



MODULE 4

Legal Issues in Business Development Contracts

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 provides an overview of the legal principles that are required for operating in the Business Development environment. It considers in detail the key different types of research and commercial agreements that are deployed in the Pharma industry, as well as the key legal aspects that underpin the negotiation and conclusion of Business Development agreements. In addition the module considers other legal issues such as IPRs regulatory and compliance, competition law and product liability.

CONTENT:

Unit 1: Understanding the Law, provides a basic introduction to law and legal processes. It considers the origins of the law in Europe in relation to how this may apply to the business development environment.

Unit 2: Tort. This Unit focuses on the concepts of the law of tort, negligence, product liability and the law of confidence. These principles are fundamental and essential as a basis for forming the contractual relationships that are required to operate in business development.

Unit 3: Contract. This unit addresses the Contract – the formation and drafting of contracts, the interpretation and management of breach of contract.

Unit 4: Preliminary and Ancillary Documents, Due Diligence. In business development, there are a range of ancillary agreements which are entered into ahead of formal negotiations for major transactions such as license agreements. This Unit underpins the legal rationale and reviews these basic contracts in the business development context.

Unit 5: Collaboration Agreements, addresses the key issues in concluding research alliance agreements. For example, the ownership and access to intellectual property rights which emanate from such collaborations. It reviews the contentious issues between parties, in particular at the industry academia interface.

Unit 6: Option Agreements, Pre Agreement Documents, Contract Research & outsourcing. Building on the knowledge gained in the earlier Units, Unit 6 moves on to consider the management of risk by the use of Option Agreements which are frequently a precursor to major transactions.

Unit 7: Pharmaceutical Licensing Agreements, addresses all of the key components of a standard licence agreement and provides a legal perspective on the terms that have to be considered in this business arrangement.

Unit 8: Alternative Arrangements for Marketing, Promotion and Exploitation of Pharmaceutical Products. This Unit addresses the key elements of marketing alliance agreements i.e. those agreements that govern marketing as opposed to R&D alliances.

Unit 9: Supply and Distribution Agreements, looks at the standard legal provisions of a supply agreement and highlights the differences between a licence and distribution arrangement.

Unit 10: Successful Contract Drafting and Negotiation. This Unit reviews some non legal aspects which are essential during the conduct of the negotiation in order to reach a fair and equitable settlement.

Unit 11: Background Legal Issues in Business Development and Licensing Agreements, provides some more details on some of the key ancillary areas that are relevant to business development agreements. So although for each of these specialised fields, it is most important to consult one's legal advisor, this gives a business person's insight into these key topics.