

2017 Annual Meeting

15th Anniversary ISPE Japan Affiliate

[A Brave New World of Innovation—What Does it Hold for Us?](#)

Dates: 18th & 19th May, 2017

Place: Toyama International Conference Center

Host: ISPE Japan Affiliate

With the collaboration of:

Toyama Prefecture

Toyama City

Toyama Pharmaceutical Association

With Asia-Pacific as a major pharmaceutical market along with North America and Europe, a vigorous period of growth has been enjoyed by the Affiliate since its establishment in 2001. Membership has reached well over 800, a remarkable increase from the below 100 level of the pre-inauguration days, and the majority of the Affiliate's activities are performed by its 16 COPs.

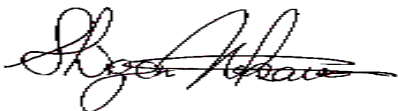
At this time, it is our great pleasure to invite you to join us for the 2017 ISPE Japan Affiliate Annual Meeting, the 15th in the series, to be held on 18th May and 19th May, at Toyama International Conference Center, in Toyama Prefecture. This special Meeting is the leading event in the Affiliate's busy yearly calendar.

For the Anniversary Meeting, we have an international cast of invited speakers, full program of sessions, Table Top Exhibition and events that include our popular Networking Party. We will be highlighting our 15 years of history, with a firm eye also on the future in meeting the trends of our industry.

As always, speakers and registrants will comprise regulators, a full representation from the pharmaceutical field, and academe. Simultaneous interpretation between the Japanese and English languages will be provided during the first day of the Meeting sessions.

An APAC meeting is scheduled on 17th May for eligible persons. For a further level of networking opportunities, there will be a golf competition on 20th May.

We look forward to receiving you in Japan at our Special Anniversary Event in Toyama!



Shigeru Nakamura
Chairman of the Board
ISPE Japan Affiliate



Katsuhiko Nagao
Chairperson, Organizing Committee
15th Anniversary Annual Meeting 2017

Dates

18th (Thu) & 19th (Fri), May 2017
Reception start: 9:00 a.m. on 18th / 8:00 a.m. on 19th)

Location

Toyama International Conference Center <http://www.ticc.co.jp>
1-2 Otemachi, Toyama-city, 930-0084 Japan [Tel:076-424-5931](tel:076-424-5931)

Access

- * From JR Toyama Station:
Approx. 10 minutes walk
By Bus: "Joushi kouen mae" stop (5 minutes)
By City train: "Kokusai kaigijo mae" stop (7 minutes)
- * From Toyama Airport
Approx. 20 minutes by taxi / About 25minutes by airport bus
- * By car
Approx. 10 minutes from Toyama IC/ 20 minutes from Toyama Nishi IC

PARTICIPATION REGISTRATION FEE

Register Now!

	Industry	University Faculty	Government	Young Professional	Student
Member	JPY45,000	JPY10,000	JPY10,000	JPY10,000	JPY2,000
Non-member	JPY70,000	JPY15,000	JPY10,000	JPY15,000	

* **Registration fee for Non-member** includes conference registration and ISPE annual membership. Please consider joining ISPE now.

* **Registration fee for Young Professional**

If 35-years-old or under, you can attend all programs for the two days upon payment of the specially discounted registration fee shown. You are kindly required to submit proof of age. Also please note that attendance at Workshop 5 is required.

* **Attendance at networking party only (18:30 - 20:30 on 18th May)**

Networking party only is available for the below fee:

Member: JPY10,000

Non-member: JPY20,000

Government, University Faculty: JPY5,000

Student: JPY2,000

Lunch and Networking Party

- 1) Lunch will be provided on 18th May and 19th May in the Main Hall
- 2) Networking party will be held on 18th May in the Foyer. (18:00 - 20:00)

How to Join

Please complete the application form and send it by email or fax to the Japan Affiliate Office.
Email address: ispe-seminar@ispe.gr.jp Fax: +81-3-3818-0575

Final Registration Due Date by e-mail or Fax

12th May 2017 (※Walk-in registration available at reception desk on 18th May.)

Event Sponsors

*** ADVERTISEMENT IN PROGRAM: JPY 50,000**

Your company advertisement in the program handouts to be distributed to all registrants.

*** TABLE TOP EXHIBITION (two days): JPY 100,000**

Your booth in the Foyer (3F) for two days.

*** POSTERS: JPY 30,000**

Your space for a poster at the entrance of the Mail Hall.

*** LUNCHEON SEMINAR: JPY 200,000**

Luncheon seminar will be held on 18th May & 19th May in the Main Hall.
One company presentation for each day.

*** COMPANY LOGO on the 15th Anniversary Commemorative Tote Bag: JPY 200,000**

15th anniversary commemorative tote bags will be distributed to all attendees.
How about printing your company's LOGO on this bag? Limited to three (3) companies.

For further information please contact Japan affiliate office: ispe-seminar@ispe.gr.jp

Conference and Workshops

Program schedule Date 18th May 2017 Toyama International Conference Hall

Annual General Meeting and Annual Meeting will be held in the Main Hall for two days.
Attendance at Networking Party only will also be welcomed.

18th May Thursday		3F Main Hall
10:00-11:00	Annual General Meeting	
11:00-11:40	Annual Meeting	Welcome Remarks by 2017 New Chairman of ISPE Japan Affiliate Congratulatory speech by special guest(s) ISPE Strategic Plan by John Bournas, ISPE CEO and President
11:40-12:25	Keynote speech 1	Disruptive innovation in pharma industry - Beyond medicines - Norikazu Eiki, Former Chairman of Bayer Japan, Member of GPMLF
12:25-13:35	Lunch time	
13:35-14:20	Keynote speech 2	ISPE GAMP Guide: Records and Data Integrity Sion Wyn Conformity Ltd
14:20-14:45	Coffee break	
14:45-15:30	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
15:30-16:15	Keynote speech 4	Recent Topic of PMDA Shingo Sakurai PMDA Office of Manufacturing / Quality and Compliance, Office Director
16:15-16:25	Coffee break	
16:25-17:10	Special Lecture 1	Transformation at Takeda Thomas Wozniewski, TAKEDA PHARMACEUTICAL CO., LTD.
17:10-17:55	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"
18:00-20:00	Networking party	

* Program may be changed without any notice

Program schedule Date: 19th 2017

Toyama International Conference Hall

19th May, Friday		Workshop	Theme
8:30 - 12:30	Workshop 1	Facilities of the Future	Emerging technologies will change our future
	Workshop 2	GAMP COP	GAMP-Data Integrity / Latest status and Interim report of Special Interest Groups
	Workshop 3	SPP COP	Dig deeper into the trend of Sterile pharmaceutical processes
	Workshop 4	IP COP	Patient Centric Approach for Clinical Supply in new era
	Workshop 5	YP	"Young professional seminar "Engineering and Validation by risk based approach" - Let's learn how to make user requirement specification document
10:00 - 12:30	Workshop 6	PAT COP	Verification of Measurement Accuracy on PAT Tools for Low Content Formulations
12:30 - 13:30	3F Lunch time (Main Hall)		
13:30 - 17:30	Workshop 7	Regulatory Committee	Global GMP Update for Quality and Compliance Excellence
	Workshop 8	Containment COP	Risk Based Approach for manufacturing of highly potent products
	Workshop 9	Pharma PSE COP	The role of model-based design in pharmaceutical manufacturing
	Workshop 10	TERM COP	Regulatory Requirement and Manufacturing Process of Cell and Gene Therapy Products
	Workshop 11	EM/C&Q COP	Risk-based approach and User Requirement Specifications (URS)

For further information, [CLICK HERE](#)

* Program may be changed without any notice.

Workshop Room Assignment

	3 F Main Hall	2F	2F	2F	2F	2F
AM	Workshop 1: Facilities of the Future	Workshop 2: GAMP COP	Workshop 3: SPP COP	Workshop 4: IP COP	Workshop 5: YP	Workshop 6: PAT COP
PM	Workshop 7: Regulatory Committee	Workshop 8: Containment COP	Workshop 9: Pharma PSE COP	Workshop 10: TERM COP	Workshop 11: EM / C&Q	

Presentation Materials Download (Electronic data only)

Download materials are available from the ISPE Homepage.

Access period: From one week before the conference until one month after the conference.

Special ID and password will be informed when your registration is completed.

Please note that we will not offer any hard copy (paper) materials for the conference.

Cancellation

In case of cancellation after submitting the application form, please kindly inform us.

→ Tel: 03-3818-6737 / Email: ispe-seminar@ispe.gr.jp

Inquiries

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