TRAINING

Basic Principles of Computerised Systems Compliance : Applying the GAMP5® Guide : A Risk-Based Approach to Compliant GxP Computerized System

1 – 2 April 2013
Kompleks Eureka, USM, Penang

ISPE
Connecting a World of Pharmaceutical Knowledge

Malaysia Affiliate

This 2-day fundamental course by an ISPE International certified trainer introduces participants to regulatory requirements for computerized systems in the healthcare industry and explores tried, tested, and internationally recognized methods of meeting those requirements. GAMP guidance provides a pragmatic and effective framework for achieving computerized systems that are fit for intended use and meet current regulatory requirements, by building upon existing industry good practice in an efficient and effective manner.

Course topics include:

- FDA and EU regulatory requirements for GxP computerized systems
- Revised EU Annex 11 Computerized Systems
- FDA 21 CFR Part 11 Overview
- Overview of GAMP® 5 Guide: A Risk-based Approach to Compliant GxP Computerized Systems
- Quality Risk Management for computerized systems
- Role of users and suppliers - assessment ,cooperation and leveraging supplier activities and documentation
- Testing in GAMP - principles and practical approaches
- Pragmatic and efficient practices - cost effective compliance

Who Must Attend:

✓ Quality assurance and quality control specialists, validation specialists, manufacturing supervisors, technical support personnel, engineers, MIS professionals and all levels of management who need a fundamental understanding of computerized system compliance and regulations

✓ Computer system vendors or consultants, engineering contractors, and validation service companies

ALL ATTENDEES WILL RECEIVE A COMPLIMENTARY COPY OF THE GAMP 5® GUIDE (RM 400 VALUE)

Dr Margetts has been involved with the ISPE and the development of Good Automated Manufacturing Practice (GAMP) since 1991. He was chairman of the team that created the first GAMP Guide and then became chairman of the editorial board of the GAMP Forum and led the editorial review of GAMP 4 and GAMP 5.

ENQUIRIES : contact

- ❑ ispe.malaysia@gmail.com
- ❑ **Tel : 03-2161 2826(Elyna)**

TRAINING

Basic Principles of Computerised Systems Compliance : Applying the GAMP5® Guide : A Risk-Based Approach to Compliant GxP Computerized System

1 – 2 April 2013

Kompleks Eureka, USM, Penang

ISPE
Connecting a World of Pharmaceutical Knowledge

Malaysia Affiliate

REGISTRATION FORM

Name	
ISPE Membership Number	
Contact email	
Contact telephone number	
Company name and address (for proforma invoice if required)	

CATEGORY	FEE (RM)	PLEASE TICK
Member (industry)	2,000	
Non Member (industry)	2,350	
Member (academia/government)	1,150	
Non Member (academia/government)	1,500	
Member (Student)	650	
Non Member (Student)	670	

❑ **Please tick if Proforma Invoice required**

Payment

Payment in the form of cheque made out to "ISPE Malaysia" can be sent to

ISPE MALAYSIA c/o Synertec Asia (M) Sdn Bhd
Level 5, Menara Atlan
161, Jalan Ampang
Kuala Lumpur, 50450

Please either

- Email the completed form to ispe.malaysia@gmail.com or
- Fax the completed form to **03- 2161 2832**

A confirmation email shall be sent on receipt of the form .