

ISPE THAILAND ANNUAL MEETING 2012

“Good Engineering Practice (GEP)”

Thursday 26th - Friday 27th July 2012, Arnoma Hotel, Bangkok

"Good engineering practice" or "GEP" is a term applied to engineering and technical activities to ensure that a company manufactures products of the required quality as expected by the relevant regulatory authorities. Good engineering practices are to ensure that the engineering or software development methodology generates deliverables that support the requirements for qualification or validation. Good engineering practices are applied to all industries that require engineering; they do not solely apply to the pharmaceutical industry.

BACKGROUND AND OBJECTIVE:

The use of "Good engineering practice" is good practice for managing pharmaceutical industry projects and will reduce time and resources spent on qualification and validation.

This event will be two day seminar which will be focused on following:

- Applicable Regulations
- Risk Management
- Practical application of science and risk based approach to process and system equipment verification
- Making best use of supplier documentation
- Practical approach to documentation and document approvals
- Change management and how to gain acceptance of this
- Opportunity to take part in group exercises to use tools in real life examples

WHO SHOULD ATTEND

Pharmaceutical Industry Managers and Professionals, QA, Production, Engineering and Supplier Companies

AGENDA

| DAY 1 – Thursday 26 July 2012 | | DAY 2 – Friday 27 July 2012 | |
|-------------------------------|---|-----------------------------|--|
| 09.00 | Welcome | 09.00 | Welcome |
| 09.20 | Why GEP? Presented By Ms. Sanhaluck Buasuang | 09.05 | Factory Planning and Risk Management * Presented By Mr. Alain Kupferman |
| 10.00 | Good Engineering Practices Principle * Presented By Dr. Anthony Margetts | 10.40 | Coffee Break |
| 10.40 | Coffee Break | 11.00 | Factory Planning and Risk Management * Presented By Mr. Alain Kupferman |
| 11.00 | URS* Presented By Dr. Anthony Margetts | 12.00 | Lunch |
| 12.00 | Lunch | 13.00 | ISPE Thailand Summary Presented By Ms. Sorada Wangmethukul, ISPE Thailand President |
| 13.00 | <ul style="list-style-type: none"> • Design Review * • Change Control * Presented By Dr. Anthony Margetts | 13.30 | <ul style="list-style-type: none"> • Project Execution plan • Project Quality Management Presented By Ms. Jittaporn Wattanaseree |
| 15.00 | Coffee Break | 14.30 | Coffee Break |
| 15.20 | Document Management Presented By Ms. Chompunut Apinan | 14.50 | <ul style="list-style-type: none"> • GMP Assessment & Risk Analysis * • Case study of GEP + Validation * Presented By Dr. Anthony Margetts |
| 16.30 | Closure | 16.30 | Lucky Draw & Closure |

* Sessions are conducted in English and translated by Mr. Totsapon Santitewagun and Ms. Jittaporn Wattanaseree.

REGISTRATION FORM

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VENUE: 3rd Floor, Arnoma 3, Arnoma Hotel Bangkok: 99 Ratchadamri Road, Pathumwan, Bangkok, BTS: Chidlom

WAYS TO REGISTER OR ENQUIRY:

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

latest by Wednesday, July 18, 2012

GROUP REGISTRATION DISCOUNT

- From 3 delegates onwards from the same company will enjoy 300 Baht discount off the Basic Fees
- To apply for a group discount, please using “GROUP REGISTRATION FORM”

CONTACT 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: _____

FEES: The following rates INCLUDE VAT 7%

| Type | Basic Rate/per person |
|-----------------|-----------------------------|
| | 1-2 persons |
| ISPE Member | <input type="radio"/> Free |
| Non ISPE Member | <input type="radio"/> 2,461 |

All registration must be accompanied by FULL PAYMENT. The registration fee includes tea breaks, lunches and a set of conference proceedings.

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 \$75

MODE OF PAYMENT:

TRANSFER

Transfer to THAI PHARMACEUTICAL MANUFACTURERS ASSOCIATION,

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

CHEQUE PAYMENT

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

Cheque/ DD No. _____

Date: _____ **Branch:** _____

Bank: _____

CANCELLATION & SUBSTITUTION POLICY:

Notice of withdrawal must be given in writing at least 7 working days (latest by 18 July 2012) before the commencement of the event. No refund of fees will be made for cancellations on or after 18 July 2012 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.

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This form is eligible for registration of 3 persons onwards

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

Company: _____

Address: _____

Contact Person: _____ Tel: _____

| PREFIX | FIRST NAME | LAST NAME | JOB TITLE | EMAIL |
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| Type | Amount | Discount Rate / Person (Baht) | Total Fees (Baht) |
|-----------------|-----------------|-------------------------------|-------------------|
| Non ISPE Member | _____ Person(s) | 2,140 | _____ Baht |

MODE OF PAYMENT:

TRANSFER: Transfer to THAI PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Account No: 036 - 2 - 64381-1 **Siam Commercial Bank (SCB) Branch: Samyaeak Faichai**

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

Cheque/ DD No. _____ Date: _____ Branch: _____ Bank: _____

SPEAKER

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DR. ANTHONY MARGETTS
Compliance Manager, Factorytalk Co., Ltd.

Dr Tony Margetts who is ISPE approved trainers which retired from AstraZeneca and now lives in Thailand, he works part time as a consultant and gives training courses for ISPE.

Dr Margetts has been involved with the ISPE and the development of Good Automated Manufacturing Practice (GAMP) since 1991. He was chairman of the editorial board of the GAMP Forum and lead the editorial review of GAMP 4 and GAMP 5.

He was also heavily involved in producing the GAMP/ISPE good practice guides A Risk Management Approach to Compliant Electronic Records and Signatures and Validation of Process Control Systems.



MR. ALAIN KUPFERMAN
Lectuer at the Universite de Strasbourg, France,
Faculty of Pharmacy

We are very honourable to have Mr. Alain Kupferman as one of our speaker who has a long experience in pharmaceutical process planning and Risk Management.

Mr. Alain Kupferman is active in the pharmaceutical industry since 1967. With over 40 years of experience in feasibility and conceptual studies, Master planning, GMP aspects, Technological aspects and personnel training to many pharmaceutical organizations in both the region and also international. Now he is a Lecturer at the Universite de Strasbourg, France, and Faculty of Pharmacy since 2006 until now.