

Annual Meeting 2018

ISPE Japan Affiliate

Emerging Technology

- Age of Digital and Disruptive Innovation

Dates: 24th & 25th May, 2018
Place: Tower Hall Funabori (Edogawa-ku, Tokyo)
Host: ISPE Japan Affiliate



Our industry is faced by paradigm shifts in pharmaceutical manufacturing, with the introduction of latest technologies that include continuous manufacturing and 3D-printing, as well as in health care using regenerative technologies, Big Data and AI. Innovative technologies will maximize quality and minimize issues in the manufacturing phase, ensuring that pharmaceutical products are stably and economically provided to patients.

The expectation is to save lives, improve quality of life for patients and create breakthrough medical products by the development of new healthcare technologies. Significant economic benefits and new business opportunities are predicted.

Emerging Technology is the focus of the 2018 ISPE Japan Affiliate Annual Meeting. On the first day, professionals, academia and regulators invited from industry, universities and governmental authorities in Japan, the United States and Europe will discuss status, strategies and outlook for emerging technologies. The second day COP workshops provide a forum for a more concrete discussion of the technologies.

Together with our Annual Meeting participants, we will consider the future development of the pharmaceutical industry and how to get involved. Our since wish is for the Annual Meeting to contribute to the promotion of innovation. We look forward to receiving you in Japan.



Hirofumi Suzuki
Chairman of the Board
ISPE Japan Affiliate



Ayako Nakajima
Chairperson, Organizing Committee
Annual Meeting 2018

Dates

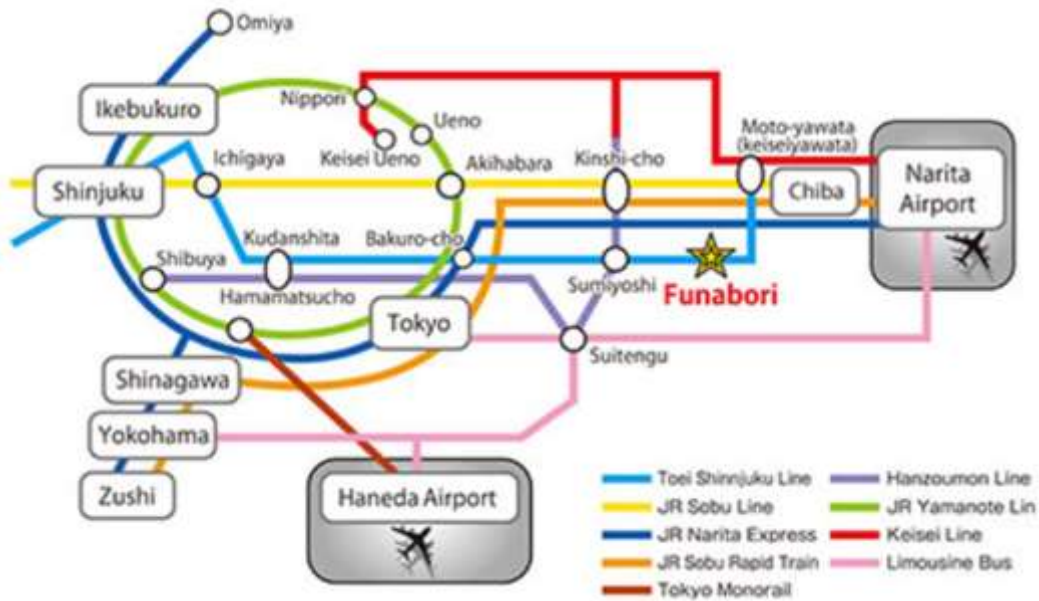
24th (Thu) & 25th (Fri), May 2018
 Reception start: 9:15 a.m. on 24th / 8:45 a.m. on 25th)

Location

Tower Hall Funabori <http://www.towerhall.jp>
 4-1-1 Funabori, Edogawa-ku, Tokyo, Japan Tel: 090-8845-6737

Access

* 1 Minute walk from Funabori station, Toei-Shinjuku line



PARTICIPATION REGISTRATION FEE

	Industry	University Faculty	Government	Young Professional	Student
Member	JPY45,000	JPY10,000	JPY10,000	JPY10,000	JPY2,000
Non-member	JPY75,000	JPY15,000	JPY10,000	JPY15,000	

* **Registration fee for Non-member** includes conference registration and ISPE annual Membership fee. 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 3 is required.

* **Attendance at networking party only (18:00 - 20:00 on 24th 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 24th May and 25th May in the Event Hall
- 2) Networking party will be held on 24th May in the Event Hall. (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

17th May 2018 (※Walk-in registration available at reception desk on 24th 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 : JPY 50,000**

Your booth in the 2nd floor on 24th May.

*** POSTERS: JPY 30,000**

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

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

Luncheon seminar will be held on 24th May during the lunch time.

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

Conference and Workshops

Program schedule Date 24th May, 2018 Tower Hall Funabori

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

24th May Thursday		2F Main Hall
09:30-10:30	Annual General Meeting	
10:40-11:20	Annual Meeting	Welcome Remarks by 2018 New Chairman of ISPE Japan Affiliate
11:20-12:10	Keynote speech 1	「FDA “Emerging Technology Program”」 (TBD) Sau (Larry) Lee, Deputy Director, Emerging Technology Team Chair Office of Testing and Research / OPQ / FDA
12:10-13:10	Lunch time	2F Event Hall (Luncheon Seminar, TT Exhibition)
13:10-13:55	Keynote speech 2	「Strategy of Drug & Medical Device for Overseas Business」 Kentaro Kishimoto / Director, International Business Promotion Office, Healthcare Industries Division, Commerce and Service Industry Policy Group METI (Ministry of Economy, Trade and Industry)
13:55-14:40	Special lecture 1	「From Industry 4.0 to Pharma 4.0 – The Holistic Control Strategy」 Christian Woelbeling / Senior Director Global Accounts, WERUM
14:40-15:25	Special lecture 2	「Personalized Medicine and its Consequences on Manufacturing, Emerging Technologies for HSE」 Andreas Flueckiger / Chief Occupational Health Officer, F. Hoffmann-La Roche Ltd.
15:25-16:10	Coffee break	2F Event Hall (Luncheon Seminar, TT Exhibition)
16:10-17:00	Special lecture 3	「Redefining Healthcare System with Emerging Technology」 Naohisa Yahagi / Associate Professor , Graduate School of Media and Governance Keio University
17:00-17:50	Keynote speech 3	「The Landscape of Continuous Manufacturing in Japan 」 Yoshihiro Matsuda / Senior Scientist (for Quality) Pharmacist, PMDA (Pharmaceuticals and Medical Devices Agency)
18:00-20:00	Networking party	

* Program may be changed without any notice.

Program schedule Date: 25th May 2018 Funabori Tower Hall

25th May, Friday	Workshop	Theme	
9:15 - 12:30	Workshop 1-1	Containment COP	Risk Based Approach for manufacturing of highly potent products
	Workshop 2	BIO COP	Trends in Biopharmaceutical Process Development
	Workshop 6-1	API COP	Continuous manufacturing of API ~issues and the challenge~
	Workshop 3	YP (Workshop for Young Professionals)	"Engineering and Validation by risk based approach" - Let's learn how to make user requirement specification document –
	Workshop 4	IP COP	A New Challenge toward Patient Centricity (Patient Survey) ~The new technology (GDP/ Ultra low temperature), standardization (IRT), and disruptive innovation (DtP) for Clinical supply ~
12:30 - 13:30	2F Lunch time		
13:30 - 17:00	Workshop1-2	Containment COP	Setting health based exposure limits for preventing cross contamination
	Workshop 5	SPP COP	Dig Deeper into the Trend of Sterile Pharmaceutical Processes
	Workshop 6-2	API COP	Continuous manufacturing of API ~issues and the challenge~
	Workshop 7	EM / C&Q COP	Way of applying commissioning data as a qualification evidence
	Workshop 8	PACKAGING COP	Pharmaceutical Package Integrity Evaluation ~Test to be carried out on the current level of any moisture vapor and oxygen leaks/transmission, as well as any penetration of microorganisms in/out of the packages~ ~Make the guideline how to set the maximum allowable leakage limits~

For further information, [CLICK HERE](#)

* Program may be changed without any notice.

Workshop Room Assignment

	Zuiun	Heian	Fukuju	Togen	Hourai
AM	Workshop 1-1: Containment COP	Workshop 2: BIO COP	Workshop 6-1: API COP	Workshop 3: YP (Workshop for Young Professionals)	Workshop 4: IP COP
PM	Workshop 1-2: Containment COP	Workshop 5: SPP COP	Workshop 6-2: API COP	Workshop 7: EM/C&Q COP	Workshop 8: PACKAGING COP

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 in the third week in May.

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-admi@ispe.gr.jp

Inquiries

ISPE Japan Affiliate: (Email : ispe-admi@ispe.gr.jp)

Ishijima Bldg. 7F, 1-11-10 Yushima, Bunkyo-ku, Tokyo 113-0034

TEL:03-3818-6737 FAX:03-3818-0575

www.ispe.gr.jp