JAPAN CORPORATION	Suzuki Takeshi	Merck Ltd.
	10:45-10:55	10	Coffee Break					
	10:55-11:30	35	Program3	Digitalization and AI in biopharmaceutical manufacturing	Yoshida Takashi	Rockwell Automation Japan Ltd.	Izumi Toshiaki	Endress+Hauser Japan
	11:30-12:00	30	Program4	Adaptation to Changes in the Regulatory Environment for Biopharmaceutical Manufacturing.	Mizunuma Takato	JGC JAPAN CORPORATION	Shirokizawa Osamu	Life Scientia Limited
	12:00-12:05	5	Coffee Break					
	12:05-12:45	40	Program5	Striking the Right Balance Understanding the Trade-Offs between Sustainability and Costs of Mab	Abe Miki	Biopharm Services Ltd	Kaminagayoshi Takeshi	Takeda Pharmaceutical Company Limited.
	12:45-13:45	60	Lunch	(Mini-Luncheon Seminar)				
	13:45-17:00 Workshop 7 CONTAINMENT & EHS COP							
	Theme : Shin Containment				MC: Masahiro Yamamoto	Takeda Pharmaceutical Company Limited		
	13:45-14:45	60	Special lecture	Current Consideration on Control of Cross-Contamination in Shared Facilities and the Recent Observations of GMP Inspections	Ryusei Ishii	Pharmaceuticals and Medical Devices Agency(PMDA)	Morihiro Takeda	Pharma Solutions Co., Ltd.
	14:45-15:45	60	Special lecture	Forefront of Containment Technology in Highly Potent API Manufacturing ~Containment facility construction concept and verification example~	Daisuke Hirasawa	Chugai Pharma Manufacturing Co., Ltd.	Takahide Hashizume	HATA TEKKOSHO CO.,LTD.
	15:45-16:00	15	Coffee Break					
	16:00-16:15	15	Containment COP	Aiming to expand on PEEM-DB : 2023 Activity Report	Haruka Futamura	Airex Co., Ltd.	Youhei Sasaki	Takenaka Corporation
16:15-17:00	45	EHS COP	Issues ,concerns and suggestions about exposure control of pharmaceutical ingredients powders	Mototsugu Mine	Catalent Shiga Co., Ltd.	Nobuaki Kato	Cimic CMO Co., Ltd.	

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2F Togen	9:30-12:45 Workshop 4 API COP				MC : Ami Nozue	Shin Nippon Yakugyo Co., Ltd.		
	Theme : Future perspectives for API manufacturing with digital technology							
	09:30-09:40	10	Opening Remarks	Opening Remarks	Muneki Kishida	Mitsubishi Tanabe Pharma Co.		
	09:40-10:05	25	COP Report 1	Utilization of Cyberspace in API Manufacturing Part 1 Modeling & Simulation Trend Survey	Masayuki Seto	Mitsubishi Tanabe Pharma Factory Ltd.		
	10:05-10:30	25	COP Report 2	Utilization of Cyberspace in API Manufacturing Part 2 Study Report on Digital Twin Application	Makoto Nakaya	Yokogawa Electric Corp.		
	10:30-11:10	40	Lecture 1	Computer Science/ Modeling at Pharmaceutical Development and Manufacturing: Role and Application	Koji Muteki	Pfizer Japan Inc.	Masatoshi Ikeya	TEC Project Services Corp.
	11:10-11:20	10	Coffee Break					
	11:20-12:00	40	Lecture 2	Applications of modeling of drug product and API performance including release and dissolution	Guillaume Louit	Siemens K.K.	Masaaki Nakata	Siemens K.K.
	12:00-12:40	40	Lecture 3	The Digital Plant of Now ~ Cytiva's Approach to Factory Digitalization	Kate Marinczak	Global Life Sciences Technologies K.K. (Cytiva)	Yoshihiko Ishikawa	Global Life Sciences Technologies Japan K.K. (Cytiva)
	12:45-13:30	45	Lunch					
13:45-17:00 JPMLF				MC :				

Venue	Time	minutes	Title		Speaker	Affiliation	Moderator	Affiliation
2F Horai	9:30-12:45 Workshop 5 IP COP							
	Theme : Patient Centricity				MC : Minoru Mihara	Marken Japan Limited.		
	9:30 - 09:35	5		IP COP Introduction	Minoru Mihara	IP COP Chair, Marken Japan Limited.		
	9:35 - 10:10	45		The GAP between Regulations and Actual activities in Investigational product, and the proposals	Yoshihiro Sawada	Regulatory & Customs WG Lead, Astra Zeneca K.K.	Yoshihiko Sato	Regulatory & Customs WG, Mitsubishi Logistics Corporation
	10:10 - 10:45	35		Current situations and issues of outsourcing in clinical supply (2024 problem and Temperature control)	Kenichi Kuchiki	Outsourcing WG Lead, Mitsui-Soko Holdings Co.,Ltd.	Yoshihiko Sato	Outsourcing WG, Mitsubishi Logistics Corporation
	10:45 - 10:55	10	Coffee Break					
	10:55- 11:30	35		Direct to Patient Delivery (Current Challenge and future prospect)	Minoru Mihara	DTP/DFP WG Lead, Marken Japan Limited.	Naoya Okamura	DTP/DFP WG, Mitsubishi Logistics Corporation
	11:30 - 12:05	35		IRT utilization survey result and other outcomes	Tomoyuki Yamashita	IRT WG Lead, SUVODA LLC	Yoshiharu Naka	IRT WG, Otsuka Pharmaceutical Co., Ltd.
	12:05 - 12:40	35		Future label with 2D-code on Investigational Products: Initiatives for Best Practice and Roadmap	Hitomi Okuhara	2D-Code WG Lead, Bayer Yakuhin, Ltd.	Yumiko Nakao	2D-Code WG, Bayer Yakuhin, Ltd.
	12:40 - 12:45	5		IP COP closing	Minoru Mihara	IP COP Chair, Marken Japan Limited.		
	12:45-13:45	60	Lunch					
	13:45-17:00 Workshop 8 EL & WIP							
	Theme : A Passport to the Future Connected by Legends - To the Yong Professionals on the Global Stage							
	13:45-14:45	60	Emerging Leader (EL)	"Shaberiba"(A Fireside Chat) Learning from the past to understand the new: What is the New Quality Guidance with Legends?	Tetsuhito Takarada	Pharma Planning Co., Ltd. Senior Consultant	Hiroyuki Miyazaki	Takeda Pharmaceutical Company Limited.
	13:45-13:50	5	Introduction	Introduction of ISPE's Emerging Leader (EL)	Hiroyuki Miyazaki	Takeda Pharmaceutical Company Limited		
	13:50-14:20	30	Q&A / Interview session	The Origins of Validation The Untold Story of the Birth of ICH Guidelines	Tetsuhito Takarada Kohei Asato Takanori Tatsuzawa	Pharma Planning Co., Ltd. Senior Consultant Takeda Pharmaceutical Company Limited DAIICHI JITSUGYO Co.,Ltd.		
	14:20-14:45	25	Q&A / Interview session	Differences in Work Styles between the West and Japan The Key Perspectives in Forming a Career Path	Tetsuhito Takarada Kohei Asato Takanori Tatsuzawa	Pharma Planning Co., Ltd. Senior Consultant Takeda Pharmaceutical Company Limited DAIICHI JITSUGYO Co.,Ltd.		
	14:45-15:00		Coffee Break					
	15:00-17:00	120	Women in Pharma (WIP)	"Shaberiba" (A Fireside Chat) Illuminating Your Career Path: Overcoming Challenges and Making Decisive Moves	Vivianne J.Arenciba	Modrna Vice President, Global Quality Systems and Compliance	Wakako Kawada	Patheon K.K. (Thermo Fisher Scientific)
	15:00-15:05	5	Introduction	Introduction of ISPE's Women in Pharma activities & Vivianne J.Arenciba	Wakako Kawada	ISPE Japan Affiliate, Director Patheon K.K. (Thermo Fisher Scientific)		
15:05-15:35	35	Keynote Presentaion	Title : Navigating the Path to Leadership (TBD)	Vivianne J.Arenciba	Modrna Vice President, Global Quality Systems and Compliance			
15:35-16:05	30	Q&A / Interview session	Theme: Building a Luminous Career: Key Steps for Success Interview with Vivianne by Emerging Leader & Young Professional	Vivianne Emiko Yamada Mayuko Shimokawa Ai Taguchi	Modrna Vice President, Global Quality Systems and Compliance Mitsubishi Chemical Engineering Corporation TAIYO Pharma Tech Co., Ltd. IBP Inc			
16:05-16:55	45	Round table Breakout session	Interactive Exchange and Networking round table: A Collaborative Dialogue on Selected Topics	Vivianne J.Arenciba Facilitators (TBD)				
16:55-17:00	5	Summary	Reflecting on Insights: Key Takeaways from Today's Luminaries	Wakako Kawada	Patheon K.K. (Thermo Fisher Scientific)			