

Pharma Society 5.0

The Era of Technologists

2022 Annual Meeting Program (Japan Affiliate) TENTATIVE

As of 2022/5/13

May 19 Annual General Meeting 9:30-10:15

2 F Event Hall	9:30-10:15	45		MC: Akihiro Matsuki	Head of Secretariat	
			Welcome	Hiroshi Yamaguchi	Chairman	
			Nomination and Election of AGM chairman			
			2021 Activity Report	Akihiro Matsuki	Head of Secretariat	
			2021 Financial Report	Tetsuro Noguchi	Treasurer	
			2021 Internal Audit Report	Shigeru Nakamura	Japan Affiliate Auditor	
			2022 Action Plan	Akihiro Matsuki	Head of Secretariat	
			2022 Budget Proposal	Tetsuro Noguchi	Treasurer	
	2022 Election Results of Board & Officers	Ayumu Yamada	2021 Head of Election Committee			

May 19 Annual Conference 10:25-17:15

Venue	Time	minutes	Title		Speaker	Affiliation	Moderator	Affiliation
2F Event Hall	10:25-10:30	5	Orientation		MC: Daisuke Hirasawa	Chugai Pharma Manufacturing Co., Ltd.		
	10:30-10:40	10	Opening Remarks	Welcome and Opening	Chair, ISPE Japan Affiliate	ISPE Japan Affiliate 2022 Chair		
	10:40-11:25	45	Keynote Speech 1	Evidence Based Public Health	Hiroshi Mizushima	Chief Senior Researcher, Center for Public Health Informatics National Institute of Public Health	Hirokazu Kisaka	Kyowakirin. Co., Ltd.
	11:25-12:10	45	Keynote Speech 2	MHLW Update	Fumi Yamamoto	Councilor for Pharmaceutical Affairs Minister. S Secretariat, MHLW	Junya Soma	GlaxoSmithKline K.K. Japan
2F Event Hall	12:10-13:10	60	Lunch (Luncheon Seminar)					
2F Event Hall	13:10-13:30	20	Update from ISPE Global	Update from ISPE International and General State of the Pharmaceutical Industry	Joerg Zimmermann	Chair, International Board of Directors of ISPE		
	13:30-14:15	45	Keynote Speech 3	EMA Regulatory Update	Andrei Spinei	Manufacturing Group Coordinator, Inspections Office, EMA		
	14:15-15:05	50	Keynote Speech 4	Introduction to Computer Software Assurance (CSA) from an industries perspective	Marc Koetter	Senior Manager and Global Process Owner Computer Software Validation (CSV)		
		FDA Perspective on Computer System Assurance		Francisco Vicenty	Case for Quality Program Manager, FDA			
2F Event Hall	15:05-15:30	25	Break					
2F Event Hall	15:30-15:40	10	Update from ISPE Global	ISPE Foundation Program	Antonio Moreira	ISPE Foundation Chair		
	15:40-16:25	45	Special Lecture 1	Digital Lighthouse Journey – Bayer Supply Center Garbagnate	Marco Signorini	Head of Operational Excellence & Digital Transformation, Bayer HealthCare Manufacturing – Italy		
	16:25-17:10	45	Special Lecture 2	Pharma PSE: a multiscale approach for “reimagining” pharmaceutical manufacturing	Hirokazu Sugiyama	Professor, Department of Chemical System Engineering, Tokyo University	Hiroshi Yamaguchi	UCB SA
	17:10-17:15	5	Closing Remark for Day 1		Junya Souma	Chairman, 2022 Annual Meeting Organizing Committee/Japan Affiliate Board of Director		

May 20 Workshops 9:30-17:00

9:30-17:00

Venue	Time	minutes	Title		Speaker	Affiliation	Moderator	Affiliation
2 F Zuiun	9:30-12:45 Workshop 1 FoF							
AM	Theme : Facilities of the Future Smart Factory				MC : Akihiro Matsuki	Mitsubishi Chemical Engineering Co.,Ltd.		
	9:30-10:00	30	Lecture 1	Facilities of the Future Smart Factory	Hirkazu kisaka	Kyowa Kirin Co.,Ltd		
	10:00-10:30	30	Lecture 2	Digital Transformation Activity Report	Rei Kobayashi	DAIICHI SANKYO PROPHARMA CO.,LTD		
	10:30-11:30	60	Lecture 3	Smart Factory	Yoshiyuki Yamashita	Tokyo University of Agriculture and Technology		
	11:30-11:45	15	Break					
	11:45-12:30	45	Panel Discussion	Panel Discussion	Eiichi Hasegawa	INFORMATION SERVICES INTERNATIONAL-DENTSU, LTD.		
					Yuki Kumanomido	Mitsubishi Chemical Engineering Co.,Ltd.		
					Hiroshi Akitomo	Kyowa Kirin Co., Ltd.		
Kazuhiro Numata					Astellas Pharma Inc.			
Hideaki Hosaka					Chugai Pharma Manufacturing Co.,Ltd.			
Mariko Okoshi	Tobii Technology K.K.							
Koichi Hayashida	Staubli KK							
12:45-13:45	60	Lunch	(Mini-Luncheon Seminar)					
2 F Zuiun	13:45-17:00 Workshop 5 Containment COP + EHS COP							
PM	Theme : Risk Based Approach for manufacturing of highly potent products				MC : Nobuaki Kato	Chugai Pharmaceutical Co., Ltd.		
	13:45-14:30	45	Special Lecture	Assessment of risks and prevention of troubles and accidents due to human error	Professor Takeshi Nakajo	Chuo University	Morihiro Takeda	Pharma Solutions Co., Ltd.
	14:30-14:50	20	Containment COP	Risk assessment for cross contamination caused by human error	Hiroaki Matsumoto	Office Kiseki Co., Ltd.	Kenichi Yoshida	Higuchi Industries Ltd.
	14:50-15:15	25	Containment COP	Aiming to spread PEEM-DB! : Now and Future	Syunsuke Kumazawa	Toshiba Nanoanalysis Corporation	Takahide Hashizume	Hata Iron Works Co., Ltd.
	15:15-15:30	15	Break					
	15:30-16:15	45	Containment COP	Report of the reserch about handling of hihghy potent parmaceuticals '2022	Shunta Hashimoto	KIT CO., LTD	Yohei Sasaki	Takenaka Corporation
	16:15-16:25	10	EHS COP	Introduction of EHS COP activities	Tomoyuki Hasegawa	ONO PHARMACEUTICAL. CO., LTD	Nobuaki Kato	Chugai Pharmaceutical Co., Ltd.
16:25-17:00	35	EHS COP	Q&A and introduction of case studies about the control of exposure to chemical substances.	Mariko Kawamoto	Shionogi Pharma Co., Ltd.	Nobuaki Kato	Chugai Pharmaceutical Co., Ltd.	
2 F Heian	9:30-12:45 Workshop 2 SPP COP							
AM	Theme : Doubt your common sense. Be free from biases.				MC: Kodai Chiba	TEC Project Services Corporation		
	9:30-9:40	10		Introduction of SPP COP	Kentaro Nakamura	SPP COP Leader, JGC JAPAN CORPORATION	Kodai Chiba	TEC Project Services Corporation
	9:40-10:35	55		What would be CQA/CPD for aseptic filling isolators?	Ken Nagai Hironobu Sunayama	Airex Co., Ltd. Shibuya Kogyo Co., Ltd.	Kentaro Nakamura	JGC JAPAN CORPORATION
	10:35-11:35	60		An investigation of the Relationships between air velocity and air flow pattern around the manufacturing equipment	Katsuya Inoue	ASAHI KOGYOSHA CO.,LTD.	Kodai Chiba	TEC Project Services Corporation
	11:35-11:50	15		Break				
	11:50-12:40	50		SPP COP Interactive Active Discussion -We are all worried about various GxP contents!-	Kosuke Konishi	TOYOBO CO., LTD.	Kentaro Nakamura	JGC JAPAN CORPORATION
	12:40-12:45	5		Progress report on the publication of "Baseline Guide Vol.3 : Sterile Product Manufacturing Facilities Third Edition" Japanese translation	Shigeru Okumura	TEC Project Services Corporation	Kodai Chiba	TEC Project Services Corporation
	12:45-13:45	60		Lunch				
2 F Heian	13:45-17:00 Workshop 6 API COP							
PM	Theme: Implementation of Continuous Manufacturing in API Synthesis							
	13:45-13:50	5	Opening Remarks	Opening Remarks	Masatoshi.Ikeya	TEC Project Survice		
	13:50-14:30	40	Lecture 1	Roadmap for Practical Use of Continuous Manufacturing System iFactory®	Takao Saito	iFactory, Ltd.(TAKASAGO CHEMICAL CORPORATION)	Masatosh Murakami	Mitsubishi Tanabe Pharma Corporation
	14:30-15:10	40	Lecture 2	Innovation of Continuous Filter Machinery & Continuous Dryer Machinery	Takehiko Hosono	Mitsubishi Kakoki Kaisha, Ltd.	Shintaro Yamaguchi	Fuji Rebio Inc.
	15:10-15:20	10	Break					
	15:20-16:00	40	Lecture 3	Development of Continuous Manufacturing Technology for Drug Substances and Intermediates in Shionogi Pharma/Pharmira	Hideyuki Kitamura	Pharmira Co., Ltd.	Ayako Nakajima	Q&EHS Solutions, Co., Ltd.
16:00-16:40	40	Lecture 4	Development of Continuous Manufacturing for Fine Chemicals -Activities at AIST	Nagatoshi Koumura	The National Institute of Advanced Industrial Science and Technology	Masatoshi Ikeya	TEC Project Survice Corporation	

Venue	Time	minutes	Title		Speaker	Affiliation	Moderator	Affiliation
2 F Fukuju	9:30-12:45 Workshop 3 BIO COP + TERM COP							
AM	Theme : Adapting to New Modalities				MC: Takashi Kaminagayoshi MC: Tsutomu Igarashi	BIO COP Leader, TAKEDA PHARMACEUTICAL CO., LTD. TERM COP Leader, TAKEDA PHARMACEUTICAL CO., LTD.	— —	— —
	09:30-09:45	15	Introduction	COP Activities & Today's Agenda	Takashi Kaminagayoshi Tsutomu Igarashi	BIO COP Leader, TAKEDA PHARMACEUTICAL CO., LTD. TERM COP Leader, TAKEDA PHARMACEUTICAL CO., LTD.	— —	— —
	09:45-10:35	50	Lecture 1	Biopharmaceutical Roadmap	Hiroyasu Tomoda	FUJIFILM Engineering Co., Ltd.	Masashi Oda Kazuya Sato	Hitachi Plant Services Co., Ltd. KAJIMA CORPORATION
	10:35-10:45	10	Break					
	10:45-11:35	50	Lecture 2	Manufacturing Process of Biopharmacy	Takashi Kaminagayoshi Kentarō Nagatomo Takashi Ichii	TAKEDA PHARMACEUTICAL CO., LTD. DAIICHI SANKYO CO., LTD. Nihon Pall Ltd.	Hirokaki Kawasaki	KANEKA Corporation
	11:35-11:45	10	Break					
	11:45-12:45	60	Lecture 3	Dual Use Study Based on Existing Antibody Manufacturing Facility	Shuji Ninomiya	JGC JAPAN CORPORATION	Osamu Shirokizawa Seiji Takahashi	Life Scientia Limited Life Scientia Limited
12:45-13:45	60	Lunch	(Mini-Luncheon Seminar)					
2 F Fukuju	13:45-17:00 Workshop 3 BIO COP + TERM COP							
PM	Theme : Adapting to New Modalities				MC: Takashi Kaminagayoshi MC: Tsutomu Igarashi	BIO COP Leader, TAKEDA PHARMACEUTICAL CO., LTD. TERM COP Leader, TAKEDA PHARMACEUTICAL CO., LTD.	— —	— —
	13:45-14:00	15	Reflection	COP Activities & Today's Agenda	Takashi Kaminagayoshi Tsutomu Igarashi	BIO COP Leader, TAKEDA PHARMACEUTICAL CO., LTD. TERM COP Leader, TAKEDA PHARMACEUTICAL CO., LTD.	— —	— —
	14:00-14:40	40	Lecture 4	Manufacturing Process of Cellular Medicine	Mai Inoue Yoko Tsuyuki	Obayashi Corporation Hitachi Plant Service Co., Ltd.	Tsutomu Igarashi	TAKEDA PHARMACEUTICAL CO., LTD.
	14:40-14:50	10	Break					
	14:50-15:50	60	Lecture 5	Requirements for PIC / S GMP Guidelines Annex 2A in ATMP Manufacturing	Kaori Shimizu Hiroaki Takamura	JGC JAPAN CORPORATION Chiyoda Corporation	Ayumu Yamada Ryo Ueda	JGC JAPAN CORPORATION Chiyoda Corporation
	15:50-16:00	10	Break					
16:00-17:00	60	Lecture 6	Digitalization in Biopharmaceutical Facilities & Equipment	Iyo Terashima Takashi Yoshida	Merck Ltd. Rockwell Automation Japan Co., Ltd.	Toshiaki Izumi Makoto Sekine	Endress Hauser Japan Co., Ltd. MARUBISHI BIOENGINEERING Co., Ltd.	
Venue	Time	minutes	Title		Speaker	Affiliation	Moderator	Affiliation
2 F Horai	9:30-12:45 Workshop 4 IP COP							
AM	Theme : IP Society 5.0 – Real Two-way player of Clinical Supply							
	09:30-09:35	5		IP-COP Introduction	Mr.Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation		
	09:35-10:15	40	Lecture 1	The GAP between Regulations and Actual activities in Investigational product, and the proposals	Mr.Yoshihiro Sawada	IP-COP Regulatory Lead, Astra Zeneca K.K.	Mr.Shinya Otsuji	IP-COP Regulatory WG, Saroute Co.,Ltd.
	10:15-10:55	40	Lecture 2	IRT Best Practices: Algorithms implemented in IRT and Tips to improve Data Quality for Clinical Supply	Mr.Shuji Hongo	IP-COP IRT WG Lead, Mitsubishi Logistics Corporation	Ms.Yuki Hyakutake	IP-COP IRT WG, Toray Industries, Inc.
	10:55-11:10	15	Break					
	11:10-11:50	40	Lecture 3	DtP/DfP – Local Pain Points and the solution	Mr.Minoru Mihara	IP-COP DtP/DfP WG Lead, Marken Japan Limited.	Mr.Naoya Okamura	IP-COP DtP/DfP WG, Mitsubishi Logistics Corporation
	11:50-12:30	40	Lecture 4	Approaches and Challenges from both Sponsors and Logistics vendors regarding BCP and BCM in Clinical Supply Activities (Warehousing and Transportation)	Mr.Kenichi Kuchiki	IP-COP Outsourcing Lead, Mitsui-Soko Holdings Co.,Ltd.	Mr.Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation
	12:30-12:40	10		IP-COP Closing	Mr.Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation		
12:45-13:45		Lunch						