

# MSc. Course in Pharmaceutical Business Development and Licensing

## Module 4

### Legal

This module on Legal provides a basic understanding of the legal concepts supporting contracts, a familiarity with different contracts and the key issues that support pharmaceutical, biotechnology and healthcare licensing, research, distribution and promotion deals. This unit will not only address the legal aspects but also the business implications of these basic legal concepts.

The module comprises two main sections [see overleaf] and is supported by a short programme of seminars and lectures which will provide direct contact time.

#### Course requirements

Entry requirements for this course are an appropriate degree or relevant industrial experience of not less than three years. So for example, this may be a first degree e.g. a Bachelor of Arts or a Bachelor of Science degree. Alternatively, if you have been working within the business development environment for a minimum of three years then this would be relevant.

It is possible that potential students may have studied similar modules as part of an MA course. The modules which form this MSc course are specific to business development and licensing, therefore are likely to differ in content and focus to those studies within an MA course.

#### Costs

The basic cost of each module is £1,110 therefore the entire MSc. course [eight modules plus a 600 hour project] will cost £8,880 to complete. Travel or accommodation costs associated with attending lectures and workshops are not included in these fees.

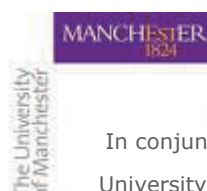
#### Timings

It is anticipated that each module comprising interviewing, distance learning, private study and direct contact time will take not less than four months to complete. Assuming there are no other commitments, it might therefore be possible to complete the MSc. over a three year period.

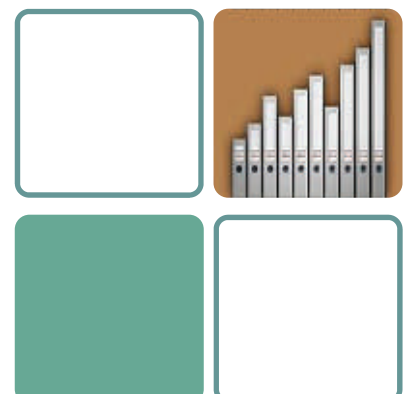
The initial two modules will be available from the March 2007 [Industry, and Finance]. The remaining modules will be available later in the year



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In conjunction with the  
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## Purpose

To provide an insight and appreciation of the basic legal concepts in English and European legislation as required to work in a business development environment within a pharma or biotech company. This module will also provide a business perspective on the key legal issues in licensing deals.

### Contract and Civil Law

- Contract Law
- Civil Law
- Choice of Jurisdiction
- ADRs
- EU
- WTO GATT

### CDAs, MTAs and due diligence

- CDAs
- MTAs
- Key Clauses
- Housekeeping issues
- IP
- Due Diligence

### Collaboration Agreements

- Key Clauses
- IP foreground/background
- Defections of success
- Lambert Agreements

### Contract Research and Outsourcing

- Standard Clauses
- Performance and Deliverables

### Option agreements and pre agreement commitments

- Management of risk
- Standard formats
- Letters of intent
- binding and Non binding elements
- Law

### License Agreements

- Grant of rights
- IPRs strategy and Management
- Commercial Terms
- Performance Issues
- Foreground/background

### Supply and Distribution Agreements

- Standard terms
- Floor prices
- Exchange provisions
- Supply and Purchase of products
- Technology Transfer
- IP Issues

### Product Liability

- Who hold liability?
- Insurance
- Maintaining Paper trails
- Phamacovigilance

### Competition Law

- EU competition Law
- Art 81 82
- Block Exemptions
- Fines and Penalties
- US Antitrust Law