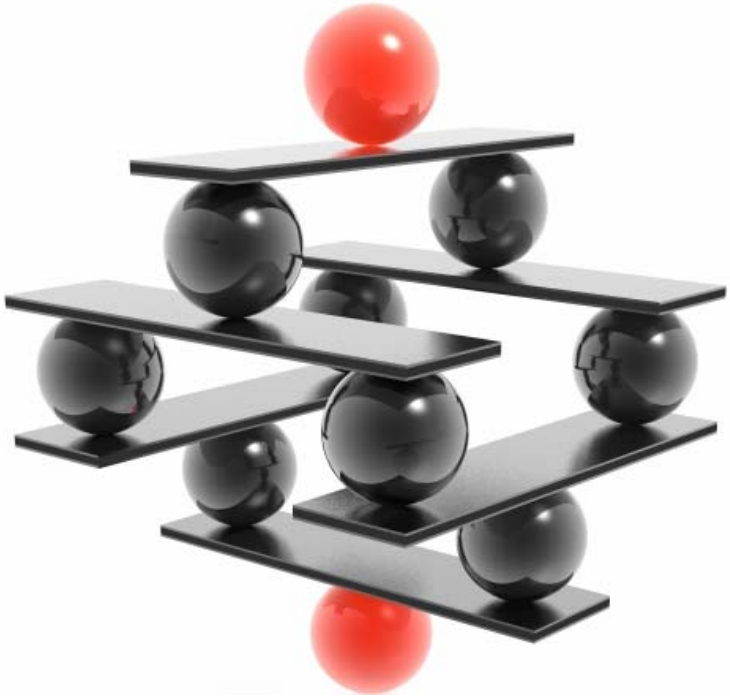
MANCHESTER 1824
The University of Manchester

Continuous Professional Development in Pharmaceutical Business Development & Licensing



CPD STUDENT HANDBOOK

PLG
pharmaceutical licensing group

providing continuous professional development

CONTENTS

CONTINUOUS PROFESSIONAL DEVELOPMENT (CPD) IN PHARMACEUTICAL BUSINESS DEVELOPMENT & LICENSING

Welcome to the Pharmaceutical Licensing Group range of CPD modules which form part of the PLG/University of Manchester MSc programme. Each module can be studied independently, but should you wish to continue studying for a Certificate, Diploma or MSc you can do this as long as you do not buy more than 3 individual modules from the PLG, and register as a student with the University of Manchester within 3 years. Each module has a number of informal assignments and one formal assignment. Passed formal assignments will count towards a University of Manchester qualification (Certificate, Diploma or MSc.).

PROGRAMME STRUCTURE

Each module runs on a distance learning basis supported by a tutorial course, supplemented with directed projects and guided reading lists.

WORKBOOK

The course materials are available on the PLG Masters website as pdf documents, with supporting materials in Microsoft Excel, Word or Powerpoint files. You will have full access to the module support materials on the PLG Masters website, including access to the PLG Library for reference materials.

Your covering email will give full logon details.

TUTOR GUIDANCE

You will be allocated a tutor to support your study. Your module tutor is there to help and support you through the module and they are an industry expert in their field. You will be informed of the tutor's contact details in your covering email.

Please be aware that many of our tutors have other academic and industrial duties so please give adequate time for their replies.

ASSIGNMENTS

Your progress through the module will be assessed via informal assignments, which should be sent to your tutor as you complete each unit. The tutor will provide feedback on the quality of each informal assignment.

The set formal assignment, which is used to assess your learning, has a word count of 6,000 words (range 5,400 to 7,500). Word counts do not include table of contents, reference lists or appendices, but text within tables is included. Your formal assignment should be submitted for marking within 12 months of your start date.

See Appendix 1 for full details on Formal Assignment requirements including marking and submission.

WINTER SCHOOL

You are invited to attend the two day Winter School, which takes place in London in December. The school consists of four hour intensive sessions taking you through the module content in depth. Tutors present the programme and take students through those areas which may prove challenging, along with reviewing assignments and workbook content.

The Winter School culminates with a PLG networking event to which you are also invited. This allows you to network with Business Development Executives from across the industry. Attendance at the Winter School is optional, but recommended.

For full details please contact Linda Sterrett at linda.sterrett@plgmasters.com

COURSE MODULES

Module 1	Introduction to the Healthcare Industry
Module 2	Business Development Operations
Module 3	Financial Aspects of Business Development and Licensing
Module 4	Legal Aspects in Business Development Contracts
Module 5	Negotiation and Interpersonal Skills
Module 6	Marketing and Commercialisation
Module 7	Intellectual Property Rights
Module 8	Research & Development and Manufacturing

MODULE 1: INTRODUCTION TO THE HEALTHCARE INDUSTRY

CONTENT:

Unit 1: Industry Overview and Historical Perspective
Unit 2: The Pharmaceutical industry's Key Statistics and Metrics
Unit 3: Structure of Healthcare Systems
Unit 4: Drug Discovery
Unit 5: Clinical Development
Unit 6: Regulatory Issues
Unit 7: Market Dynamics, Companies Strategies and the Role of Business Development
Unit 8: The Industry in the Future

AIMS:

- Understand the history and development of the pharmaceutical industry.
- Appreciate the contribution made by the industry with emphasis on the contribution from intercompany licensing of products.
- Appreciate the different company strategies within the industry and the role of business development in each type of company.
- Introduce the framework of the industry - research, development, manufacture and distribution of pharmaceutical products on an international level.
- Understand the relevant regulatory procedures applicable to the research, development and marketing of pharmaceutical products within the European Union, USA and Japan.
- Have an insight into the legislation relevant to the manufacturing and commercialisation of pharmaceutical products.
- Understand the role of Business Development within different types of pharmaceutical companies.
- Familiarise with Business Development operational metrics and norms within companies, the ethics of Partner of Choice.

OBJECTIVES:

- Gain an appreciation of the history and development of the pharmaceutical industry.
- Gain an understanding on a global basis of the basics of health economics with emphasis on the development and pricing of new products.
- Gain an insight into the contribution made by different types of businesses in the healthcare arena.
- Gain an awareness of the role and contribution made by pharmaceutical and biotechnology business development activities to corporate growth.
- Recognise the key drivers which shape and govern the industry.
- Contrast the different means by which pharmaceutical business raise their finance.
- Appraise the impact of such finance on the cost of capital of the organisation and its effect on appraisals of company value and deal structures.
- Undertake a range of analyses of corporate strategy and tactics identifying the strengths and weaknesses of different pharmaceutical businesses.
- Demonstrate ability to use a range of communication pathways to produce a Partner of Choice campaign package using a number of methodologies.
- Assess a business proposal and to critically appraise the strengths and weaknesses of an opportunity.
- Understand the impact of risk on the industry and on individual company strategies
- Explain the nature and importance of business development within a typical pharmaceutical business and construct basic information relevant for making decisions on business development strategy.

MODULE 2 BUSINESS DEVELOPMENT OPERATIONS

MODULE CONTENT:

Unit 1: Portfolio Management
Unit 2: Partnering Processes
Unit 3: The Due Diligence Process
Unit 4: Academic Technology Transfer
Unit 5: Research & Development Agreements
Unit 6: Technical Aspects in Licence Agreements
Unit 7: Alliance Management

AIMS:

- To provide an understanding of the full range of business development and licensing operations starting from product portfolio analysis, through partnering and finishing with alliance management
- To provide an understanding of the role and understand how business development and licensing works in different types of companies
- To assess and evaluate the management of due diligence systems in various types of pharmaceuticals companies.
- To understand how academic technology transfer differs from business development in companies
- To understand the role and challenges of alliance management

OBJECTIVES:

- Assess and evaluate the management of due diligence systems
- Understand the relevant regulatory processes which are applicable to medicinal products in the United Kingdom to that of the relevant European Union Directives.
- Introduce the framework for the development and manufacture of medicinal products on an international level.
- Provide an appreciation of the role of business development within the corporate structure

MODULE 3 FINANCIAL ASPECTS OF BUSINESS DEVELOPMENT & LICENSING

MODULE CONTENT:

Unit 1: Basic Financial Concepts
Unit 2: Financial Performance Measures, Working Capital and Cash Flow
Unit 3: Cost and Management Accounting
Unit 4: Long Term Decision Making
Unit 5: Financial Modelling
Unit 6: Valuation Methods and Management of Risks

AIMS:

- To develop an understanding of the basic financial and accounting concepts with emphasis on application in a pharmaceutical and biotechnology business development and licensing context.
- To provide an appreciation of the sources of finance available to companies and the impact it has on deal structures.
- To develop an understanding of financial modelling techniques to evaluate different types of licensing and business development deals.
- To provide an appreciation of valuation techniques and their applicability in different situations.
- To develop a practical capability to undertake financial modelling and valuations for different types of business development deals.
- To provide an appreciation of trends in deal values for different types of deals.
- To provide an appreciation of accounting treatment, currency and tax and the effect on deal valuations and negotiations.

OBJECTIVES:

- Recognise the key components of published corporate financial information and distinguish between their principal functions whilst reviewing the key conceptual issues which underpin the production of the information;
- Undertake a range of calculations to demonstrate the financial strengths and weaknesses of pharmaceutical businesses, to recognise the limitations of such information and to communicate the information in an appropriate manner;
- Explain the nature and importance of internal business costs and cost behaviour within a typical pharmaceutical business and construct information relevant for internal decision-making in different deal scenarios;
- Contrast the different means by which pharmaceutical business raise their finance and appraise the impact of such finance on the cost of capital of the organisation and its effect on appraisals of company value and deal structures;
- Demonstrate ability to use a computer spreadsheet to produce financial information using a number of methodologies in order to value a business proposal and to appraise critically the strengths and weaknesses of the information and methodologies used, including the impact of risk on the outcome;
- Understand a number of critical financially related ‘deal’ terms and evaluate critically ‘deal’ and ‘valuation’ data for a number of different scenarios from the viewpoint of both the buyer/licensee and the seller/licensor and communicate the information to a required audience in an appropriate manner.

MODULE 4 LEGAL ISSUES IN BUSINESS DEVELOPMENT CONTRACTS

MODULE CONTENT:

Unit 1: Understanding the Law
Unit 2: Tort
Unit 3: Contract
Unit 4: Preliminary and Ancillary Documents, Due Diligence
Unit 5: Collaboration Agreements
Unit 6: Option Agreements, Pre Agreement Documents, Contract Research & outsourcing
Unit 7: Pharmaceutical Licensing Agreements
Unit 8: Alternative Arrangements for Marketing, Promotion and Exploitation of Pharmaceutical Products
Unit 9: Supply and Distribution Agreements
Unit 10: Successful Contract Drafting and Negotiation
Unit 11: Background Legal Issues in Business Development and Licensing Agreements

AIMS:

- To provide a background to law and legal processes and an insight into applicable legislation.
- To understand the different types of agreements used in the industry .
- To provide an appreciation of the basic legal concepts relevant to English and European legislation
- To develop an understanding of the basic legal concepts with emphasis on application in a pharmaceutical and biotechnology business development and licensing context.
- To develop an understanding of the legal principles to differentiate different types of licensing and business development deals.
- To develop a practical capability to undertake a review and recommendation of different types of business development deals.
- To provide an appreciation of trends in deal types

OBJECTIVES:

- To recognise the key components of legal agreements and distinguish between their functions role and relevance in protecting businesses and business arrangements;
- Understand a number of critical ‘deal’ terms and evaluate their importance to an overall business ‘deal’ from the viewpoint of both the buyer/licensee and the seller/licensor and communicate the information to a required audience in an appropriate manner
- Interpret the key clauses in an agreement and to communicate the information in an appropriate manner;
- Demonstrate ability to understand and summarise the key information in order to critically appraise the strengths and weaknesses of a given contract, including its business impact;
- To develop a practical capability to undertake basic drafting of terms sheets for different types of business development agreements

MODULE 5 NEGOTIATION AND INTERPERSONAL SKILLS

MODULE CONTENT:

Unit 1: The Negotiator : Individual Perspectives
Unit 2: Organisational Perspectives
Unit 3: Negotiating Face-to-Face Encounters
Unit 4: Negotiating Faceless Negotiating Encounters
Unit 5: Negotiating Team Encounters
Unit 6: Preparing to Negotiate
Unit 7: Managing the Negotiations

AIMS:

- To provide an introduction to negotiating business development deals in the pharmaceutical and biotech industry
- To provide knowledge and understanding of a range of negotiating styles at a personal and organisational level and how these vary in different cultures.
- To provide knowledge and understanding to critically review and enhance the effectiveness of internal teamwork in the preparation for and the management of negotiations to secure robust deals.
- To provide knowledge and understanding to assess and evaluate the utilisation of basic behavioural models.
- To provide knowledge and understanding to understand, implement and critically evaluate an effective communications programme

OBJECTIVES:

- Develop interpersonal skills sufficient to plan, participate and/or lead and successfully conclude a third party negotiation.
- Develop, utilise and display mastery of a variety of planning tools during the negotiating preparation process phase.
- Demonstrate an ability to understand the negotiation issues being encountered and to critically appraise these issues and provide suggestions how these issues may be dealt with to ensure the negotiation is successfully concluded. achieve key communications skills

MODULE 6 MARKETING AND COMMERCIALISATION

MODULE CONTENT:

Unit 1: Introduction to Sales and Marketing
Unit 2: Marketing Strategies
Unit 3: Market Intelligence and Competition
Unit 4: Marketing Media in Promotion
Unit 5: Price Regulation, Other Forms of Cost Control and Parallel Trade
Unit 7: Generics

AIMS:

- To provide an introduction to the principles of commercialisation in the pharmaceutical industry
- To provide an insight into legislation and codes of practice applicable to the marketing of pharmaceutical products
- To understand the framework for distribution of pharmaceutical products on an international level.
- To develop an understanding of the value of market intelligence, analytical techniques for clinical and pharmaceutical data, especially limitations of the quality of the statistics.
- To provide an appreciation of the marketing practices in Europe, the USA and Rest of the World markets.
- To provide an understanding of the effect on commercialisation of different types of business development deals

OBJECTIVES:

- Undertake a market analysis using different market intelligence sources; to recognise the limitations of data available;
- Review corporate marketing strategy and tactics identifying the strengths and weaknesses of different pharmaceutical businesses and to communicate the information in an appropriate manner;
- Demonstrate ability to develop / recommend a commercial strategy for a new product or technology using a number of methodologies;
- Assess a marketing plan and critically appraise the strengths and weaknesses of an opportunity and understand the inherent risk in deploying different marketing / commercial deal strategies;

MODULE 7 INTELLECTUAL PROPERTY

MODULE CONTENT:

Unit 1: Introduction to Intellectual Property Rights
Unit 2: Patents
Unit 3: Know How
Unit 4: Trade Marks, Branding and Passing Off
Unit 5: Pharmaceutical Associated Intellectual Property Rights
Unit 6: Licensing and Exploitation of Intellectual Property Rights

AIMS:

- To develop an understanding of the value and limitations of IPRs in encouraging innovation with emphasis on the use and application of IPRs in a pharmaceutical and biotechnology business development and licensing context.
- To provide an appreciation of the range of IPRs available to companies and the essential nature of IP in deal structures
- To develop an understanding of the national nature of IPRs and to evaluate the different types IPRs in the product life cycle.
- To provide an appreciation of the costs and benefits of filing maintaining and prosecuting IPRs in different situations.
- To provide an appreciation of role of IP in start up companies and the effect of IP in deal valuations and negotiations
- To provide an appreciation of the issues related to infringement of IP rights

OBJECTIVES:

- On completion of this module the student should be able to: Recognise the limitations of the information available on IPRs, know what questions to ask and to communicate the information in an appropriate manner;
- Demonstrate the ability to produce IP information in order to support a business proposal and to appraise critically the strengths and weaknesses of an IP portfolio including the impact of risk.

MODULE 8 RESEARCH & DEVELOPMENT AND PRODUCTION

MODULE CONTENT:

Unit 1: Drug Discovery including high throughput screening, identifying leads and lead optimisation
Unit 2: Pre-clinical development including toxicology, ADME, animal studies and other pre-clinical work
Unit 3: Formulation, development, stability studies and pilot scale manufacture
Unit 4: Clinical development
Unit 5: R & D Agreements
Unit 6: Secondary Manufacturing
Unit 7: Manufacturing of Biopharmaceutical Products
Unit 8: Quality Assurance, Quality Control and GMP
Unit 9: Manufacturing Considerations for Licence Agreement Terms

AIMS:

- To develop an awareness of the development process for pharmaceutical products with an emphasis on the key issues that are relevant to the negotiation and implementation of licensing and business development deals.
- To understand the resources and operational metrics and norms that apply within companies and the standards that are required to ensure the safe development of new products.
- To understand the manufacturing and logistical issues that has an impact on the supply of pharmaceutical products.
- To understand the impact of the foregoing on business development deals and the success of pharmaceutical companies.

OBJECTIVES:

- To develop an appreciation of the scientific rationale underpinning the different processes and how the results are interpreted.
- To understand and explain the business rationale and key components of the various agreements that are developed to manage and control deals relating to R&D, manufacture and QC
- To have sufficient understanding of the elements of each of the processes and results for R&D, manufacturing and QA/QC to identify the key issues that have to be resolved.
- To demonstrate an ability to understand and summarise the information in order to critically appraise the key issues and provide suggestions how these issues may be dealt with in an agreement
- To be able to explain to a general audience the nature of the R&D, manufacturing and/or QA/QC project, the key issues and how these may be solved
- To be able to communicate to a technical or scientific audience how the terms of their agreements may affect their area of expertise and to discuss and agree with them how the key issues and obligations could be dealt with in an agreement.
- To be able to explain to the legal team how the R&D, manufacturing and QA/QC project and issues may be dealt with in an agreement.

CONTACT

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THE PHARMACEUTICAL LICENSING GROUP

The Pharmaceutical Licensing Group (PLG) has been established for over 25 years in the UK as the professional association for those active in pharmaceutical and biotechnology business development and licensing. It is the premier and original networking group for this industry sector. There are around 200 members in the UK and over a 1000 overseas. All sectors of the industry are represented including multinationals, medium and small pharmaceutical companies, biotechnology, generic and consumer companies. The PLG is a not for profit organisation managed by a committee of licensing and business development executives from member companies.

As a professional association, the Company mission is to provide its members with a forum to meet and discuss matters of general interest, to promote best practice in the profession and to provide training and education in the field of pharmaceutical and biotechnology business development and licensing.

PLG has contracted with Medius Associates Ltd to manage and administer the PLG training courses. Senior licensing executives active in the industry are selected to deliver these courses and all presentations are peer reviewed. To date more than 800 participants have enjoyed the PLG courses since their inception in 1994.

The main rationale for the PLG courses is to enhance the level of professional skill within the industry rather than to promote and deliver courses for commercial gain. This means that there is a limit to the number of delegates per course and the PLG employs a broad faculty of tutors, each an expert in their own field. At the last count this means the PLG delivered a combined 300+ years of business development experience!

APPENDIX 1

This Appendix only applies to formal assignments submitted by students who have purchased individual modules as part of their Continuous Professional Development. If the student has registered with the University of Manchester for a University qualification, the student should refer to the Student Handbook issued by the University.

FORMAL ASSIGNMENTS

Your tutor will set and mark the formal assignments. Formal assignments are intended to represent a significant piece of work and require the candidate to utilise/put into practice the skills and knowledge gained by working through the workbook. Whilst the assignment may require the gathering of data from alternative sources, it will not expect the candidate to use research methodologies. Assessment is based on factual content, logical presentation and the derivation of conclusions or findings. A general marking scheme is shown below.

Dependent on the module you are studying a formal assignment may be one main question or made up of two or three questions. This will be explained on the individual module page.

For all Pharmaceutical Business Development and Licensing modules the word count is 6,000 words (range 5,400 to 7,500). Word counts do not include tables of contents, reference lists or appendices. Text in tables is included. Appendices are not marked; core information must be included within the allocated word limit.

SUBMITTING FORMAL ASSIGNMENTS

Assignments must be submitted by email to your tutor. They must include a cover page with the module title, assignment question and your name. Each topic will be marked on its own merit and a composite mark arrived at. A generalised marking scheme for assignments to give an indication of the levels required for the award of a range of marks is given below.

Relevance to assignment set	15
Accuracy of content	15
Depth of content	30
Use of practical examples	20
Structure/presentation	15
References	5
Total	100

Once your assignment has been marked, you will receive notification of this mark, along with the tutor's comments.

EXCEEDING WORD LIMITS

A fixed penalty system will be applied where a student exceeds the set word count. The reduction of an absolute (not proportional) 10 percent will apply to the assessment only and will be calculated on the final mark awarded for the assessment, so, for example, if the mark awarded for this particular assessment was 60% and the student was over the word limit for this assessment, then the mark awarded will be 50%. If the mark awarded was 71%, the mark will be reduced to 61%.

Word limits should not include text in the bibliography/reference list, figure legends and tables and appendices (if relevant). However, students cannot use figure legends or text within tables to try and side step the word limit (i.e. figure legends and table must be of appropriate length) and must be warned that if they do so they will be penalised.

Penalties:

- Up to 50% over limit: mark reduced by 10%
- over 51% over limit: work will not be marked

Where these mark reductions result in a fail, the unit will be treated as a failed unit.

A marking scheme for assignments to give an indication of the levels required is given below

Classification	Mark as %	Criteria
Distinction	100	Perfect critique with outstanding degree of originality. Provides novel insights, including the ability to apply concepts to related fields.
	80	Excellent, well organised critique with clear evidence of understanding. Contains examples of original ideas and supplementary reading.
	70	Outstanding. Shows clear understanding of topic, examples of supplementary reading and cross-referencing of material. Very well presented.
Merit	69	Very good. Well structured and presented report that is able to convey the central aspects of the tutorial material.
	60	Good. Comprehensive answer with accurate facts but largely limited to material covered in the tutorial class.
Pass	59	
	50	Adequate answer with some errors or omissions. Limited to tutorial class material.
Unacceptable	49	Incomplete/inadequate answer with contains relevant information but demonstrates an incomplete understanding of tutorial material.
	40	Clearly incomplete/inadequate answer with sparse relevant information and poor understanding of tutorial material.
Fail	39	Deficient answer with many inaccuracies and little evidence of understanding of the tutorial topic.
	0	No relevant material presented whatsoever.

REFERENCE SYSTEMS

When writing your assignment, you will be asked to "put references in a uniform acceptable style". This means using a reference system accurately and consistently throughout your piece of work. The system the PLG modules use is the Harvard System:

THE HARVARD SYSTEM

The Harvard System is an author-date system. When a document is cited in the text, the author's surname and the year of publication are included. A full list of the references cited in the text is included at the end of the essay or, in a longer document such as a thesis, at the end of each chapter. The references are presented in alphabetical order by author. If there is more than one publication by the same author, these are arranged by date, with the earliest first. If there is more than one publication by an author in the same year, then a letter is added (e.g. 2005a, 2005b)

Citations in the text:	References at the end of the essay – bibliography:
the study undertaken by Smith[1] (1998) in the north of England.....	SMITH, H.J. (1998) Smith and Williams' introduction to the principles of drug design and action. Harwood Academic
the conclusions drawn by Jones[2] (2003) in a recent paper...	JONES, A. (2003) Combining trastuzumab (Herceptin) with hormonal therapy in breast cancer: what can be expected and why? Annals of Oncology, 14, 1697-704.
whilst Jones[2] found no evidence of	Note that should you refer, for example, to the paper by Jones again in the text, this is done in just the way as the first time.