Regulatory Training Programme:

Getting to be Competent Regulatory Affairs Professionals

Jointly organized by

Department of Pharmacy and Pharmacology, University of Hong Kong

Regulatory Affairs Taskforce, The Hong Kong Association of Pharmaceutical Industry

About this Programme

Regulatory professionals play critical roles throughout the healthcare product lifecycle, from concept through product obsolescence. They provide strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safe and effective products around the world. Continuous evolution in science and changes in the regulatory environment, health sector and general economics each shape the dynamic and expanding scope of the regulatory profession.

They give strategic and technical advice at the highest levels in their companies, making important contributions both commercially and scientifically to the success of a development program and the company overall. Regulatory is a dynamic discipline that brings the individual into contact with almost all of a company's various departments and disciplines.

This programme consists of five core courses and three optional courses, with the format of lectures and workshops, provides the essential knowledge and training of what is required as regulatory professionals at pharmaceutical industry in Hong Kong and Macau.

Audience profile

1. **Existing Regulatory Professionals – to enhance the understanding of regulatory framework in Hong Kong and Macao, and provide training on Good Submission Practice**
2. **Potential Regulatory Professionals - to obtain the essential basic knowledge to be a Regulatory Professional systematically**
3. **Commercial Executives in Pharma industry – to understand the work of regulatory affairs professionals and how to leverage their knowledge to cope with the business strategy**
4. **Pharmaceutical Distribution professionals – to better understand the regulatory framework in Hong Kong and Macao in order to work with their principles strategically**
5. **Academics in Pharmaceutical Practices – provide a platform to share the most update and firsthand information of the regulatory affairs in pharmaceutical affairs development in the Pharmaceutical industry in Hong Kong and Macao.**

At the completion of the Workshop

You will be able to:

1. **Have a good understanding of the role of pharmaceutical affairs professionals in the product life cycle**
2. **Leverage the role of pharmaceutical professionals in developing business**

strategy of pharmaceutical companies

3. **Ensure the regulatory compliance of the companies**
4. **Apply Good Submission Practice in order to provide regulatory submission success in first submission**
5. **Understand the difference of the regulatory framework and requirements between Hong Kong and Macao**

Course Content

Core courses:

1. **The role of Regulatory Affairs in the Research and Development of innovative drug (C1)**
2. **Overview of Pharmaceutical Regulatory Framework in Hong Kong (C2)**
3. **Legal Regulatory Compliance of Pharmaceutical business in Hong Kong (C3)**
4. **Patient Safety: From pharmacovigilance to regulatory monitoring (C4)**
5. **Overview of Pharmaceutical Regulatory Framework in Macau (C5)**

Optional courses:

1. **Clinical Research from a RA perspective (C6)**
2. **An introduction on EU and US regulatory System (C7)**
3. **Quality Assurance (C8)**

Course Title	Learning Outcomes	Proposed speakers	Duration
The role of Regulatory Affairs in the Research and Development of innovative drug (C1)	· To understand the role of the Regulatory Affairs (RA) in drug development and product life cycle management · To understand regulatory compliance as the foundation of pharmaceutical business to operate from commercial perspectives · Trend of international drug regulations changes in the recent decades · Role of industry in working with policy makers/regulators on patient safety and beyond	Prof Ian Wong (40min) • Overview of drug development (phase 1-4) • Role of RA in the drug development (insights fm regulators meetings to trial design development, to the output of Clinical Technical Dossiers, and the final label; how to achieve accelerated review for breakthrough compound) • Role of RA in the life cycle management (new formulation, new indication) Margaret Rumpf (30min) • How Regulatory compliance is the foundation of business to operate from the commercial leader's perspectives • RA is critical in leading the x-f(x) discussion in local RA strategy for new cpd and local implementation of Change of Particulars. Dr Kenneth Hartagon Go (40min) • How international drug regulations change in the recent decade • Role of industry in working with regulator in the view of patient safety. Panel: " Meeting the Expert" Panelists: Professor Ian Wong, Dr. Kenneth Hartagan Go, Margaret Rumpf, Dr. George Leung (40 min) Facilitator: Mr. Stephen Leung · RA works with internal stakeholders are important from R&D developments to product commercialization in this fast evolving and highly regulated environment and be the good partner with the regulator in ensuring drug safety. · How to develop RA as a profession locally and reference to international experience	150 min (Dec 6, 2016)

Overview of Pharmaceutical Regulatory Framework in Hong Kong (C2)	• 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 other legal considerations when interacting with regulatory agency	Proposed :Drug Office key officer (40 mins) • Regulatory framework and Governance body of drug safety in HK • The importance of regulatory compliance with the view of Cap 138, Cap 132 Proposed: Drug Office key officer (40 mins): • Manufacturing: what is PIC/S • WDL inspection expectation – Code of Practice • ASP inspection expectation – Code of Practice Proposed: Subject expert (30 mins) • Interactions with regulatory agency - Relevant legal considerations Workshop (70mins) • Prepare to ensure oblige to licensing conditions	180 mins (Jan 17, 2017)
Legal Regulatory Compliance of Pharmaceutical business in Hong Kong (C3)	• Drug registration – to demonstrate efficacy, quality and safety in pharmaceutical registration • To learn about Good Submission Practice • To understand the relevant legal and regulatory framework in effective medical communications – to HCPs and to the public	Proposed: Drug Office Key Officer (40 mins) • Details of ordinances on pharmaceutical registration and illustrated by different examples Proposed: Subject expert (40 mins) • Understanding of UMAO & Trade Description Ordinance Workshop (100 mins) • Case studies - how to prepare a good submission package for various kinds of application • Case studies - Review advertising material	180min (March 27, 2017)

Patient Safety: From pharmacovigilance to regulatory monitoring (C4)	• To understand the fundamentals of pharmacovigilance and how it results to label change of pharmaceutical product • 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	Speaker with PV background (40mins) • To understand the pre-marketing and post-marketing adverse event surveillance and reporting requirements in HK; PV requirement of named patient importation; • What is black box warning • How should RA and PV work together on RMP preparation and also the RMP execution (as part of the RA approval's obligation) …. • How PV surveillance would result to label change Speaker with regional pharma industry background (40min) • How is international/regional regulations on regulatory compliance • Considerations and efficient communications in product recalls Workshop (100min) Session 1 • To get a deeper insight as to why change of artwork is important • To learn the essential techniques and steps in proof-reading of artwork • To gain an understanding on planning COP implementation, internal communications and alignment to external communications Session 2 • Case study on how to execute a product recall and its communication plan	180 mins (Q3 2017)
Overview of Pharmaceutical Regulatory Framework in Macau (C5)	• To learn the Healthcare system in Macau • To understand the governance body of drug safety in Macau • To understand the Regulations in Macau related to our industry	Proposed: Subject expert(40 mins) • Overview of healthcare system in Macau • Any partnership between govn and private hospitals Proposed: Representative from DAF (40 mins) • governance body of drug safety in	(May 30, 2017)

		Macau • Details of ordinances and technical documents, illustrated by different examples Workshop (100 mins) • Practical tips sharing with Macau Pharmaceutical Trade Association on regulatory submissions	

Optional Courses	Learning Outcomes	Duration
Clinical Research from a RA prospective (C6)	• To consolidate the understanding on clinical development such as protocol development, study design, evaluation and assessment of clinical information • What Good Clinical Practice is • To learn the practical requirements for proper informed consent, adverse event reporting and post-market support studies.	120 mins
An introduction on EU and US regulatory System (C7)	• This course presents an overview of the regulatory agencies and regulations for drugs and biologics in the EU and the US regulatory system. • To explore international harmonization efforts, pre-marketing and post-marketing regulations • To apply knowledge of international regulations to formulate strategy for product development	180 mins
Quality Assurance (C8)	• To understand the Hong Kong Guide to GMP for the secondary packaging of Pharmaceutical Products	120 mins

Accreditation
With 100% completion of the first four Core Courses (C1-C4) as outlined above and pass result of the 60mins examination, a Regulatory Affairs Certificate will be granted.
Course Fees
Commercial companies **HKAPI members: HK$ 920 per course, HK$ 4,200 for five core courses (C1 – C5)** **Non-HKAPI members: HK$ 1,050 per course, HK$ 4,800 for five core courses (C1 – C5)**

NGOs and Academics

Non-profit making companies and NGOs : HK$ 520 per course
University students: Each university (HKU & CUHK) will have 25 quota for each course - HK$ 120
Academic staff – free of charge – welcome to join for discussions