



**Thailand
Affiliate**

JOINT MEETING

BETWEEN ISPE THAILAND, TIPA AND TPMA 2015

“PICS Requirements for Quality Management”

Wednesday, 7th October 2015
Ambassador Hotel Bangkok, Sukhumvit 11, BTS: Nana – Room: Convention C, 1st Floor

Agenda

08.30 – 09.00	Registration
09.00 – 09.10	Welcome and Opening by Mrs Sorada Wangmethukul, ISPE Thailand President
09.10 – 10.10	Upcoming changes to EU and PIC/S GMP requirements
10.10 – 10.30	Break
10.30 – 12.00	Introduction to Quality Management System
12.00 – 13.00	Lunch
13.00 – 14.30	Quality System requirements, Change Control Practices ; Product Quality Review, complaints , contracts, supplier audits, deviation ,etc.
14.30 – 14.45	Break
14.45 – 16.00	Good Inspection Practices and Common GMP deficiencies and how to correct the problem
16.00 – 16.30	Q&A/Closure



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REGISTRATION FORM

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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 Wednesday, Sep 30, 2015

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: _____

ENTRY FEE 2,140 BAHT PER PERSON

The rate above INCLUDE VAT 7%

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

MODE OF PAYMENT:

TRANSFER

Transfer to THAI PHARMACEUTICAL MANUFACTURERS ASSOCIATION,

Account No: 036 - 2 - 64381-1
Siam Commercial Bank (SCB)
Branch: Samyaeek 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 28 Sep 2015) before the commencement of the event. No refund of fees will be made for cancellations on or after 28 Sep 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.



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SPEAKER

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Mrs. Helena Baião

INFARMED I.P. – Health Minister - Portugal

She is a Pharmacist (Lisbon Pharmacy University) with a Master Degree in Pharmaceutical Science. She worked in Macau Ministry of Health first as Hospital Pharmacist Assessor (coordinator of production, information/education and products management) and later as expert in drug assessment and finally GMP inspector (traditional and modern medicines) before joining INFARMED I.P. in 1997.

The main activities and responsibilities are or was GMP/GCP/GPvP/GDP inspections of human/veterinary MP and API in Portugal and overseas; complaints, quality defects alerts and recalls of the market; Quality Management System, representation of INFARMED I.P. at Communitarian and International level.

Since 1998 she is a member of PIC/S Committee assessor. She participated at Expert Circles, JVP, JRP among others and consequently organized PIC/S meetings.

She has worked as PIC/S co-rapporteur for EOF – Greece and MHRA- UK and JRP of Swissmedic – Switzerland and KA - Liechtenstein and JRP for Brazil's application.

She is a member of PIC/S Executive Bureau since 2008. PIC/S Chairperson 2012-2013.

From February 2013 is Regulatory and Scientific Advice Manager, INFARMED I.P.