

2016 Annual Meeting Program (Japan Affiliate)

Beyond the New Horizon: Implementation of the Global Standard

Venue: Tower Hall Funabori

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

As of 2016/4/7

April 14 Annual General Meeting 10:00-11:00

5F 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				
			2015 Activity Report	Hirofumi Suzuki	Head of Secretariat		
			2015 Financial Report	Ayako Nakajima	Treasurer		
			2015 Internal Audit Report	Tsutomu Samura	Japan Affiliate Auditor		
			2016 Action Plan	Hirofumi Suzuki	Head of Secretariat		
			2016 Budget Proposal	Ayako Nakajima	Treasurer		
			Bylaw Revision	Yuichi Watanabe	Past Chairman		
			2016-2017 Election Results of Board & Officers	Hirofumi Suzuki	Executive Director / Head of Election Committee		

April 14 Annual Conference 11:00-17:00

Venue	Time	Minutes	Title	Speaker		Moderator	
5F Main Hall	11:00-11:20	20		MC:Hirofumi Suzuki	Japan Affiliate Head of Secretariat, Bayer Yakuhi, Ltd.		
			Welcome Remarks	2016 Japan Affiliate Chairman	ISPE Japan Affiliate		
5F Main Hall	11:20-12:20	60	Special Lecture 1 Becoming the First to Deliver Differentiated Value -Mitsubishi Tanabe Pharma Corporation will Open up the Future of Medicine-	Masanori Mitsuka	Mitsubishi Tanabe Pharma Corporation President	Shigeru Nakamura	Japan Affiliate Chairman/CM Plus Corporation
2F Event Hall	12:20-13:30	70	Lunch				
5F Main Hall	13:30-14:30	60	Special Lecture 2 Regulatory Science Initiative and PMDA International Strategic Plan 2015	Naoyuki Yasuda	PMDA	Yuichi Watanabe	Japan Affiliate Past Chairman/ Otsuka Pharmaceutical Co., Ltd.
5F Main Hall	14:30-15:30	60	Keynote Speech 1 Current State of Continuous Manufacturing	Theodora Kourti	Senior Vice President, Global Regulatory Affairs, ISPE	Yuichi Watanabe	Japan Affiliate Past Chairman/ Otsuka Pharmaceutical Co., Ltd.
2F Event Hall	15:30-16:00	30	Coffee Break				
5F Main Hall	16:00-17:00	60	Keynote Speech 2 Regulatory Developments in Data Integrity: Trends and Strategy for a Global Supply Chain	David Churchward	MHRA Expert GMDP Inspector	Katsuhiko Nagao	Japan Affiliate Vice Chairman/ DAIICHI SANKYO PROPHARMA CO., LTD
5F Main Hall	17:00-18:00	60	Keynote Speech 3 Product and Process Robustness	Daniel (Yingxu) Peng,	FDA A Lead Chemist in the Office of Pharmaceutical Quality (OPQ)/CDER	Ayako Nakajima	Japan Affiliate Treasurer/NISSAN CHEMICAL INDUSTRIES, LTD.
2F Event Hall	18:00-20:00	120	Networking Party				

April 15 Workshops 9:00~17:00

Venue	Time	Minutes	Title	Speaker	Moderator		
2F Zuiun/Heian	9:00-12:30 Workshop 1-1: Regulatory Committee						
AM	ICH Harmonization and Japan's Globalization						
	9:00-9:10	10	Opening Remarks	MC: Ayako Nakajima	NISSAN CHEMICAL INDUSTRIES, LTD.		
	ICH Harmonization						
	9:10-9:40	30	Lecture 1	Impact of ICH Restructuring: Expansion of Membership to Include Several Emerging Markets Countries & the Mandatory Implementation of ICH Q1, Q7, and E6 Guidelines	Hironobu Saito	DAIICHI SANKYO CO., LTD.	—
	9:40-10:20	40	Invited Guest Lecture 1	ICH Quality Guidelines – Current Activities and Future Opportunities	Moheb Nasr	GlaxoSmithKline	—
	10:20-10:40	20	Special Lecture 1	ICH Q12 (Pharmaceutical Product Lifecycle Management) : PMDA's Perspective	Yasuhiro Kishioka	PMDA	—
	10:40-11:10	30	Lecture 2	Expectation to QbD/PAT/Continuous Manufacturing -Based on Experience of Product Development with Enhanced QbD Approach-	Hiroshi Nakagawa	DAIICHI SANKYO CO., LTD.	—
	11:10-11:20	20	Coffee break				
	Japan's Globalization Initiatives						
	11:20-11:55	35	Special Lecture 2	A PMDA's GMP Perspective -PIC/S and Beyond-	Masatoshi Morisue	PMDA	—
11:55-12:30	35	Special Recture 3	PMDA Perspective and Initiatives for Pharmaceutical Globalization	Yoshihiro Matuda	PMDA	—	
12:30-13:30	60	Lunch					
2F Zuiun/Heian	13:30—17:00 Workshop 1-2 Regulatory Committee						
PM	Challenges with ICH Harmonization Programs and Japan's Globalization Initiatives						
	13:30-14:05	35	Invited Guest Lecture 2	An Industry Perspective on Implementation of ICH & Future Opportunities for Regulatory Harmonization	Roger Nosal	Pfizer Inc.	—
	14:05-14:35	30	Lecture 3	A Japanese Company's Perspective on GMP/CMC ICH Harmonization and Japan's Globalization Initiatives	Kazuhiro Okochi	TAKEDA PHARMACEUTICAL CO., LTD.	—
	14:35-15:05	30	Lecture 4	Regulatory and Quality Considerations for Continuous Manufacturing: Challenges on Globalization and Harmonization	Kimiya Okazaki	GlaxoSmithKline K.K	—
	15:00-15:20	20	Coffee break				
	15:20-16:50	90	Round Panel Duscusion		Panelists: all Speakers and Mark Rosolowsky, BMS		Tetsuhito Takarada ISPE Adjunct Director, Mochida Pharmaceutical Co., LTD.
	16:50-17:00	10	Closing		Touru Kawanishi	NIHS	—
2F Fukujuyu	9:15—12:30 Workshop 2: SPP COP						
AM	Issues of RABS, Isolator and HEPA filter						
	9:15-9:25	10	SPP-COP	About SPP COP	Akihiro Yukinari	Chugai Pharma Manufacturing Co., Ltd.	
	9:25-10:15	50	SPP-COP	Isolator and RABS Survey Report 2016	Kentaro Nakamura	JGC Corporation	Tamon Tanaka Kyowa Hakko Kirin Co.,Ltd.
	10:15-11:15	60	SPP-COP	Risk-Based Approach for the Design of RABS	Michiyoshi Ono	Pharma Solutions Co., Ltd	Tamon Tanaka Kyowa Hakko Kirin Co.,Ltd.
	11:15-11:30	15	Coffee break	Break			
	11:30-12:30	45	SPP-COP	Approach to optimization against the challenges in the HEPA filter's integrity testing.	Yusuke Iga Hitoshi Kohno	The Research Foundation for Microbial Diseases of Osaka University ASAHI KOGYOSHA CO.,LTD.)	Koji Kawasaki Airex Co.,Ltd.
	12:30-13:30	60	Lunch				

2F Fukuju	13:30-17:00 Workshop 3: Containment COP			MC: Kazuhito Tanimoto	SHIBUYA KOGYO CO., LTD.			
PM	Risk Based Approach for handling of pharmaceutical and chemical products							
	13:30-14 : 15	45	Containment COP	Our Expectations for the Japanese toxicologist	Yuji Yamaura	Asahi Kasei Finechem Co., Ltd.	Kazuhiro Tanimoto	SHIBUYA KOGYO CO., LTD.
	14 : 15-15:00	45	Containment COP	Current Status and a sample of Pharmaceutical Equipment Exposure Measurement - Data Base (PEEM-DB)	Haruka Futamura /Takahide Hashizume	Airex Co., Ltd /Hata Iron Works Co., Ltd.	Jun Ooyama	KIKUSUI SEISAKUSHO LTD
	15:00-15:15	15	Coffee break					
	15 : 15-16 : 00	45	Containment COP	The powder properties of surrogate materials which are used for assessing the containment performance.	Kenichi Nagasaki /Ayumi Hasegawa	JGC Corporation / Sumika Chemical Analysis Service, Ltd.	Shinichi Kuriyama	CellSeed Inc.
	16:00-17:00	60	honor lecture	Guidance on Risk assessment for Chemical Substances and Mixtures Based on Industrial Safety and Health Act.	Kenji Ando	Japan Industrial Safety and Health Association	Takahiro Tsugami	Mitsubishi chemical engineering corporation
2F Togen	9:15-12:30 Workshop 4:Workshop for Young Professional			MC:Hidekazu Haramoto	Chugai Pharma Manufacturing CO LTD			
AM	Engineering and Validation Activity Applied for Risk -bases Approach And Group Work							
	9:15~9:30	15	Intoroduction	Intoroduction	Hidekazu Haramoto	Chugai Pharma Manufacturing CO LTD	—	—
	9:30~10:30	60	Lectucher	Engineering and Validation Activity Applied for Risk -bases Approach	Tadashi Inatani	Astellas Pharma Inc.	Hidekazu Haramoto	Chugai Pharma Manufacturing CO LTD
	10:30~11:15	45	Group Work	Group Work	Tadashi Inatani	Astellas Pharma Inc.	—	—
	11:15~11:30	15	Coffee break					
	11:30~12:30	60	YP12 URS Presentation	Vial Filler URS Report PTP Packaging Machine URS Report HVAV for Sterile Facility URS Report	Takenori Sumi Kazunori Kosaka Toshihiko Katsuyama	Asahi Kasei Pharma Corp Kyowa Hakko Kirin Co., Ltd. DHL Supply Chain Ltd.	Tadashi Inatani	Astellas Pharma Inc.
	12:30~13:30	60	Lunch	Presentation of the Group work	—	—	—	—
2F Togen	13:30-17:00 Workshop 5: Pharma PSE COP			MC:Hirokazu Sugiyama	The University of Tokyo			
PM	Pharmaceutical Process Systems Engineering (Pharma PSE) for realizing "Excellence by Design"							
	13:30-13:45	15	Introduction	Background of the establishment of Pharma PSE COP and Overview of the workshop	Hiroshi Yamaguchi	ISPE Japan Affiliate Executive Director	Hirokazu Sugiyama	The University of Tokyo
	13:45-14:20	35	COP activity report	Systematization of process design in drug development - basic design considerations in development -	Yoshihito Ikeda	SEIKAGAKU CORPORATION	Kazuo Tozaki	IPP management
	14:20-14:55	35	COP activity report	Improvement of process design activities with taking selection of filling machine as an example	Takeshi Yamaguchi	BOSCH Packaging Technology K.K	Joji Murakami	Yokogawa Electric Corporation
	14:55-15:15	20	Coffee break					
	15:15-15:50	35	COP activity report	Comparative evaluation of single-use and multi-use technologies as a process alternative	Haruku Shirahata	The University of Tokyo	Daisuke Yamakawa	Nihon Pall
	15:50-16:25	35	COP activity report	Analyzing generation process of unused medicine and its reduction support method	Akira Hashimoto	The University of Tokyo	Yukihiro Yazaki	Airex Co., Ltd.
16:25-17:00	35	Presentation	Next steps of Pharma PSE research and expansion as COP	Hirokazu Sugiyama	The University of Tokyo	Hiroshi Yamaguchi	ISPE Japan Affiliate Executive Director	
2F Hourai	9:15-12:30 Workshop 6:IP COP			MC: Daisuke Yamagata	ISPE Japan Affiliate IP COP Vice Leader			
AM	A new era for clinical supply -Enhancing globalization in Japan-							
	9:15-9:25	10		IP-COP introduction	Zene Matsumoto	UCB Japan Co. Ltd.		
	9:25-10:05	40	IP-COP	Challenge interaction to PIC/S GMP on blinding randomization of IP under GCP in JAPAN	Zene Matsumoto	UCB Japan Co. Ltd.	Kaoru Oda	Novartis Pharma K.K.
	10:05-10:45	40	IP-COP	Compass for establishing Security Measures for IP transportation under GDP in JAPAN	Yoshihiko Sato	Mitsubishi Logistics Corporation	Kenichi Kuchiki	Mitsui-Soko Co. Ltd.
	10:45-10:55	10	Coffee break					
	10:55-11:55	60	IP-COP	Vista of Clinical Supplies from Customer Satisfaction - site survey & patient survey- (Site & Patient Survey)	Chiaki Yamauchi Chie Igushi Esther Sadler-Williams Lynn Wang	Nippon Boehringer Ingelheim Co., Ltd. Pfizer Japan Inc. Catalent Pharma Solutions Merck, Corp. Inc.	Hirofumi Suzuki	Bayer Yakuhin Ltd.
	11:55-12:30	35	Special Lecture	The Future of Clinical Trial Supplies (where we have come from, where we are going and the potential opportunities for we as an IP organization)	Mike Arnold	Pfizer Inc.	Tony Collins	Pfizer Japan Inc.
	12:30-13:30	60	Lunch					