ISPE THAILAND WORKSHOP

"Preparing for the new PIC/s GMP Annex 15"

Process Development, Process Validation and QbD - How to Manage the Requirements of the New EU/PICS Annex 15

Tuesday 26th May 2015 - Wednesday 27th May 2015, Ambassador hotel bangkok,

BACKGROUND AND OBJECTIVE:

Here in Asian Region we have to follow PICS regulations, EU /PICS annex 15 states the following:

Process Validation should be based on documented critical process parameters (CPP's) and critical quality attributes (CQA's) as a result of risk assessment activities as applicable. If a design space justification is used, the process knowledge and statistics used to confirm a state of control should be available. Validation batches (including continuous process verification) that are released to the market should fully comply with GMP & Marketing Authorisation and meet all validation acceptance criteria.

What do companies need to do to comply with this?

- What companies need to know, overview including regulatory review USA, EU, Asian, and requirements of new PICS GMP Annex 15 for process validation
- Process understanding, CQA, CPP
- Development of acceptable operation range
- Required statistical processes
- Practical application of the ideas-Case Study on generic product
- Review of past records to determine CPP-Case Study (focus)
- Can Continuous Process Verification be developed for existing products?
- Company organization required
- Benefits

SPEAKER:

Mr. Bikash Chatterjee, Project Executive, Pharmatech Associates, Inc.

Organised by
Intern. Society for Pharm. Engineering (ISPE) Thailand
&
Thai Pharmaceutical Manufactures Association (TPMA)

ISPE THAILAND WORKSHOP

"Preparing for the new PIC/s GMP Annex 15"

Process Development, Process Validation and QbD - How to Manage the Requirements of the New EU/PICS Annex 15

Tuesday 26th May 2015 - Wednesday 27th May 2015, Ambassador hotel bangkok,

AGENDA:

DAY 1 - Tuesday 26th May 2015 (Lecture)

Venue: Convention Hall A, Ground Floor, Ambassador Hotel Bangkok

09:00-09:30	The new process validation paradigm - USFDA, EMA, PIC/S
09:30-10:30	Comparing the USFDA 1987 and 2011 guidance's, EMA Annex 15 and PIC/s Annex 15
10:30-10:45	Coffee Break
10:40-11:45	What is QbD?
11:45-12:00	Risk management Tools and identifying CPPs and CMAs
12:00-13:00	Lunch
13:00-14:00	Process Understanding, Knowledge Space, Design Space, Process Characterization Study Identifying CPPs and CMAs
14:00-14:30	Development of acceptable operation range
14:30-15:00	Required statistical processes
15:00-15:15	Coffee Break
15:15-16:15	Practical application of the ideas-Case Study on generic product
16:15-16:45	Review of past records to determine CPP-Case Study- Legacy products
16:45-17:00	Can Continuous Process Verification be developed for existing products? Company organization required

DAY 2 - Wednesday 27th May 2015 (Workshop)

Venue: Orchid 2, 3rd Floor, Ambassador Hotel Bangkok

Time: 9:00 – 17:00

The workshop will provide attendees with a hands-on experience focusing on real case studies.

Improve your understanding of process validation (based on the requirements of new EU/PICS GMP Annex 15 for process validation) by hands on case studies covering the following :-

- Process understanding, CQA, CPP , learn how to determine these for your processes
- Benefits of developing an acceptable operation range
- Required statistical processes
- Case study to review past records to determine CPP
- Case Study on generic product to show a practical application of the ideas
- Use of Continuous Process Verification for existing products

Organised by
Intern. Society for Pharm. Engineering (ISPE) Thailand
&
Thai Pharmaceutical Manufactures Association (TPMA)

REGISTRATION FORM

"Preparing for the new PIC/s GMP Annex 15"

Process Development, Process Validation and QbD - How to Manage the Requirements of the New EU/PICS Annex 15

Tuesday 26th May 2015 - Wednesday 27th May 2015, Ambassador hotel bangkok,

WAYS TO REGISTER OR ENQUIRY:

1. Fill-out this form with your details
2. E-mail to **register@ispeth.org** or fax to **ISPE Thailand Affiliate 02-630-4527**
3. Make a payment with your chosen of payment below.

latest by Tuesday, May 21, 2015

REGISTRANT DETAIL:

○ Mr. ○ Ms. ○ Dr. ○ Others(_____)

First Name: _____

Last Name: _____

Job Title: _____

Email: _____

Tel: _____ **Fax:**_____

Management Level: ○ Senior ○ Middle ○ Junior

FOR TAX INVOICE: *Please provide us the official NAME and ADDRESS for Tax Invoice* ***(IN THAI)***

Company: _____

Address: _____

_____

_____

CANCELLATION & SUBSTITUTION POLICY:

Notice of withdrawal must be given in writing at least 7 working days (latest by 15 May 2015) before the commencement of the event. No refund of fees will be made for cancellations on or after 15 May 2015 or "no show" participants. Substitutions are acceptable in writing to the organizer; however, non-members substituting for members must pay the difference in fees prior to the event.

FEES: The following rates INCLUDE VAT 7%

Type	per person
Seminar only (26th May)	○ **2,140**
Seminar and Workshop (26th -27th May)	○ **3,745**

All registration must be accompanied by full payment. *Workshop seats are limited and will be based on a first come, first served basis.*

MODE OF PAYMENT:

○ **TRANSFER**

Transfer to THAI PHARMACEUTICAL MANUFACTURERS ASSOCIATION,

Account No: 036 - 2 - 64381-1
Siam Commercial Bank (SCB)
Branch: Samyaek Faichai

○ **CHEQUE PAYMENT**

All cheque payments must be made payable to THAI PHARMACEUTICAL MANUFACTURERS ASSOCIATION

Cheque/ DD No. _____

Date: _____ **Branch:** _____

Bank: _____

To join ISPE Thailand as member, please visit ISPE Thailand's Website: www.ispeth.org or call 0-2630-4525
Industry Member - US 239
Emerging Economy Member - US $175

SPEAKER

"Preparing for the new PIC/s GMP Annex 15"

Process Development, Process Validation and QbD - How to Manage the Requirements of the New EU/PICS Annex 15

Tuesday 26th May 2015 - Wednesday 27th May 2015, Ambassador hotel bangkok,

MR.BIKASH CHATTERJEE
Project Executive, Pharmatech Associates, Inc.

Mr. Chatterjee has more than 30 years of experience in the, pharmaceutical, biosciences, medical device/diagnostic, veterinary and nutraceutical/dietary supplement industries. He has held senior management positions in operating companies for more than a decade and has successfully brought multiple drug and product platforms through the FDA regulated development process to market. Throughout his career he has been responsible for the commercialization of over a dozen products which have been approved and marketed in over 40 different countries around the world.

Mr. Chatterjee has broad experience in the establishment of quality management systems with specific direct hands-on experience in the design and defense of commercial readiness systems for the purpose of a pre-approval inspection. Mr. Chatterjee has conducted multiple Pre-Approval Inspection (PAI) readiness projects in preparation for US FDA, EMA, WHO, PIC/s, China's CFDA, Japan's Ministry of Health and Welfare and DMA assessments.

His experience encompasses all elements of device design and manufacturing, solid, semi-solid and aseptic manufacturing, vaccine, cell culture and purification processing for human and veterinary products. His significant experience includes device development, scale-up and technology transfer He has extensive understanding of sterilization and EM program requirements and has built and validated multiple manufacturing, and support facilities. His strong experience in product and process development from molecule identification and product design through commercial launch and Phase IV pharmacovigilance is the foundation for the thoughtful and effective design and implementation of risk management systems throughout the device and drug development process.