ISPE Malaysia Affiliate

2016 Education Seminar Series

FOREIGN GMP REGULATORY INSPECTION and MANAGING CHANGES OF LICENSED FACILITY

DATE:
26 Oct 2016 (Wednesday)

TIME:
9.30am-3.30pm

VENUE:
Hotel Royale Chulan Damansara

TENTATIVE PROGRAM

9.30am | Registration: Morning Coffee & Networking
10.15-10.30am | Welcome Remarks
10.30-11.15am | Foreign GMP Regulatory Inspection
11.15-12.00pm | Managing Changes of Licensed Facility
12.00-12.15pm | Q &A
12.15-2.00pm | Lunch
2.00-2.30pm | Application process for Foreign GMP Inspection
2.30-3.00pm | Evaluation of GMP Evidence
3.00-3.30pm | Q &A
3.30pm | End of session

REGISTRATION FEE

RM550 | ISPE Member
RM800 | Non ISPE Member
RM300 | Government & Academia Member
RM250 | Young Professional Member
USD180 | Foreign ISPE Member
USD250 | Foreign Non ISPE Member

TO REGISTER

Please register via the following link:
http://tinyurl.com/ispeforeignGMP

PAYMENT DETAILS

BANK TRANSFER/DEPOSIT
Account name | ISPE Malaysia
Bank | United Overseas Bank (M) Berhad
A/C No. | 1623023449
SwiftCode | UOVBMYKLXXX

CHEQUE
Payable to | **'ISPE Malaysia'**
Address | 6th Floor, Block C, Kelana Business Centre, 97, Jalan SS7/2, 47301 Kelana Jaya, Selangor

SPEAKERS:

From the National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia.

OBJECTIVES:

1. To disseminate information about the latest regulatory requirements relating to foreign GMP regulatory inspections and management of changes to licensed facility.
2. To provide guidance on how to make a Foreign GMP Inspection application with NPRA.
3. To provide opportunities for the company and NPRA to share issues relating to foreign GMP inspections.

WHO SHOULD ATTEND

Manufacturers, Importers,
Regulatory Affairs Managers/Executives,
Product Registration Holder,
Product Owners.

FOR FURTHER INFO:

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