

# ISPE

**ISPE**

Secretariat ISPE Indonesia Affiliate  
 PT Pharma-Pro International  
 PIC : Ms. Silvia (0816 995 230)  
 or Wendy (0812 1880 2756)  
 Ms. Wendy (0812 1880 2756)  
 Tel : (021) 6386 9503  
 Fax : (021) 6386 9503  
 E-mail : secretariat.ispeind@gmail.com  
 silvia@pharma-pro.com  
 wendy@pharma-pro.com

Platinum Sponsor:

**NAGANO SCIENCE**



**Indonesia Affiliate**

PHARMACEUTICAL DEVELOPMENT    TECHNOLOGY TRANSFER    COMMERCIAL MANUFACTURING    PRODUCT DISCONTINUATION

INVESTMENTAL PRODUCTS

GMP

MANAGEMENT RESPONSIBILITY

PROCESS PERFORMANCE AND QUALITY MONITORING SYSTEM  
 CAPA SYSTEM  
 CHANGE MANAGEMENT SYSTEM  
 MANAGEMENT REVIEW

ENABLERS

KNOWLEDGE MANAGEMENT

QUALITY RISK MANAGEMENT



## ISPE Implementation of Pharmaceutical Quality System (IPQS) Across Product Lifecycle Considering Risk Management (QRM)

21 - 22 May 2013  
**Gran Molla Hotel**  
 Jakarta

**ANNUAL CONFERENCE**

➔ **Track 1**

**PQS Across Product Lifecycle**

➔ **Track 2**

**QRM Across Product Lifecycle**

Pharmaceutical Quality System (PQS) is a management system to direct and control pharmaceutical company with regard to quality. The implementation of PQS will facilitate robustness of drug quality across lifecycle (from development, technology transfer, commercial process and product discontinuation), through facilitation of continual improvement, science and risk-based evaluation. It will also reduce risk of product failure and recalls thereby providing greater assurance of drug product quality and better process performance, therefore, enhance manufacturers' and regulators' confidence in product quality.

This Annual Conference will discuss both implementation of PQS and Quality Risk Management (QRM) across product lifecycle, which enable industry and regulators to have clearer understanding of the application of a Quality System across product lifecycle, and also increase understanding between industry and regulator.

Presenting International Speakers as follow :

- Karen Ginsbury (UK)
- Mimi Yuliani Syahputri (Singapore)
- Roland Krebs (Malaysia)



**Indonesia Affiliate**



**Karen Ginsbury (UK)**

Karen Ginsbury has trained personnel in GMP, enrichment topics and "on-the-job" skills for the past 25 years. She has given "train-the-trainer" sessions to multi-national pharma companies as well as working with start-ups and contract service providers to bring their personnel up to par. Karen regularly lectures at conferences, provides courses and workshops around the globe including sharing conferences such as IVT's flagship Validation Week and ACE meetings. Karen is an instructor for PDAs Training Research Institute (TRI) and recently gave a course on the Expanding Role of Quality Professionals at the PDA/EMA Conference in London, England.

**Mimi Yuliani Syahputri (Singapore)**

Mimi Syahputri is Head of Quality Management and Industrialization ASEAN at GlaxoSmithKline. A knowledgeable pharmacist in Pharmaceutical industry with more than 10 years of work experience in positions such as Manufacturing Technologist, Validation Specialist, Quality Investigator, Quality Compliance, QA Section Head, QA Batch Release Engineer, QA Product Transfer and Process Validation, Site Change Coordinator and Regulatory CMC Facilitator under Quality Department. Mimi lectures at conferences such as IVT Validation Week.

**Roland Krebs (Malaysia)**

Roland Krebs is chemist, holds marketing communication diploma (SAM Switzerland) and has a PhD in laboratory medicine (International Eoenergy Institute Baku Azerbaijan). Since 2011 Roland is certified risk assessor for stability testing processes for the pharmaceutical industry.

Roland is a business development consultant counselling manufacturing companies supplying scientific and analytical equipment and services to the pharmaceutical industry and provides marketing and sales support to enhance and improve their business development process in Asia/Pacific.

**DAY 1, 21<sup>st</sup> May 2013, 08.00-18.30**

### SESSION SCHEDULE

- Registration
- Plenary, All Participants
- Progress Report ISPE Indonesia Affiliate
- Keynote Speech
- Regulatory Overview
- General Overview of PQS

#### Track I : PQS Across Product Lifecycle

- PQS In Pharmaceutical Development
  - PQS in Product Development
  - Managing API Source
  - Future Trend in Product Registration
  - Developing Dossier

- Cocktail and Networking
- Members are expected to participate in the Election for President of ISPE Indonesia Affiliate

**DAY 2, 22<sup>nd</sup> May 2013, 07.30-17.30**

- Registration
- Track I : PQS Across Product Lifecycle

- PQS in Technology Transfer
  - Process Validation & Scaling Up
  - Validation of Computer System
- PQS in Commercial Manufacturing
  - GMP and PQS Element
  - Managing Changes
  - Stability Program
  - Continuous Process Verification: Managing quality across product lifecycle
  - PQS in Product Discontinuation

- Wrap-up & Closing

#### Track II : QRM Across Product Lifecycle

- Establish a Standard Risk Based Lifecycle Model
- QRM in Technology Transfer
  - Risk analysis during Product and Process Technology Transfer
  - Risk management in stability testing processes
- QRM in Commercial Manufacturing
  - Risk Analysis during Commercial Production
  - Risk management in Storage and Distribution
  - QRM in Product Discontinuation

### REGISTRATION FORM

#### Seminar Fee :

- o ISPE Member : USD 400
- o Non Member : USD 750

We do not accept registration and payment at the venue

Please fill in with capital letters:

Complete Name \_\_\_\_\_

ISPE member, No. \_\_\_\_\_

Non member ISPE

Company \_\_\_\_\_

Department \_\_\_\_\_

E-mail address \_\_\_\_\_

#### Seminar Track Choice:

- Plenary Session
- Track 1
- Track 2

Please choose Track 1 or Track 2

#### Main Business

- Pharmaceutical Industry
- Other Pharmaceutical Related (Distributor, Pharmacy, etc)
- Suppliers and other pharmaceutical industry services
- Others

Phone No. \_\_\_\_\_

Fax No. \_\_\_\_\_

Signature \_\_\_\_\_

#### Please transfer registration fee to:

ISPE Indonesia  
 A/C No. : 0713019060  
 Bank Central Asia (BCA)  
 Fatmawati Branch  
 Jl. Rs. Fatmawati No. 1CD

Please specify participant's name/company on the bank transfer receipt

#### Please send registration form to:

PT. Pharma-Pro International  
 PIC : Ms. Silvia (0816.995.230) or  
 Ms. Wendy (0812.1880.2756)  
 Phone : (021) 6386.9502  
 Fax : (021) 6386.9503/ 6386.9505  
 Email : secretariat.ispeind@gmail.com  
 silvia@pharma-pro.com  
 wendy@pharma-pro.com

Along with bank transfer receipt at the latest by 6 May 2013