

2015 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 2015/04/10

April 16 Annual General Meeting 10:00-11:00

5F Main Hall	10:00-11:00	60	10:00-11:00 Annual General Meeting	MC: Masayuki Akutagawa	Head of Secretariat		
			Welcome	Yuichi Watanabe	Chairman		
			Nomination and Election of AGM chairman				
			2014 Activity Report	Masayuki Akutagawa	Head of Secretariat		
			2014 Financial Report	Ayako Nakajima	Treasurer		
			2014 Internal Audit Report	Hiroshi Kyogoku	Japan Affiliate Auditor		
			2015 Action Plan	Masayuki Akutagawa	Head of Secretariat		
			2015 Budget Proposal	Ayako Nakajima	Treasurer		
			2015-2016 Election Results of Board & Officers	Katsuhiko Araki	Executive Director / 2014 Head of Election Committee		

April 16 Annual Conference 11:00-17:00

Venue	Time	Minutes	Title	Speaker	Moderator		
5F Main Hall	11:00-11:20	20	Welcome Remarks 1	MC:Masayuki Akutagawa 2015 Japan Affiliate Chairman	Japan Affiliate Head of Secretariat, Pharma Planning Co., Ltd. ISPE Japan Affiliate		
	11:20-12:20	60	Keynote Speech 1	A Fully Integrated Role for ISPE In the Pharmaceutical Industry: Introducing the ISPE Quality Metrics Pilot Program (Tentative) John Bourmas	ISPE New CEO	Shigeru Nakamura	CM Plus Corporation
2F Event Hall	12:20-13:30	70	Lunch				
	13:30-14:30	60	Keynote Speech 2	Recent Topics in Quality Control of Pharmaceuticals in Association with Their Internationalization Toru Kawanishi	Director General National Institute of Health Sciences	Yuichi Watanabe	Otsuka Pharmaceutical Co., Ltd.
5F Main Hall	14:30-15:30	60	Keynote Speech 3	Update of PMDA Takao Yamori	Director, Center for Product Evaluation Pharmaceutical and Medical Devices Agency (PMDA)	Ayako Nakajima	NISSAN CHEMICAL INDUSTRIES, LTD.
2F Event Hall	15:30-16:00	30	Coffee Break				
5F Main Hall	16:00-17:00	60	Special Lecture 1	Developments in Asia Pacific GMP Update and Outlook Bob Tribe	ISPE Regulatory Affairs Advisor for the Asia-Pacific region	Tetsuhito Takarada	Mochida Pharmaceutical Co., LTD.
5F Main Hall	17:00-18:00	60	Special Lecture 2	Current Status and Issues of Pharmaceutical Development in Japan: Toward Healthy Social Security Finances and Pharmaceutical Industry Growth Yoshihide Esaki	Healthcare Industries Division, Commerce and Information Policy Bureau, Ministry of Economy, Trade and Industry	Hirofumi Suzuki	Bayer Yakuhin, Ltd.
2F Event Hall	18:00-20:00	120	Networking Party				

April 17 Workshops 9:00~17:00

Venue	Time	Minutes	Title	Speaker	Moderator		
2F Zuiun	9:15-12:30 Workshop 1-1: SAM&GMP COP API COP						
AM	Implimentation of Global Standards -API-						
	9:15-10:00	45	SAM&GMP COP	Technology Transfer of API Manufacturing Process Based on Q-Quartet	Ayako Maki	Kyowa Hakko Kirin Co., Ltd.	Junya Souma GlaxoSmithKline K.K. Japan
	10:00-10:50	50	API COP	A Risk Assessment of API Plant-HAZOP Study Based on Baseline Guide	Tomohiro Mizusako	JGC CORPORATION	Susumu Honda NIPRO PHARMA CORPORATION
	10:50-11:10	20	Coffee break				
	11:10-11:50	40	Lecture 1	API Micronizing Technologies	TBD	Powrex Corporation	Fumio Kishimoto Shin Nippon Yakugyo Co., Ltd.
	11:50-12:30	40	Lecture 2	The Importance of the Solid-State-Chemistry Strategy Capability on the Pharmaceutical Products R&D	Kazuhide Ashizawa	Eisai Food & Chemical Co., Ltd.	Fumio Kishimoto Shin Nippon Yakugyo Co., Ltd.
2F Zuiun	13:30-17:00 Workshop 1-2 SAM&GMP COP API COP Implimentation of Global Standards -Recent Rgulatory To						
PM	13:30-14:10	40	Special Lecture	Q12(Pharmaceutical Product Life Cycle Management) Current Status and Future Perspectives	Hiroyasu Kishioka	PMDA	Tetsuhito Takarada Mochida Pharmaceutical Co., Ltd.
	14:10-15:10	60	Lecture 3	Quality Assurance Through Product Lifecycle -Sakura Bloom Tablet P2 Mock	Kimiya Okazaki	GlaxoSmithKline K.K. Japan	Ayako Nakajima Nissan Chemical Co., Ltd.
	15:10-15:30	20	Coffee break				
	15:30-16:10	40	Lecture 4	GSK's Lifecycle Approach to Process Validation	Keiji Inoue	GlaxoSmithKline K.K. Japan	Tsutom Kojima Ono Pharmaceutical.co.jp
	16:10-17:00	50	Lecture 5	PIC/S GMP Supply Chain Management and GDP	Ayako Nakajima	Nissan Chemical Industries, Ltd.	Tsutom Kojima Ono Pharmaceutical.co.jp

2F Heian	9:15-12:30 Workshop 2: Containment COP			MC: Yuji Yamaura	Asahi Kasei Finechem Co., Ltd.		
AM	Risk Based Approach for manufacturing of highly potent products						
	9:15-10:00	45	Containment COP	Report of the Research About the Handling of High Potent Pharmaceutical Products '2015	Kazuhiro Tanimoto	SHIBUYA KOGYO CO.,LTD	Kenichi Nagasaki JGC CORPORATION
	10:00-10:45	45	Containment COP	Concerns About Setting PDE/ADE	Yuji Yamaura	Asahi Kasei Finechem Co., Ltd.	Mahito Nakagawa Mitsubishi Rubber Co.,Ltd
	10:45-11:00	15	Coffee break				
	11:00-11:45	45	Containment COP	The Powder Properties of Surrogate Materials which are Used for Assessing the Containment Performance.	Masaharu Tanahashi Satoshi Yoshikawa	HOSOKAWA MICRON CORPORATION SHIONOGI & CO., LTD.	Jun Oyama KIKUSUI SEISAKUSHO LTD
	11:45-12:30	45	Containment COP	Create and Apply Exposure Database	Haruka Futamura Takahide Hashizume	Airex Co., Ltd. Hata Iron Works Co., Ltd.	Yuko Takahashi IHI Plant Engineering Corporation
	12:30-13:30	60	Lunch				
2F Heian	13:30-17:00 Workshop 3: SPP COP						
PM	Comparative Study between ISPE Baseline Guide vol.3 and PHSS Technical Monograph, Operational excellence for Sterile Products						
	13:30-13:35	5	SPP COP	Introduction	Koji Kawasaki	Airex Co., Ltd.	
	13:35-15:05	90	SPP COP	RABS Variation and Operation A Comparative Study Between ISPE Baseline Guide vol.3 and PHSS	Tamon Tanaka Michiyoshi Ono	Kyowa Hako Kirin Co., Ltd. Pharma Solutions Co., Ltd.	Kazuhiro Tanimoto SHIBUYA KOGYO CO.,LTD
	15:05-15:20	15	Coffee break				
	15:20-15:55	35	SPP COP	Frontier of Engineering Research on OPEX	Hirokazu Sugiyama	The University of Tokyo	Hiroshi Yamaguchi ISPE Japan Affiliate, Executive Director
	15:55-16:25	30	SPP COP	Supporting Method for the Choice Between Single- and Multi-Use Technologies in Manufacturing Sterile Drug Products	Haruku Shirahata	The University of Tokyo	Seiji Shimura Pall corporation
	16:25-16:55	30	SPP COP	Process Improvement in Sterile Drug Product Manufacturing Using Mathematical Models	Keishu Yabuta	The University of Tokyo	Masahiko Yamauch AY Pharmaceuticals Co.,Ltd.
16:55-17:00	5	SPP COP	Future Perspective of OPEX WG	Hiroshi Yamaguchi	ISPE Japan Affiliate, Executive Director	-	-
2F Fukujyu	9:15—12:30 Workshop 4: BIO COP						
AM	Japanese Translation of ISPE Baseline® Guide, Volume 6, Biopharmaceutical Manufacturing Facilities (Second Edition)						
	9:15-10:15	60	Lecture 1	Outline of Baseline® Guide, Biopharmaceutical Manufacturing Facilities (2nd Ed.) (1)	Takaya Nakagawa	Toyo Engineering Corporation	Sei Murakami Hitachi, Ltd.
	10:15-11:15	60	Lecture 2	Outline of Baseline® Guide, Biopharmaceutical Manufacturing Facilities (2nd Ed.) (2)	Tsutomu Igarashi	FUJIFILM Engineering Co., Ltd.	
	11:15-11:30	15	Coffee break	Break			
	11:30-12:30	60	Lecture 3	Quality Assurance of Biopharmaceuticals Produced in Single-Use System	Sei Murakami	Hitachi, Ltd.	Sei Murakami Hitachi, Ltd.
	12:30-13:30	60	Lunch				
2F Fukujyu	13:30-17:00 Workshop 5: GAMP COP						
PM	GAMP—Approach to New Technology						
	13:30-13:45	15	Lecture 1	Outline of GAMP Japan COP Activities and GAMP 5 Related Guidances	Hirokazu Hasegawa	GAMP COP Leader	
	13:45-14:30	45	Lecture 2	Special Session: Computer Systems Compliance: Trends, Citations, and Innovations	Sion Wyn	Conformity Ltd	Michihiro Osakabe JGC CORPORATION
	14:30-15:15	45	Lecture 3	The Proposal for CSV Based on PIC/S Annex11	Hiroto Owada	Sumitomo Dainippon Pharma Co., Ltd.	
	15:15-15:30	15	Coffee break				
	15:30-16:15	45	Lecture 4	Smart / Wearable Devices Applied to Clinical Research - Are You Ready to Validate Them?	Yumi Wakabayashi	Chugai Pharmaceutical Co., Ltd.	Michihiro Osakabe JGC CORPORATION
16:15-17:00	45	Lecture 5	Current Status of the Introduction of Virtualization Environment in GMP, and the Considerations	Isao Nishida	Azbil Corporation		

2F Togen	9:15-12:30 Workshop 6: C&Q COP EM COP								
AM	Engineering and Risk-based C&Q in Pharmaceutical Project								
	09:15-09:45	30	Speech 1	Project Stages and Deliverables	Tsuneki Harada	JGC CORPORATION	Katsushi Ito	KAJIMA CORPORATION	
	09:45-10:15	30	Speech 2	Summary of ISPE Guide FSE and ISPE GPG ARM	Ryohei Ogawa	Toyo Engineering Corporation			
	10:15-10:45	30	Speech 3	Study for Risk-based C&Q of Japan Site (interim report)	Tadashi Inatani	Astellas Pharma Inc.			
	10:45-11:00	15	Coffee break						
	11:00-11:30	30	Speech 4	Project Turning over Activities	Koichi Miyake	OBAYASHI CORPORATION	Katsushi Ito	KAJIMA CORPORATION	
	11:30-12:30	60	Panel discussion	Discussion for Project Engineering and Risk-based C&Q	Tadashi Inatani Takashi Tokunaga Ryohei Ogawa Masahiko Yamaguchi Itaru Kimura Koichi Miyake	Astellas Pharma Inc. Maruho Co.,Ltd. Toyo Engineering Corporation Kyoto Seisakusho Co., Ltd. JGC CORPORATION OBAYASHI CORPORATION	Akio Hayashi	Inter-Pharma Express Inc.	
	12:30-13:30	60	Lunch						
2F Togen	13:30-17:00 Workshop 7: PAT COP								
PM	Continuous Processing and PAT								
	13:30-14:00	30	General lecture 1	US FDA's Perspective on Continuous Manufacturing	Munetaka Hattori	Independent Consultant	Masaki Yamada	Kissei Pharmaceutical Co., Ltd.	
	14:00-14:40	40	General lecture 2	Introduction of White Paper 2 on Continuous Manufacturing at MIT & CMAC Symposium	Munetaka Hattori	Independent Consultant			
	14:40-15:00	20	Coffee break						
	15:00-15:30	30	COP Report 1	Preciseness of Raw Material Receiving Test	Tomoyuki Monobe	Towa Pharmaceutical Co., Ltd.	Satoru Arai	Toray Industries, Inc.	
	15:30-16:00	30	COP Report 2	Real Time Monitoring and Control for Fluid-bed Granulation	Takuya Nagato	Powrex Corporation			
	16:00-16:30	30	COP Report 3	Real-time Monitoring of Drug Content and Evaluation of Content Uniformity During Mixing and Tableting Process	Takayuki Murakami	Sumitomo Dainippon Pharma Co., Ltd.			
16:30-17:00	30	COP Report 4	Analysis of Coating Film Thickness and Density by Terahertz Spectroscopic Imaging System	Mayumi Yasuda	Kissei Pharmaceutical Co., Ltd.				
2F Hourai	9:15-12:30 Workshop 8: IP COP								
AM	Ticket to Global standard for Clinical Supply –Our best practices in PIC/S GMP and GDP and what is best for patient from our clinical supply (Site Survey) –								
	9:15-9:25	10		IP-COP introduction	Zene Matsumoto	IP-COP lead, GSK K.K.			
	9:25-10:15	50	IP-COP	Benchmark of Blinding Randomization Considering PIC/S GMP in Japan	Zene Matsumoto	PIC/S GMP Working Group Lead, GSK K.K.	Kaoru Oda	Novartis Pharma	
	10:15-11:05	50	IP-COP	Storage, Distribution, Returns and Recalls Management of Investigational Medicinal Products in Japan for Near Future to Adjust to PIC/S GMP	Shigemi Maki	PIC/S GMP Working Group Sub-Lead, Mitsubishi Logistics Corporation	Hiroaki Ishii	Mitsui Soko	
					Kaoru Ide	PIC/S GMP Working Group, Toray Industries, Inc.	Hiroaki Ishii	Mitsui Soko	
					Hiroshi Shimokai	PIC/S GMP Working Group, Yakult Honsha Co.,Ltd.	Hiroaki Ishii	Mitsui Soko	
	11:05-11:20	15	Coffee break						
	11:20-12:10	50	IP-COP	Compass for Establishing Cold Chain for IP transportation under GDP in JAPAN	Yoshihiko Sato	GDP Working Group Lead, Mitsubishi Logistics Corporation	Shuji Hongo	Astellas Pharma	
12:10-12:30	20	IP-COP	Site Survey on Clinical Supply in Japan	Chiaki Yamauchi	Site Survey Working Group Lead, Nippon Boehringer Ingelheim Co., Ltd.	Hirofumi Suzuki	Bayer Yakuhin, Ltd.		
12:30-13:30	60	Lunch							