ISPE THAILAND
15TH ANNIVERSARY
ANNUAL MEETING 2018

16 - 18 JULY 2018

AT CONVENTION HALL, AMBASSADOR HOTEL BANGKOK

QUALITY BEYOND COMPLIANCE

CPE ACCREDITED
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 delivering 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

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

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 (BEC)

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

**Message from the President**

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**
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 list is subject to change depending on the availability of each regulator

DAY 2: MONDAY 16 JULY 2018

TRADE 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

TRADE 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.

TRADE 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 Winningenckx
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

TRADE 4  BIOPHARMACEUTICAL  Entitled to 15 CPE credits
09:00 - 09:45 | Fundamental on Biopharmaceutical Technology
Yanglin Mok
09:45 - 10:30 | Planning for modern Biopharmaceutical facilities
Christopher Sweeney

TRADE 5  CROSS CONTAMINATION  Entitled to 15 CPE credits
09:00 - 10:30 | Cross Contamination Control in Multi-Product Facilities - GMP requirements and best practices
Gordon Farquharson

TRADE 6  OSD  Entitled to 15 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

DAY 2: TUESDAY 17 JULY 2018

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

TRADE 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 Practice 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

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

TRADE 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

MORE INFO AND REGISTRATION:
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)

Government Pharmaceutical Organization (GPO) ISPE MEMBER ONLY
PLANT A: RANGSIT PLANT (OSD Manufacturing)
This plant has just won ISPE Facility of the Year Award (FOYA) 2018 1,500 THB
PLANT B: SARABURI PLANT Influenza Vaccine Production and Biopharmaceutical Manufacturing 1,500 THB

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.

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.

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

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SUPPORTED BY: TIPA
MAIN SPONSORS: QUALITY BEYOND COMPLIANCE

REGISTER NOW! at www.ispeth.org/agm2018
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.

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.