



ISPE®

Thailand
Affiliate

ISPE THAILAND **15TH ANNIVERSARY** ANNUAL MEETING 2018

16 - 18 JULY 2018

AT CONVENTION HALL, AMBASSADOR HOTEL BANGKOK



QUALITY BEYOND COMPLIANCE

EARLY BIRD ARE AVAILABLE!

CPE ACCREDITED

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 update you the view of PIC/S to their country.

As always, we have an international cast of invited 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

Jesusa Joyce N. CIRUNAY

Field Regulatory Operations Office, Philippines Food and Drug Administration

Helena Paula Baião

PIC/S Former Chairperson

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



Frans Mardi Hartanto, PhD.

Professor of Management of the Department of Industrial Engineering and Management, Bandung Institute 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



Yanglin Mok

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



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

Duangratana Shuwisitkul, PhD.

Faculty of Pharmacy, Srinakharinwirot University, Thailand

Frederic Dietrich

Managing Director, Dietrich Engineering Consultants (DEC)

Roland Krebs

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

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 availability 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**
TBC

16:15 - 17:00 | **Updated from Thai FDA**
TBC

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 Winnepeninckx

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

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 Biopharmaceutical 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 Practise 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



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

REGISTRATION WILL BE CLOSED ON 6 JULY 2018 OR WHEN ALL SEATS ARE FULLY RESERVED.

FEE PER DELEGATE 16 - 17 JULY 2018 (9:00 - 17:00)	EARLY BIRD RATE *BEFORE 15 JUNE 2018	STANDARD RATE *AFTER 15 JUNE 2018
ISPE MEMBER/TIPA MEMBER	3,500 THB	4,000 THB
NON ISPE MEMBER	5,250 THB	6,000 THB
ACADEMIC / REGULATORY (applies to full time faculty/students/regulatory personnel; proof may be requested onsite)	3,500 THB	4,000 THB

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)

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
Flu 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

SUBSTITUTION / CANCELLATION

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

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GOVERNMENT PHARMACEUTICAL ORGANIZATION

The Government Pharmaceutical Organization (GPO) is recognized by the judging panel for its success in applying Quality by Design principals and international best practices to construct the Rangsit Pharmaceutical Production Plant 1 to manufacture affordable, HIV medicines for the people of Thailand.



GPO is the largest pharmaceutical producer and distributor in Thailand. The Company purchases API from outside countries and produces formulated products which it distributes through government contracts. In 2016, GPO received accreditation with the GMP PIC/S International standard from Thailand's Food and Drug Administration.

The Rangsit project, constructed in association with the WHO program to create regional supplies of critical medicines, set out to satisfy three core needs:

1. Provide medicines to address Thailand's dengue fever, malaria and HIV epidemics. The HIV problem is particularly severe in Thailand with an estimated 450,000 living with HIV.
2. Provide these medicines at a cost affordable to the local population as product sourced externally is unaffordable to many.
3. Manufacture these medicines in accordance with PIC/S, the regulatory standard recently adapted by the ASEAN group of nations.



Traditionally, GPO used paper-based systems for all processes which required a large amount of manual data entry and transcription with a varying effect on product quality. The company had a major challenge managing their existing paper records. So, from the outset, the Rangsit project team worked to provide an integrated IT system to control the various processes and ensure data integrity using paperless operations drawing from international inspection standards.

The team mapped existing manual processes and an existing ERP system to identified gaps with PIC/S. They applied an ISA 95 based approach to develop the integrated IT solution and a GAMP 5 approach to use standard modules and components to reduce validation requirements and project risk. Systems from leading vendors provided the best practice and lowest cost solution to meet their needs and compliance standards. The building, its support systems and OSD manufacturing equipment were installed in accordance with PIC/S standards.

The result was the localized production facility with efficiencies gained from its integrated IT systems is reported to produce the HIV medicines for a price 20 times lower than imported medicines while achieving global quality standards.

The FOYA judges compliment GPO's new facility, its deployment of a modern quality management system and honors its success in providing affordable HIV medicines to the people of Thailand.