15th Anniversary Annual Meeting Program (Japan Affiliate)

A Brave New World of Innovation-What Does it Hold for Us?

As of 2017/05/08

Venue：Toyama International Conference Center
〒930-0084
1-2 Ote-machi Toyama-city, Toyama
MAP
Tel +81 76 424 5931
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May 18 Annual General Meeting 10:00-11:00

3F Main Hall	10:00-11:00	60	**10:00-11:00 Annual General Meeting**	MC: Hirofumi Suzuki	Head of Secretariat		
			Welcome	Shigeru Nakamura	Chairman		
			Nomination and Election of AGM chairman				
			2016 Activity Report	Hirofumi Suzuki	Head of Secretariat		
			2016 Financial Report	Katsuhiko Nagao	Treasurer		
			2016 Internal Audit Report	Tsutomu Samura	Japan Affiliate Auditor		
			2017 Action Plan	Hirofumi Suzuki	Head of Secretariat		
			2017 Budget Proposal	Katsuhiko Nagao	Treasurer		
			Election Results of Board & Officers	Yuzuru Wakabayashi	Executive Director / Head of Election Committee		

May 18 Annual Conference 11:00-17:55 Networking Party 18:00-20:00

Venue	Time	Minutes		Title	Speaker		Moderator	
3F Main Hall	11:00-11:40				MC:Akihiro Matsuki	Mitsubishi Chemical Engineering Co., Ltd		
			Welcome Remarks			New Chairman of ISPE Japan Affiliate		
		20		congratulatory speech by guests of honor				
				congratulatory speech by guests of honor				
		20		ISPE Strategic Plan	John Bournas	ISPE CEO and President		
3F Main Hall	11:40-12:25	45	Keynote Speech 1	Disruptive innovation in pharma industry - Beyond medicines -	Norikazu Eiki	Former Chairman of Bayer Japan, a Member of GPMLF	Shigeru Nakamura	Japan Afiliate Chairman / CM Plus Corporation
3F Main Hall	12:25-13:35	70	Lunch					
3F Main Hall	13:35-14:20	45	Keynote Speech 2	ISPE GAMP® Guide: Records and Data Integrity	Sion Wyn	Conformity Ltd	Takayuki Sugimoto	Former GAMP COP Leader, Former ISPE Treasurer, SOAS Inc.
3F Lobby	14:20-14:45	25	Coffee Break					
3F Main Hall	14:45-15:30	45	Keynote Speech 3	How will emerging markets impact on regulator workloads?	Harry Rothenfluh	PIC/S Assistant Secretary Manufacturing Quality Branch, Therapeutic Goods Administration Department of Health	Hirofumi Suzuki	Japan Affiliate Head of Secretariat / Bayer Yakuhin, Ltd.
3F Main Hall	15:30-16:15	45	Keynote Speech 4	Recent Topic of PMDA	Shingo Sakurai	PMDA Office of Manufacturing/Quality and Compliance, Office Director	Ayako Nakajima	Japan Affiliate Vice Chairman / NISSAN CHEMICAL INDUSTRIES, LTD.
3F Lobby	16:15-16:25	10	Coffee Break					
3F Main Hall	16:25-17:10	45	Special Lecture 1	Transforming into a new Takeda and the contribution of Global Manufacturing	Thomas Wozniewski	Global Manufacturing & Supply Officer, TAKEDA PHARMACEUTICAL CO., LTD.	Katsuhiko Nagao	Japan Affiliate Treasurer / DAIICHI SANKYO PROPHARMA CO., LTD.
3F Main Hall	17:10-17:55	45	Special Lecture 2	Emergency Medical Helicopter in Japan, Present and Future	Takaji Kunimatsu	President Emergency Medical Network of Helicopter and Hospital Former Director General of National Police Academy	Hiroshi Yamaguchi （TBD)	Fresenius Medical Care Japan K. K.
3F Lobby	18:00-20:00	120	Networking Party					

May 19 Workshops 8:30-17:30

Venue	Time	Minutes		Title	Speaker		Moderator	
3F Main Hall	**8:30-12:30 Workshop 1: Facilities of the Future**				MC:Hirofumi Suzuki	Japan Affiliate Head of Secretariat / Bayer Yakuhin, Ltd.		
AM	**Emerging technologies will change our future**							
	8:30-8:40	10	Opening Remarks		Norikazu Eiki	Former Chairman of Bayer Japan, a Member of GPMLF		
	8:40-9:25	45	Lecture 1	What is Factory of the Future?	Bob Chew	CAI	Hirofumi Suzuki	Bayer Yakuhin, Ltd.
	9:25-10:10	45	Keynote	Significant Bio manufacturing Capacity Expansion Drivers, Scale, Consequences	Andrew Skibo	Head of Global Biologics Operations & Global Engineering, MedImmune/AstraZeneca	Bob Chew	CAI
	10:10-10:25	15	Coffee break					
	10:25-11:10	45	Lecture 2	Modeling and Optimization in Pharmaceutical Drug Developments	Koji Muteki	Pfizer Inc.	Bob Chew	CAI
	11:10-11:40	30	Lecture 3	PMDA Perspectives on Continuous Manufacturing	Yoshihiro Matsuda	PMDA	Bob Chew	CAI
	11:40-12:25	45	Lecture 4	3D Printing in Healthcare	Joseph Sendra	Johnson &Johnson	Bob Chew	CAI
	12:25-12:30	5	Closing Remarks		Bob Chew	CAI		
	12:30-13:30	60	Lunch					
3F Main Hall	**13:30-17:30 Workshop 7: Regulatory Committee**				MC:Ayako Nakajima	Head of Regulatory Committee, Japan Affiliate Vice Chairman / NISSAN CHEMICAL INDUSTRIES, LTD.		
PM	Global GMP Update for Quality and Compliance Excellence							
	13:30-14:00	30	Lecture 1	FDA GMP Update（Tentative)	(TBD)	FDA	Robert Tribe	Former Chair man of PIC/S, Advisor, Asia Pacific Regulatory Affairs
	14:00-14:30	30	Lecture 2	EU & MHRA GMP Update	Gerald W Heddell	Director, Inspection Enforcement & Standards Division MHRA	Robert Tribe	Former Chair man of PIC/S, Advisor, Asia Pacific Regulatory Affairs
	14:30-15:00	30	Lecture 3	GMP inspection experience of PMDA and future perspective of GMP in Japan	Ryoko Naruse	Division Director, Office of Manufacturing / Quality and Compliance	Robert Tribe	Former Chair man of PIC/S, Advisor, Asia Pacific Regulatory Affairs
	15:00-15:20		Coffee break					
	15:20-15:50	30	Lecture 4	Why do we need a single GMP standard?	Harry Rothenfluh	PIC/S Assistant Secretary Manufacturing Quality Branch, Therapeutic Goods Administration Department of Health	Robert Tribe	Former Chair man of PIC/S, Advisor, Asia Pacific Regulatory Affairs
	15:50-16:20	30	Lecture 5	WHO Inspection Update: Roles of the Prequalification Team & Experiences in Developing Countries	Vimal Sachdeya	WHO	Robert Tribe	Former Chair man of PIC/S, Advisor, Asia Pacific Regulatory Affairs
	16:20-16:30	10	Break					
	16:30-17:30	60	Panel Discussion	Global Regulatory GMP Updates		All	Robert Tribe	Former Chair man of PIC/S, Advisor, Asia Pacific Regulatory Affairs

2F 201/202	**8:30-12:30 Workshop 2: GAMP COP**				MC: Isao Nishida	Azbil Corporation		
AM	**GAMP-Data Integrity/The latest status and Interim report of Special Interest Groups**							
	8:30-8:40	10	COP Report	GAMP COP Activities Summary	Hirokazu Hasegawa	Novartis Pharma K.K.		
	8:40-9:00	20	SIG Report 1	Interim report of translation of "A Risk-Based Approach to GxP Compliant Laboratory Computerized Systems Second Edition" and report of translation of "A Risk-Based Approach to Testing of GxP Systems Second Edition"	Fumitoshi Usami	Yokogawa Solution Service Corporation		
	9:00-9:20	20	SIG Report 2	Interim report of GDP SIG	Akira Kounoike	Feeler Systemz Inc.		
	9:20-9:40	20	SIG Report 3	Investigation report of the implement status for Initial Risk Assessment - Case of control system of API manufacturing facilities -	Makoto Ikeda	TEC Project Services Corporation		
	9:40-9:45	5	Break					
	9:45-10:45	60	Panel Discussion	Data Integrity Panel Discussion	Masato Kato Miho Nakama Hiroomi Nishimura Hisao Sueyoshi Yoshinori Souma Hitoshi Matsui Michihiro Osakabe	MSD K.K. Novartis Pharma K.K. Shimadzu Corporation Toyo Businesss Engineering Corporation Toyo Businesss Engineering Corporation CAC Croit Corporation JGC Corporation		
	10:45-11:00	15	Coffee break					
	11:00-12:30	90	Special Lecture	Data Integrity – A Practical Approach Using the New ISPE GAMP® Guid	Sion Wyn	Conformity Ltd		
3F Main Hall	12:30-13:30	60	Lunch					
2F 201/202	**13:30-17:30 Workshop 8: Containment COP**				MC: Yuji Yamaura	Asahi Kasei Finechem Co., Ltd.		
PM	**Risk Based Approach for manufacturing of highly potent products**							
	13:30-14:15	45	Containment COP	Current Status and a sample of Pharmaceutical Equipment Exposure Measurement – Data Base (PEEM-DB) 2017 “Current status and introduction of archived data”	Nobuyuki Tsuduki Naoki Nakashima	Powex Corporation Toray Engineering Co., Ltd.		
	14:15-15:00	45	Containment COP	Current Status and a sample of Pharmaceutical Equipment Exposure Measurement – Data Base (PEEM-DB) 2017 “Sample of application and future plan”	Haruka Futamura Takahide Hashizume	Airex Co., Ltd. Hata Iron Works Co., Ltd.		
	15:00-15:15	15	Coffee break					
	15:15-16:00	45	Containment COP	Dispersion simulation of physical properties for surrogate materials	Koji Yamada Takahiro Tsugami	Pfizer Global Supply Japan Inc. Mtsubishi Chemical Engineering Corporation		
	16:00-16:30	30	Containment COP	Leak testing methods for containment enclosures	Takashi Ochiai	HOSOKAWA MICRON CORPORATION		
	16:30-17:30	60	Containment COP	Report of the research about the handling of high potent pharmaceutical products '2017	Kazuhito Tanimoto	SHIBUYA KOGYO CO..,LTD		

2F203	**8:30-12:30 Workshop 3: SPP (Sterile Products Processing) COP**				MC:Kentaro Nakamura	JGC CORPORATION		
	Dig deeper into the trend of Sterile pharmaceutical processes							
	8:30-8:40	10	First	SPP introduction	Koji Kawasaki	Airex Co Ltd		
	8:40-10:00	80	Lecture 1	Study on standardization of RABS design specifications	Shinobu Ito	Toray Engineering Co Ltd		
	10:00-10:15	15	Coffee break					
AM	10:15-11:15	60	Lecture 2	Survey and analysis on HEPA filter integrity test	Osamu Ishii Minoru Tamura	Asahi Kogyosasya Co., Ltd. TAKEDA PHARMACEUTICAL CO., LTD.		
	11:15-12:15	60	Lecture 3	Proposal for Risk-based Environmental Monitoring in Sterile Product Processing Area	Kiyoshi Mochizuki Shunsuke Kato Munetomo Matsuda Daigo Mizutake	Xpro Associates CHIYODA CORPORATION Mitsubishi Tanabe Pharma Corporation ASKA Pharmaceutical Co.,		
3F Main Hall	12:30-13:30	60	Lunch					
2F203	**13:30-17:30 Workshop 9: Pharma PSE COP**				MC: Hirokazu Sugiyama	The University of Tokyo		
	The Role of model-based design in pharmaceutical manufacturing							
	13:30-14:00	30	Lecture 1	The role of model-based design in pharmaceutical manufacturing	Hirokazu Sugiyama	The University of Tokyo	Hirokazu Sugiyama	The University of Tokyo
	14:00-14:30	30	Lecture 2	Model 1: Decision on the choice of single- and multi-use technologies in sterile drug product manufacturing	Haruku Shirahata	The University of Tokyo	Shigeru Tanaka	JGC Corporation
	14:30-15:00	30	Lecture 3	Model 2: Design of decontamination processes using hydrogen peroxide	Keisho Yabuta	The University of Tokyo	Shigeru Tanaka	JGC Corporation
PM	15:00-15:15	15	Coffee break					
	15:15-15:45	30	Lecture 4	Model 3: Decision on the choice of continuous and batch technologies in solid drug product manufacturing	Kensaku Matsunami	The University of Tokyo	Takeshi Yamaguchi	Bosch Packaging Technology
	15:45-16:15	30	Lecture 5	Model 4: Improvement of CIP/SIP processes considering uncertainty	Gioele Casola	The University of Tokyo	Takeshi Yamaguchi	Bosch Packaging Technology
	16:15-16:45	30	Lecture 6	Model-based design from industrial viewpoint - from the standpoints of drug makers, equipment manufacturers, engineering companies,	Tetsuro Kitagawa, Takuetsu Oishi, Yukinobu	Chugai Pharmaceuticals, K.T. MFG., JGC Corporation, Yokogawa, Niho	Hirokazu Sugiyama	The University of Tokyo
	16:45-17:15	30	Lecture 7	Panel discussion	All presenters		Hirokazu Sugiyama	The University of Tokyo
2F204	**8:30-12:30 Workshop 4: IP (investigational Products) COP**				MC: Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation		
	Patient Centric Approach for Clinical Supply in new era							
	08:30-08:40	10		IP-COP Introduction	Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation		
	08:40-09:20	40	Special Lecture	Clinical Trial Supplies – The Future From A Patient Centric Perspective	Mike Arnold	Chairman ISPE, Pfizer Inc.	Robert Kamphuis	Pfizer Japan Inc.
	09:20-10:00	40	Lecture1	The guide for SOP on warehousing and distribution of IP based on PIC/S GDP	Yoshihiko Sato	IP-COP GDP WG Lead, Mitsubishi Logistics Corporation	Kaoru Oda	Novaltis Pharma K.K.
AM	10:00-10:20	20	Coffee break					
	10:20-11:00	30	Lecture2	Outcome of Patient Survey in Japan	Chie Igushi	Pfizer Japan Inc.	Zene Matsumoto	UCB Japan Co., Ltd.
	11:00-11:40	40	Lecture3	Challenge for improvements in IRT practical usage based on the site survey	Kazuyuki Ito	IP-COP GDP IRT Lead, Cenduit Japan G.K.	Shuji Hongo	Astellas Pharma Inc.
	11:40-11:50	10		Closing	Yoshihiko Sato	IP-COP Chair, Mitsubishi Logistics Corporation		
3F Main Hall	12:30-13:30	60	Lunch					
2F204	**13:30-17:30 Workshop 10: TERM（Tissue Engineering and Regenerative Medicine）COP**				MC: Seiji Takahashi	Life Scientia Limited		
	Reguratory Requirement and Manufacturing Proceess of Cell and Gene Therapy Products							
	13:30-13:40	10	Opening Remarks	Intoroduction to TERM COP	Seiji Takahashi	Life Scientia Limited		
	13:40-14:20	40	Lecture 1	Manufacturability of Therapeutic Cells	Masahiro Kinooka	Osaka Univ.		
	14:20-15:00	40	Activity Report	Activity Report of Manufacturing Process WG in TERM	Ryo Ueda Mai Inoue	Chiyoda Corp. Obayashi Corporation.		
PM	15:00-15:20	20	Coffee break					
	15:20-16:00	40	Lecture 2	Global Regulatory Perspectives on the Quality and Safety of Cell-Based Therapeutic Products	Yoji Sato	The National Institute of Health Sciences (NIHS)		
	16:00-16:40	40	Activity Report	Activity Report of Manufacturing Process WG in TERM	Hidetoshi Kimura	Chiyoda TechnoAce		
	16:40-17:20	40	Panel Discussion	TBD	Masahiro Kinooka, Yoji Sato, TERM's speakaers			

2F Special	**8:30-12:30 Workshop 5: YP （Workshop for Young Professionals)**				MC: Hajime Inoue	Mitsubishi chemical engineering		
AM	**Young professional seminar「Engineering and Validation by risk based approach」 ～ Let's learn how to make user requirement specification document ～**							
	8:30-8:45	15	introduction about YP	Introduction-Purpose of Activities for Young Professional	Hidekazu Haramoto	Chugai pharma manufacturing	–	–
	8:45-9:15	30	Explanation for group work	Guidance for Making URS and Critical Parameter by Rice Cooker as Sample	Miho Ojima	Sumitomo Mitsui construction	–	–
	9:15-10:25	70	URS report from team (4 team)	URS report from seminar participant in 2016 1G tableting machine	Youshke Hashimoto Ojima Miho	Mitsubishi Tanabe pharma Sumitomo Mitsui construction	–	–
	10:25-10:40	15	Coffee break					
	10:40-11:45	65	Group work	Execution of group work for making CPP,CQA,URS by rice cooker as sample	Miho Ojima	Sumitomo Mitsui construction	–	–
	11:45-12:00	15	answer of group work	answer of group work	Miho Ojima	Sumitomo Mitsui construction	–	–
	12:00-12:30	30	Special lecture	Message to young professional people with future potential	Vasiliki Georgia Revithi	F. Hoffmann-La Roche	–	–
3F Main Hall	12:30-13:30	60	Lunch					
2F Special	**13:30-17:30 Workshop 11: EM（Engineering Management）/ C&Q COP**				MC：Tadashi Inatani. Koichi Miyake	Astellas Pharma inc.,OBAYASHI CORPORATION		
PM	**Risk-based approach and User Requirement Specifications（URS）**							
	13:30-13:40	10	Opening Remarks		Tadashi Inatani	Astellas Pharma inc.		
	13:40-14:10	30	Lecture 1	UR（User Requirements ：PUR/GUR）and URS	Takashi Hoshino	Star Enterprise	Tadashi Inatani	Astellas Pharma inc.
	14:10-14:40	30	Lecture 2	URS and Risk Assessment	Daisuke Hamaguchi	Chugai Pharma Manufacturing Co., Ltd.	Tadashi Inatani	Astellas Pharma inc.
	14:40-15:10	30	Lecture 3	URS Example of Reactor	Noboru Osaka	IHI Plant Engineering Corporation	Tadashi Inatani	Astellas Pharma inc.
	15:10-15:30	20	Coffee break					
	15:30-16:10	40	Lecture 4	URS Example of Sterile Process HVAC Systems	Yasuyuki Suga Shingo Goto	Shimizu Corporation Chugai Pharmaceutical Co., Ltd.	Koichi Miyake	Obayashi Corporation.
	16:10-17:00	50	Panel discussion	Risk-based approach and URS	Takashi Hoshino Daisuke Hamaguchi Noboru Osaka Yasuyuki Suga Shingo Goto Masahiko Yamaguchi	Star Enterprise Chugai Pharma Manufacturing Co., Ltd. IHI Plant Engineering Corporation Shimizu Corporation Chugai Pharmaceutical Co., Ltd. Kyoto Seisakusho Co., Ltd.	Koichi Miyake	Obayashi Corporation.
2F 205	**10:30-12:30 Workshop 6：PAT COP**				MC: Satoru Arai	Toray Industries, Inc		
AM	**Verification of Measurement Accuracy on PAT Tools for Low Content Formulations**							
	10:30-11:10	40	Lecture 1	Past report on application examples of PAT tools	Munetaka Hattori	PAT COP Leader, Former ISPE Chairman, Independent consultant		
	11:10-11:20	10	Lecture 2	Discussion on measurement preciseness of PAT tools required for CU test	Munetaka Hattori	PAT COP Leader, Former ISPE Chairman, Independent consultant		
	11:20-12:10	50	Stydy report	Verification of measurement accuracy on PAT tools for low content formulations	Ryosuke Nakamura	Bushu Pharmaceutical Ltd.		
	12:10-12:30	20	Lecture 3	Controls strategy and application of PAT for Continuous processing	Munetaka Hattori	PAT COP Leader, Former ISPE Chairman, Independent consultant		