

Product Life Cycle Management from Regulatory Perspective and Best Practice Workshop

17th Oct 2019

Time	Topic	Speaker
9:30 – 10:00	Registration	
10:00 – 10:15	Opening	HKU representative (TBC) Ms. Sabrina Chan Senior Executive Director, HKAPI
10:15 – 11:15	Presentation #1: Brief Review of CORP Guidelines - An overview on the CORP guideline - Common pitfall: statistics, most frequent deficiency - Understanding on safety label update and foreign health authority monitoring - Q&A (15 mins)	Mr. Henry Lau Ag. Senior Pharmacist, Drug Registration CORP Unit, Drug Office, Department of Health
11:15 – 11:30	Break	
11:30 – 12:30	Presentation #2: Brief Review of Recall Guidelines and Its Implementation - An Overview on the Recall Guideline - Statistics: most common reasons for product recall - Responsibilities of Licensee during recall - Common gaps in recall implementation - Q&A (15 mins)	Ms. Blouie Tse Pharmacist, Pharmacovigilance Unit, Drug Office, Department of Health
12:30 – 13:30	Networking Lunch	
13:30 – 13:45	Afternoon Best Practice Workshop - Opening remarks - Good Regulatory Practice Roadmap recap	HKAPI Regulatory Affairs Taskforce Representative
13:45 – 14:15	Briefing on the four cases	Facilitators
14:15 – 15:30	15 mins: Studying the case 45 mins: Discussion & presentation slides write up (assisted by facilitators) Case 1: Table 1, 2 Case 2: Table 3, 4 Case 3: Table 5, 6 Case 4: Table 7, 8	/
15:30 – 15:40	Break	
15:40 – 16:55	10 mins: Table 2 presents – 2 presenters 5 mins: Table 1 provides additional comments	/

	<p>10 mins: Table 4 presents - 2 presenters 5 mins: Table 3 provides additional comments</p> <p>10 mins: Table 6 presents - 2 presenters 5 mins: Table 5 provides additional comments</p> <p>10 mins: Table 8 presents - 2 presenters 5 mins: Table 7 provides additional comments</p>	
16:55 – 17:05	Closing	<p>Ms. Karen Yuen Lead, HKAPI Regulatory Affairs Taskforce</p>

To sign up or for more information, please contact Ms. Catherine Chau at catherine.chau@hkapi.hk or 2528 3061.