

2017 Education Seminar Series:

GMP/GDP Inspection on Biopharmaceuticals 2017

13 November 2017 (Monday)

Venue

Royale Chulan Damansara Hotel
Petaling Jaya

Time

8.00 am – 5.00 pm

Who should attend

-Pharmaceutical & Biopharmaceutical Manufacturers
-Biopharmaceutical Importers & Distributors

Fees

Ordinary ISPE Member : RM 650
Non ISPE Members : RM 850
Government Agencies & Academia ISPE Members : RM 450

PAYMENT DETAILS

•Bank transfer /deposit:

Account name : ISPE Malaysia.
Bank : United Overseas Bank (M) Berhad
A/C No.: 1623023449 (Swift Code: UOVBYMYKL)

•Cheque:

Payable to 'ISPE Malaysia'
Address : C/O: Synertec Asia (M) Sdn Bhd
11th Floor, Block C, Kelana Business Centre,
97, Jalan SS7/2, 47301 Kelana Jaya, Selangor

REGISTRATION

Click the link below to REGISTER

https://docs.google.com/forms/d/1yIm1XWcVFSFTOe3Bc1_Kjg_J3eSavjFGD02jBvIXia5w/edit

Notes on Registration:

1) Confirmation

- Confirmation of registration email will be sent to participant after registration fee has been made.
- A copy of the Confirmation email is to be presented during registration on 13 Nov 2017.

2) Cancellation

- No refund will be given upon cancellation. However, a replacement will be accepted at no additional cost with consent of the Secretariat.

Closing Date: 3 November 2017

ENQUIRIES : contact

- ☐ Registration (NPRA)
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- ☐ Payment & HDRF (ISPE)
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Human Resource
Development
Fund (HRDF)
'Claimable'

Jointly
Organised By:

Objective of Training

- ✓ Highlight the requirements of GMP and GDP on manufacturing and distribution activity of biopharmaceutical products.
- ✓ To share NPRA's experience during GMP and GDP inspection related to biopharmaceutical products.

MONDAY 13 NOVEMBER 2017

0800 – 0845	Arrival of Participant, Registration, Welcome Coffee and Networking
0845 – 0900	Opening Speech and Doa Recitation
0900 – 0945	Approaches for Biopharmaceutical Inspection -What to prepare Speaker: NPRA
0945 – 1015	Morning Break and Networking
1015 – 1100	Common Deficiencies Related to Biopharmaceutical Manufacturer Speaker: NPRA
1100 – 1145	Cold Chain Inspection: Common Issues Speaker: NPRA
1145 – 1230	Inspection of Critical Areas for Manufacturing of Drug Substance (DS) & Drug Product (DP) Speaker: NPRA
1230 – 1245	Q & A
1245– 1400	Lunch Break
1400 – 1500	Quality Control : Lot Summary Protocol Speaker: NPRA
1500 – 1600	Sharing Session with Industry Speaker: Industry
1600 – 1630	Q & A
1630 – 1700	End of Session & Afternoon Break

Lunch and all breaks shall be provided



NPRA, MOH



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Affiliate