PharmaQMtraining.eu

A 1-day non-residential course in London

AN INTRODUCTION TO PHARMACEUTICAL PRODUCTS AND LICENSING

TIMETABLE	VENUE
Date to be advised Registration 09.15h Start 09.30h Finish 16.45h	Royal Society of Chemistry Burlington House Piccadilly London WIJ 0BA, UK

WHY SHOULD YOU ATTEND

You are taking your first or early steps into the world of pharmaceutical regulatory affairs, which is a huge territory involving administrative requirements, pharmaceutical, non-clinical and clinical awareness.

You may puzzle over licensing jargon and wonder about the meanings of particular terms or a multitude of abbreviations /acronyms and wish you knew where to find help and advice.

This course offers a broad coverage of issues at a basic or intermediate level. The training is delivered by our experienced Speakers. Many of the subjects, although not all, will be dealt with in 'slots' of five to fifteen minutes, which at the introductory level is sufficient for you to get your bearings. In addition you will be told or shown how to find much more information in official documents and from other sources. You will have plenty of opportunities for open discussion and development of themes of interest.

PROGRAMME

Introduction, Welcome and Discussion of Objectives

What is pharmaceutical licensing?

Who provides pharmaceutical licences [Marketing Authorisations (MAs)] and why does my company need them?

How do I find out about medicines licensing authorities in the EU, where they are and how to contact them?

What is an active ingredient (drug substance, active pharmaceutical ingredient, API)?

What is a medicine (medicinal product, drug product, dosage form, finished product, finished pharmaceutical product)?

What is the Summary of Product Characteristics (SPC, SmPC) and why is it so important?

How can I find copies of the European pharmaceutical legislation? What help is available to understand the requirements of EU pharmaceutical law?

Do the same requirements, policies and practices apply across all EU Member States? Can they sometimes apply beyond the EU?

How can I use guidelines, pharmacopoeias and official templates to help me in my work?

As the chemical and pharmaceutical industries often operate globally, what progress has been made towards harmonisation of regulatory requirements and standards?

What is ICH and why is this important in the EU and much of the rest of the world?

What is the Common Technical Document and how might it impact on my regulatory work?

What do the classifications Quality, Safety and Efficacy or Pharmaceutical, Non-clinical and Clinical mean and cover in regulatory work?

Why are the various 'Good Practices' so important?

Why are 'Commitments' and 'Compliance' such important regulatory subjects to all who work in the pharmaceutical industry?

What is a variation application or more commonly what are ‘Variations’?

WHO SHOULD ATTEND

Participants are likely to:

- be new to pharmaceutical regulatory affairs
  - either because they have recently joined the pharmaceutical industry or
  - have had a job transfer into a regulatory affairs/registration or associated department or
- have other reasons for wanting to improve their understanding of pharmaceutical regulatory licensing subjects

COURSE LEADERS

Professor Derek Calam
Dr Mike Robertson