

ISPE THAILAND ANNUAL GENERAL MEETING (AGM) 2023

▶▶ 18-20 JULY 2023



Get Back on Track

AT AMBASSADOR HOTEL
BANGKOK, THAILAND

Entitle to 10.5 CPE Credits



MESSAGE FROM THE PRESIDENT

On behalf of ISPE Thailand Affiliate, we are pleased to invite you to ISPE Thailand Annual Meeting 2023 being held on July 18-20th, 2023 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 medicines for patients all along. This year ISPE Thailand Annual Meeting focuses on updated Trends, innovations, and developments in the fields of quality and compliance of Pharmaceutical & Biopharmaceutical Manufacturing in this region.

As always, we have international 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.

Join us for a day of insightful learning and networking, as we continue our ISPE theme **“Get Back on Track”** to ensure we are back on track to convey important information on best practices for the industry.

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

Mr. Totsapon Santitewagun
ISPE Thailand President



Why you should attend ISPE Thailand AGM 2023

- ✓ 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 2023, where the winners will join the Competition in ISPE Conference at Singapore
- ✓ View Technology and Innovation from over 20 exhibitors
- ✓ Connect with Local and International Pharmaceutical and Biopharmaceutical Professionals
- ✓ Last but not least, GET BACK ON TRACK to connect pharmaceutical knowledge across the globe

AGENDA (DAY 1)

DAY 1: TUESDAY 18TH JULY 2023

PLENARY SESSION

- 8:50 – 9:00 **Opening Remark by Mr. Totsapon Santitewagun** (*ISPE Thailand President*)
- 9:00 – 9:45 **ISPE Thailand Update & Hackathon 2023**
- 9:45 – 10:30 **Keynote Speaker by Prof. Yingyos Avihingsanon, M.D.**
(Deputy Dean of Faculty of Medicine, Chulalongkorn University)
New paradigm of advanced therapy by qualified cell and gene products
- 11:00 – 12:00 **Keynote Speaker by Thai FDA**
Mr. Pramote Akarapanon
*(Deputy Director of Medicines Regulation Division,
 Head of New Drug and Investigation Drug, Thai FDA)*
Update on Thai FDA Regulations

TRACK 1: QbD & PAT
TRACK 2: ATMP
TRACK 3: ISPE Training

Process Analytical Technology (PAT) tools for pharmaceutical Industry
Dr.Shobha Nagappayya
(ENDRESS+HAUSER)

Regulatory Guidelines for ATMP
Dr.Piyanan Boonprasirt
*(Pharmacist, Professional Level,
 Medicines Regulation Division,
 Thai FDA)*

**Process Validation:
 Stage 1 - Process Design
 (VDO Recorded)**

Limited to 40 attendees

The implementation of Quality by Design (QbD) in Regulatory Dossiers
Assoc. Prof. Dr. Satit Puttipipatkachorn
*(Faculty of Pharmacy,
 Mahidol University)*

ATMP quality development and manufacturing standard
Dr.Chaiyong Koaykul
*(Manager of Excellence Center for Advanced Therapy Medicinal Products,
 Chulalongkorn Hospital)*

**Process Validation:
 Stage 2 - Process Performance Qualification
 or Process Validation
 (VDO Recorded)**

Design Space Concept in Cleaning Process
Mr. Richard Chai (*STERIS*)

CAR-T cells manufacturing facility: The first GMP-certified cell and gene therapy biotech company in Thailand
Dr.Kitipong Uaesoontrachoon
(GENEPEUTIC BIO CO.,LTD.)

Limited to 40 attendees

Note: 1. Topics & Time are subject to change as appropriate.
 2. ISPE Training Track is VDO Recorded, licensed by ISPE.

AGENDA (DAY 2)

	TRACK 4: HVAC	TRACK 5: PHARMA4.0 & GAMP5	TRACK 6: ISPE Training
09:00 – 10:00	HVAC Design Considerations for Pharma Facilities in Tropical Climate Mr. Totsapon Santitewagun <i>(ISPE Qualified Trainer for HVAC System & NEBB Cleanroom Certifier, USA)</i>	Pharma 4.0 Mr. David Margetts <i>(FACTORYTALK & ISPE Qualified Trainer for GAMP)</i>	Challenges & Successes of ICH Q12 Related Submissions (VDO Recorded) Limited to 40 attendees
10:30 – 12:00	Pitfalls & Challenges in Pharma HVAC System Mr. Totsapon Santitewagun <i>(ISPE Qualified Trainer for HVAC System & NEBB Cleanroom Certifier, USA)</i>	Update GAMP5 Mr. David Margetts <i>(FACTORYTALK & ISPE Qualified Trainer for GAMP)</i>	
	TRACK 7: Annex 1	TRACK 8: FACILITY	TRACK 9: ISPE Training
13:30 – 15:00	Interpretation and Key Updates of EU GMP Annex 1 Mr. Somasundaram G. <i>(MERCK)</i>	The Project Management for a Facility Start up Mr. Christopher Sweeney <i>(Former Senior GM, Kalbio Global Medika, Indonesia)</i>	Process Validation: Stage 3 - Continued Process Verification or Ongoing Process Verification (VDO Recorded) Limited to 40 attendees
15:30 – 17:00	Quality Risk Management for Cleaning and Disinfection Mr. Richard Chai <i>(STERIS)</i>	Critical Utility GMP Compliance Mr. Gaston Loo <i>(ESCO ASTER PTE LTD & Former Senior Engineering Manager of MSD, Singapore)</i>	Unravelling Manufacturing Control Strategies: Maturity Model & Case Studies (VDO Recorded) Limited to 40 attendees

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AGENDA (DAY 3)

ADD ON - OPTIONAL

ISPE Member Only

DAY 3
THURSDAY 20TH JULY 2023

PLANT VISIT 1: GPO's Medical Cannabis Cultivation Facilities

- 7:15 am Meeting at Main Lobby, Ambassador Hotel
- 7:30 am Depart for GPO Herbal Plant
- 9:00 am Welcome Speech & Presentation from GPO Herbal Plant
- 10:00 am Plant Tour
- 12:15 pm Lunch
- 13:30 pm Depart for Ambassador Hotel
- 15:00 pm Arrive at Ambassador Hotel

NOTE: Seats are limited to 25 people with first come first serve basis & final eligible participants will be reviewed by GPO.

Government Pharmaceutical Organization (GPO) conducts a medical cannabis project, in response to the policy of the Ministry of Public Health, in order to enable Thai people to have access to medical cannabis products which are effective, safe and reasonably priced. The first legalized medical cannabis cultivation to be undertaken in Thailand was at GPO, Thanyaburi District, Pathum Thani Province.

GPO conducted the whole supply chain of medical cannabis in accordance with the international guidelines comprise the following 7 G quality standards. GPO's medical cannabis cultivation facilities comprise of indoor and greenhouses with are certified with Good Agricultural Practice (*GAP*). The production of medical cannabis extracts and GPO's medical cannabis sublingual drops are in accordance with GMP. At present, four types of GPO medical cannabis sublingual drops have already been included on the National List of Essential Medicinal Herbs B.E. 2021, which will help patients within the public health service system to reduce the expenses on medication and gain easier access to medical cannabis



AGENDA (DAY 3)

ADD ON - OPTIONAL

ISPE Member Only

DAY 3
THURSDAY 20TH JULY 2023

PLANT VISIT 2: The Excellence Center for Advanced Therapy Medicinal Products (EC-ATMPs), under the King Chulalongkorn Memorial Hospital, the Thai Red Cross Society

- 8:30 am Meeting at Room 1217, 12th Floor of Bhumisiri Mangkhalanusorn, the King Chulalongkorn Memorial Hospital**
- 9:00 am Welcome Speech & Presentation from ET-ATMPs**
- 10:00 am Plant Tour**
- 12:15 pm Lunch**
- 13:30 pm Q&A**
- 14:45 pm Closing Speech from ET-ATMPs**

NOTE: Seats are limited to 25 people with first come first serve basis & final eligible participants will be reviewed by ET-ATMPs.

Excellence Center for Advanced Therapy Medicinal Products (EC-ATMPs) is located in Bhumisiri Mangkhalanusorn Building at King Chulalongkorn Memorial Hospital (KCMH), the Thai Red Cross Society. This EC-ATMPs was obtained a Thai FDA-approved for manufacturing layout for production platforms of ATMPs, Medical devices for clinical uses with quality control platform having completed cell analysis evaluation including potency testing.

By joint management between the KCMH, which is a tertiary care hospital, and Faculty of Medicine, Chulalongkorn University, this manufacturing plant is a national center focusing on technology translation from laboratory research to clinical study based on quality development-based GMP manufacturing plant in accordance with FDA regulatory pathway to accelerate development of advanced medical products in Thailand for public uses.



REGISTRATION FEE

REGISTRATION TYPE	EARLY BIRD RATE Before 1 st July 2023	LATE REGISTRATION 1 st July 2023 & After
ISPE/TIPA Member	2,000 THB	3,000 THB
Non Member	3,500 THB	5,000 THB
Plant Visit (Add-on) (ISPE Member Only)	1,500 THB	

HOW TO REGISTER

1 ONLINE REGISTRATION

WWW.ISPETH.ORG/AGM2023

2 CONFIRMATION

ISPE staff will confirm your registration via email, if not receiving email after submitted the form, please contact

+6688-090-4664

3 PAYMENT

Make a payment BEFORE 15 JULY 2023 to reserve your seat & capture/scan transferred evidents to email below

✉ 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

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