

As of 2013/4/3

**Register Now!**

**April 11 Annual General Meeting 9:30-10:30**

5F Main Hall	09:30-10:30	60	<b>9:30-11:30 Annual General Meeting</b>	MC: Shigeru Nakamura	Head of Secretariat		
			Welcome	Tatsuro Miyagawa	Chairman		
			Nomination and Election of AGM chairman				
			2012 Activity Report	Shigeru Nakamura	Head of Secretariat		
			2012 Financial Report	Yuichi Watanabe	Treasurer		
			2012 Internal Audit Report	Hiroshi Kyogoku	Japan Affiliate Auditor		
			2012 Action Plan	Shigeru Nakamura	Head of Secretariat		
			2013 Budget Proposal	Yuichi Watanabe	Treasurer		
			Bylaw Revision	Tsutomu Samura	Past Chairman		
2013-2014 Election Results of Board & Officers	Katsuhiko Nagao	Executive Director / 2012 Head of Election Committee					

**April 11 Annual Conference 10:40-18:00**

Venue	Time	Minutes	Title	Speaker	Moderator		
5F Main Hall	10:40-10:50	10		MC:Shigeru Nakamura	Japan Affiliate Head of Secretariat, CM Plus Corporation		
			Welcome Remarks 1	2013 Japan Affiliate Chairman	ISPE Japan Affiliate		
	10:50-11:30	40	Keynote Speech 1	Situation of PIC/S accession of Japan and revision of GMP notification	Shingo Sakurai	PMDA	Tetsuhito Takarada Japan Affiliate Executive Director, Mochida Pharmaceutical Co., LTD.
	11:30-12:10	40	Keynote Speech 2	ASEAN Harmonization on GMP Inspection and Training of Inspectors	Sia Chong Hock	Singapore HSA (health Sciences Authority )	Tetsuhito Takarada Japan Affiliate Executive Director, Mochida Pharmaceutical Co., LTD.
2F Event Hall	12:10-13:10	60	Lunch				
5F Main Hall	13:10-13:50	40	Keynote Speech 3	EU and PIC/S, what is new in GMPs, in APIs and in GDPs	Vasiliki Revithi	PIC/S Executive Bureau Member, Chair of Compliance Group monitoring new applications to PIC/S, ex-Head of the GMDP Inspectorate at the National Organization for Medicines of Greece (EOF)	Tsutomu Samura Past Chairman Sanofi K.K.
2F Event Hall	13:50-14:00	10	Break				
5F Main Hall	14:00-15:20	80	Panel Discussion	The Growing Influence of PIC/S Internationally	Shingo Sakurai, Sia Chong Hock, Vasiliki Revithi, Tetsuhito Takarada,	Three Regulators and a Panelist from Industry	Bob Tribe Former Chair of PIC/S, Asia-Pacific Regulatory Affairs Adviser, ISPE
2F Event Hall	15:20-15:50	30	Coffee Break				
5F Main Hall	15:50-16:40	50	Special Lecture 1	Overcoming Challenges: Growth Strategy of MSD as Global Healthcare Company	Tony Alvarez	MSD KK, Representative Director and President	Yuichi Watanabe Japan Affiliate Treasurer, MSD KK
	16:40-17:30	50	Special Lecture 2	Our Quest for Growth	Taro Iwamoto	Otsuka Pharmaceutical Co., Ltd. Representative Director and President	Tatsuro Miyagawa Japan Affiliate 2012 Chairman, CMIC CMO CO., LTD.
2F Event Hall	18:00-20:00	120	Networking Party				

# April 12 Workshops 9:00~17:00

Venue	Time	Minutes	Title		Speaker		Moderator	
2F Zuiun	9:00-17:00 Workshop 1: Regulatory Committee (PQLI, SAM&GMP) / API COP							
AM	New Evolution of Global GMP - Challenge and Realization				MC: Tsutomu Kojima	Ono Pharmaceutical Co., Ltd.		
	Part1: Global GMP and PQS (ICHQ10)							
	9:00-9:40	40	Special Lecture 1	GMPs in EU and ICH Q10 impact	Vasiliki Revithi	PIC/S Executive Bureau Member, Chair of Compliance Group monitoring new applications to PIC/S, ex-Head of the GMDP Inspectorate at the National Organization for Medicines of Greece (EOF)	Tetsuhito Takarada	Japan Affiliate Executive Director, Mochida Pharmaceutical Co., LTD.
	9:40-10:20	40	Special Lecture 2	Towards a Robust & International GMP Inspection System Opportunities, Benefits & Challenges	Sia Chong Hock	Singapore HSA (health Sciences Authority )		
	10:20-10:40	20	Break					
	10:40-11:20	40	Lecture 1	Example of introduction of PQS to GQP	Tetsuhito Takarada	Mochida Pharmaceutical Co., Ltd.	Yoshio Kitazawa	Japan Affiliate Board of Director, Chair of Regulatory Committee, National Institute of Health Science
	11:20-12:00	40	Lecture 2	Approach to Global Quality / GMP System	Shigehiro Higuchi	Takeda Pharmaceutical Co., Ltd.	Takayuki Oowaki	Japan Affiliate Board of Director, PQLI Leader, Eisai Co., Ltd.
	12:00-13:00	60	Lunch					
2F Zuiun	Part 2: New Paradigm for Development and Manufacturing of API and Drug Product							
PM	13:00-13:50	50	Special Lecture 3	ICH Q11, Expectations and Status	Kazunori Takagi	PMDA	Ayako Nakajima	Japan Affiliate Board of Director, NISSAN CHEMICAL INDUSTRIES, LTD.
	13:50-14:30	40	Report 1	Development of Virtual API HMCIN based on ICHQ11and Risk Based Approach for the Plant Design	Yasutaka Takada	Nissan Chemical Industries, Co., Ltd.	Susum Honda	Japan Affiliate Board of Director, NIPRO PHARMA CORPORATION
	14:30-15:20	50	Report 2	Risk Based Approach to Planning and Designing the Virtual HMCIN Manufacturing Plant	Masahiro Kawano	JGC		
	15:20-15:40	20	Break					
	15:40-16:20	40	Report 3	Control Strategy for Fluid-bed Granulation	Satoru Arai	Toray Industries, Inc.	Menetaka Hattori	PAT COP Leader, Former Japan Affiliate Chairman
	16:20-17:00	40	Report 4	A Simulation and Model-building for the Virtual Drug Development of HM Tablet by Introducing the Concept of Quality Engineering	Tsuyoshi Sago	Mochida Pharmaceutical Co., Ltd.	Masaki Hasegawa	Leader of SAM&GMP Committee, Mie Pref Science & Technology Promo Ctr
2F Heian	9:00-12:30 Workshop 2 : BIO COP				MC: Sei Murakami	Chair of BIO COP, Hitachi, Ltd.		
AM	Trends in Biopharmaceutical Manufacturing and Single-Use Technologies						Sei Murakami	Chair of BIO COP, Hitachi, Ltd.
	9:00-10:00	60	Lecture	Trends in Biologics Development and Regulation	Teruhide Yamaguchi	National Institute of Health Sciences		
	10:00-12:00	120	Workshop	Single-Use Technologies in Biopharmaceutical Manufacturing	Atsushi Wakai	Thermo Fisher Scientific K.K.		
					Satoshi Igarashi	SARTORIUS K.K.		
					Mami Okudaira	GE Healthcare Japan Corporation		
					Satoshi Tomita	TAITEC CORPORATION		
Hirotohi Awatsu					Nihon Pall Ltd.			
Hiroyuki Matsuda					FUJIMORI KOGYO CO.,LTD			
Takashi Maekawa					MATSUBO Corporation			
12:00-12:15	15	Workshop	ASME BPE 2012 Outline	Sei Murakami	Chair of BIO COP, Hitachi, Ltd.			
12:30-13:30	60	Lunch						
2F Heian	13:30-17:00 Workshop 4 :GAMP COP				MC: Akiko Sugiura	FUJI XEROX INFORMATION SYSTEMS CO., LTD.		
PM	Further Enhancement of GAMP 5 Related Guidance							
	13:30-13:50	20	Lecture 1	Summary of GAMP Japan COP Activities and GAMP 5 Related Guidance	Takayuki Sugimoto	Chair of GAMP Japan COP, SOAS Inc.		
	13:50-14:40	50	Lecture 2	Introduction to GAMP® Good Practice Guide: A Risk-Based Approach to GxP Process Control Systems Second Edition	Hirokazu Hasegawa	GAMP COP SIG2 Sub Leader, Mylan Seiyaku Ltd.	Takayuki Sugimoto	Chair of GAMP Japan COP, SOAS Inc.
	14:40-15:10	30	Coffee Break					
	15:10-16:00	50	Lecture 3	Introduction to GAMP® Good Practice Guide: Manufacturing Execution Systems -A Strategic and Program Management Approach (Japanese version)	Kazuhiro Matsumura	GAMP COP SIG1 Leader, Nihon Techno Kaihatsu Co.,Ltd	Takayuki Sugimoto	Chair of GAMP Japan COP, SOAS Inc.
	16:10-17:00	50	Lecture 4 and Panel Discussion	Panel Discussion	Hiroomi Nishimura, Masato Kato	GAMP COP SIG4 Leader, Shimadzu Corporation, GAMP COP SIG4, MSD K.K.		
MC:Hiroomi Nishimura					Shimadzu Corporation			
				Masato Kato, Naoki Ozawa, Atsushi Aminaka, Yoshihiko Suzuki	MSD K.K., Nippon Shinyaku Co., Ltd., CAC EXICARE Corporation, NEC Corporation			
2F Fukujuyu	9:00-12:30 Workshop 3 :IP COP				MC: Shuji Hongo	IP-COP lead, Astellas Pharma Inc.		
AM	Seminar for Newly Published Japanese Edition of "Comprehensive Guide to Clinical Materials: A Handbook for Training Clinical Materials Professionals"							
	9:00-9:05	5		Opening remarks	Shuji Hongo	IP-COP lead, Astellas Pharma Inc.	Hirofumi Suzuki	Japan Affiliate Board of Director, Bayer Yakuin, Ltd.
	9:05-9:35	30	Chapter 1	Introduction	Yu Kushimoto	IP-COP, Fisher Clinical Services Japan K.K.		
			Chapter 2	Acknowledgements				
			Chapter 3	Regulatory/GxP Information				
	9:35-10:05	30	Chapter 4	Project Planning and Management and Clinical Trials Design	Shuji Hongo	IP-COP lead, Astellas Pharma Inc.		
	10:05-10:45	40	Chapter 5	Manufacturing	Kaoru Oda, Chie Igushi	IP-COP, Novartis Pharma K.K. IP-COP, Pfizer Japan Inc.	Chiaki Yamauchi	IP-COP, Nippon Boehringer Ingelheim Co., Ltd.
	10:45-11:00	15	Break					
	11:00-11:30	30	Chapter 6	Distribution and Returns	Toshiya Soejima	IP-COP, Bayer Yakuin, Ltd.		
	11:30-12:00	30	Lecture 1	IVRS/IVRS	Satoru Kono	IP-COP, e-Trial Co.,Ltd.	Yoshihiko Sato	IP-COP, Mitsubishi Logistics Corporation
	12:00-12:30	30	Lecture 2	IP Warehousing and Distribution in Clinical Trials	Kazuaki Abe	IP-COP, WORLD COURIER		
	12:30-13:30	60	Lunch					