2014 Annual Meeting Program (Japan Affiliate)

Venue：Tower Hall Funabori
〒134-0091 4-1-1 Funabori Edogawa-ku Tokyo

As of March 20, 2014

April 10 Annual General Meeting 10:00-11:00

5F Main Hall	09:30-10:30	60	**9：30-11:30 Annual General Meeting**	MC: Masayuki Akutagawa	Head of Secretariat		
			Welcome	Kenzo Toyashima	Chairman		
			Nomination and Election of AGM chairman				
			2013 Activity Report	Masayuki Akutagwa	Head of Secretariat		
			2013 Financial Report	Yuichi Watanabe	Treasurer		
			2013 Internal Audit Report	Hiroshi Kyogoku	Japan Affiliate Auditor		
			2014 Action Plan	Masayuki Akutagwa	Head of Secretariat		
			2014 Budget Proposal	Masayuki Akutagwa	Treasurer		
			2014-2015 Election Results of Board & Officers	Hirofumi Suzuki	Executive Director / 2012 Head of Election Committee		

April 10 Annual Conference 11:00－18:00

Venue	Time	Minutes		Title	Speaker		Moderator	
5F Main Hall	11:00-11:20	20	Welcome Remarks 1		MC:Masayuki Akutagawa	Japan Affiliate Head of Secretariat, Pharma Planning Co., Ltd.		
					2014 Japan Affiliate Chairman	ISPE Japan Affiliate		
	11：20－12：20	60	Keynote Speech 1	Update on "Office of Pharmaceutical Quality," What's new in CDER and how it affects your process （2013 ISPE Annual Meeting Plenary Session in Washington DC Video)	Janet Woodcock	the Director of the Center for Drug Evaluation and Research (CDER) at the FDA.	Yuichi Watanabe	Japan Affiliate Treasurer, MSD K.K. Merck & Co.,INC.
2F Event Hall	12:20-13:30	70	Lunch					
	13:30-14:30	60	Keynote Speech 2	Disease Treatment Based on Enhancement of Natural Healing Potentials - Regeneration Therapy and Regeneration Research-	Yasuhiko Tabata	Institute for Frontier Medical Science Kyoto University	Tatsuro Miyagwa	Japan Affiliate Past Chairman
5F Main Hall	14:30-15：30	60	Keynote Speech 3	Establishment of New Regulation for Regenerative and Cellular Therapy Products, Gene Therapy Products in Japan	Yumiko Nomura	MHLW	Tetsuhito Takarada	Japan Affiliate Executive Director, Mochida Pharmaceutical Co., LTD.
2F Event Hall	15:30-16:00	30	Coffee Break					
5F Main Hall	16:00-17:00	60	Special Lecture 1	Global Use of Medicines: Perspectives on and Outlook of the Global Pharmaceutical Market	Alan Thomas	IMS	Shigeru Nakamura	Japan Affiliate Vice Chairman, CM Plus Corporation
	17:00-18:00	60	Special Lecture 2	Boehringer-Ingelheim --Its Strengths as Family Owned Business and Pursuit for Global Talent Development	Masao Torii	President / Boehringer Ingelheim Japan	Kenzo Toyoshima	Japan Affiliate Chairman, SSP CO., LTD.
2F Event Hall	18:00-20:00	120	Networking Party					

April 11 Workshops 9:00~17:00

Venue	Time	Minutes		Title	Speaker		Moderator	
2F Zuiun/Heian	**9:00-17:00 Workshop 1: QbD Workshop**							
AM	**Global and Japanese aspects of QbD**				MC:Katsuhiko Nagao	Chair, Organizing Committee 2014 Annual Meeting, DAIICHI SANKYO PROPHARMA CO., LTD		
							Tetsuhiro Takarada (suggested)	Japan Affiliate Executive Director, Mochida Pharmaceutical Co., LTD.
	9:00-9:05	5	Opening & Welcome		Kenzo Toyoshima	ISPE Japan Affiliate Chairman		
	9:05-9:25	20	Lecture 1	Global aspect of QbD: ICH Perspective	Moheb Nasr	Vice president , Regulatory, GSK, Former Director of ONDQA, FDA		
	9:25-9:45	20	Lecture 2	QbD Parallel Review Pilot Program: Overview from industry applicant's view	Roger Nosal	Pfizer Vice president, Global CMC		
	9:45-10:10	25	Lecture 3	Example of QbD Filing: J-NDA Filling of Inlyta Tablets Introducing Design Space	Yutaka Sugie	Pfizer-Japan, Global CMC		
	10:10-10:35	25	Lecture 4	Control Strategy of Votrient Tablet for J-NDA filing	Mio Yamazaki	GlaxoSmithKline-Japan CMC RA, Regulatory Affairs		
	10:35-10:50	15	Break					
	10:50-11:15	25	Lecture 5	How global firms file QbD in Japan?: Eliquis Tablets J-NDA filing- Real Time Release Testing	Ineko Kondo	Bristol-Myers Squibb CMC Regulatory		
	11:15-11:40	25	Lecture 6	Post Approved Change Filling for the Product Approved by Real Time Release Testing - PCA, Additional Dosage etc.-	Eiichi Mano	MSD-Japan, Manager CMC Regulatory Affairs		
	11:40-12:05	25	Lecture 7	How global firms file QbD in Japan?: Post approval Change filing of Champix Real Time Release Testing	Hirotoshi Sato	Pfizer-Japan, Global CMC		
	12:05-12:30	25	Lecture 8	QbD in a Domestic Company	Tomoyuki Watanabe	Daiichi Sankyo Co., Ltd.		
	12:30-13:30	60	Lunch					
2F Zuiun/Heian	**13:30－17:00 Workshop 1-2 QbD Workshop**						Ayako Nakajima (suggested)	Japan Affiliate Executive Director NISSAN CHEMICAL INDUSTRIES, LTD.
	13:30-13:55	25	Lecture 9	Current Status and Future Strategy for QbD Application with PAT Implementation	Masafumi Dohi	Astellas Pharma Inc.		
PM	13:55-14:25	30	Special Lecture 1	Seeking Outcome QbD Application	Kazunori Takagi	Pharmaceutical and Medical Devices Agency		
	14:25-14:55	30	Special Lecture 2	What is the Difference of GMP Compliance Inspection and Traditional Approach Products	Yujiro Kameyama	Pharmaceutical and Medical Devices Agency		
	14:55-15:10	15	Break					
	15:10-16:50	100	Panel Discussion / Audience Participation	FDA CPGM: Points to Consider in the Inspection and Case Study	All participants			
	16:50-17:00	10	Closing	Final Remarks (Video)	Haruhiro Okuda (Video message)	Deputy Director- General, National Institute of Health Sciences, MHLW		
2F Fukujyu	**9:00-12:30 Workshop 2-1:Containment COP**				MC: Morihiko Takeda	Pharma Solutions Co., Ltd.		
	Risk Based Approach for Manufacturing of Highly Potent Products							
	9:00-9:15	15	Introduction	Requirements for cross-contamination to be revised in EU・PIC/S-GMP	Morihiko Takeda			
	9:15-10:15	60	Special Lecture 1	Risk Assessment on Mutagenic Impurities and Outline of ICH M7 Draft Guideline	Tsuneo Hashizume	Takeda Pharmaceutical Company Limited		
AM	10:15-10:30	15	Break					
	10:30-11:30	60	Containment COP	Update of Baseline Guide "Cleaning"	Hiroaki Matsumoto	Asahi Kasei Finechem Co., Ltd.		
	11:30-12:30	60	Special Lecture 2	Establishment of ADE / OEL and Exposure Levels Assessment in Pharmaceutical Industries	Ichiro Tsunenari	Boehringer Ingelheim		
	12:30-13:30	60	Lunch					
2F Fukujyu	**13:30-17:00 2-2:Containment COP**				MC: Masahiro Oda	Pall Corporation		
	Risk Based Approach for Manufacturing of Highly Potent Products							
	13:30-14:15	45	Containment COP	About Survey Report of Manufacturing Highly Potent Products in Japan	Yuji Yamaura	Asahi Kasei Finechem Co., Ltd.		
	14:15-14:45	30	Containment COP	New Trend to Control the Properties of Industrial Waste Water	Ayumi Hasegawa	Sumika Chemical Analysis Service, Ltd.,		
PM	14:45-15:00		Break					
	15:00-15:30	30	Containment COP	HEPA Filters for Containment Equipment	Jyun Oyama	Kikusui Seisakusho Ltd.		
	15:30-16:00	30	Containment COP	Airborne Properties According the Particle Properties of Lactose	Masaharu Tanahashi	Hosokawa Micron Corporation		
	16:00-17:00	60	Special Lecture 3	Introduction of Shionogi's New Manufacturing Facility for the High Potent APIs	Makoto Takagi	Shionogi & Co., Ltd.		
2F Togen	**9:00-12:30 Workshop 3:IP COP**				MC: Shuji Hongo			
	Ticket to Global Standard for Clinical Supply							
	9:00 - 9:10	10		IP-COP introduction	Shuji Hongo	IP-COP lead, Astellas Pharma Inc.	-	
	9:10 - 9:20	10	IP-COP	GDP introduction	Yu Kushimoto	IP-COP, Fisher Clinical Services Japan K.K.	-	
	9:20 - 10:20	60	Special Lecture 1	Our experiences and sponsors' reaction towards GDP	Paul O'Connor	Almac Clinical Services	Yu Kushimoto	IP-COP, Fisher Clinical Services Japan K.K.
	10:20 - 11:20	60	Special Lecture 2	Perspectives of GMP for Investigational Products in Japan - Recognizing the Accession to PIC/S -	Shinichi Kodato	Amgen Astellas Biopharma	Keiko Mizushi	IP-COP, AstraZeneka K.K.
AM	11:20 - 11:40	20	Break					
	11:40 - 12:30	50	Special Lecture 3	Site patient survey –A read out on the ISPE IP COP Survey on Patient Experience related to Investigational Medicinal Products (IMPs)-	Christine Milligan	Catalent Pharma Solutions	Hirofumi Suzuki	Japan Affiliate Board of Director, Bayer Yakuhin, Ltd.
	12:30-13:30	60	Lunch					
2F Togen	**13:30-17:00 Workshop 4 SPP COP**				MC: Koji Kawasaki	SPP CoP Leader, Airex Co.,Ltd.		
	Operational Excellence in Sterile Drug Product Manufacturing, FDA CPGM and Rogue BI							
	13:30-13:35	5	Introduction	Introduction of SPP COP	Koji Kawasaki	SPP CoP Leader, Airex Co.,Ltd.		
	13:35-15:20	5	OPEX	Introduction of Operational Excellence (OPEX) WG	Hiroshi Yamaguchi	SPP CoP Director		
		15	OPEX	What is OPEX in Pharmaceutical Manufacturing Plant ?	Tomohiro Maeda	SPP CoP, Santen Pharmaceutical Co., Ltd.		
		25	OPEX	Case Study 1 Methods for Product Loss Reduction in Sterile Drug Product Manufacturing	Hirokazu Sugiyama	SPP CoP, The University of Tokyo		
PM		25	OPEX	Case Study 2 Survey of Fill-volume Control and Opportunities for Process Improvement	Kouji Takimoto	SPP CoP, Daiichi Sankyo Co., Ltd.		
		25	OPEX	Case Study 3 Introduction of QC Circle Activities in Pharmaceutical Manufacturing Shop-floor	Seiji Ueno	SPP CoP, Chugai Pharmaceutical Co., Ltd.		
		10	OPEX	Conclusion (OPEX part)	Hiroshi Yamaguchi	SPP CoP Director		
	15:20-15:35		Break					
	15:35-16:25	25	FDA CPGM	The Latest Trends of FDA Sterile Drug Process Inspection	Atsushi Takiishi	SPP CoP, Astellas Pharma Inc.		
		25	FDA CPGM	FDA CPGM: Points to Consider in the Inspection and Case Study	Tamon Tanaka	SPP CoP, Kyowa Hakko Kirin Co., Ltd.		
	16:25-17:00	20	Rogue BI	Problem of the BI Quality for Sporicidal Process	Koji Kawasaki	SPP CoP Leader, Airex Co.,Ltd.		
		15	Rogue BI	Conclusion (Rogue BI part)	Kazuhito Tanimoto	SPP CoP, Shibuya Kogyo Co., Ltd.		