Regulatory Training Programme - Course Seminar 4

TOPIC: Patient Safety: From Pharmacovigilance to Regulatory Monitoring

Learning Outcomes:

- To understand the international trends of pharmacovigilance
- To understand the considerations when preparing a Risk Management Plan (RMP)
- To understand a detailed overview of the package insert submission process to the DOH and proof-reading skill
- To gain practical tips on planning COP implementation, internal communications and alignment to external communications
- To understand the implication of regulatory non-compliance: Recall process, how to make a recall decision

Date: 9 January 2018

Venue:

Morning: Lecture Theatre 4 (LT4), 1/F, William MW Mong Block, 21 Sassoon Road, Pokfulam
Afternoon: Exhibition Area, G/F, William MW Mong Block, 21 Sassoon Road, Pokfulam
Agenda:

Time	Topic	Speaker
9:00 – 9:30	Registration	
9:30 – 9:35	Opening Remarks	**Dr. George Leung** Acting Head & Associate Professor Department of Pharmacology & Pharmacy The University of Hong Kong
9:35 – 10:20	Keynote Speaker: The Importance of Pharmacovigilance as in Regulatory Regime and its Development in International Legislations	**Prof. Ian Wong** Vice-President, International Society of Pharmacovigilance Professor, The UCL School of Pharmacy and The University of Hong Kong
10:20 - 11:05	Regulatory framework • ADR Reporting Requirements for Pharmaceutical Industry in Hong Kong • Market Surveillance of Registered Pharmaceutical Products in Hong Kong • The worldwide drug safety monitoring system in Hong Kong: PharmWatch • Additional licensing conditions for pharmaceutical products containing new chemical entity in Hong Kong	**Mr. Raccoon Chung** Pharmacist of the Drug Office Traders Licensing and Compliance Division Department of Health **Ms. Julianna Li** Pharmacist of the Drug Office Drug Registration and Import/Export Control Division Department of Health

11:05 - 11:25	Break	
11:25 - 12:10	What is a Risk Management Plan? From Preparation to Execution.	**Prof. Ian Wong** Vice-President, International Society of Pharmacovigilance Professor, The UCL School of Pharmacy and The University of Hong Kong
12:10- 12:45	Pharmaceutical Companies' Perspective: Practical Tips in Regulatory Compliance and Efficient Communications during Recall.	**Mr. Donald Chong** Member, Regulatory Affairs Taskforce, HKAPI Regulatory Affairs Director, GlaxoSmithKline Consumer Healthcare (Hong Kong) Limited
12:45 – 13:15	Panel Discussion: How to Ensure the Practice of Pharmacovigilance System Protects Patient Safety	**All Speakers + Ms. Karen Yuen** (Lead of HKAPI Regulatory Affairs Taskforce)
13:15 – 13:30	Closing Remarks	**Ms. Sabrina Chan** Senior Executive Director, HKAPI
13:30 - 14:30	Lunch	
14:30 - 15:15	Session 1 Case study on Submission of an RMP in an NCE registration. • US REM • EU RMP • Company Core requirements • Formation of a local RMP commitment review team • Comparison of RMPs • RMP and Labeling update • Clinical studies to further investigate identified risk	**Regulatory Affairs Taskforce** **-Ms. Susanna Yim and table facilitators**
15:15 - 15:25	Break	
15:25 – 16:10	Session 2 Case study on product labeling management • To get a deeper insight as to why change of artwork is important	**Regulatory Affairs Taskforce** **-Mr. Donald Chong and table facilitators**

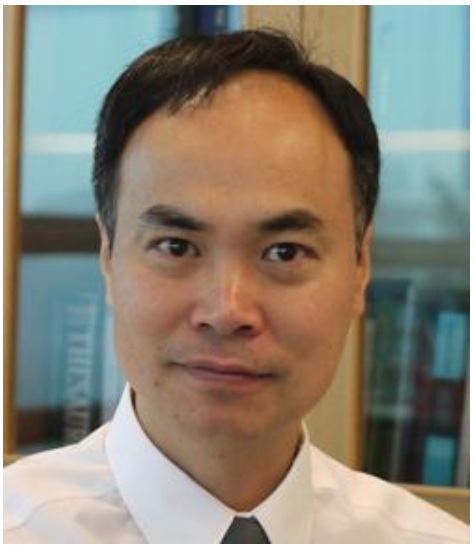
	• To learn the essential techniques and steps in proof-reading of artwork • To gain an understanding on planning CORP implementation, internal communications and alignment to external communications	
16:10 - 16:20	Break	
16:20 – 17:05	Session 3 Case study on how to execute a product recall and its communication plan • Formation of recall action team • Recall level • Impact analysis (distribution) • Communication plan (internal and external) • Reporting documents (HHE, Investigation report, DOH Recall form, distribution channel & record) • CAPA • Call center and customer management • Closure of event	**Regulatory Affairs Taskforce** **-Ms. Isobel Yeung and table facilitators**
17:05 – 17:15	Closing Remarks	

Dr. George Leung
Acting Head & Associate Professor
Department of Pharmacology & Pharmacy
The University of Hong Kong

George Leung obtained his BPharm and PhD (Physiology) at The Chinese University of Hong Kong. After his post-doctoral training at the Department of Medicine, the Johns Hopkins University, USA, he joined the Department of Pharmacology and Pharmacy, the University of Hong Kong, as the Research Assistant Professor in 2003. He is currently the Acting Head and Associate Professor of the Department.

Dr. Leung's research focuses on the vascular pharmacology. He has published over 85 full length papers in international scientific journals including British Journal of Pharmacology, European Journal of Pharmacology, Biochemical Pharmacology, American Journal of Physiology and Circulation Research. He got four General Research Funds from the Research Grant Council and one Health and Medical Research Fund from Food and Health Bureau. He also served as the reviewers for National Medical Research Council of Singapore and journals such as Biochemical Pharmacology, American Journal of Physiology and Clinical & Experimental Pharmacology & Physiology. He was the recipient of the Young Physiologist Scheme of the Physiological Society of UK in 1999. He also organised the Annual Conferences of Institute of cardiovascular Science and Medicine and Scientific meetings from 2008 to 2014. He is currently the Treasurer of the Asian Society for Vascular Biology.

Dr. Leung is the Deputy Director of the BPharm programme at the University of Hong Kong. He was awarded the Faculty Teaching Medal in 2009. He is currently the Board member of the Pharmacy and Poisons Board of Hong Kong and the Chairman of the Examination Committee in the Board. He also serves as the Academic Assessor and External Examiner of various healthcare and pharmacy-related programmes at the HKU School of Professional and Continuing Education, Open University of Hong Kong and Hong Kong Institute of Vocational Education.



Prof. Ian Wong
BPharm., MSc., PhD.
Vice-President, International Society of Pharmacovigilance
Professor, The UCL School of Pharmacy and The University of Hong Kong

Professor Ian Wong is Head of Research Department of Practice and Policy at the UCL School of Pharmacy in London. Prior to his appointment, Professor Wong was the first professor of pharmacy at the University of Hong Kong and served as a board member of the medicines regulatory authority of Hong Kong (Pharmacy and Poisons Board). Professor Wong was founding director of the Centre for Paediatric Pharmacy Research, set up in 2002, at University College London & Great Ormond Street Hospital for Children.

As recipient of a UK Department of Health Public Health Career Scientist Award in 2002, Professor Wong is the only pharmacist to date to have received such an award. In recognition of his work in paediatric medicines research, Professor Wong was awarded an Honorary Fellowship of the Royal College of Paediatrics and Child Health in 2011, Fellowship of the Royal Pharmaceutical Society in 2012 and Honorary Fellowship of Hong Kong College of Pharmacy Practice in 2013.

Mr. Raccoon Chung
Pharmacist of the Drug Office
Traders Licensing and Compliance Division
Department of Health

Mr. Raccoon CHUNG is a pharmacist working in the Drug Office, Department of Health. He obtained his Bachelor degree of Pharmacy from the Chinese University of Hong Kong, and his Master degree in Clinical Pharmacy and in Regenerative Medicine from the University of Sunderland and the University of Edinburgh respectively. He also obtained a Bachelor degree of Laws and a postgraduate diploma of Laws in the specialization of Medicine and the Law from the University of London. Even though he has recently changed his post to the Manufacturers Regulatory Unit, he worked in the Pharmacovigilance Unit for many years and was responsible for handling the adverse drug reaction reports.

Ms. Julianna Li
Pharmacist of the Drug Office
Drug Registration and Import/Export Control Division
Department of Health

Ms. Julianna LI graduated with a Bachelor degree of Pharmacy from the Chinese University of Hong Kong. She has also obtained her second Bachelor degree of Science in Traditional Chinese Pharmacy from the China Pharmaceutical University and a Master degree of Science in Clinical Pharmacy from the University of Sunderland. She is currently the pharmacist of Drug Registration Unit of Drug Office and is responsible for handling the application of registration of pharmaceutical products.

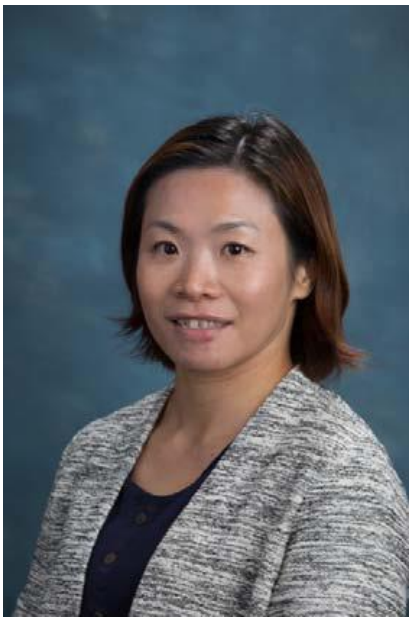
Mr. Donald Chong
Member, Regulatory Affairs Taskforce, HKAPI
Regulatory Affairs Director, GlaxoSmithKline Consumer Healthcare (Hong Kong) Limited

Donald Chong, B.Sc (Pharmacy, University of British Columbia, Canada) and MBA (Health Services Management, University of Hull, U.K.) is currently the Regulatory Affairs Director of GlaxoSmithKline Consumer Healthcare (Hong Kong) Limited.

Apart from being a licensed pharmacist in both Hong Kong and Canada, he is a Certified Master NLP Coach awarded by the American Association of NLP (Neurolinguistic Programming). He is also a certified coach awarded by the Worldwide Association of Business Coaching. Besides his regular work, he has myriad contribution in coaching, patient education and university teaching.

Currently, he is teaching business development in the higher diploma course Health Products Management at the HKU SPACE. He is presently the adjunct tutor for pharmacy students at the School of Pharmacy at the Chinese University of Hong Kong. He has also been invited by different patient associations and hospitals to deliver various kinds of training over the past few years. More noticeably, he is the course developer for the course "Understanding Western Medicine" at the Open University of Hong Kong.

In his leisure time, he contributes articles to the Hong Kong Pharmaceutical Journal in areas such as diseases and treatments as well as more lately in leadership and coaching. He is currently the section editor of Pharmacy Practice and Education of the journal. With over 20 years' experience in the pharmaceutical industry, he wishes to make more positive impact to people's lives and well-being through coaching and teaching.



Ms. Karen Yuen
Lead, Regulatory Affairs Taskforce, HKAPI
Medical Director, AbbVie Limited

Ms. Karen Yuen, currently the Medical Director of AbbVie Limited, has joined the HK pharmaceutical industry for more than 17 years. She has extensive regulatory affairs and medical affairs expertise and previously worked at Sanofi as Regulatory and Medical Manager and AstraZeneca as Medical Affairs Director. She has served the Regulatory Taskforce of the HKAPI for more than 10 years. Karen is a registered pharmacist and has a Master degree in Science.

Ms. Sabrina Chan
Senior Executive Director, HKAPI
Chair, Advisory Board of the Bachelor of Pharmacy Programme, The University of Hong Kong

Ms. Sabrina Chan is the Senior Executive Director of Hong Kong Association of the Pharmaceutical Industry, Member of the HKSAR High Level Steering Committee on Antimicrobial Resistance; Member of Business Facilitation Advisory Committee under the Financial Secretary's Office; Chair of the Advisory Board of the Bachelor of Pharmacy Programme, University of Hong Kong; Adjunct Assistant Professor in the School of Pharmacy, Chinese University of Hong Kong and a Member of APEC Biopharmaceutical Working Group on Business Ethics.

As the Sr. ED of HKAPI, Sabrina manages member association of international R&D Pharmaceutical companies providing over 70% of the treatment drugs for Hong Kong population. She defines strategic direction with HKAPI Board and advances mission of ensuring expedient access to innovative and effective drugs for patients.