

Regulatory Training Programme

Lecture 2: Pharmaceutical Regulatory Framework and be a compliant licensee in Hong Kong

Learning Outcomes

- To understand the regulatory framework and governance body of drug safety in HK
- To understand the regulatory compliance from regulator's perspective
- To understand the requirement and its application as a licensee of Wholesale dealer licensee and also related license such as PIC/S and retailers in Hong Kong
- To understand the other legal considerations when interacting with regulatory agency

- Date: Jan 17, 2017
- Time: 1:30 – 5:30pm
- Venue: Lecture Theatre 3, Cheung Kung Hai Conference Centre, G/F, William MW Mong Block, 21 Sassoon Road, Pokfulam, Hong Kong.

The programme:

Time	Agenda	Speakers
1:15 – 1:30pm	Registration	
1:30 – 1:35pm	Opening Address – expected learning outcome of today	Ms. Sabrina Chan Executive Director, The Hong Kong Association of the Pharmaceutical Industry Chair, Advisory Board, BPharm Programme, The University of Hong Kong
1:35– 2:15pm	Regulatory framework and Governance body of drug safety in HK <ul style="list-style-type: none">• Regulatory framework and government bodies• The importance of regulatory compliance with the view of Cap 138, Cap 132• Case sharing	Mr. Lot Chan, Chief Pharmacist, Licensing and Inspection, Drug Office

2:15 – 3:05pm	<p>Regulatory compliance - the Licensing requirements</p> <ul style="list-style-type: none"> Manufacturing: what is PIC/S; WDL inspection expectation – Code of Practice; ASP inspection expectation – Code of Practice 	<p>Mr Edwin Lam, Senior Pharmacist, Drug Office Pharmacovigilance and Risk Management Division</p>
	<p>HKAPI inspection & WDL COP survey results sharing</p>	<p>Ms. Karen Yuen Lead, Regulatory Affairs Taskforce, HKAPI Medical Affairs Director, AbbVie</p>
3:05 – 3:35pm	<p>Interacting with Government Officials and HCPs - Laws, regulations, guidelines and Code</p>	<p>Dr. Isabella Liu Partner, Baker & McKenzie Honorary Legal Advisor, HKAPI</p>
3:35 3:40pm	<p>Closing remark of the lecture</p>	<p>Dr. George Leung Acting Head, Department of Pharmacy and Pharmacology, The University of Hong Kong</p>
3:40 – 4:10pm	<p>Coffee Break</p>	
4:10 – 5:20pm	<p>Workshop – Prepare for your inspection (Industry people/academic staff only) Venue - Seminar Room 5 (LG, Laboratory Block, 21 Sassoon Road, Pokfulam)</p>	<p>Facilitators: HKAPI Regulatory Taskforce members</p>
5:21 – 5:30pm	<p>Wrap up – key learning of the workshop</p>	<p>Ms. Karen Yuen Lead, Regulatory Affairs Taskforce, HKAPI Medical Affairs Director, AbbVie</p>

We welcome members and also non-members. Fees as below:

Commercial companies

HKAPI members: HK\$ 920 per lecture, HK\$ 4,200 for five core courses (C1 – C5)

Non-HKAPI members: HK\$ 1,050 per lecture, HK\$ 4,800 for five core courses (C1 – C5)

For registration, please contact Ms. Lee of HKAPI at 2528 3061