# **ISPE MALAYSIA** Presents

# 2018 Education Seminar Series:

Analysis of Findings from GMP Inspections of Pharmaceutical Manufacturers & Introduction to 'Guidance Document of Pre-Approval GMP Inspection'

# 17 October 2018 (Wednesday) | 9.30 am - 4.00 pm

#### Venue

THE ROYALE CHULAN DAMANSARA HOTEL, **Petaling Jaya** 

#### Who should attend

Manufacturers and relevant personnel in various departments in pharmaceutical industry.

### REGISTRATION

**Click the link below to REGISTER** https://goo.gl/forms/adllGflBG3CA3in93

#### **Registration Fee**

(The fee includes course materials, lunch and refreshments)

: RM 495 Ordinary ISPE Member Non ISPE Members : RM 695 **Government Agencies** : RM 295 & Academia ISPE Members



#### **Payment Details**

- Bank transfer / deposit:
  - Account name : ISPE Malaysia. Bank : United Overseas Bank (M) Berhad A/C No. : 1623023449 (Swift Code: UOVBMYKL)
- Cheque:
  - Payable to 'ISPE Malaysia'

Address : Level 41, Vista Tower, The Intermark 348, Jalan Tun Razak, 50400 Kuala Lumpur

#### **Registration Terms & Conditions**

- 1) Payment & Confirmation
  - An invoice will be issued by ISPE after the registration via google link (above).
  - · Due to the limited availability of seats, full payment is required within 2 weeks from the date of registration.
  - The company is required to send proof of payment via email to ISPE.
  - · Registration confirmation email will be sent by ISPE after the payment is processed.
  - · A copy of the confirmation email is to be presented during registration on 17 October 2018.
- 2) Cancellation & Transfer
  - No refund will be given upon cancellation. However, a substitute participant is welcome at no extra charge Please provide the name of the substitute participant at least 2 working days prior to the event

#### **ENQUIRIES**:

- Registration (NPRA)
  - Liew Fei Hoong feihoong@npra.gov.my Tel: +603 7801 8553
- Payment & HDRF (ISPE) Rohani Mohammad

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National Pharmaceutical Regulatory Division (NPRA) Ministry of Health Malaysia

# Jointly Organised by:





# **Objectives**

- To share with the industry the analysis of findings from GMP inspections of pharmaceutical manufacturers.
- To enhance the understanding of GMP requirements in pharmaceutical manufacturers
- To introduce a new document by NPRA 'Guidance document of Pre-approval GMP Inspection'
- · A platform for sharing GMP inspection related issues between NPRA and industry

#### **17 OCTOBER 2018 - WEDNESDAY**

0930 – 1000	Registration – Morning coffee & Networking
1000 – 1200	Analysis of GMP Audit Findings of Pharmaceutical facilities for year 2016-2017 Speaker: Mr. Muhammad Lukmani Ibrahim, NPRA
1200 – 1230	Q & A
1230 – 1400	Lunch Break
1400 – 1530	Introduction to 'Guidance Document of Pre-approval GMP Inspection' Speaker: Ms. Belinna Abu Bakar, NPRA
1530 – 1600	Q & A
	End of Session

Limited seats available on a first-come, first-served basis! Deadline for registration: 5.00pm, 10 October 2018

ISPE Malaysia