

2018 Annual Meeting Program (Japan Affiliate)

Venue: Tower Hall Funabori

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

As of 2018/05/15

May 24 Annual General Meeting 9:30-10:30

5F Main Hall	09:30-10:30	60	9:30-10:30 Annual General Meeting	MC: Akihiro Matsuki	Head of Secretariat		
			Welcome	Hirofumi Suzuki	Chairman		
			Nomination and Election of AGM chairman				
			2017 Activity Report	Akihiro Matsuki	Head of Secretariat		
			2017 Financial Report	Hiroshi Sakai	Treasurer		
			2017 Internal Audit Report	Tatsuro Miyagawa	Japan Affiliate Auditor		
			2018 Action Plan	Akihiro Matsuki	Head of Secretariat		
			2018 Budget Proposal	Hiroshi Sakai	Treasurer		
2018 Election Results of Board & Officers	Itaru Kimura	Executive Director / 2018 Head of Election Committee					

May 24 Annual Conference 10:40-17:50

Venue	Time	Minutes	Title	Speaker	Affiliation	Moderator	Affiliation
5F Main Hall	10:40-11:20	30		MC:Akihiro Matsuki	ISPE Japan Affiliate Head of Secretariat / Mitsubishi Chemical Engineering Co., Ltd		
			Opening Remarks	ISPE Japan Affiliate Chairman	ISPE Japan Affiliate		
	11:20-12:10	50	Keynote Speech 1	Emerging Technologies for Pharmaceutical Modernization	Sau (Larry) Lee	Deputy Director, Emerging Technology Team Chair Office of Testing and Research/OPQ/FDA	Ayako Nakajima Japan Affiliate Vice Chairman/ NISSAN CHEMICAL INDUSTRIES, LTD.
2F Event Hall	12:10-13:10	60	Lunch				
5F Main Hall	13:10-13:55	45	Keynote Speech 2	Strategy of Drug & Medical Device for Overseas Business	Kentaro Kishimoto	Director, International Business Promotion Office, Healthcare Industries Division Commerce and Service Industry Policy Group METI (Ministry of Economy, Trade and Industry)	Shigeru Nakamura Japan Affiliate Past Chairman /CM Plus Corporation
	13:55-14:40	45	Special Lecture 1	From Industry 4.0 to Pharma 4.0 – The Holistic Control Strategy	Christian Woelbeling	Senior Director Global Accounts WERUM	Hirokazu Kisaka ISPE Japan Affiliate Board of Director / TAKEDA PHARMACEUTICAL CO., LTD.
	14:40-15:25	45	Special Lecture 2	Personalized Medicine and its Consequences on Manufacturing, Emerging Technologies for HSE	Andreas Flueckiger	Chief Occupational Health Officer F. Hoffmann-La Roche Ltd.	Daisuke Hirasawa ISPE Japan Affiliate New Board of Director / Chugai Pharmaceutical Co., Ltd.
2F Event Hall	15:25-16:10	45	Coffee Break				
5F Main Hall	16:10-17:00	50	Special Lecture 3	Redefining Healthcare System with Emerging Technology	Naohisa Yahagi	Associate Professor Graduate School of Media and Governance Keio University	Hiroshi Yamaguchi ISPE Japan Affiliate Executive Director / Fresenius Medical Care Japan K. K.
	17:00-17:50	50	Keynote Speech 3	The Landscape of Continuous Manufacturing in Japan	Yoshihiro Matsuda	Senior Scientist (for Quality) Pharmacist, PMDA (Pharmaceuticals and Medical Devices Agency)	Ayako Nakajima Japan Affiliate Vice Chairman/ NISSAN CHEMICAL INDUSTRIES, LTD.
2F Event Hall	18:00-20:00	120	Networking Party				

May 25 Workshops 9:15-17:00

Venue	Time	Minutes	Title		Speaker	Affiliation	Moderator	Affiliation
2F Zuiun	9:15-12:30 Workshop 1-1: CONTAINMENT COP				MC:Yuji Yamaura	Containment COP Leader / Asahi Kasei Finechem Co., Ltd.		
	Risk Based Approach for manufacturing of highly potent products							
	9:15-9:45	30	Containment COP	Introduction of Containment COP Activities	Yuji Yamaura	Asahi Kasei Finechem Co., Ltd.		
	9:45-10:45	60	Special Lecture	Practical Aspects of Containment	Andreas Flueckiger	Chief Occupational Health Officer F. Hoffmann-La Roche Ltd, Basel		
	10:45-11:00		Break					
	11:00-11:45	45	Containment COP	Case Study of Risk Assessment of OSD Manufacturing	Masahiro Yamamoto	Takeda Pharmaceutical Company Limited.		
	11:45-12:30	45	Containment COP	Current Status and a Sample of Pharmaceutical Equipment Exposure Measurement - Data Base (PEEM-DB) 2018	Haruka Futamura / Syunsuke Kumazawa	Airex Co., Ltd / Toshiba Nanoanalysis Corporation		
	12:30-13:30	60	Lunch					
2F Zuiun	13:30-17:00 Workshop 1-2:CONTAINMENT COP							
PM	Setting health based exposure limits for preventing cross contamination				MC:Shinichiro Matsunaga / Nobuaki Kato	Takeda Pharmaceutical Company Limited./ Chugai Pharmaceutical Company Limited		
	13:30-14:00	30	Containment COP	Introduction of PDE Setting Roundtable in Japan	Shinichiro Matsunaga	Takeda Pharmaceutical Company Limited.		
	14:00-14:45	45	Containment COP	Progress of PDE Setting Roundtable Activity	Tomoyuki Hasegawa	Ono Pharmaceutical Company Limited.		
	14:45-15:00		Break					
	15:00-16:00	60	Special Lecture	Determining Occupational Exposure Limit (OEL) and Permitted Daily Exposure (PDE) values	Silke Weber	Occupational Health Specialist F. Hoffmann-La Roche Ltd, Basel		
	16:00-16:30	30	Special Lecture	PDE Derivation Based on the Concepts of Toxicology and Risk Assessment	Akihiko Hirose	Director, Division of Risk Assessment National Institute of Health Sciences		
	16:30-17:00	30	Special Lecture	ASSESSMENT AND CONTROL OF DNA REACTIVE (MUTAGENIC) IMPURITIES IN PHARMACEUTICALS	Masamitsu Honma	Director, Division of Genetics and Mutagenesis National Institute of Health Sciences		
2F Heian	9:15-12:30 Workshop 2:BIO COP				MC: Sei Murakami	BIO COP Leader		
AM	Trends in Biopharmaceutical Process Development							
	9:15-9:30	15	Lecture	Introduction of BIO COP	Sei Murakami	Hitachi, Ltd.		
	9:30-10:10	40	Lecture	ISPE Guide: Biopharmaceutical Process Development and Manufacturing (1) Regulation, Facility	Ryuji Nakano Kazuya Nakagawa	Kajima Corporation TEC Project Services Corporation	Hiroki Takamura	Chiyoda Corporation
	10:10-10:50	40	Lecture	ISPE Guide: Biopharmaceutical Process Development and Manufacturing (2) QbD, Upstream	Teruo Ogawa Kaori Shimizu	Chugai Pharma Manufacturing Co., Ltd. JGC Corporation	Hiroki Takamura	Chiyoda Corporation
	10:50-11:05	15	Break					
	11:05-11:45	40	Lecture	ISPE Guide: Biopharmaceutical Process Development and Manufacturing (3) Downstream (Chromatography)	Akira Takeuchi Yuji Aoki	Chugai Pharma Manufacturing Co., Ltd. Nihon Pall Ltd.	Hiroki Takamura	Chiyoda Corporation
	11:45-12:30	45	Lecture	Made-in-Japan Platform Technology for Therapeutic Antibody Manufacturing - Perspective for Project MAB	Takeshi Omasa	Graduate School of Engineering Osaka University	Hiroki Takamura	Chiyoda Corporation
12:30-13:30	60	Lunch						
2F Heian	13:30-17:00 Workshop 5: SPP COP				MC:Koji Kawasaki	K.T.MFG.CO.,LTD.		
PM	Dig deeper into the trend of Sterile pharmaceutical processes							
	13:30-13:40	10	First	SPP introduction	Koji Kawasaki	K.T.MFG.CO.,LTD.		
	13:40-14:25	45	Lecture 1	To Use or Not to Use Single-use System When Planning New Production Lines~ Using Check Sheet ~	Seiji Shimura	Pall Corporation	Mikio Fujiwara	Nagase Medicals Co., Ltd.
	14:25-14:50	25	Lecture 2	Lessons learned from FDA 483s issued for Sterile Products Processing	Kiyoshi Mochizuki Daigo Mizutake Dai Oyama	Xpro Associates, LLC ASKA Pharmaceutical Co.,Ltd. Astellas Pharma Inc.	Kiyoshi Mochizuki	Xpro Associates, LLC
	14:50-15:00	10	Break					
	15:00-15:45	45	Lecture 3	Outline of the draft revision of PIC/S Annex1 on RABS	Kentaro Kozuki Michinari Nishizuka	K.T.MFG.CO.,LTD. Teva Takeda Pharma Ltd.	Tamon Tanaka	Kyowa Hakko Kirin Co., Ltd.
	15:45-16:30	45	Lecture 4	Report of air flow pattern studies	Yusuke Ando	Astellas Pharma Inc.	Hitoshi Kono	ASAHI KOGYOSHA CO.,LTD.
16:30-17:00	30	Lecture 5	Topics of revision draft of EU and PIC/S GMP Annex 1	Kentaro Nakamura	JGC CORPORATION	Shigeru Okumura	Toyo Engineering Corporation	

2F Fukujyu	9:30-12:30 Workshop 6-1:API COP			MC: Masahito Watanabe	Kaken Pharmaceutical co., Ltd.		
AM	Continuous manufacturing of API -issues and the challenge-						
	9:30-9:35	5	Welcome Remarks	Akira Kunimatu	API COP(Leader) / Sunsho Pharmaceutical Co., Ltd		
	9:35-10:25	50	Lecture1	The manufacturing industry will be redefined with continuous manufacturing.	Takao Saito	TAKASAGO CHEMICAL CORPORATION	
	10:25-10:55	30	Lecture2	A case study of continuous manufacturing in mock-up API (HMCIN) plant	Tomohiro Mizusako	API COP/JGC Corporation	Tsutomu Kojima
	10:55-11:10	15	Break				
	11:10-11:30	20	Lecture3	The Feature of Small Continuous Crystallizer and Examples of Crystallization	Ryo Harada	TOKUJU CORPORATION	Masahito Watanabe
	11:30-11:50	20	Lecture4	Features of Milli-reactor and Continuous reactions	Yosuke Kaidai	NISSO ENGINEERING CO.,LTD.	Masahito Watanabe
	11:50-12:10	20	Lecture5	The role of PAT in the continuous processes of pharmaceuticals	Yuki Hara	METTLER TOLEDO	Masahito Watanabe
	12:10-12:30	20	Lecture6	Introduction of an approach for pharmaceutical continuous manufacturing by CONTINUOUS pharmaceuticals	Masahiro Kawano	JGC Corporation	Masahito Watanabe
12:30-13:30	60	Lunch					
2F Fukujyu	13:30-17:00 Workshop 6-2:API COP			MC: Masahito Watanabe	Kaken Pharmaceutical co., Ltd.		
PM	Continuous manufacturing of API -issues and the challenge-						
	13:30-14:20	50	Lecture7	Movement on continuous manufacturing of APIs and the effort in DAIICHI SANKYO	Hiroshi Nagasawa	DAIICHI SANKYO COMPANY, LIMITED	Yoshiaki Kato
	14:20-15:10	50	Lecture8	Innovation of API Production Using Flow Fine Synthesis	Shu Kobayashi	Department of Chemistry, School of Science, The University of Tokyo	Yoshiaki Kato
	15:10-15:30	20	Break				
	15:30-16:50	80	Panel discussion	Continuous manufacturing of API -issues and the challenge-	Takao Saito, Tomohiro Mizusako, Hiroshi Nagasawa, Shu Kobayashi (Lecture Order), Yoshihiro Matsuda	TAKASAGO CHEMICAL CORPORATION, API COP/JGC Corporation, DAIICHI SANKYO COMPANY, Department of Chemistry School of Science The University of Tokyo, PMDA	Tsutomu Kojima, Ayako Nakajima
16:50-16:55	5	Closing Remarks		Yoshiaki Kato	Teijin Pharma Limited		
2F Togen	9:15-12:30 Workshop 3:YP (Workshop for Young Professionals)			MC:Miho Ojima	Sumitomo Mitsui Construction Co.,Ltd		
AM	"Engineering and Validation by risk based approach" - Let's learn how to make user requirement specification document						
	9:15-9:30	15	introduction about YP	Introduction-Purpose of Activities for Young Professional	Yohei Hayashi	Azbil Corporation	
	9:30-10:00	30	Explanation for group wo	Guidance for Making URS and Critical Parameter by Home bakery as Sample	Takahito Takeshima	IKEDAMOHANDO CO.,LTD.	
	10:00-11:00	60	URS report from team (3 team)	URS report from seminar participant in 2017 1G Bioreactor 2G Sterile Products Filling Equipment 3G Refrigerated Warehouse System	Kota Tomaya Takayuki Miyaji Emiko Suga Norihiko Sugimoto	YAMASA CORPORATION Chugai Pharma Manufacturing Co., LTD Dalton Corporation MSD K.K.	
	11:00-11:10	10	Break				
	11:10-12:10	60	Group work	Execution of group work for making CPP,CQA,URS by home bakery as sample	Takahito Takeshima	IKEDAMOHANDO CO.,LTD.	
	12:10-12:30	20	answer of group work	answer of group work	Takahito Takeshima	IKEDAMOHANDO CO.,LTD.	
	12:30-13:30	60	Lunch				
2F Togen	13:30-17:00 Workshop 7:EM/C&Q COP						
PM	Way of applying commissioning data as a qualification evidence			MC: Daisuke Hamaguchi	C&Q COP		
	13:30-13:40	10	Introduction		Daisuke Hamaguchi	C&Q COP	
	13:40-14:05	25	Lecture1	Commissioning Overview	Koichi Miyake	EM COP	
	14:05-14:35	30	Lecture2	Commissioning and its Deliverable for Pharmaceutical	Masahiko Yamaguchi	C&Q COP	
	14:35-15:05	30	Lecture3	Example of SAT(Site Acceptance Test) Referring Qualifications – for HVAC	Tadashi Inatani	C&Q COP	
	15:05-15:20	15	Break				
	15:20-16:00	40	Lecture4	Point to Consider - Applying Commissioning Data as a Qualification Evidence	Hinako Aoki	EM/C&Q COP	
	16:00-17:00	60	Panel discussion	Way of Applying Commissioning Data as a Qualification Evidence	Masahiko Yamaguchi Tadashi Inatani Hinako Aoki Yasuyuki Suga Toshiaki Izumi Daisuke Hamaguchi	C&Q COP C&Q COP EM/C&Q COP EM COP C&Q COP C&Q COP	Koichi Miyake EM COP

2F Horai	9:15-12:30 Workshop 4:IP COP			MC: Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation		
AM	A New Challenge toward Patient Centricity (Patient Survey) ~ The new technology (GDP/ Ultra low temperature) , standardization (IRT), and disruptive innovation (DtP) for Clinical supply ~						
	09:15-09:20	5		IP-COP Introduction	Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation	
	09:20-10:00	40	Special Lecture1	The Near-Term Viability and Benefits of eLabels for Clinical, Sites and Patients	Shuji Hongo	Astellas Pharma Inc.	Robert Kamphuis Pfizer Japan Inc.
	10:00-10:30	30	Lecture1	Compass for Establishing Ultra Cold Chain for Regenerative IP Under PIC/S GDP in Japan	Shinya Otsuji Yoshihiko Sato	IP-COP GDP WG Lead, Saroute Co.,Ltd. IP-COP Chair, Mitsubishi Logistics Corporation	Kaoru Oda Novartis Pharma K.K.
	10:30-11:00	30	Lecture2	Think Again What is the Usefulness and the Usage of IRT - The challenge of Standardization from Site User Perspective -	Kazuyuki Ito	IP-COP IRT WG Lead, Cenduit Japan G.K.	Satoru Harada Sumitomo Dainippon Pharma Co., Ltd.
	11:00-11:10		Break				
	11:10-11:40	30	Lecture3	"Investigational Medicinal Products (IMPs)-Patient survey: A consolidated comparative analysis of responses from Japan, North America, EU and China "	Ms. Julie Delaney	Catalent, Inc	Chiaki Yamauchi IP-COP Site/Patient Survey Lead Nippon Boehringer Ingelheim Co.,Ltd
	11:40-12:20	30	Lecture4	An Introduction to Direct-to-Patient Methodology for Clinical Trial Logistics	Mr. Pierre-Alain Guillon	Marken Limited	Naoya Okamura Mitsubishi Logistics Corporation
	12:20-12:30	10		IP-COP Closing	Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation	
	12:30-13:30	60	Lunch				
2F Horai	13:30-17:00 Workshop 8:PACKAGING COP			MC: Fujio Isemoto	PACKAGING COP Leader		
PM	Pharmaceutical Package Integrity Evaluation ~Test to be carried out on the current level of any moisture vapor and oxygen leaks/transmission, as well as any penetration of microorganisms in/out of the packages~ ~Make the guideline how to set the maximum allowable leakage limits~						
	13:30-13:40	10		Introduction	Fujio Isemoto		
	13:40-14:20	40		Pharmaceutical Package Integrity Evaluation and the Maximum Allowable Leakage Limits	Yasuhiko Higuchi	Fukuda Co., Ltd.	
	14:20-14:50	30		Test report on the actual measurement of moisture vapor leaks from the pinholes(5µm & others) and the standard pinholes for the highly accurate measurement.	Mayu Hirata	Fukuda Co., Ltd.	
	14:50-15:00	10	Break				
	15:00-15:20	20		Test report on the actual measurement of moisture vapor transmission from the pockets of PTP plastic film, PVC and CPP.	Kenji Takahashi	Daiichi Sankyo Co., Ltd.	
	15:20-16:30	70		"WORK-SHOP" Discussion on the issues, solutions and suggestions how to make the guideline.			COP members