

Regulatory Training Programme

Lecture 3: Legal Regulatory Compliance of Pharmaceutical Business in Hong Kong

- Date: Mar 27, 2017
- Time: 1:30 – 5:30pm
- Venue: For the Lecture: Lecture Theatre 4, Cheung Kung Hai Conference Centre, G/F, William MW Mong Block, 21 Sassoon Road, Pokfulam, Hong Kong.
For the Workshop: Exhibition Area, G/F, William MW Mong Block, 21 Sassoon Road, Pokfulam, Hong Kong.

Learning outcomes:

To understand the drug registration – to demonstrate efficacy, quality and safety in pharmaceutical registration

To understand the Good Submission Practice

To understand the relevant legal and regulatory framework in effective medical communications – to HCPs and to the public

The programme:

Time	Agenda	Speakers
1:15 – 1:30pm	Registration	
1:30 – 1:35pm	Opening Address – expected learning outcome of today	Dr. George Leung Acting Head, Department of Pharmacy and Pharmacology, The University of Hong Kong
1:35– 2:15pm	Pharmaceutical registration: relevant legislations and it's applications	Mr. Clive Chan Sr. Pharmacist, Drug Registration and Import/Export Control Division, Drug Office
2:15 – 2:45pm	Understanding of Undesirable Medical Advertisements Ordinance (UMAO)	Mr. Michael Yim Pharmacist, Drug Registration and Import/Export Control Division, Drug Office
2:45 – 3:05pm	Medicinal Advertisements under Trade Description Ordinance	Ms. Grace Wong Counsel, Baker & McKenzie
3:05 – 3:15pm	Medicinal Advertisements under HKAPI Code of Practice	Ms. Karen Yuen Lead, Regulatory Affairs Taskforce, HKAPI Medical Director, AbbVie

<p>3:15 - 3:30pm</p>	<p>Q &A with a panel discussion: Medicinal advertisement of the Pharmaceutical Industry – Legal and Compliance Boundaries Panelists: Mr. Michael Yim, Ms. Grace Wong and Ms Karen Yuen</p>	<p>Ms. Sabrina Chan Senior Executive Director, The Hong Kong Association of the Pharmaceutical Industry Chair, Advisory Board, BPharm Programme, The University of Hong Kong</p>
<p>3:30 – 3:50pm</p>	<p><i>Coffee Break</i></p>	
<p>3:50 – 5:25pm</p>	<p>Workshop – Case Studies- how to prepare a good submission package NCE application Case Studies – Review advertising material Venue - Exhibition Area, G/F, William MW Mong Block, 21 Sassoon Road, Pokfulam, Hong Kong.</p>	<p>Facilitators: HKAPI Regulatory Taskforce members</p>
<p>5:25 – 5:30pm</p>	<p>Wrap up – key learning of the workshop</p>	<p>Ms. Karen Yuen Lead, Regulatory Affairs Taskforce, HKAPI Medical Affairs Director, AbbVie</p>