



MODULE 8

Research & Development and Manufacturing

This module forms part of the PLG MSc course in Pharmaceutical Business Development and Licensing. It can be studied on its own for a module credit or as part of a Certificate, Diploma or MSc degree.

The module covers the operational aspects of the development process for pharmaceutical products. As with the other modules, the emphasis is firmly on the issues that are relevant to the negotiation and implementation of Licensing and Business Development Agreements.

It opens with a review of early stage development and moves on to a review of key issues in clinical development. It builds on the early concepts that are addressed in Module 1, allowing an understanding of the operational metrics and norms that apply within companies and the standard that are required to ensure the safe development of new products.

CONTENT:

Unit 1: Drug Discovery including high throughput screening, identifying leads and lead optimisation. This unit supplies a background on the research process, explaining why research is essential to the pharmaceutical industry, as a basis for further addressing the research, development and manufacturing process in later sections of this course.

Unit 2: Pre-clinical development including toxicology, ADME, animal studies and other pre-clinical work. This unit supplies a background on pre-clinical research processes including toxicology, ADME and animal studies, explaining why research is essential to the pharmaceutical industry, as a basis for further addressing the research, development and manufacturing process in later sections of this course.

Unit 3: Formulation, development, stability studies and pilot scale manufacture, supplies a background on pharmaceutical formulation, drug development and stability studies and pilot scale manufacture. It concentrates on the process of turning a chemical lead into a formulated drug ready for administration to humans.

Unit 4: Clinical development. This unit provides a description of the underlying principles and requirements for the clinical development of a new product. It also addresses the issues that arise during clinical development and how these are managed by clinical trial management.

Unit 5: R & D Agreements. This unit provides knowledge of the processes, equipment and facilities utilised in primary manufacture. An additional objective is to provide an understanding of various primary manufacturing issues and how these are dealt with.

Unit 6: Secondary Manufacturing, provides knowledge of the processes, equipment and facilities utilised in secondary manufacture of different pharmaceutical formulations. In addition it considers the various technical problems encountered in secondary manufacturing and packaging and how they may affect the product characteristics.

Unit 7: Manufacturing of Biopharmaceutical Products The objective of this unit is to provide knowledge of the processes, equipment and facilities utilised in manufacture of biopharmaceutical products. In addition it provides an understanding of the special conditions and equipment needed for dealing with biological organisms during manufacture.

Unit 8: Quality Assurance, Quality Control and GMP. This recognises the key elements of quality assurance, quality control and good manufacturing practice and the effect this has on licensing and business development deals.