

# ANNUAL GENERAL MEETING (AGM) 2025



21-23 July 2025



Ambassador Hotel Bangkok, Thailand

PHARMACEUTICAL INDUSTRY





21-23 July 2025

On behalf of ISPE Thailand Affiliate, we are pleased to invite you to **ISPE Thailand Annual Meeting 2025** being held on July 21st-23rd, 2025 at the Ambassador Hotel, Bangkok Thailand.

ISPE Thailand Affiliate has been delivered technical and operational solutions to support pharmaceutical industry in the manufacture of quality, safety and efficiency medicines for patients all along. This year ISPE Thailand Annual Meeting focuses on broadening pharmaceutical industry to mitigate risks associated with potential safety of patients, market fluctuation, regulatory changes, supply chain disruption and etc. We, therefore, come up with theme "Diversifying in Pharmaceutical Industry" this year.

Diversifying can lead to innovative solutions, ability to adapt to change, new markets, new therapeutic areas or product categories. It also involves an upgrade in skills, knowledge and technology.

As always, we have international subject matter expert speakers, full program of sessions, table top exhibition and special gifts for attendees. For the meeting, speakers and attendees will comprise regulators, pharmaceutical and biopharmaceutical industry, academia and vendors. It is the signature of ISPE, the meeting is not just an opportunity to learn but also to connect.

Join us for a day of insightful learning and networking, exchange insights, and update trends technologies and services.

We look forward to your participation at this special event and hope that this experience will be of benefit to you and your organization.

# Message from the President



Mr. Totsapon
Santitewagun
ISPE Thailand President

# Why you should attend ISPE Thailand AGM 2025

- Share expertise and point out practical issues facing global pharmaceutical & biopharmaceutical manufacturing and how they will influence your operations and shape the future of the industry.
- Update Status & Trend of Pharmaceutical Manufacturing in South East Asia countries.
- Give your support to Thai Students on the ISPE Hackathon Competition 2025, where the winners will join the Hackathon Competition in ISPE Conference at Singapore.
- View Technology and Innovation from over 30 exhibitors.
- Connect with Local and International Pharmaceutical and Biopharmaceutical Professionals.
- Last but not least, explore the opportunities to new markets, new therapeutic areas or product categories to manage potential risks and promote business growth, along with this year theme "DIVERSIFYING IN PHARMACEUTICAL INDUSTRY".

## ISPE Thailand Affiliate

### ISPE THAILAND

ANNUAL GENERAL MEETING (AGM) 2025

### 21-23 July 2025

### AGENDA DAY 1: MONDAY 21st JULY 2025

09:00 - 09:10

 Opening Remark by Mr. Totsapon Santitewagun, ISPE Thailand President

09:10 - 09:45

ISPE Thailand Hackathon Winner Presentation

09:45 - 10:30

Diversifying in Pharmaceutical Industry



Keynote Speaker by Mr. Vivek Dhawan, CEO/Chief Coach, Mega Lifesciences

11:00 - 12:00

 Diversified approach to achieve Quality Culture Excellence



Guest Speaker by Dr. Hiroshi Yamaguchi, ISPE Asia Pacific Affiliate Council Chair

### TRACK 1 Biotech/ATMP

### ATMPs: State of the industry and emerging trends



Speaker: Dr. Peiqing Zhang, ISPE Singapore President/Cytiva

### Manufacturing Network Management



Speaker: Mr. Chris Lee, Head of Singapore, Wuxi Biologics

### TRACK 2 OSD

### Lean Manufacturing for OSD Production



Speaker: Mr. Gaston Loo, Head of Engineering, Esco Aster/Former Senior Enginering Manager MSD, Singapore

### TRACK 3 Annex 1

- Annex 1 requirements from a former regulator view and part of the Annex 1 working group
- Personal training as gowning and aseptic behavior



Speaker: Mr. Richard Denk, Senior Consulting Aseptic Processing & Containment, SKAN AG



Ms. Tracy Moore, Former GMP Inspector of the UK Medicines Regulator - MHRA, UK

Limited to 80 attendees

# Key success from research to commercial of ATMPs



Speaker:

Mr. Tishwant Kanwarjit, Executive Director, Head of Quality, Autolus Therapeutics, UK

# Continuous Improvement of Manufacturing through Automation

Speaker:



Mr. Gaston Loo, Head of Engineering, Esco Aster/Former Senior Enginering Manager MSD, Singapore

16:00-17:00

### Envisioning New Concepts for Pharmaceutical 3D Printing and Solubility Enhancement



Speaker: Mr. Rimson Muara Jaya, Merck

### Environmental Monitoring and Annex 1 requirement

APS Introduction



Speaker:
Mr. Richard Denk,
Senior Consulting Aseptic Processing
& Containment, SKAN AG



Ms. Tracy Moore, Former GMP Inspector of the UK Medicines Regulator - MHRA, UK

Limited to 80 attendees

#### Please note:

- The agenda is subject to change as necessary.
- The order of Track 3 & 6 topics may be changed as appropriate.

### Thailand

### ANNUAL GENERAL MEETING (AGM) 2025

### AGENDA DAY 2: TUESDAY 22ND JULY 2025

### TRACK 4 Quality

**Data Integrity Risk** Assessment - Identify and Mitigate Data Gaps



Speaker:

Ms. Vivien Santillan, Regional Director, Asia, Novatek

**Practical Strategies for Digital Quality** Management



Speaker: Ms. Pornsiri Sahib. Project Manager, Factorytalk

Risk Management Plan (RMP) in the **Pharmaceutical Lifecycle** 



Speaker:

Mr. Paul Marvin Ouizon. ISPE Philippines President

### TRACK 5 Facility & Equipment

### **Facility Design for ATMPs**

Speaker:



Mr. Tishwant Kanwarjit, Executive Director, Head of Quality, Autolus Therapeutics, UK

### **Use Technologies** versus Stainless Steel **Systems**



Speaker:

Ms. Yvonne Lim, Technical Sales Specialist, Thermo Fisher Scientific

# Considerations for Single –



Speaker:

the results

Mr. Richard Denk, Senior Consulting Aseptic Processing & Containment, SKAN AG

Limited to 80 attendees

TRACK 6

Annex 1

(Continue session

from Track 3)

PIC/s Annex 1, PIC/s Annex

2A and the revision of the

**EU GMP Part IV for ATMPs**,

Isolators, First Air, Indirect **Product Contact parts,** 

transfers in Grade A Part 1-2

 Workout in Groups about Barrier with presentation of

**ORM** and CC

• Barrier as RABS and

**Gloves and Material** 

### TRACK 7 Pharma 4.0

### ISPE Pharma 4.0



Speaker:

Ms. Vivien Santillan, Regional Director, Asia, Novatek International

**Holistic Digital** Transformation for **Brownfield API Factories: Maximizing Impact** Through Strategic Planning



Speaker:

Mr. Krishna Chaitanya, Senior Manager & Industry Specialist, Yokogawa Engineering Asia Pte Ltd.





Speaker:

Mr. Bernard Corcoran, Senior Informatics Engineer, Lonza

**Transforming Manufacturing** Efficiency: How to Successfully Implement EBR and MES Systems



Speaker:

Ms. Suthira Sakdejayont, Senior Project Manager, Körber Pharma Software

### TRACK 8 **Cleanroom and HVAC System**

**HVAC Cooling Efficiency Evaluation:** Excellent, Good, Fair or **Need improvement** 



Speaker:

Mr. Komsan Sripavatakul, President of Air Conditioning Association of Thailand

**Introduction to ISPE Good Practice** Guide: Heating, Ventilation, & Air Conditioning (2nd Edition) and Training Course (T14) HVAC & **Environmental Control for Life Science Facilities** 



Speaker:

Mr. Totsapon Santitewagun, ISPE Qualified Instructor for HVAC system/ ISPE Thailand President

### Cleanroom Testing & **Monitoring for compliance** with PIC/S GMP

Speaker:



Mr. Hasim Solmaz, President of International Confederation of Contamination Control Societies - ICCCS, Switzerland/ Lighthouse

### TRACK 9 **Quality Risk Management**

- The Use of Quality Risk Management to Support Commissioning and Qualification
- QRM Based Integrated **C&Q Series -**Implementing a Science and Risk Based Approach to Commissioning & Qualification



Mr. Weerayut Chirarutsami,

(VDO Recorded)

Limited to 80 attendees



21 - 23July 2025

### AGENDA DAY 3: WEDNESDAY 23RD JULY 2025

ISPE Members only | Limited to 25 visitors / plant

### **Building a Successful Vaccine Manufacturing Capacity in Thailand**

Global Biotech Products Company Limited is the vaccine industry leader in Thailand. The company is the successful public-private partnerships for Vaccine Security more than 25 years. Now Live attenuated Japanese encephalitis recombinant vaccine is exporting to 13 countries.

With the collaboration with National Vaccine Institute, the country is enhancing on vaccine manufacturing capacity to welcome new Vaccines for National Immunization Program.

### PLANT VISIT 1 Global Biotech Products (GBP)



### **PLANT VISIT 2 SEQENS Thailand**



Segens is a worldwide leader in the development and production of active ingredients, pharmaceutical intermediates and specialty ingredients. As a leader of Acetyl Salicylic Acid (ASA) with broad experience and technical expertise allowing to serve 30% of the global demand. SEQENS masters value chains and secures customer needs with extensive care for the environment, SEOENS Consumer Health Care is a sustainable partner for its customers.

The Seqens – Bangpoo manufacturing site (dba Novacyl (Thailand) LTD) is an integral part of this pharmaceutical solution supporting worldwide supply of bulk generic Active Pharmaceutical Ingredients (APIs) within the salicylic chain offering wide range of ASA grades, from powder to DC [directly compressible] grades. The Segens -Bangpoo manufacturing site maintains pharmaceutical Good Manufacturing Practice (GMP) registration with PMDA, ANSM, USFDA and Thai FDA.'



21-23 July 2025

### **REGISTRATION FEE**

Registration type	Early Bird Rate Until 6 July 2025	Normal Rate From 7 July onwards
ISPE / TIPA Member Non Member	2,500 THB 4,000 THB	4,000 THB 6,000 THB
Plant Visit (Add-on) (ISPE members only)	2,000 THB	

### **HOW TO REGISTER**

Online Registration

1

www.ispeth.org/ agm2025 Confirmation

2

Your registration will be confirmed via email.

For any inquiries, please contact:

+6688-090-4664 or LINE OA: @ispethailand **Payment** 

3

Make a payment

BEFORE 18 JULY 2025

and capture/scan

transferred evidents to:

register@ispeth.org

### **PAYMENT TERMS**

Payment should be made in Thai Bahts.

\*\*\*GOVERNMENT TAX AND VAT ARE NOT APPLICABLE.\*\*\*

BANK KASIKORN BANK, LAD PRAO 67 BRANCH

ACCOUNT ISPE FOUNDATION

NUMBER 027-8-46566-7

SWIFT CODE KASITHBK

BANK ADDRESS 2347 LADPRAO 67, WANGTHONGLANG,

BANGKOK, THAILAND 10310

### RECORDING/ PHOTO RELEASE

ISPE reserves the rights to record the sessions and take photographs throughout the conference session for future marketing of ISPE events.

#### **PROGRAM CHANGES**

Program is subject to change. Last minute changes due to functional, private, or organizational needs may be necessary. The event organizer accepts no liability for any additional costs caused by a change of program.



21-23 July 2025

# Mark your calendar— this is the can't-miss event of the year!

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