



ISPE®

Thailand
Affiliate

ISPE Thailand Annual Meeting 2019

9-10 July 2019

Ambassador Hotel
Bangkok Thailand

Entitle to 10.5 CPE Credits

**Quality
(4.0) in
your
DNA**

MESSAGE FROM THE PRESIDENT

On behalf of ISPE Thailand Affiliate, we are pleased to invite you to ISPE Thailand Annual Meeting 2019 being held on July 9-11th, 2019 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 “Quality (4.0) in your DNA” 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.



Mr. Totsapon Santitewagun
ISPE Thailand President



Why you should attend

ISPE Thailand Annual Meeting 2019

- ✓ 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 Student Poster Competition 2019, 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, cultivate Quality as part of your DNA

HIGHLIGHTS OF ISPE THAILAND ANNUAL MEETING 2019

Plenary session by Dr. Chris Chen,

the CEO of Wu Xi Biologics, one of the largest biologics manufacturer in the world to be the first biologics company in China approved by the US FDA and EMA. Wu Xi produces various kinds of biological products such as monoclonal antibody, Cell/Gene therapy, Fusion Protein, etc. Learn from Wu Xi, how to use technology innovation to expedite biologics development.

Plenary session

by Dr. Suchart Chongprasert,

the Director of Drug Bureau, Thai FDA will share with us on what Quality 4.0 is & how culture, collaboration, competency & leadership can be improved by technology. What roles of each sector are in Quality 4.0.

Quality Track by Mr. Maurice Parlane,

an ISPE official instructor and was named ISPE Member of the year in 2016. Mr. Parlane will cover the link between ICH Q10 and Quality Culture in the Pharmaceutical Quality System including introduction to the ISPE Cultural Excellence Report, the Assessment Tool, ISPE Six Dimensions Framework and Quality Metrics.

Mr. Robert (Bob) Chew, an internationally recognized compliance consultant in the areas of risk-based qualification, validation, ASTM E2500 (key author of that standard), and ICH-Q9, Quality Risk Management. Mr. Chew has provided quality risk management consulting to some of the largest pharmaceutical and biotechnology companies in the world. Mr. Chew will share with us on Quality Risk Management (QRM) and how it can be applied to protect the product throughout the lifecycle for patients safety.

CQD Track by Mr. Robert (Bob) Chew,

an official trainer for ISPE's Commissioning and Qualification Baseline Guide and also the key author of ASTM-E2500 the Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment. Mr. Chew will speak about the update of Commissioning and Qualification Base line Guide after has been used for long time. Risk based C&Q is the major improvement of this base line guide along with the other parts.

Mr. Maurice Parlane, an ISPE official Instructor and was named ISPE Member of the year in 2016. Mr. Parlane will cover the requirement of Continued Process Verification – Stage 3 of the Lifecycle Validation approach and will discuss practical tools for implementing both traditional and continuous process verification with supporting case studies on these techniques from the ISPE Process Validation Team Discussion documents and the presenter's own experience.

HIGHLIGHTS OF ISPE THAILAND ANNUAL MEETING 2019 (CONT.)

Plenary session

by ISPE Presidents of Indonesia, Philippines, Singapore, Malaysia & Thailand

The Presidents of ISPE Indonesia, Philippines, Singapore, Malaysia & Thailand Affiliates will share with us the status and trend of Pharmaceutical & Biopharmaceutical Manufacturing in their countries.

Bio-Pharma Track

by Mr. Ashok Kuma, will share with us on how to design a bioreactor model in order to scale up a process, how to build a team and tech transfer a process & how to accurately assess the success of a tech transfer.

Mr. Ramesh Raju, will introduce a Single-Use System (SUS) is typically designed for a specific process step & share with us the challenge arises when SUS is applied in multiple processing steps. Mr. Raju will discuss how to evaluate the different single-use components with respect to compatibility and extractables and leachables. A case study will be used to demonstrate the complexity and potential concerns when performing a risk evaluation on the manufacturing process.

Facility & Equipment Track

By Ms. Sabrina Xu, will share the idea what should be considering about Quality & Supply when you choose Single Use Technology to mitigate risks. Ms. Xu will also give us idea what we should consider when using the new technology, Single Use Facility using configurable, prefabricated cleanroom platforms & what benefit we can get.

Mr. Kenny Tay, will provide A better understanding of the current requirements of pharmacopeias and be familiar with Environmental Monitoring procedure from selection of sampling equipment or method development, data trending and set up EM program.

New Technology Track

By Dr. Paul WS Heng, the principal Investigator for GEA-NUS Pharmaceutical Processing Research Laboratory, will present the manufacturing of modified release drug delivery system by using pellets, MUPS, mini-tablets which is benefit to the targeted patients. Dr. Heng will share with us how to use common process equipment in general OSD manufacturing plant to produce these kinds of special dosage form.

Serialization Track

by Mr. Shawn Chen & Thai FDA,

Mr. Chen from GS1 Thailand will give an introduction of Serialization Track & Trace System & update us on Global Pharmaceutical Serialization Track & Trace System Regulation.

Mr. Bart Vansteenkiste will share with us how to develop & Implement Pharmaceutical Serialization Track & Trace System, what technology can be applied, what the pitfalls are in the implementation.

Facility & Equipment Track

By Somasundaram G., will review the benefits of SU systems in the sampling method of drug & discuss on its benefits with the comparison of SU systems with traditional sampling methods.

AGENDA (DAY 1)

DAY 1: TUESDAY 9TH JULY 2019

PLENARY SESSION

- 8:50 – 9:00 **Opening Remark by Mr. Totsapon Santitewagun** (*ISPE Thailand President*)
- 9:00 – 9:45 **Keynote Speaker by Thai FDA**
Dr. Suchart Chongprasert (*Director of Drug Bureau*)
- 9:45 – 10:30 **Keynote Speaker by ISPE Head Quarter Representative**
Ms. Vivianne J. Arencibi (*ISPE Board of Director*)
- 11:00 – 12:00 **Wu Xi Biologics, Global Solution Provider**
Dr. Chris Chen (*WuXi Biologics*)

TRACK 1: QUALITY
TRACK 2: BIO-PHARMA
TRACK 3: CQV

Redefining the “C” in CGMP
Creating, Implementing & Sustaining Culture of Compliance
Mr. Maurice Parlane
(*ISPE Australia Affiliate, CBE Pty Ltd*)

Innovative Process & Manufacturing Technologies for Biologics
Dr. Chris Chen
(*WuXi Biologics*)

Update to ISPE Baseline Guide 5, Commissioning & Qualification
Mr. Robert Chew
(*Commissioning Agents Inc, USA*)

Quality Risk Management for Pharmaceutical and Biotech Industries
Mr. Robert Chew
(*Commissioning Agents Inc, USA*)

How Single Use Technology Support Technology Transfer
Mr. Ashok Kumar (*Merck*)

Challenges using Single Use Systems:
Functionality versus Extractables and Leachable
Mr. Ramesh Raju (*Merck*)

Continued Process Verification – Practical Application of Traditional & Continuous Methodologies
Mr. Maurice Parlane
(*ISPE Australia Affiliate, CBE Pty Ltd*)

Note: Topics & Time are subject to change as appropriate.

AGENDA (DAY 2)

- 9:00 – 10:30 **Pharmaceutical Manufacturing Status & Trends in Indonesia & Philippines & Singapore (ISPE President of Indonesia & Philippines & Singapore)**
- 11:00 – 12:00 **Pharmaceutical Manufacturing Status and Trends in Malaysia & Thailand (ISPE President of Malaysia & Thailand)**
- 12:00 – 12:15 **Student Poster Competition, Winner Announcement**

PLENARY

DAY 2: WEDNESDAY 10TH JULY 2019

13:30- 15:00

15:30 – 17:00

TRACK 4: NEW TECHNOLOGY	TRACK 5: FACILITY & EQUIPMENT	TRACK 6: SERIALIZATION
Design & Manufacture of Multi Particulate Drug Delivery Systems: Pellets, MUPS & Mini-Tablets Dr. Paul WS Heng (NUS, Singapore)	Start the end in mind-Quality and Supply management in Single Use Manufacture Ms. Sabrina Xu (Merck)	Update on Pharmaceutical Serialization Track & Trace Regulation with Introduction on Serialization Mr. Shawn Chen (GS1 Thailand)
	Key considerations for Sampling in Biopharmaceutical Production Mr. Somasundaram G.(Merck)	
	Environmental Monitoring Solutions Mr. Kenny Tay (Merck)	How to Develop & Implement serialization for patient safety & supply chain efficiencies Mr. Bart Vansteenkiste (Domino)
	Modern Bio-Manufacturing Facility Concepts & Case Study Ms. Sabrina Xu (Merck)	

Note: Topics & Time are subject to change as appropriate.

AGENDA (DAY 3)

ADD ON - OPTIONAL

ISPE Member Only

DAY 3
THURSDAY 11TH JULY 2019

PLANT VISIT: BIONET-ASIA CO., LTD.

- 7:15 am Meeting at Main Lobby, Ambassador Hotel
- 7:30 am Depart for Bionet-Asia Co., Ltd.
- 9:00 am Welcome Speech & Presentation from Bionet-Asia Co., Ltd.
- 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 Bionet-Asia Co., Ltd.

BioNet-Asia Co. Ltd is a vaccine company focused on technological innovation and market access. With a global market reach and network expertise, BioNet has created several strategic alliances fostering vaccine self-reliance leading to the production and supply of billions of doses of vaccines on all continents.

In its state-of-the-art vaccine plant in Thailand, BioNet is also building a unique expertise in genetic engineering, protein conjugation, cell-culture and vaccine formulation. The company has developed a broad pipeline with ten products in R&D and clinical stages, including vaccines and recombinant proteins such as CRM197 protein carrier, dengue and hepatitis B vaccines.

The company has transferred the technology to produce Hib meningitis vaccine which is now commercialized as a pentavalent vaccine in Asia. BioNet has recently filed a patent application for its new Recombinant Acellular Pertussis Vaccine which is now evaluated in clinical trial. BioNet is uniquely positioned as a major partner in technology transfer and market access globally.



REGISTRATION FEE

REGISTRATION TYPE	EARLY BIRD RATE Before 1 st July 2019	LATE REGISTRATION 1 st July 2019 & After
ISPE Member	1,500 THB	2,500 THB
TIPA Member, Academia & Government	2,500 THB	4,000 THB
Non Member	4,000 THB	6,000 THB
Plant Visit (Add-on) (ISPE Member Only)	1,500 THB	

HOW TO REGISTER

1 ONLINE REGISTRATION

WWW.ISPETH.ORG/AGM2019

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 9 JULY 2019 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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