ISPE® Thailand Affiliate

Entitle to
10.25
CPE Credits

ISPE THAILAND ANNUAL GENERAL MEETING (AGM) 2024

Positioning for GROWTH

17-19 July 2024

Ambassador Hotel,
Bangkok, Thailand

ISPE Thailand Affiliate

ISPE THAILAND
ANNUAL GENERAL MEETING (AGM) 2024

17 - 19 July 2024

Message from the President

On behalf of ISPE Thailand Affliate, we are pleased to invite you to ISPE Thailand Annual Meeting (AGM) 2024 being held on July 17-19th, 2024 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 development 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, ISPE Thailand theme for this year is **"Positioning for Growth"**. ISPE Thailand would like to prepare you for what the future holds by enhancing your skills, broadening your knowledge to be ready for new trends & technology.

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 AGM 2024**

- Share expertise and point out practical issues facing global pharmaceutical & biopharmaceutical manufacturing and how they will infuence your operations and shape the future of the industry
- Update Status & Trend of Pharmaceutical Industry in South East Asia countries
- Give your support to Thai Students on the ISPE Hackathon Competition 2024, 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, it is the event that connects pharmaceutical knowledge across the globe

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AGENDA DAY 1: WEDNESDAY 17TH JULY 2024

PLENARY SESSION

08:50 – 09:00 • **Opening Remark** by ISPE Thailand President

09:00 – 09:45 • **ISPE Thailand Update & Hackathon 2024**

09:45 – 10:30 • **Positioning for Growth**

Keynote Speaker by Dr. Songpon Deechongkit, Chairman of the Executive Committee, Siam Bioscience

11:00 – 12:00 • **Southeast Asia and Thailand Pharmaceutical Industry Landscape & Trend**

Guest Speaker by Mr. Nattapol Kontikame, IQVIA

	TRACK 1 QMS	TRACK 2 Facilities	TRACK 3 ISPE Training Course
			LICENSED BY ISPE
13:30– 15:00	**Quality Risk revision & why**  Speaker: Mr. Maurice Parlance, New Wayz Consulting Ltd/ CBE Pty Ltd	**ASME BPE for Pharma Equipment & Accessories**  Speaker: Dr. Chatcharit Kiattisaksri, Dockweiler Asia Co., Ltd	**Pharmaceutical Waters #1** **(VDO Recorded)**  Moderator: Mr. Weerayut Chirarutsami, Consultant
15:30 – 17:00	**Quality 4.0**  Speaker: Ms. Shan Shan Liu, No Deviation	**Biopharmaceutical Manufacturing Facilities**  Speaker: Mr. Praphon Angtrakul, Thai FDA	Limited to 40 attendees

Note:
1. Topics & Time are subject to change as appropriate.
2. ISPE Training Tracks are VDO Recorded, licensed by ISPE.

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AGENDA DAY 2: THURSDAY 18TH JULY 2024

09:00 – 10:00

TRACK 4 ATMPs

Annex 1 Implication to ATMPs

Speaker:
Mr. Richard Chai,
Steris

TRACK 5 QBD/PAT

OSD Continuous Process

Speaker:
Dr. Narueporn Sutanthavibul,
Faculty of Pharmaceutical Sciences,
Chulalongkorn University

TRACK 6 ISPE Training Course

LICENSED BY ISPE

(Continue session from Track 3)

Pharmaceutical Waters #2

(VDO Recorded)

Moderator:
Mr. Weerayut Chirarutsami,
Consultant

Limited to 40 attendees

10:30 – 12:00

Comparison among Open/ Closed/ Automated Manufacturing Processes of ATMPs

Speaker:
Ms. Shan Shan Liu,
No Deviation

The ATMPs Industry in Thailand: Opportunities and Possibilities

Speaker:
Prof. Dr. Sansanee Chaiyaroj,
Chairperson, Health and Medicine Program Board, PMUC

PAT for OSD Manufacturing

Speaker:
Dr. Satoshi Kodama,
Powrex Japan

13:30 – 15:00

TRACK 7 BIO-Safety/ Containment

Bio-Safety in Laboratory / Production Facilities

Speaker:
Mr. Dan Yoong,
BSL-3 International Certifier

TRACK 8 Digital Transformation

URS for Computerized System in Pharma

Speaker:
Ms. Vivien Santillan,
Novatek International

Digital Solutions for Growth: Transforming Pharma with EBR

Speaker:
Mr. Orchun Thakral,
BatchLine

TRACK 9 ISPE Training Course

LICENSED BY ISPE

(Continue session from Track 6)

Pharmaceutical Waters #3

(VDO Recorded)

Moderator:
Mr. Weerayut Chirarutsami,
Consultant

Limited to 40 attendees

15:30 – 17:00

Single Pass HVAC for BSL-3 and other Applications

Speaker:
Mr. Totsapon Santitewagun,
ISPE HVAC Qualified Instructor

Cleanroom VS Containment

Speaker:
Mr. Totsapon Santitewagun,
ISPE HVAC Qualified Instructor

Digitalising Pharma Facilities with Composable Tools

Speaker:
Mr. Shaokai Hong,
Tulip

Facility & Laboratory Concept & Design for Digital Transformation

Speaker:
Dr. Nizamil Fairuz,
PharmEng Technology

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AGENDA DAY 3: FRIDAY 19TH JULY 2024

Add-on (optional)

ISPE Members only | Limited to 25 visitors / plant

PLANT VISIT 1
Siam Bioscience

Siam Bioscience focuses on research, development and manufacturing of biopharmaceuticals, pharmaceuticals, medical devices, and related healthcare products. The company conducts comprehensive R&D and manufacturing starting from active pharmaceutical ingredients and biological active substances to final dosage forms and finished products. Siam Bioscience has the resolute commitments to improve patients access to high quality and affordable medicines, to facilitate healthcare security, and to care for the health of Thai people and beyonds.

PLANT VISIT 2
BSL-3 Laboratory, Biotec NSTDA

The National Center for Genetic Engineering and Biotechnology (BIOTEC) under the National Science and Technology Development Agency (NSTDA) is a premier research institute in Thailand and Asia, BIOTEC operates research units located at Thailand Science Park and specialized laboratories hosted by various universities. BIOTEC research covers a wide spectrum from agricultural science to biomedical science and environmental science. The Biosafety Level-3 (BSL-3) Laboratory , a certified lab as per international guidelines, aims to strengthen the nation's capability in biosafety to be capable of handling the risk group 3 microorganisms or airborne pathogens Typical missions are to research the various kinds of microorganism, vaccine candidates, viral vectors which contribute to developing and growing of biotechnology and biopharmaceutical industries in Thailand.

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TRACKS & SESSIONS OVERVIEW

TRACK 1
QMS

Quality Risk revision & why

The ICH has released ICH Q9 revision1: Quality Risk Management. This updated guideline aims to enhance risk assessment practices and decision-making in the pharmaceutical industry. This presentation will discuss the revised Q9 Guidance, specifically focusing on the changes introduced in the updated version. Key areas for improvement i.e. subjectivity, supply & product availability risks, formality, risk-based decision making, hazard identification and risk review will be addressed.

Quality 4.0

How can the industry leverage advanced technologies to enhance quality maturity? This presentation will discuss and explore with the audience the opportunities and challenges of Quality 4.0, regulatory requirements & expectations, and practical examples.

TRACK 2
Facilities

ASME BPE for Pharma Equipment & Accessories

This presentation explores the critical importance of ASME BPE certified piping systems for various bioprocessing applications, including pharmaceutical water, biopharma, and chemical pharma industries. The discussion highlights the role of ASME BPE standards and bodies in enhancing the level of hygiene within the process, ensuring compliance with stringent regulatory requirements for safety and performance.

Key sanitary accessories integral to these systems are highlighted, emphasizing their role in maintaining hygiene and operational efficiency. The presentation also delves into the passivation process, showcasing the methods and chemicals used to enhance the passive layer on stainless steel surfaces, thereby improving corrosion resistance and longevity.

The selection of materials according to ASME BPE standards is crucial for ensuring durability and compatibility with bioprocessing applications. Additionally, the influence of surface finish on corrosion resistance is examined, demonstrating how different treatments can significantly impact the longevity and cleanliness of the system.

Furthermore, the processes of roughing and derouging are explained, detailing their importance in preparing and maintaining piping systems. Roughing involves the initial treatment of surfaces to achieve the desired finish, while derouging focuses on the removal of iron oxide layers that form over time, ensuring the integrity and cleanliness of the system.

This comprehensive overview provides a deeper understanding of the technical specifications, processes, and benefits of ASME BPE certified piping systems, reinforcing their essential role in high-purity bioprocessing applications.

Biopharmaceutical Manufacturing Facilities

Biopharmaceutical products are the sterile products with aseptic technique processing. Moreover, some of them involve in microorganisms for specific bioprocess for producing targeted products. Care must be taken in designing biopharmaceutical manufacturing facilities. Not only in achieving the sterile products but also the biosafety for personel and environment must be put into the overall risk assessment.

TRACK 3, 6 & 9

ISPE TRAINING COURSE

(2 DAYS VIDEO RECORDED)

Pharmaceutical Waters (T32)

This training course will explore the essential concepts and principles of specification, design, commissioning/qualification of equipment and systems used to store and distribute water in pharmaceutical manufacturing. The course has been substantially updated to feature the guiding principles of the Water and Steam Systems Baseline® Guide (3rd Edition) with particular emphasis placed upon the new chapters for microbial control, laboratory water and rouging. The course material will cover methods for determining the appropriate distribution and storage strategy, including sanitization method, for various operating circumstances including an overview of optional distribution approaches and the advantages and disadvantages of each. Microbial control characteristics of the various distribution systems will be presented and compared. Point-of-use service and sample point design, materials of construction for distribution and storage systems, and instrument components will also be covered.

The course will include discussion of the upcoming European Pharmacopoeia regulatory change allowing alternative WFI production methods in addition to distillation. The change will align EP requirements closely with USP WFI production methods opening opportunities for membrane-based systems. The course will also include material from the new ISPE Good Practice Guide: Sampling for Pharmaceutical Water, Steam and Process Gases and will review optimizing sampling plans to significantly reduce operational costs.

TRACKS & SESSIONS OVERVIEW

TRACK 4 ATMPS

Annex 1 Implication to ATMPs

ATMPs are medicines for human use that are based on genes, tissues or cells with an active therapeutic substance. With the recent update of the annex 1, it is essential to understand the important considerations from annex 1 perspective on contamination control in ATMP facilities. The following topics are discussed in detail for this presentation:

- Annex 1 implications to ATMPs – Important considerations
- Best practices in contamination control for ATMP facilities

At the end of the presentation, the participants will have a better understanding on the important considerations from annex 1 perspective on ATMP facilities, and the best practices to minimize risk of microbial contamination.

Comparison among Open/Closed/ Automated Manufacturing Processes of ATMPs

Despite the global rise of ATMP products, they remain in their infancy. For ATMPs, "process defines product" is particularly true. Establishing a commercial manufacturing process that is comparable to the process in development phase, meets GMP requirements, and fulfils market demand is challenging. This session will explore these challenges and the benefits of available solutions.

The ATMPs Industry in Thailand: Opportunities and Possibilities

ATMPs Industry is very booming in Thailand and other parts of the world because these products are the new hope of therapy. As a result, Thai government offers various kinds of support from drug discovery to commercial manufacturing to create the ATMP Ecosystem. In this regard, Dr. Sansanee Chaiyaroj, Chairperson, Health and Medicine Program Board Program Management Unit for Competitiveness (PMUC) will deliver the government support program to enhance the ATMP drug development in the country.

TRACK 5 QBD/PAT

OSD Continuous Process

Continuous manufacturing processes for oral solid dosage forms have gained popularity in the pharmaceutical industry due to their potential benefits in terms of efficiency, flexibility, and quality control. Throughout the entire process, in-line monitoring and control systems are utilized to ensure the quality and consistency of the product. Continuous manufacturing offers advantages such as reduced production time, decreased waste, enhanced quality control, and increased flexibility in production scheduling. However, implementing continuous manufacturing requires careful consideration of equipment design, process parameters, and regulatory requirements.

PAT for OSD Manufacturing

PAT (Process Analytical Technology) is a system for designing, analyzing, and controlling manufacturing through timely measurements (i.e., during processing) of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality (definition from ICH Q8(R2)). The overall aim for applying PAT to OSD manufacturing is to ensure consistently high-quality products through better process understanding and continuous improvement. To apply the PAT tool for pharmaceutical manufacturing, there is a need to optimize the hardware so that the PAT monitoring will be possible, along with preparing a suitable software to control the process. In this presentation, explanation of the originally developed PAT tool (Compact BeatSensor PNIR) and its case studies to various OSD manufacturing process will be introduced. The examples of OSD manufacturing process will include applications to continuous manufacturing system. Also as the latest example, MSPC (Multivariate Statistical Process Control) and MSPC Process Monitoring System “P-i2” including its case study will be introduced.

TRACK 7 BIO-SAFETY/ CONTAIN-MENT

Bio-Safety in Laboratory / Production Facilities

This presentation will explore the crucial topics of biosafety in laboratories and production facilities. The session will begin with an overview of biosafety, outlining its importance in preventing unintentional exposure to and release of hazardous biological agents. We will cover the fundamental principles of biosafety, including risk assessment, containment strategies, and the implementation of standard operating procedures.

As the biosafety levels (BSL-1 to BSL-4) increase, the architectural and engineering requirements become increasingly stringent. Common pitfalls like over-engineering, however, can lead to unnecessary costs for clients. Understanding these principles is crucial to prevent such occurrences. This session will explore the approach to designing a fit-for-purpose facility, especially one that requires bio-containment and GMP concurrently.

An important fit-for-purpose consideration in a biologics facility will be bio-decontamination. Technologies in this field have grown over the past decade. There will be a quick overview of this industrial trend and how facility owners can benefit from it.

TRACKS & SESSIONS OVERVIEW

TRACK 7
BIO-SAFETY/ CONTAIN-MENT

Single Pass HVAC for BSL-3

Single Pass HVAC for BSL-3 plays an important role to achieve biosafety requirement while it consumes a lot of energy compared to the normal HVAC system (Recirculate air). The single pass HVAC is the first choice of consideration to prevent cross contamination in any applications. Key design factor to achieve the performance goals and energy saving will be addressing.

Cleanroom VS Containment

Cleanroom and Containment are looked similar by appearances. In fact, cleanroom has a big different features and functions from containment. Misuse of cleanroom and containment will lead to the risk of personel, product and environment safety. Cleanroom and containment usages must be clear without any confusion.

TRACK 8
DIGITAL TRANSFOR-MATION

URS for Computerized System in Pharma

The development and implementation of computerized systems in the pharmaceutical industry requires attention to User Requirements Specifications (URS) to ensure the systems are fit for their intended use, support business processes, incorporate business risk assessments, and comply with current regulatory requirements. A well-designed URS is essential for achieving compliance with regulatory standards, enhancing operational efficiency, and maintaining data integrity. This presentation will outline the critical components and considerations involved in drafting URS for computerized systems, emphasizing the integration of business processes and data workflows with an adoption of the Data Integrity by Design principle to ensure the computerized systems are robust, reliable, and compliant with industry standards.

Digital Solutions for Growth: Transforming Pharma with EBR

This presentation, "Digital Solutions for Growth: Transforming Pharma with EBR," will explore how Electronic Batch Records (EBR) are revolutionizing the way pharmaceutical companies operate, driving growth and enhancing operational excellence. This presentation will delve into the following key aspects:

- Streamlining Compliance, Quality, Efficiency, and Productivity: Discover how EBR solutions streamline regulatory compliance and improve product quality by automating documentation and real-time monitoring.
- Gaining Deeper Insights with Electronic Data: Explore how leveraging the electronic data recorded in the EBR platform provides deeper insights into manufacturing processes. See how data-driven decision-making and continuous process improvement are enabled through advanced data analytics.
- Integration with IIoT for a Connected Future: Learn about the benefits of integrating EBR solutions with Industrial Internet of Things (IIoT) devices. Discover how this integration creates a connected and intelligent manufacturing environment that enhances visibility and control over production processes.

This presentation is tailored for industry professionals eager to explore the transformative potential of digital solutions in the pharmaceutical sector. Whether you are just beginning your digital journey or seeking to enhance existing systems, this presentation will provide valuable insights and practical strategies to leverage EBR for growth and success.

Digitalising Pharma Facilities with Composable Tools

This presentation will exemplify the use of the inherent capabilities of new digital technologies in support of Pharma 4.0. The latest experiences with digital tools used for batch recording and digitisation of GMP processes and procedures have shown significantly less effort spent on achieving compliance and decreasing the cost of quality. Digital solutions provide easily accessible and interpretable documentation stored digitally with compliance built-in and are not an afterthought. Our industry is experiencing a true paradigm shift and we need to embrace change to capitalise on the promise of Pharma 4.0.

Facility & Laboratory Concept & Design for Digital Transformation

Conventional mindset towards designing new facility and laboratory is commonly towards its purposes and functionality. Facility provides controlled conditions, such as clean environment room with specific temperature, relative humidity, and level of cleanliness, and lab provides analytical testing and results for quality decision.

Digital transformation in Pharma Industry 4.0 is currently the bridging process that leverages digital technologies to digitalize existing processes, facilitate effective analytics decisions, and improving the competitiveness to align with evolving era of digitalization. Laboratory facility is a tangible aspect of cGMP, as it represents analytical quality attributes, which the current concept & design must support effectively with digitalization.

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REGISTRATION FEE

Registration type	Early Bird Rate Before 1st July 2024	Late Registration 1st July 2024 & After
ISPE / TIPA Member	2,000 THB	3,000 THB
Non Member	3,500 THB	5,000 THB
Plant Visit (Add-on) (ISPE members only)	1,500 THB	

HOW TO REGISTER

1

Online Registration

www.ispeth.org/agm2024

2

Confirmation

ISPE staff will confirm your registration via email, if not receiving email after submitted the form, please contact

+6688-090-4664
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3

Payment

Make a payment **BEFORE 16 JULY 2024** to reserve your seat & capture/scan transferred evidents to email below

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PAYMENT TERMS

Payment should be made in Thai Bahts.
GOVERNMENT TAX AND VAT ARE NOT APPLICABLE.

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PROGRAM CHANGES

Program is subject to change. Last minute changes due to functional, private, or organizational needs may be necessary. The event organizer accepts no liability for any additional costs caused by a change of program.

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