

**2019 Annual Meeting Program (Japan Affiliate)**

**Tentative**

**Pharma Society 5.0**

**Tasking Japan as an advanced nation**

As of 2019/4/15

**May 30 Annual General Meeting 9:30—10:30**

Venue: Tower Hall Funabori

〒134-0091 4-1-1 Funabori Edogaw-ku Tokyo

5F Main Hall	09:30-10:30	60	<b>9:30-10:30 Annual General Meeting</b>	MC: Akihiro Matsuki	Head of Secretariat		
			Welcome	Hirofumi Suzuki	Chairman		
			Nomination and Election of AGM chairman				
			2018 Activity Report	Akihiro Matsuki	Head of Secretariat		
			2018 Financial Report	Hiroshi Sakai	Treasurer		
			2018 Internal Audit Report	Tatsuro Miyagawa	Japan Affiliate Auditor		
			2019 Action Plan	Akihiro Matsuki	Head of Secretariat		
			2019 Budget Proposal	Hiroshi Sakai	Treasurer		
			2019 Election Results of Board & Officers	Yoshifumi Katakawa	2019 Head of Election Committee		
Bylaw Revision	Shigeru Nakamura	Past Chairman					

**May 30 Annual Conference 10:45—18:30 Networking Party 18:30—20:30**

Venue	Time	Minutes	Title	Speaker	Affiliation	Moderator	Affiliation
	<b>10:45-18:15</b>		<b>Annual Conference</b>	MC: Akihiro Matsuki			
5F Main Hall	10:45-10:55	10	Opening Remarks 1		New Chair of ISPE Japan Affiliate		
	10:55-11:25	30	Opening Remarks 2	ISPE Update	James A. Breen, Jr., PE		Chair of ISPE / Janssen Pharmaceuticals
	11:25-12:10	45	Keynote Speech 1	Japanese Government Standpoint on Healthcare Policy	Hiroyuki Kawabata		Deputy Manager, Health Policy Bureau, General Affairs Division, MHLW
2F Event Hall	12:10-13:10	60	Lunch (Luncheon Seminar / Table Top Exhibition)				
5F Main Hall	13:10-13:55	45	Keynote Speech 2	FDA Update	TBD		FDA
	13:55-14:40	45	Keynote Speech 3	Muse Cell for Reparative Medicine by LSII	Seichi Kiso		Life Science Institute, Inc.
	14:40-15:25	45	Keynote Speech 4	Artificial Intelligence that pervades society - its Past, Present, and Future	Naohiko Uramoto		President, The Japanese society for Artificial Intelligence
2F Event Hall	15:25-16:00	35	Coffee Break (TT Exhibition)				
5F Main Hall	16:00-16:45	45	Keynote Speech 5	Co-creation of Innovation through Japanese Life Science Ecosystem	Shunichi Takahashi		Bayer Yakuhin, Head of Open Innovation Center Japan
	16:45-17:30	45	Special Lecture 1	Near Infrared Photoimmunotherapy for Cancer	Hisataka Kobayashi		Senior Investigator, National Cancer Institute/NIH
	17:30-18:15	45	Special Lecture 2	Activities of Regulatory Science Center in PMDA	Hiroyuki Arai		Head of Regulatory Science, PMDA
2F Event Hall	18:30-20:30	120	Networking Party				

May 31 Workshops 9:15–17:00

Venue	Time	Minutes	Title	Speaker	Affiliation	Moderator	Affiliation
<b>2F Zuiun</b>	<b>9:15-12:30 Workshop 1- FoF (Facilities of the Future)</b>			MC:Tetsuro Noguchi	Japan Affiliate Board of Director / Mitsubishi Tanabe Pharma Corporation		
	<b>Facility of the Future –Pharma Society 5.0 and Continuous Manufacturing</b>						
	9:15-9:55	40	Lecture 1	Approach to Facility of the Future (background and status ) (TBD)	James A. Breen, Jr., PE	Chair of ISPE / Janssen Pharmaceuticals	
	9:55-10:10	15	Lecture 2	Pharma Society 5.0 driven by ISPE Japan	Hirokazu Kisaka	Japan Affiliate Board of Director / TAKEDA PHARMACEUTICAL CO., LTD.	
	10:10-10:20	10	Break				
	10:20-11:05	45	Lecture 3	Approach to implementation of soft sensor for continuous manufacturing process	Kimoto Funatsu	Professor, Tokyo University	
	11:05-11:35	30	Lecture 4	Marketing Approval Reviews on Continuous Manufacturing of Pharmaceuticals (Tentative)	Issei Takayama	Office of New Drug IV, Pharmaceuticals and Medical Devises Agency ( PMDA )	
	11:35-11:40	5	Break				
	11:40-12:30	50	FoF workshop	Facility of the Future: Pharma Society 5.0 and Continuous Manufacturing	Speakers and Attendees		
	12:30-13:30	60	Lunch				
<b>2F Zuiun</b>	<b>13:30-17:00 Workshop 6: CONTAINMENT COP</b>						
	<b>Risk Based Approach for manufacturing of highly potent products</b>						
	13:30-14:30	60	Special Lecture	Dr. Rainer Nicolai	Dr. Rainer Nicolai	F. Hoffmann-La Roche Ltd, Basel	Disuke Hirasawa Japan Affiliate Board of Director / Chugai Pharmaceutical Co., Ltd.
	14:30-15:15	45	Containment COP	Isolator vs Local exhaust ventilation, Exposure level comparison & Update for PEEM-DB	Takahide Hashizume / Tsumumi Honda	Hata Iron Works Co., Ltd. / Nara Machinery CO., Ltd.	Haruka Futamura Airex Co., Ltd.
	15:15-15:30	15	Break				
	15:30-16:15	45	Containment COP	Case Study of Risk Assessment of OSD Manufacturing.	Yoshitaka Yamaguchi / Jun Oyama	TEC Project Servicen Co. Ltd. / Kikusui Co., Ltd.	Junko Odachi Obayashi Corporation
	16:15-17:00	45	Special Lecture	Establishment of OEL / PDE and exposure levels assessment in pharmaceutical industries	Ichiro Tsunenari	Safety Evaluation Forum	Shinichiro Matsunag TAKEDA PHARMACEUTICAL CO., LTD.
<b>2F Heian</b>	<b>9:15-12:30 Workshop 2: BIO COP</b>			MC: Sei Murakami	BIO COP Leader, Hitachi,Ltd.		
	<b>Progress in Continuous Manufacturing of Biopharmaceuticals</b>						
	9:15-9:25	10	Orientation	Introduction of BIO COP	Sei Murakami	BIO COP Leader, Hitachi,Ltd.	Takaya Nakagawa Masashi Kuramoto TEC Project Services Corporation Daiichi Sankyo Co.,Ltd.
	9:25-10:20	55	Workshop 1	Continuous Biopharmaceuticals Manufacturing: Progress and Agenda (WEB Exploration 1)	Atsushi Kitajima Hirono Awa	Hitachi Plant Service Chiyoda Corporation	Takaya Nakagawa Masashi Kuramoto TEC Project Services Corporation Daiichi Sankyo Co.,Ltd.
	10:20-10:35	15	Break				
	10:35-11:30	55	Workshop 2	Continuous Biopharmaceuticals Manufacturing: Progress and Agenda (WEB Exploration 2)	Ryuji Nakano Koji Iritani Kaori Shimizu	Kajima Corporation Kaneka Corporation JGC Corporation	Takaya Nakagawa Masashi Kuramoto TEC Project Services Corporation Daiichi Sankyo Co.,Ltd.
	11:30-12:30	60	Lecture	Next Generation Downstream Processing of Biologics: Improving the Performance by Continuous Operations	Shuichi Yamamoto	Professor, Yamaguchi University	Takaya Nakagawa Masashi Kuramoto TEC Project Services Corporation Daiichi Sankyo Co.,Ltd.
	12:30-13:30	60	Lunch				
<b>2F Heian</b>	<b>13:30-17:00 Workshop 7: Pharma PSE COP</b>			MC:			
	<b>Challenge for smart manufacturing and nexus problem of drugs</b>			Hirokazu Sugiyama			
	13:30-15:15	15	Opening	Smart manufacturing and nexus problem of drugs	Hirokazu Sugiyama	The University of Tokyo	Daisuke Yamakawa Pall
		15	Academic frontier lectures	Continuous manufacturing of solid drug products	Kensaku Matsunami		
		15		Continuous manufacturing of biopharmaceuticals	Kozue Okamura / Nozomi Takahashi		
		15		Lot-size determination in injectable manufacturing	Masahiro Yamada		
		15		Selection of single-use vs multi-use	Haruku Shirahata		
		15	Process design of iPS cell freezing	Yusuke Hayashi	Tomoyuki Taguchi Chiyoda Corporation		
		15	Data-driven operation support	Anicia Zeberli			
	15	Break					
	15:30-16:30	15	Industrial frontier lectures	Challenges and actions in CMC	Atshushi Fujiwara/Tetsuro Kitagawa	Astellas Pharma / Chugai Pharmaceuticals	Yoshihito Ikeda CMC System Research Laboratory
		15		Modular concept from productional point of view	Yukinobu Maruyama	JGC	
		15		Data measurement/utilization and predictive maintenance	Takuetsu Oishi	KT Manufacturing	
		15		Logistics, customized production and block chain	Tomoyuki Taguchi	Chiyoda Corporation	
	16:30-17:00	30	Discussion	Discussion	Hirokazu Sugiyama	The University of Tokyo	

2F Fukujyu	9:15-12:30 Workshop 3: YP (Workshop for Young Professionals)			MC: Yohei Hayashi	ISPE Japan Affiliate Task Team Leader for YP / Azbil Corporation		
AM	Good Data Integrity Practice For Young Professionals & YP 2018 Seminar Reports						
	09:15-10:00	45	Introduction	ISPE Initiatives and Activities of Young Professionals	Yohei Hayashi	Azbil Corporation	
			Reports	URS Reports on YP Seminar participant in 2018	Mizuki Tabata Ryo Takada	JCR Pharmaceuticals Co.,Ltd. IKEDAMOHANDO CO.,LTD.	
	10:00-12:10 (Including 10minutes break)	120	Special Lecture on Data Integrity	Data Integrity Basics	Kiyoshi Mochizuki	Xpro Associates	
				FDA 483s in Japan			
				FDA 483s in Production			
		Summary of FDA 483s in Production					
		Top 10 Non-Compliance from FDA Inspection					
		Good Data Integrity Practice in QC Lab					
	12:10-12:30	20	Workshop	Case Study: How do you comply for Production Systems	Kiyoshi Mochizuki	Xpro Associates	
	12:30-13:30	60	Wrap-up				
			Lunch				
2F Fukujyu	13:30-17:00 Workshop 8: SPP COP			MC: Koji Kawasaki	Airex Co., Ltd.		
PM	Try to Knock the Bottom of the Aseptic Iceberg						
	13:30-14:30	60	RABS WG1	Isolator and RABS Survey Report 2019	Kazuo Yanai	FUJIFILM Engineering CO., LTD.	Kazuhito Tanimoto SHIBUYA CORPORATION
	14:30-15:20	50	HEPA WG	Comparison of Filter Integrity Test with Particle Counter and Aerosol Photometer	Yukihiko Yazaki, Tsuyoshi Kawahara	Airex Co., Ltd., OSHITARI LABORATORY, INC.	Minoru Tamura ASAHI KOGYOSHA CO.,LTD.
	15:20-15:30	10	Break				
	15:30-16:00	30	Environmental Monitoring WG	- Risk-based Approach to Prioritize - Manual Interventions to be incorporated in Process Simulation Test and Smoke Study in Sterile Products Processing	Munetomo Matsuda, Daigo Mizutake, Dai Oyama	Mitsubishi Tanabe Pharma Corporation, ASKA Pharmaceutical Co.,Ltd., Astellas Pharma Inc.	Munetomo Matsuda Mitsubishi Tanabe Pharma Corporation
	16:00-17:00	60	RABS WG2	Design of Aseptic Filling Isolator Line for Highly Potent Products	Ken Nagai, Ryota Katsumi	Airex Co., Ltd., Kyowa Hakko Kirin Co., Ltd.	Kentaro Nakamura JGC CORPORATION
2F Togen	9:15-12:30 Workshop 4: SAM&GMP COP			MC: Emi Kikuta	KATSURA CHEMICAL CO.,LTD.		
AM	Correspondence to globalization of the GMP						
	9:15-9:20	5	Opening remarks		Fumio Kishimoto	KATSURA CHEMICAL CO.,LTD.	
	9:20-10:20	60	COP Lecture 1	Lifecycle Approach to Cleaning Validation	Masahito Watanabe	KAKEN PHARMACEUTICAL CO.,LTD.	
	10:20-11:20	60	COP Lecture 1(keynote)	Example of Quality Manual for achieving ICH Q10	Seiji Mochizuki	Teijin Pharma Limited	
	11:20-11:30	10	Break				
	11:30-12:30	60	Lecture 2(keynote)	Towards forthcoming revision of the GMP Ordinance in Japan, for further harmonization with the current PIC/S GMP Guide (Tentative)	Toshiaki Kudo	MHLW	
	12:30-13:30	60	Lunch				
2F Togen	13:30-17:00 Workshop 9: API COP			MC: Muneki Kishida	Mitsubishi Tanabe Pharma Corporation		
PM	Implementation studies on continuous API manufacturing						
	13:30-13:35	5	Opening remarks		Kazufumi Shibata	KANTO CHEMICAL CO., INC.	
	13:35-14:25	50	Lecture 1(keynote)	An Early Step for Continuous Manufacturing of Drug Substances in Mitsubishi Tanabe Pharma Corporation	Masahiro Ohshima	Mitsubishi Tanabe Pharma Corporation	
	14:25-15:15	50	Lecture 2(keynote)	Continuous Flow Production of Crystalline Particles for Pharmaceuticals	Hiroshi Takiyama	Tokyo University of Agriculture and Technology	
	15:15-15:25	10	Break				
	15:25-16:00	35	COP Lecture(keynote)	A case study of continuous manufacturing in mock-up API (HMCIN) plant	Masatoshi Ikeya	TEC Project Services Corporation (API COP)	
	16:00-16:05	5	Break				
	16:05-16:55	50	Panel discussion	Issues of continuous manufacturing of API	Masahiro Ohshima, Hiroshi Takiyama, etc(TBD)	Mitsubishi Tanabe Pharma Corporation, Tokyo University of Agriculture and Technology, etc (TBD)	Tatsuya Watanabe, Masatoshi Ikeya
16:55-17:00	5	Closing remarks		Ayako Maki	Kyowa Hakko Kirin Co., Ltd.		
2F Horai	9:15-12:30 Workshop 5: IP COP			MC: Mr.Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation		
AM	IP Society 5.0 -Future of Clinical Supply (GDP, IRT, Dt/fP, Outsourcing)						
	09:15-09:20	5		IP-COP Introduction	Mr.Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation	
	09:20-10:00	40	Lecture1	Approach to Japanese GDP Guideline in Clinical Supply	Mr.Shinya Otsuji	IP-COP GDP WG Lead, Saroute Co.,Ltd.	Mr.Shunsuke Mawa IP-COP GDP WG, Sumitomo Dainippon Pharma Co., Ltd.
	10:00-10:40	40	Lecture2	Our approach in order to be effective IRT utilization - Introduction of IRT Guide & Term List -	Mr.Kazuyuki Ito	IP-COP IRT WG Lead, Cenduit Japan G.K.	Mr.Eizo Yokoyama IP-COP DtP/DIP WG, Merck Serono Co., Ltd.
	10:40-10:50	20	Break				
	10:50-11:30	40	Lecture3	Facts and challenges of Direct to Patient - Introduction of research case by global task force -	Mr.Naoya Okamura	IP-COP DtP/DIP Lead, Mitsubishi Logistics Corporation	Mr.Minoru Mihara IP-COP IRT WG, Marken Japan Limited.
	11:30-12:10	40	Lecture4	The actual situation of the outsourcing in clinical supply and the subjects to be tackled	Mr.Kenichi Kuchiki	IP-COP Outsourcing Lead, Mitsui-Soko Holdings Co.,Ltd.	Ms.Chiaki Yamauch IP-COP Outsourcing WG, Nippon Boehringer Ingelheim Co.,Ltd
	12:20-12:30	10		IP-COP Closing	Mr.Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation	
12:30-13:30	60	Lunch					