

ISPE MALAYSIA Proudly Presents

**NPRA &
Industry
experts**

2016 Education Seminar Series:

ASEAN Common Technical Dossier (ACTD) Preparation: Generic Products for Malaysian Submission

5 December 2016 (Monday)

Venue

OLIVE TREE HOTEL
Bayan Lepas, Penang

Time

8.30 am – 5.00 pm

Who should attend

- Regulatory Professionals;
- Development Scientists
- Manufacturing Professionals;
- QC / QA Professionals;
- and also of interest to: Consultants; Marketing and Operational Managers and Academia

Fees

Ordinary ISPE Member	: RM 650
Non ISPE Member	: RM 900
Government Agencies & Academia ISPE Member	: RM 485
Young Professional ISPE Member	: RM 425
Student ISPE Member	: RM 175

PAYMENT DETAILS

- **Bank transfer /deposit:**
Account name : ISPE Malaysia.
Bank : United Overseas Bank (M) Berhad
A/C No.: 1623023449 (Swift Code: UOVBMKLYXXX)
- **Cheque:**
Payable to 'ISPE Malaysia'
Address : 6th Floor, Block C, Kelana Business Centre,
97, Jalan SS7/2, 47301 Kelana Jaya, Selangor Darul
Ehsan

REGISTRATION

Closing Date: 2nd December 2016

**Register early
Seats are limited !!!**

ENQUIRIES : contact

- ask@ispemalaysia.com.my
- Tel : +6017 338 1788
(Rohani Mohammad)

MONDAY 5 DECEMBER 2016

0830 – 0900	Registration : Morning Coffee and Networking
0900 – 1000	Session 1: Organization of the dossier: Administrative data and labelling by Mazlifah binti Mohd Fahimi, NPRA
1000 – 1030	Morning Break and Networking
1030 – 1130	Session 2: API registration and data requirements by Wong Chui Shan, NPRA
1130 – 1230	Session 3: Stability studies: ACTR requirements by Zarina Noordin, ISPE Malaysia
1230 – 1330	Lunch Break
1330 – 1430	Session 4: BioEquivalence Studies : Study report and BE centre requirements by Wang Wai Meng, NPRA
1430 - 1500	Session 5: Analytical Method Validation : Data requirements and report by Rohani Mohammad, ISPE Malaysia
1500 - 1530	Afternoon Break and Networking
1530 – 1630	Session 6: Process Validation: ACTR requirement and report by Zarina Noordin, ISPE Malaysia
1630 - 1700	Session 7: Regulatory Update by Siti Noor Haryani binti Ismail, NPRA
	End of Session
	<i>Lunch and all breaks shall be provided</i>

Cancellation

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

Click the link below to REGISTER

<https://ispemsiaffiliate.typeform.com/to/tSttcA>

Event Organised By:

