ISPE® | Thailand Affiliate

ISPE THAILAND
15TH ANNIVERSARY
ANNUAL MEETING 2018

16 - 18 JULY 2018

AT CONVENTION HALL, AMBASSADOR HOTEL BANGKOK

QUALITY BEYOND COMPLIANCE

CPE ACCREDITED

ISPE® Thailand Affiliate

ISPE THAILAND ANNUAL MEETING 2018

16 - 18 JULY 2018

Message from the President

2018 marks 15 years of ISPE Thailand Affiliate

On behalf of ISPE Thailand Affiliate, we are pleased to invite you to ISPE Thailand Annual Meeting 2018 and celebrating our 15th Anniversary being held on July 16-18th, 2018 at the Ambassador Hotel, Bangkok Thailand.

For much of its 15 years history, ISPE Thailand Affiliate, following ISPE International purpose, has been delivered technical and operational solutions to support pharmaceutical industry in the manufacture of quality medicines for patients. This year to celebrate our 15th Anniversary ISPE Thailand Annual Meeting promises to be very special ever, with regulators from many countries to share with you and update you the view of PIC/S to their country.

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 (Thai and International), pharmaceutical and biopharmaceutical industry, academia and vendors.

Join us for a day of insightful learning and networking, as we continue our ISPE theme "**Quality beyond Compliance**" to ensure we 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.

Kind regards,

Totsapon Santitewagun
President - ISPE Thailand

Here are our top reasons why you should attend the 2018 ISPE Thailand Annual Conference

- ✓ **Share expertise and point out practical issues facing pharmaceutical manufacturing in our region by regulators** and how they will influence your operations and shape the future of the industry in our region.
- ✓ **Give your support to Thai Students** on the ISPE Student Poster Competition 2018, where the winners will be presented their posters in ISPE Conference at Singapore
- ✓ **View technology and innovation** from over 20 exhibitors
- ✓ **Connect with** local and international pharmaceutical and biopharmaceutical **professionals**

Sia Chong Hock
Director of Quality Assurance and Senior Consultant of Audit and Licensing at the Health Products Regulation Group of the Singapore Health Sciences Authority

Suchart Chongprasert, PhD.
Director, Bureau of Drug Control, FDA Thailand

Bob Tribe
ISPE Regulatory Affairs Advisor for the Asia-Pacific region, a member of the WHO Expert Committee on Specifications for Pharmaceutical Preparations and PIC/S Former Chairperson

Helena Paula Baião
PIC/S Former Chairperson

Jesusa Joyce N. CIRUNAY
Field Regulatory Operations Office, Philippines Food and Drug Administration

Muhamad Lukmani Ibrahim
Deputy Director of Licensing & Compliance Center, National Pharmaceutical Regulatory Division, Ministry of Health, Malaysia

GET TO KNOW OUR SPEAKERS REGULATORS AND INTERNATIONAL EXPERTS

Gordon Farquharson
Principal and Managing Director, Critical Systems Ltd., United Kingdom

Frans Mardi Hartanto, PhD.
Professor of Management of the Department of Industrial Engineering and Management, Bandung Institue of Technology, Indonesia

Christopher Sweeney
Management of PT. Kalbio Global Medika, Indonesia (ISPE FOYA winner 2017)

Michael Payne
Principal Technical Consultant, Life Sciences/ Biopharmaceutical Group Merck Millipore

Pierre Winnepenninckx
Past Chair of ISPE Asia Pacific and Past Chair of ISPE Singapore Affiliate

Richard Chai Yoke Leong
Technical Service Manager STERIS Corporation

Duangratana Shuwisitkul, PhD.
Lecturer at Department of Pharmaceutical Technology, Faculty of Pharmacy, Srinakharinwirot University, Thailand

Anthony Margetts, PhD.
Principal Consultant, Factorytalk Co., Ltd. and Vice President of ISPE Thailand Affiliate

Paul Wan Sia Heng
Professor, Department of Pharmacy National University of Singapore (NUS)

Sergio Mauri
Director, Marketing & Business Intelligence at Fedegari Group, Italy

Yanglin Mok
Manager, Manufacturing Science and Technology, Merck Life Science, Singapore

Frederic Dietrich
Managing Director, Dietrich Engineering Consultants (DEC)

Roland Krebs
Senior Manager in the business development department, Nagano Science Co., Ltd., Japan

DAY 1: MONDAY 16 JULY 2018

PLENARY SESSION
Entitled to 2 CPE credits

09:00 - 09:20 | **Opening by ISPE Thailand President**

TOPIC: Does PIC/S membership make a difference to industry and regulator?

09:20 - 09:40 | **Muhamad Lukmani Ibrahim**, National Pharmaceutical Regulatory Division, Ministry of Health, Malaysia

09:40 - 10:00 | **SIA Chong Hock** (Video Presentation), the Health Products Regulation Group of the Singapore Health Sciences Authority

10:30 - 10:50 | **Jesusa Joyce N. CIRUNAY**, Philippines Food and Drug Administration

10:50 - 11:10 | **Dr. Suchart Chongprasert**, Director of Drug Bureau, Thai Food and Drug Administration

11:10 - 12:00 | **Panel Discussion** Moderated by Bob Tribe

Helena Paula Baião (PIC/S Former Chairperson), Regulators from Singapore, Malaysia, Philippines, Laos, Myanmar and Thailand

* Panel lists subject to change depending on the availibilty of each regulator

TRACK 1 — REGULATORY
Entitled to 3 CPE credits

13:30 - 14:15 | PIC/S Update
Helena Paula Baião

14:15 - 15:00 | GMP Update - Asia Pacific and Beyond
Bob Tribe

15:30 - 16:15 | BOI for Pharmaceutical Industries
Kritsana Saeheng

16:15 - 17:00 | Updated from Thai FDA
Wittawat Viriyabancha

TRACK 2 — CROSS CONTAMINATION
Entitled to 3 CPE credits

13:30 - 17:00 | Cross Contamination Control in Multi-Product Facilities - GMP requirements and best practices
Gordon Farquharson

TRACK 2, 5 and 8 is a continuous course. Participants need to attend Track 2, 5 and 8 all together.

TRACK 3 — QUALITY CULTURE
Entitled to 3 CPE credits

13:30 - 14:15 | Building and Fostering an Enduring Culture of Quality
Dr. Frans Mardi Hartanto

14:15 - 15:00 | ISPE Cultural Excellence Assessment Tool
Pierre Winnepenninckx

15:30 - 16:15 | The process of Building a Quality Culture
Dr. Frans Mardi Hartanto

16:15 - 17:00 | Enhance Quality Culture with Technology
Dr. Anthony Margetts

DAY 2: TUESDAY 17 JULY 2018

TRACK 4 — BIOPHARMACEUTICAL
Entitled to 1.5 CPE credits

09:00 - 09:45 | Fundamental on Biopharmaceutical Technology
Yanglin Mok

09:45 - 10:30 | Planning for modern Biopharmaceutical facilities
Christopher Sweeney

TRACK 5 — CROSS CONTAMINATION
Entitled to 1.5 CPE credits

09:00 - 10:30 | Cross Contamination Control in Multi-Product Facilities - GMP requirements and best practices
Gordon Farquharson

TRACK 6 — OSD
Entitled to 1.5 CPE credits

09:00 - 09:45 | Common Challenges in cleaning in OSD facility
Richard Chai Yoke Leong

09:45 - 10:30 | Advances in Tableting
Prof. Paul WS Heng

PLENARY SESSION
Entitled to 0.25 CPE credits

11:00 - 11:20 | **ISPE Thailand Annual Report Year 2017**

11:20 - 11:40 | **TCELS Roadmap in Bio/Pharmaceutical Industries**
Dr. Nares Damrongchai

11:40 - 11:55 | **MOUs of collaboration among TCELS & ISPE & TIPA**

11:55 - 12:10 | **Student Poster Competition 2018 : Winner Announcement**

TRACK 7 — FACILITIES/TECHNOLOGY
Entitled to 3 CPE credits

13:30 - 14:15 | Start of Biopharma-ceutical Facilities & how to avoid unnecessary costs
Christopher Sweeney

14:15 - 15:00 | Latest Development in High Contained OSD facility
Frederic Dietrich

15:30 - 16:15 | Best Practicse on Bioburden Control, Cleaning and Disinfection in Cleanrooms
Richard Chai Yoke Leong

16:15 - 17:00 | Microbiological Contamination Monitoring and Control in Biopharmaceutical Processes
Michael Payne

TRACK 8 — CROSS CONTAMINATION
Entitled to 3 CPE credits

13:30 - 17:00 | Cross Contamination Control in Multi-Product Facilities - GMP requirements and best practices
Gordon Farquharson

TRACK 2, 5 and 8 is a continuous course. Participants need to attend Track 2, 5 and 8 all together.

TRACK 9 — PROCESS DEVELOPMENT
Entitled to 3 CPE credits

13:30 - 14:15 | PAT
Prof. Paul WS Heng

14:15 - 15:00 | QbD
Dr. Duangratana Shuwisitkul

15:30 - 16:15 | Integrated Isolation Technology for Aseptic Manufacturing
Sergio Mauri

16:15 - 17:00 | Risk Management in Storage Stability Testing
Roland Krebbs

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‘QUALITY BEYOND COMPLIANCE’

HOW TO REGISTER

1 Online Registration
Browse website below, fill-in delegate details and click submit
WWW.ISPETH.ORG/AGM2018

2 Confirmation
ISPE staff will confirm your registration status via email. If not receive email within 2 working days after submitted the form, please contact our staff.
+6688-090-4664

3 Payment
Make a payment to reserve your seats and capture/ scan transferred evidents eg: payslip to email below.
REGISTER@ISPETH.ORG

FIND OUT MORE INFO & CONTACT US: WWW.ISPETH.ORG REGISTER@ISPETH.ORG +6688-090-4664

FEE PER DELEGATE
16 - 17 JULY 2018 (9:00 - 17:00)

ISPE MEMBER/TIPA MEMBER	4,000 THB
NON ISPE MEMBER	6,000 THB
ACADEMIC / REGULATORY (applies to full time faculty/students/regulatory personnel; proof may be requested onsite)	4,000 THB

PLANT TOUR - OPTIONAL ADD-ON
18 JULY 2018 (9:00 - 15:00)

ISPE MEMBER ONLY

Government Pharmaceutical Organization (GPO)

PLANT A: 1,500 THB
RANGSIT PLANT (OSD Manufacturing)
This plant has just won ISPE Facility of the Year Award (FOYA) 2018

PLANT B: 1,500 THB
SARABURI PLANT
Influenza Vaccine Production and Biopharmaceutical Manufacturing

PAYMENT TERMS

Payment must be received prior to the event otherwise the reservation will be cancelled.

All payments should be made in Thai Baht.

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

TERMS AND CONDITIONS

All fees stated include luncheons, refreshments and documentation. It does not include the cost of accommodation and travel.

VENUE INFORMATION

CONVENTION HALL, GROUND FLOOR

AMBASSADOR HOTEL BANGKOK
171 Soi Sukhumvit 11, Khwaeng Khlong Toei Nuea, Khet Watthana, Bangkok 10110, Thailand

(BTS Nana Station Exit 3)

SUBSTITUTION / CANCELLATION

Substitute delegates are not allowed. Cancellations must be received in writing at least 10 business days before the start of the event.

REGISTER NOW! at www.ispeth.org/agm2018

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apply now at www.ispe.org and earns membership benefits right away

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ISPE® Thailand Affiliate

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MORE INFO AND REGISTRATION: WWW.ISPETH.ORG REGISTER@ISPETH.ORG +6688-090-4664

PLANT A: RANGSIT PLANT

GOVERNMENT PHAMACEUTICAL ORGANIZATION

GPO
Government Pharmaceutical Organization

For more than 5 decades, GPO has been committed to manufacturing, and supplying the highest quality pharmaceutical products to the patients. Under our mission, those patients could gain complete access to the drug treatment, especially for the antiretroviral products according to the national health care plan policy launched since 2005.

The company's desire to boost capacity led to a major construction project, a new medicine manufacturing facility located at Rangsit, Pathumthani province. In the new facility, the current production capacity is approximately 1.7 billion tablets and capsules annually, and can reach 4.5 billion by 2020 once it fully operates at maximum capacity. Rangsit 1 plant has integrated IT systems that allow an entirely paperless operation in this facility.

The production process is operated in the clean room using building automation system (BAS) controlling the system which is the main system in order to keep cleanliness and environmental control in the room.The manufacturing execution system, MES) is used to control production and inventory management with the electronic batch record format to be replaced the manual recording. Laboratory information management system (LIMS) is used in for any data management and laboratory analysis both in chemistry and microbiology. Electronic Quality Management System (EQMS) manages document, training and quality system as well as having 24-hour quality assurance officer to audit and approve weighing, production, packing in accordance with the international standards to ensure confidence to all customers for quality, safety and product efficacy.

FOYA 2018
Facility of the Year Awards
CATEGORY WINNER
Facility of the Future

Rangsit 1 plant is also accredited by the PIC/s international good manufacturing practices (GMP) by the FDA of Thailand and officially approved to produced Efavirenz Tablets 600mg by WHO. This is a good start for us to prove that the quality of our product has been elevated to the international standard. GPO is therefore the first plant in ASEAN region built specially to supply HIV medicines affordably to the local population as well as to the ASEAN region in the near future. In addition an Honorable Mention of the FOYA Awards 2018 was given to GPO for its success in applying Quality by Design principals and international best practices to manufacture affordable HIV medicines to the people of Thailand.

INFLUENZA VACCINE PLANT

GOVERNMENT PHARMACEUTICAL ORGANIZATION

Production Technology

The trivalent IIV (Inactivated influenza Vaccine) by GPO is produced by well-known egg-based technology. The high quality embryonate eggs (white eggs shell) were injected with each influenza seed virus. The allantoic fluids is collected after 2-3 days of incubation. This allantoic fluids will be operated through production process e.g. splitting, inactivation until the final product of IIV are made.

Production Capacity

To meet the needs of the national seasonal influenza vaccination program, the installed equipments of an upstream process such as eggs incubators, candling machine and harvester were designed to support a large quantities of 25,000-60,000 eggs per batch and can be supplied the trivalent IIV more than 2 million doses a year. Moreover, the capacity will increase from 2 million doses to the maximum capacity of 10 million doses per year.

Our Awards

- National Innovation Awards, NIA, 2015
- Excellent Research Award, NRCT, 2016
- Winner for Best Bioprocessing Excellence in Thailand, IMAPAC, Singapore , 2017
- Grand Winner for Best Bioprocessing Excellence in South East Asia, IMAPAC, Singapore , 2017

Security of the Nation

In 2005, a year after highly pathogenic avian influenza outbreaks in Thailand, the Thai Government issued a National Strategy Plan for Pandemic Influenza Preparedness, a major objective of which was the domestic production of seasonal influenza vaccine. It was considered that sustained influenza vaccine production was the best guarantee of a pandemic vaccine in the event of a future pandemic. The Government decided to provide funds around 1.4 billion baht to establish an industrial-scale influenza vaccine production plant, and gave responsibility for this challenging project to the Government Pharmaceutical Organization (GPO).

The construction of the first Influenza Vaccine Plant in Thailand that located in Saraburi province is now fully completed. The machines and equipment are being installed and test-run under the standard of the WHO and Thai FDA. The production process that is developed from pilot-scale with technically supported by KAKETSUKEN, the leading vaccine manufacturing, Japan is now well established and ready to be optimised and performed the process performance qualification (PPQ) in the industrial scale this year, 2018. The GPO trivalent IIV vaccine is expected to be licensed by Thai FDA in 2020.