

ISPE THAILAND ANNUAL GENERAL MEETING 2017

16TH - 18TH AUGUST 2017

AT CONVENTION HALL, AMBASSADOR HOTEL BANGKOK

**PHARMACEUTICAL
MANUFACTURING
FACILITY
FOR THE FUTURE**



Message from the President

I am pleased to invite you to the 2017 ISPE Thailand Annual Conference during August 16-18, 2017 at the Ambassador Hotel, in Sukhumvit, Bangkok. Join us for two days of insightful learning and networking, and one day of plant visits as we continue our ISPE theme to provide important information on best practices for our local members.

This conference will bring together key international thought-leaders to share their expertise and point out practical issues facing pharmaceutical manufacturing in our region. Throughout the meeting, you will learn more about opportunities and challenges that our region faces, including:

- > Best practices for design and operation of HVAC and water systems
- > Understanding cleanroom issues, especially contamination controls
- > OSD and improvements for sterile manufacturing

We look forward to seeing you in Bangkok!

Kind regards,

Totsapon Santitewagun
President - ISPE Thailand Affiliate



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Here are our top reasons why you should attend the 2017 ISPE Thailand Annual Conference

- ✓ **Get updated on new trends** and how they will influence your operations and shape the future of the industry in our region.
- ✓ **Understand the important issues** regarding GMP compliance
- ✓ **Engage with regulators**
- ✓ **Gain insight from industry leaders'** on practical issues
- ✓ **Network with colleagues and speakers** from the ASEAN region as you explore best practices, new technologies, and industry trends
- ✓ **Join Plant visits** to learn more

GET TO KNOW OUR SPEAKERS



Gordon Farquharson, Critical Systems Ltd.

Gordon Farquharson, B.Sc.(Hons), C.Eng. is a Chartered Consulting Engineer with more than 35 years experience of quality & safety critical processes and facilities used by industries such as Healthcare, Life Science, Micro-electronics, etc. He is Principal and Managing Director of Critical Systems Ltd, an international consultancy firm with partnerships with PharmOut Pty Ltd, a consulting business based in Australia, Factorytalk based in Thailand, and CM Plus Corporation of Japan.



Dr. B. DÜthorn, Bosch Packaging Technology GmbH, Germany

After his degree as pharmacist in 1986 Dr. DÜthorn served as research fellow and teacher at the university of Erlangen-Nürnberg, Germany. In 1996 Dr. DÜthorn joined R. BOSCH GmbH, currently is holding a position as Vice President within the Packaging Technology Division, Product Division Pharma of R. Bosch GmbH with global responsibility. He also published several articles on isolation technology.



Philip Vanbeek

Highly driven professional with 30 years of experience in cleanrooms and technical applications concerning Contamination Control. Professional education on Contamination Control with accredited courses like Cleanroom testing professional, Cleanroom Technology. He has more than ten years of experience as a trainer for Contamination Control courses such as Cleanroom Behaviour, Cleaning Cleanrooms and Testing Cleanrooms.



J. Lim, Bosch, Bosch Packaging Technology, Singapore

Jon Lim is from Bosch Packaging Technology Singapore, Pharmaceutical Business Unit for S.E. Asia, Bangladesh and Taiwan region. He has more than 30 years' experience in the food and pharmaceutical processing and packaging industry. He was first trained at the various Bosch factories in 1985 while working for their Singapore agent and then finally joined Bosch in June 2001.



Shigehiro Tahara, PT. CMPlus Consulting Indonesia

In 1982, he joined JGC Corporation and engaged in basic design, detail design supervision, design coordination, commissioning and validation for many sites. Then in 2008, he joined in CM Plus Corporation, worked as PMr, EMr of various projects such as SOD, parenteral, high active products manufacture. Simultaneously was appointed as COO of the CMPlus Singapore, Director of CM Plus Vietnam, and Chief Technical Officer of PT. CMPlus Consulting Indonesia.



Don Grubb, Rieckermann Engineering Operations

He is a manufacturing specialist with over 30 years' experience of the pharmaceutical industry. Don delivers strategic consultancy, new facility design, project management and USFDA and PIC/S GMP compliance for an increasing list of clients in the Middle East, South East Asia and China. He specialises in sterile production, solid dose manufacturing and in containment and isolator technology.



David Newell, Matcon Group Limited

An Engineer by trade, trained at Rolls-Royce UK before migrating to Australia in 1988, where he worked in the mining industry for a while before moving to Matcon. Dave has now been at Matcon for 21 years He has been responsible for managing the Matcon business unit in Australia and also developing the business in South East Asia. Dave Newell relocated to Singapore in March 2015 where he heads Matcon Group Limited Asia-Pacific Sales and Business Development Operation.

DAY 1: WEDNESDAY 16TH AUGUST 2017

09:00 - 09:30 OPENING PLENARY SESSION AND ISPE ANNUAL MEETING

TRACK 1

09:30 - 17:00

HVAC Environmental Control Principles – best practices for GMP compliance

Gordon Farquharson, Critical Systems Ltd.

TRACK 2

09:30 - 17:00

Cleanroom Behavior

The course provides an essential introduction to cleanrooms and to cleanroom behaviour

Philip Vanbeek

(This is an intensive course, only 50 Seats available - no substitutions allowed)

TRACK 2 and 5 are the same course.

TRACK 3

09:30 - 12:15

Modern OSD factory design: Vertical and horizontal flows, closed system and containment.

Don Grubb, Rieckermann Engineering Operations

13:45 - 15:15

CASE STUDY: OSD Project in Vietnam

Shigehiro Tahara, PT. CMPlus Consulting Indonesia

15:45 - 17:00

OSD Process Improvement using Intermediate Bulk Containers (IBCs)

David Newell, Matcon Group Limited

DAY 2: THURSDAY 17TH AUGUST 2017

TRACK 4

09:00 - 17:00

Pharmaceutical Water Systems – Essential features and practice GMP facilities

Gordon Farquharson, Critical Systems Ltd.

TRACK 5

09:00 - 17:00

Cleanroom Behavior

The course provides an essential introduction to cleanrooms and to cleanroom behaviour

Philip Vanbeek

(This is an intensive course, only 50 Seats available - no substitutions allowed)

TRACK 2 and 5 are the same course.

TRACK 6

09:00 - 12:15

Process Design and Scale Up methods - Relevance of Hot Melt Extrusion and Twin Screw Granulation

Dr. Ansgar Frendel, Thermo Fisher Scientific

14:15 - 17:00

Manufacturing Processes - New Technologies & Trends

Dr. B. Dühorn, Bosch Packaging Technology GmbH, Germany and **J. Lim, Bosch**, Bosch Packaging Technology, Singapore

13:45 - 14:15 PLENARY SESSION - STUDENT POSTER ANNOUNCEMENT

DAY 3: FRIDAY 18TH AUGUST 2017



PLANT A

(9:00 - 12:00)

Greater Pharma Co., Ltd.

ISPE 2016 Facility of the Year Award (FOYA) Honorable Mention Winners

Production: OSD, liquids and creams

LIMITED TO 20 PERSONS

Greater Pharma Manufacturing Co Ltd, located in Bangkok, Thailand is the first of its kind to apply western standards to design, build and operate a pharmaceutical facility for tablets, capsules, sachets and liquids to produce pharmaceuticals for the local ASEAN market. With the production and use of this facility, they accomplished several milestones for the Thai pharmaceutical industry:

1. The plant is the first in Thailand to use the closed processes from raw material to the finished products and is the first plant to use the vertical concept.
2. It is the first pharmaceutical facility to use energy conservation design concept.
3. The plant uses locally sourced design solutions and equipment
4. Capital cost was at the low end of plant cost in Thailand but more efficient running costs.



PLANT B

(9:00 - 12:00)

Queen Saovabha Memorial Institute (QSMI) and Thai Red Cross Society (TRCS)

Production: Vaccines and Sera

LIMITED TO 20 PERSONS

This centre was officially opened on April 26, 1913 under the name "Pastura Sabha" which was later changed to "Sathan Pasteur" in recognition of Louis Pasteur, the pioneer in rabies vaccine production. In 1917, HM King Vajiravudh changed the name of Sathan Pasteur to "Pasteur Institute" and transferred all activities to Thai Red Cross Society (TRCS). In 1922, the production and service activities at the science division included production of rabies vaccine, small pox, typhoid and cholera vaccine followed by snake antivenoms. BCG vaccine was started in 1953. The Blood Service started at Rangsit Nusorn Building on October 13, 1969.

Products include Snake Antivenom, TRCS ERIG (rabies immunoglobulin), Rabies vaccine, BCG vaccine, and Tuberculin PPD.



16TH - 18TH AUGUST 2017

HOW TO REGISTER

1 Online Registration
Browse website below, fill-in delegate details and click submit
WWW.ISPETH.ORG/AGM2017

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.

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 CLOSES ON 5 AUGUST 2017 OR WHEN ALL SEATS ARE FULLY RESERVED.

FEE PER DELEGATE	PACKAGE RATE	conference package includes 2 days conference pass and networking dinner
FOR NON THAI RESIDENT		
ISPE MEMBER	12,000 THB	
NON ISPE MEMBER	15,000 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

EXCLUSIVE FOR ISPE MEMBER ONLY

PLANT A: GREATER PHARMA CO., LTD.

3,000 THB

PLANT B: QUEEN SAOVABHA MEMORIAL INSTITUTE

3,000 THB

PAYMENT TERMS

Payment must be received 10 days 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 > KASITBKK
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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GREATER PHARMA CO., LTD.



ISPE 2016 Facility of the Year Award (FOYA) Honorable Mention Winners

Greater Pharma Manufacturing Co Ltd, located in Bangkok, Thailand is the first of its kind to apply western standards to design, build and operate a pharmaceutical facility for tablets, capsules, sachets and liquids to produce pharmaceuticals for the local ASEAN market. With the production and use of this facility, they accomplished several milestones for the Thai pharmaceutical industry:

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2. It is the first pharmaceutical facility to use energy conservation design concept.
3. The plant uses locally sourced design solutions and equipment
4. Capital cost was at the low end of plant cost in Thailand but more efficient running costs.

This facility will be recognized as the model facility in Thailand and allow other local companies in ASEAN region to emulate and develop similar facilities to improve the quality of medicines provided by local companies for the majority of patient population. In addition local regulatory agency also benefited from the inspection and interactions with this facility. Therefore ISPE will honor this facility and the team with Honorable Mention award.



GREATERPHARMA MANUFACTURING CO., LTD

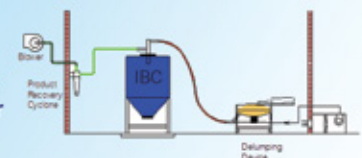


CLOSED PROCESS OSD MANUFACTURING

The current situation is that most companies use open processing for OSD manufacture as they have done since the industry started 45 years ago. Open processing produces dust which is bad for many reasons including :-

- dust is a major concern for cross contamination
- dust is bad for operator health
- dust can block the HVAC system

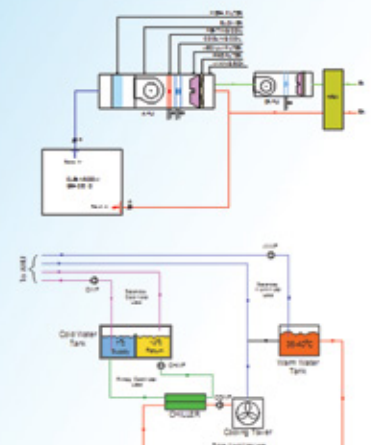
For the first time in Thailand the whole OSD Process is a closed process. The charging and discharging for each unit operation is closed using locally sourced equipment with no extra cost.



ENERGY CONSERVATION HVAC SYSTEM

Major features

- Low input KW/Ton , Water cooled chiller
- Humidity control by condenser water reheating
- Energy recovery (sensible and latent heat) from exhaust air by Heat Recovery Wheel (Enthalpy Wheel)
- Mass recovery from OAHU condensate for cooling tower make up water





QUEEN SAOVABHA MEMORIAL INSTITUTE (QSMI) THE THAI RED CROSS SOCIETY (TRCS)



This centre was officially opened on April 26, 1913 under the name “Pastura Sabha” which was later changed to “Sathan Pasteur” in recognition of Louis Pasteur, the pioneer in rabies vaccine production. At that time the mission was to produce vaccines against rabies, small pox, cholera, typhoid and other infectious diseases

In 1917, HM King Vajiravudh changed the name of Sathan Pasteur to “Pasteur Institute” and transferred all activities to Thai Red Cross Society (TRCS)

Following the Royal Cremation Ceremony of HM Queen Saovabha on May 24, 1920. HM King Vajiravudh decided to build a permanent building in her memory to be used for research in medical science. He granted the Thai Red Cross Society a big sum of money and a piece of land at the corner of Henry Dunant and Rama IV Road for the main building and permanent headquarters of the TRCS.

In 1922, the production and service activities at the science division included production of rabies vaccine, small pox, typhoid and cholera vaccine followed by snake antivenoms. BCG vaccine was started in 1953. The Blood Service started at Rangsit Nusorn Building on October 13, 1969.

Products include Snake Antivenoms, TRCS ERIG (rabies immunoglobulin), TRCS Speeda (rabies vaccine), BCG vaccine and Tuberculin PPD

Biological Products : GMP Production standards are established in the Sabhanayika building in June 2003. A new production and quality control building for biological products with involved modernized equipment and clean rooms according to the principles of Standards of Good manufacturing practice (GMP) and quality management system for BCG vaccine, snake antivenoms and rabies immunoglobulins. QSMI is the first biological plant that received GMP certificate from Thai FDA in 2003 and the Laboratory has been accredited ISO/IEC 17025 from the Ministry of Public Health in 2005.

Sterile vaccine filling operations : QSMI has imported bulk vaccines for filling. rabies vaccine was imported in 2010, JE vaccine in 2012 from Liaoning Cheng Da BioTechnology Co.Ltd., China, Td vaccine from PT Bio Farma (Persero), Indonesia in 2013 and Influenza vaccine from Sinovac Biotech Co.Ltd., China in 2014. These vaccines were imported for validation the filling plant facility and registration. A manufacturing license of TRCS Speeda (rabies vaccine) from Thai FDA has been approved in 2014 and product has launched since 2014. Sterile Pharmaceuticals Production Department has produced four important orphan drugs used for antidotes since 2010 and these products have been distributed to toxicology centers in the hospitals by NHSO (National Health Security Organization).

