ISPE Thailand Annual Meeting 2019

9-10 July 2019
Ambassador Hotel
Bangkok Thailand

Entitle to 10.5 CPE Credits
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
**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.

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.

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.

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)

**PLenary SESSION**

**DAY 1: TUESDAY 9TH JULY 2019**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>8:50 – 9:00</td>
<td>Opening Remark by <strong>Mr. Totsapon Santitewagun</strong> (<em>ISPE Thailand President</em>)</td>
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<td>9:00 – 9:45</td>
<td>Keynote Speaker by Thai FDA&lt;br&gt;<strong>Dr. Suchart Chongprasert</strong> (<em>Director of Drug Bureau</em>)</td>
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<td>9:45 – 10:30</td>
<td>Keynote Speaker by ISPE Head Quarter Representative&lt;br&gt;<strong>Ms. Vivianne J. Arencibi</strong> (<em>ISPE Board of Director</em>)</td>
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<td>11:00 – 12:00</td>
<td>Wu Xi Biologics, Global Solution Provider&lt;br&gt;<strong>Dr. Chris Chen</strong> (<em>WuXi Biologics</em>)</td>
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**TRACK 1: QUALITY**

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<tr>
<th>Time</th>
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<tr>
<td>13:30 – 15:00</td>
<td>Redefining the “C” in CGMP&lt;br&gt;Creating, Implementing &amp; Sustaining Culture of Compliance&lt;br&gt;<strong>Mr. Maurice Parlane</strong> (<em>ISPE Australia Affiliate, CBE Pty Ltd</em>)</td>
</tr>
<tr>
<td>15:30 – 17:00</td>
<td>Quality Risk Management for Pharmaceutical and Biotech Industries&lt;br&gt;<strong>Mr. Robert Chew</strong> (<em>Commissioning Agents Inc, USA</em>)</td>
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**TRACK 2: BIO-PHARMA**

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<tr>
<td>13:30 – 15:00</td>
<td>Innovative Process &amp; Manufacturing Technologies for Biologics&lt;br&gt;<strong>Dr. Chris Chen</strong> (<em>WuXi Biologics</em>)</td>
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<tr>
<td>15:30 – 17:00</td>
<td>How Single Use Technology Support Technology Transfer&lt;br&gt;<strong>Mr. Ashok Kumar</strong> (<em>Merck</em>)</td>
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**TRACK 3: CQV**

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<tr>
<td>13:30 – 15:00</td>
<td>Update to ISPE Baseline Guide 5, Commissioning &amp; Qualification&lt;br&gt;<strong>Mr. Robert Chew</strong> (<em>Commissioning Agents Inc, USA</em>)</td>
</tr>
<tr>
<td>15:30 – 17:00</td>
<td>Continued Process Verification – Practical Application of Traditional &amp; Continuous Methodologies&lt;br&gt;<strong>Mr. Maurice Parlane</strong> (<em>ISPE Australia Affiliate, CBE Pty Ltd</em>)</td>
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**Note:** Topics & Time are subject to change as appropriate.
### AGENDA (DAY 2)

**PLENARY**

**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

<table>
<thead>
<tr>
<th>TRACK 4: NEW TECHNOLOGY</th>
<th>TRACK 5: FACILITY &amp; EQUIPMENT</th>
<th>TRACK 6: SERIALIZATION</th>
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<tbody>
<tr>
<td><strong>13:30 – 15:00</strong></td>
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<tr>
<td>Design &amp; Manufacture of Multi Particulate Drug Delivery Systems: Pellets, MUPS &amp; Mini-Tablets</td>
<td>Start the end in mind-Quality and Supply management in Single Use Manufacture</td>
<td>Update on Pharmaceutical Serialization Track &amp; Trace Regulation with Introduction on Serialization</td>
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<tr>
<td>Dr. Paul WS Heng <em>(NUS, Singapore)</em></td>
<td>Ms. Sabrina Xu <em>(Merck)</em></td>
<td>Mr. Shawn Chen <em>(GS1 Thailand)</em></td>
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<tr>
<td><strong>15:30 – 17:00</strong></td>
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<tr>
<td>Environmental Monitoring Solutions</td>
<td>How to Develop &amp; Implement serialization for patient safety &amp; supply chain efficiencies</td>
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<tr>
<td>Mr. Kenny Tay <em>(Merck)</em></td>
<td>Mr. Bart Vansteenkiste <em>(Domino)</em></td>
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<td>Modern Bio-Manufacturing Facility Concepts &amp; Case Study</td>
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<tr>
<td>Ms. Sabrina Xu <em>(Merck)</em></td>
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*Note: Topics & Time are subject to change as appropriate.*
AGENDA (DAY 3)  
ADD ON - OPTIONAL

ISPE Member Only

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

<table>
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<tr>
<th>Registration Type</th>
<th>Early Bird Rate Before 1st July 2019</th>
<th>Late Registration 1st July 2019 &amp; After</th>
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<tbody>
<tr>
<td>ISPE Member</td>
<td>1,500 THB</td>
<td>2,500 THB</td>
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<tr>
<td>TIPA Member, Academia &amp; Government</td>
<td>2,500 THB</td>
<td>4,000 THB</td>
</tr>
<tr>
<td>Non Member</td>
<td>4,000 THB</td>
<td>6,000 THB</td>
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### Plant Visit (Add-on) (ISPE Member Only)

- **Early Bird Rate**: 1,500 THB
- **Late Registration**: 1,500 THB

## How to Register

1. **Online Registration**
   - [WWW.ISPETH.ORG/AGM2019](http://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

## 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, Wanthonglang, Bangkok, Thailand 10310

## Payment

Make a payment BEFORE 9 JULY 2019 to reserve your seat & capture/scan transferred evidents to email below

- REGISTER@ISPETH.ORG

## Organized By

- ISPE
- TIPA

## Main Sponsors

- M-cleans
- Repassa
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- Panel
- Camfil
- Airplus Apply
- ESM
- Atlas Copco
- Merck

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9-11 July 2019