

Pharma society 5.0
"Moonshot" - Our Strategic Path Forward

2021 Annual Meeting Program (Japan Affiliate)

As of 2021/5/13

May 13 Annual General Meeting 9:30-10:15

AM	9:30-10:15	45	9:30-10:30 Annual General Meeting	MC: Akihiro Matsuki	Head of Secretariat		
			Welcome	Ayako Nakajima	Chairman		
			Nomination and Election of AGM chairman				
			2020 Activity Report	Akihiro Matsuki	Head of Secretariat		
			2020 Financial Report	Hiroshi Yamaguchi	Treasurer		
			2020 Internal Audit Report	Shigeru Nakamura	Japan Affiliate Auditor		
			2021 Action Plan	Akihiro Matsuki	Head of Secretariat		
			2021 Budget Proposal	Hiroshi Yamaguchi	Treasurer		
			2021 Election Results of Board & Officers	Tetsuro Noguchi	2020 Head of Election Committee		

May 13 Annual Conference 10:15-17:15

Venue	Time	minutes	Title	Speaker	Affiliation	Moderator	Affiliation
2F Event Hall	10:15-10:20		Orientation	MC:Akihiro Matsuki	Head of Secretariat, Mitsubishi Chemical Engineering Corporation.		
	10:20-10:25	5	Opening Remarks 1	Welcome and Opening	ISPE Japan Affiliate 2021 Chair		
	10:25-11:10	45	Keynote Speech 1	Future Generational Concerns in the Medical and Pharma World - Growth in a Turbulent Era	Norikazu Eiki	Former Chair of Bayer Yakuin Ltd.	Hirofumi Suzuki ISPE International Board, Bayer Yakuin, Ltd.
	11:10-11:55	45	Keynote Speech 3	Tumor Re-Engineering: Developing Novel Immuno-Gene Therapies for Cancer (Recorded)	Brian R. Champion, Ph.D.	Chief Scientific Officer at PsiOxus Therapeutics	
2F Event Hall	11:55-12:50	55	Lunch (Luncheon Seminar)				
2F Event Hall	12:50-13:15	25	Keynote Speech 4	2020 Annual Meeting Keynote GSK - Manufacturing Autologous Ex Vivo Genetically Modified Cell Therapies Have Challenges but the Future is Bright	S. Joseph Tarnowski, Ph.D.	Senior Vice President, Cell & Gene Therapy Platform, GSK	
	13:15-13:45	30	Keynote Speech 5	KASA: Opportunity for Modernizing Regulatory Assessment and Submission	Lawrence Yu, Ph.D.	Director, Office of New Drug Products, CDER, FDA	
2F Event Hall	13:45-14:00	15	Break				
2F Event Hall	14:00-14:45	45	Keynote Speech 2	MHLW Update (Tentative)	Fumi Yamamoto	Councilor for Pharmaceutical Affairs Minister. S Secretariat MHLW	Ayako Nakajima ISPE Japan Affiliate Chair, Q&EHS Solutions, Co., Ltd.
	14:45-15:05	20	Update from ISPE Global	ISPE for the 21st Century and Beyond	Joanne R. Barrick, RPh	ISPE Global Chair	
2F Event Hall	15:05-15:40	35	Lunch (Luncheon Seminar)				
2F Event Hall	15:40-16:25	45	Special Lecture 1	The Challenge of Digital Transformation of Chugai Pharmaceutical	Yoshito Nakanishi	Chugai Pharma Manufacturing Co., Ltd.	Daisuke Hirasawa ISPE Japan Affiliate Board of Directors Chugai Pharma Manufacturing Co., Ltd.
	16:25-17:10	45	Special Lecture 2	Development of Data-Driven Chemistry	Kimito Funatsu	Professor, Tokyo University	Tetsuro Noguchi ISPE Japan Affiliate Board of Directors Nobelpharma Co., Ltd.
	17:10-17:15	5	Closing Remarks for Day 1		Tetsuro Noguchi	Chairman, 2021 Annual Meeting Organizing Committee/ Japan Affiliate Board of Director	

May 14 Workshops 9:30-17:00

Venue	Time	minutes	Title	Speaker	Affiliation	Moderator	Affiliation
2 F Zuiun	9:30-12:45 Workshop 1 FoF (Facilities of the Future)						
AM	Theme: Facility of the Future/ Implementation of Soft sensor for Quality Control in Continuous Manufacturing						
	9:30-9:35	5	Opening Remarks	Tetsuro Noguchi	Japan Affiliate Board of Director / Nobelpharma Co.,Ltd.		
	9:35-9:50	15	Continuous manufacturing - Quality control for Granulation Process -	Takashi Terada	FREUND CORPORATION		
	9:50-10:05	15	Continuous manufacturing - Quality control for Tableting Process -	Shinsuke Fushimi	KIKUSUI SEISAKUSHO LTD.		
	10:05-10:20	15	Continuous manufacturing - Quality control for Coating Process -	Kazuhiro Uchida	POWREX CORPORATION		
	10:20-10:35	15	Points of attention for Continuous Manufacturing using NIRS (Near-infrared spectroscopy)	Munetaka Hattori	PAT COP Leader/Pharmaceutical Consultant		
	10:35-10:50	15	Break				
	10:50-11:30	40	Toward implementation of soft sensor for continuous production process	Kimito Funatsu	Professor, Tokyo University		
	11:30-11:40	10	Break				
	11:40-12:15	35	PMDA's Activities for Continuous Manufacturing	Yoshihiro Matsuda	Specialist(Quality), Pharmaceuticals and Medical Devises Agency (PMDA)		
	12:15-12:25	10	Break				
12:25-12:45	20	FOF Q & A session	All speaker				
12:45-13:45	60	Lunch					
2 F Zuiun	13:45-17:00 Workshop 6 C&Q COP						
PM	テーマ : The first revision in 18 years, the outline of ISPE Baseline Guide Volume 5 Commissioning and Qualification Second Edition						
	13:45-13:50	5	Orientation	Hinako Aoki	C&Q COP	N/A	
	13:50-14:15	25	1. Introduction	Daisuke Hamaguchi	C&Q COP	N/A	
	14:15-14:40	25	2. User Requirements Specification 3. System Classification	Mayo Mimura	C&Q COP	N/A	
	14:40-15:05	25	4. System Risk Assessment 5. Design Review and Design Qualification	Daisuke Hamaguchi	C&Q COP	N/A	
	15:05-15:30	25	6. C&Q Planning 7. C&Q Testing and Documentation	Masahiko Yamaguchi	C&Q COP	N/A	
	15:30-15:45	15	Break				
	15:45-16:10	25	8. Acceptance and Release 9. Periodic Review	Mototsugu Mine	C&Q COP	N/A	
	16:10-16:35	25	10. Vendor Assessment for C&Q Documentation Purpose 11. Engineering Quality Process	Noboru Osaka	C&Q COP	N/A	
	16:35-17:00	25	12. Change Management 13. Good Documentation Practice for C&Q 14. Strategies for Implementation of Science and Risk-Based C&Q Process	Masataka Tsuda	C&Q COP	N/A	

Venue	Time	minutes	Title	Speaker	Affiliation	Moderator	Affiliation
2 F Heian	9:30-12:45 Workshop 2 SPP COP			MC: Koji Kawasaki	SPP COP Leader, Airex Co.,Ltd.		
AM	Theme: Shhh Slashing The Microbial Kingdom						
	9:30-9:40	10	Introduction of SPP COP	Koji Kawasaki	SPP COP Leader, Airex Co.,Ltd.		
	9:40-10:20	40	Study of Material Transfer to Grade A	Ken Inagai	Airex Co., Ltd.	Kentaro Nakamura	JGC JAPAN CORPORATION
	10:20-11:20	60	The same way as Multi-use system? ~ Inherent risks and consideration timings for Single-use	Seiji Shimura Noriaki Masui	Toray Engineering Co. Ltd. Nagase Medical Co. Ltd.	Seiji Shimura	Nihon Pall Ltd.
	11:20-11:35	15	Break				
	11:35-12:35	60	Time dependency of HEPA Filter performance during load test with high concentration	Kodai Chiba	TEC Project Services Corporation	Katsuya Inoue	ASAHI KOGYOSHA CO.,LTD.
	12:35-12:45	10	Progress report on the publication of "Baseline Guide Vol.3 : Sterile Product Manufacturing Facilities Third Edition" Japanese translation	Shigeru Okumura	TEC Project Services Corporation	Shigeru Okumura	TEC Project Services Corporation
	12:45-13:45	60	Lunch				
2 F Heian	13:45-17:00 Workshop 7 Containment COP			MC:Yuji Yamaura/Shinichiro Matsunaga	Asahi Kasei Finechem Co., Ltd./Takeda Pharmaceutical Co., Ltd.		
PM	Theme: Risk Based Approach for manufacturing of highly potent products						
	13:45-14:45	60	Special Lecture Current Thinking on Control of Cross-Contamination in Shared Facilities	Ryusei Ishii	Pharmaceuticals and Medical Devices Agency(PMDA)		
	14:45-15:00	15	Containment COP Introduction of Containment COP Activities	Yuji Yamaura	Asahi Kasei Finechem Co., Ltd.		
	15:00-15:35	35	Containment COP Aiming to spread PEEM-DBI Correlation visualizing by analysis of exposure measurement.	Yutaro Ishikawa/Takuya Nagato	NARA Machinery Co., Ltd./Powrex Corporation		
	15:35-15:50	15	Break				
	15:50-16:00	10	PDE setting roundtable Progress of PDE setting roundtable in Japan	Shinichiro Matsunaga	Takeda Pharmaceutical Co., Ltd.		
	16:00-16:35	35	PDE Setting Roundtable Activities of Low-Molecular Weight Substances Subcommittee	Ichiro Tsunenari	Safety Evaluation Forum		
	16:35-17:00	25	PDE Setting Roundtable Activities of High-Molecular Weight Substances Subcommittee	Nobuaki Kato	Chugai Pharmaceutical Co., Ltd.		
2 F Fukuju	9:30-12:45 Workshop 3 SAM&GMP COP			MC:Mamoru Kusumoto	Shin Nippon Yakugyo Co., Ltd		
AM	テーマ: Close in upon the Essence of GMP ! ~ in light of the Revised J-GMP Ministerial Ordinance ~						
	9:30-9:35	5	Opening	Satoru Arai	Toray Industries, Inc.		
	9:35-10:25	50	Points for Revision of GMP Ministerial Ordinance and Future Prospects	Koki Akazawa	Pharmaceuticals and Medical Devices Agency Office of Manufacturing Quality for Drugs	Fumio Kishimoto	Katsura Chemical Co., Ltd
	10:25-11:10	45	Pharmaceutical quality management system and Fostering quality culture	Toshio Kawakita	Shionogi Pharma Co., Ltd.	Junya Soma	GlaxoSmithKline K.K.
	11:10-11:20	10	Break				
	11:20-12:00	40	Cleaning Validation case study from a perspective of revised J-GMP ministerial ordinance	Yusuke Enya, Mieko Suganuma	Shin Nippon Yakugyo Co., Ltd, Sanofi K.K.		
	12:00-12:45	45	Panel Discussion	Koki Akazawa, Toshio Kawakita, Ayako Nakajima	Pharmaceuticals and Medical Devices Agency, Shionogi Pharma Co., Ltd., Q&EHS Solutions Corporation	Tsutomu Kojima	SymBio Pharmaceuticals Limited
	12:45-13:45	60	Lunch				
2 F Fukuju	13:45-17:00 Workshop 8 API COP						
PM	テーマ: Continuous Manufacturing for API: Future outlook of Impemetation						
	13:45- 13:50	40	Opening Remarks	Masatoshi.Ikeya	TEC Project Survice		
	13:50- 14:30	40	Some application at Continuous Manufacturing Process	Kouji.Muteki	Pfizer Pharma	Tsutomu.Kojima	SymBio Pharmaceuticals Limited
	14:30-15:10	40	Examples of API intermediate manufacturing at TAKASAGO	Michio.Kida	Takasago	Tatsuya.Watanabe	Takasago Chemical
	15:10-15:20	10	Break				
	15:20-15:50	30	What we can see from the API COP discussion(Continuous Manufacturing API)	Ryouta.Sugiyama	Chugai Pharmaceutical		
	15:50-16:30	40	Continuous API, what should you know?	Malcolm Berry	MB Chemistry Consulting LTD	Yoshio.Hitaka	Takeda Pharmaceutical
	16:30-17:15	45	PD	Yoshihiro Matsuda	PMDA		

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2F Togen	9:30-12:45 Workshop 4 BIO COP				Speaker	Affiliation	Moderator	Affiliation
AM	Strategy for biomanufacturing facility in the age of living with COVID-19				MC: Takashi Kaminagayoshi	BIO COP Leader, Takeda	–	–
	9:30-9:40	10	Orientation	Activities Introduction	Takashi Kaminagayoshi	BIO COP Leader, Takeda	–	–
	9:40-10:35	55	Workshop 1	Business Continuity Plan in Response to Emerging Infectious Diseases	Koji Iritani Masashi Oda	Kaneka Hitachi Plant Services	Yuu Kamine	Kirin Engineering
				Environmental Analysis Business Continuity Plan				
	10:35-10:45	10	Break					
	10:45-11:40	55	Workshop 2-1	Facility Planning against Emerging Infectious Diseases	Iyo Terashima Yuji Aoki	Merck Nihon Pall	Takashi Ichii	Nihon Pall
				Preconditions Equipment Configuration				
	11:40-11:50	10	Break					
11:50-12:45	55	Workshop 2-2	Facility Planning against Emerging Infectious Diseases	Takato Mizunuma Hiroaki Takamura	IHI Plant Services Chiyoda	Takashi Kaminagayoshi	BIO COP Leader, Takeda	
			Layout Plan Digital Tools					
12:45-13:45	60	Lunch						
2F Horai	9:30-12:45 Workshop 5 IP COP							
AM	The first year of Clinical Supply 5G							
	09:30-09:35	5		IP-COP Introduction	Mr.Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation		
	09:35-10:35	60	Lecture1	Current Regulatory situation and challenges for Clinical Supply activities	Mr.Yoshihiro Sawada	IP-COP Regulatory Lead, Astra Zeneca K.K.	Shinya Otsuji	IP-COP Regulatory WG, Saroute Co.,Ltd.
	10:35-11:35	60	Lecture2	Dtp/DfP Tips for the local further growth	Mr.Minoru Mihara	IP-COP DfP/DfP WG Lead, Marken Japan Limited.	Naoya Okamura	IP-COP DfP/DfP, Mitsubishi Logistics Corporation
	11:35-11:40	5	Break					
	11:40-12:40	60	Lecture3	Roles and Challenges of Clinical Supply in Airport	Mr.Kenichi Kuchiki	IP-COP Outsourcing Lead, Mitsui-Soko Holdings Co.,Ltd.	Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation
	12:40-12:45	5		IP-COP Closing	Mr.Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation		