MSc course in Pharmaceutical Business Development & Licensing

COURSE PROSPECTUS

providing continuous professional development
CONTENTS

MSC Course in Pharmaceutical Business Development & Licensing ................................................. 4
  Course Objective ................................................................................................................................. 4
  Academic structure ............................................................................................................................. 4
  Success options ................................................................................................................................. 4
  Course content ................................................................................................................................. 5
  Potential participants ......................................................................................................................... 5
  Tutors .................................................................................................................................................. 5

Frequently Asked Questions .............................................................................................................. 8
  How did the concept for the course evolve? ......................................................................................... 8
  Can I Purchase and Study Individual Modules only? ......................................................................... 8
  When do the modules start? ................................................................................................................ 8
  How long will each module take? ........................................................................................................ 8
  What are the Course Materials like? ................................................................................................... 8
  How is the Directed Learning and Direct Contact Hours organised? ................................................ 8
  What are the Academic Course Requirements? ................................................................................ 9
  Is CPD required in business development and licensing? ................................................................. 9
  What are the responsibilities of the registered students? ................................................................. 9

Course Module Outlines ..................................................................................................................... 10
  Module 1: Introduction to the Healthcare Industry ............................................................................ 10
  Module 2 Business Development Operations .................................................................................. 11
  Module 3 Financial Aspects of Business Development & Licensing ............................................... 12
  Module 4 Legal Issues in Business Development Contracts .......................................................... 13
  Module 5 Negotiation and Interpersonal Skills ................................................................................ 14
  Module 6 Marketing and Commercialisation ................................................................................... 15
  Module 7 Intellectual Property .......................................................................................................... 16
  Module 8 Research & Development and Production ....................................................................... 17

Application and Guidance notes ........................................................................................................ 18
  How do I apply? ................................................................................................................................. 18

CONTACTS: ......................................................................................................................................... 18
  The University of Manchester ............................................................................................................ 19
  The Pharmaceutical Licensing Group ............................................................................................... 19
MSC COURSE IN PHARMACEUTICAL BUSINESS DEVELOPMENT & LICENSING

The Pharmaceutical Licensing Group’s MSc programme is a modular based distance learning MSc in Pharmaceutical Business Development which is part of the University of Manchester’s Pharmaceutical Industrial Advanced Training (PIAT) programme. It is designed to provide high level training for executives working in the pharmaceutical, biotechnology and related industries. This course offers a range of accredited distance learning modules all taught at Masters level, which can be studied independently or sequentially to secure a full MSc qualification.

Each module provides a general review of the concepts underpinning the subject and specific applications in the bioscience industry with an emphasis on applications in business development. As such it provides the student with a unique insight into the scientific, operational and commercial aspects of the industry. The modules are regularly updated to incorporate the latest information to provide the best facility for knowledge transfer and thought leadership.

The modules are written by authors with extensive experience in the healthcare industry. They include informal assignments that are marked by the tutors and provide the student with the opportunity to test their understanding and knowledge. Each module is assessed by a 6,000 word Formal Assignment.

COURSE OBJECTIVE

To provide a series of educational modules that will allow practitioners to undertake accredited postgraduate and continuous professional development in the fields of business development and technology transfer that could lead to a certificate, diploma or MSc for successful participants.

The University of Manchester provides appropriate quality assurance for course provision and staff. The course faculty are all experienced business development professionals.

ACADEMIC STRUCTURE

Each module merits 15 MCAT points and comprises 150 hours; consisting of 10 direct contact hours, 70 hours directed [distance] learning and 70 hours individual private study.

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

Two course leaders lead the MSc course, an industry business development professional in parallel with a University staff member. Each module also has a Module Leader responsible for the academic quality of the module and an individual tutor.

The company Medius Associates Ltd is contracted by the PLG UK Ltd to manage and administer its training programmes.

SUCCESS OPTIONS

1 module : Continuous Professional Development (CPD) recognition
4 modules : Post Graduate Certificate
8 modules : Diploma
8 modules + dissertation : MSc in Pharmaceutical Business Development & Licensing

To receive a Certificate, one needs to succeed in 4 modules from a choice of 8 basic modules. For a Diploma all 8 modules need to be passed and for an MSc there is a requirement for an additional 60 unit Research Project dissertation.
COURSE CONTENT
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

POTENTIAL PARTICIPANTS
The course has a broad appeal as noted below:

- Industry business development executives at all levels
- Graduates seeking a career change
- Academic Technology Transfer staff
- Financial Analysts [Specific modules only]
- Health care lawyers [Specific modules only]
- Patent agents [Specific modules only]
- Alliance managers
- Other industry executives seeking an understanding of specific subject areas e.g. IP, Legal, Finance

TUTORS
JOHN ANSELL  John Ansell is a pharmaceutical industry consultant based in Thame, near Oxford, UK. He concentrates on international projects with a commercial and strategic emphasis, reflecting his previous industry experience. A biochemistry graduate with an MA in business studies, John Ansell’s 20-year career in the UK and Holland included positions with Organon, Schering AG, Fisons, Solvay and Glaxo Holdings. Subsequently, John is the author of over 40 articles and reports on strategic industry issues. John was a long-standing member of the Editorial Advisory Board of the US journal Pharmaceutical Executive (1990-2002), and has been Chairman of the Advisory Board of Decision Resources since its inception in 2005.

TONY BRATT  Tony is an experienced biopharmaceutical executive with an outstanding track record in leadership, strategic marketing and tactical implementation across the full product life cycle in orphan, specialist and mass markets within Europe. His experiences include business planning, new product launches & market shaping, portfolio management, strategic and local alliances and partnership management.

PETER COZENS  Peter is CEO of ProPharma Partners Limited, a European partner of an established San Francisco Bay Area consultancy, ProPharma Partners Inc. Peters has extensive experience in International Pharma licensing, working for major pharma companies including Medeva and Wellcome during his career.
SHARON FINCH
Sharon Finch is the CEO of Medius Associates, a specialised pharma business development consultancy group. Sharon has more than 30 years proven experience in business development having worked in-house at the Wellcome Foundation, Medeva plc and Ono Pharmaceutical Co. Ltd. prior to founding Medius in 1994. Sharon is Editor of the Business Development & Licensing Journal and the Course Director for the MSc in Pharmaceutical Business Development and Licensing run at the University of Manchester. She is also a past Chairman of the UK Pharmaceutical Licensing Group Ltd, a past President of the European PLG Council and a member of the LES Healthcare Committee in the UK.

ROGER DAVIES
Roger Davies works as a consultant in pharmaceutical licensing and business development. Having personally completed over 80 deals he specialises in valuations, deal structuring and negotiating licensing and acquisition deals. He is a former Chairman of the UK Pharmaceutical Licensing Group, the professional association of licensing and business development executives and is the Finance module leader for the Business Development MSc at the University of Manchester. He was formerly the Group Director of Licensing and Business Development at Bioglan Pharma Plc where he was responsible for the global licensing and acquisition of products and drug delivery technologies as well as European distributors and the Legal department. Prior to joining Bioglan in 2000, Roger was employed at Mundipharma International for 10 years as Director of International Business Development where he was responsible for product and company acquisitions/disposals, inward and outward product licensing and European pricing. Roger has a Masters degree in Economics.

MIKE HERMAN
Mike Herman is a consultant on Accounting and Finance. His current responsibility are: Post graduate diploma and MBA workshops, In-company training courses as consultant for RDI Ltd., Coventry. He has lectured extensively for various Universities including Nothampton, Leicester, Coventry and Manchester.

KLAUS MALECK
Klaus is Chairman of the Supervisory Board European Screening Port GmbH, Hamburg. He is a past executive board member at Evotec and BioGenerix AG. He has lecturer at the University of Applied Science, Mannheim Germany.

PAUL RANSON
Paul spent the early part of his career as an in-house lawyer for Smith Kline and Merck Sharpe & Dohme. He is a specialist in the commercial business development and regulatory aspects of the above industries. He has written and lectured extensively in legal issues for the sector including on licensing and outsourcing within the field. His publications include six report-length papers for the FT, Bridgehead and Legalease. He is also Head of the Editorial Board of Health Science Law and Business (Legalease). He is on the Legal Issues Committee of the ABHI and has been a member of a local 7 Ethics Committee for five years.

STEPHEN REESE
Stephen is a Partner in Olswang's Intellectual Property Group and leads its Life Sciences practice. Stephen advises clients on both contentious and non-contentious intellectual property matters including patents, trade marks, trade secrets and copyright. He represents and advises a broad range of clients in relation to the protection, exploitation and enforcement of their intellectual property rights. Stephen is currently an examiner for one of the papers for CIPA (Patent Attorneys) and ITMA (Trade Mark Attorneys) students and has given many external lectures on topics including IP audits, co-marketing and co-promotion agreements, research and development contracts and injunctions.
TIM SAMPSON  Tim qualified as a Barrister in 2000 and his practice now covers all aspects of UK and European intellectual property law, competition law, biotech commercialisation and bio-regulatory matters, as well as more general commercial litigation. His experience includes dealing with matters before the High Court, the Technology and Construction Court and the Court of Appeal in the UK, as well as the European Patent Office and OHIM. Prior to becoming a barrister Tim took a B.Sc.(Hons) in Molecular Biology & Biochemistry, at Durham University and a Ph.D. in Biochemistry at the University of Cambridge; where he carried out research into the insect receptor proteins for Bacillus thuringiensis delta-endotoxins.

ALAN WARRANDER  Alan Warrander has over 25 years wide-ranging experience in the Pharmaceutical Industry having worked both in Pharma companies and as a Consultant. Until the end of 2007, Alan was Senior Vice President, Life Sciences at Wood Mackenzie, the global consultancy firm where he provided consultancy advice and expert scientific opinion to Pharma, Biotech companies, Finance groups and Law firms primarily in the areas of Partnering, Due Diligence and Strategic Planning. Alan was also responsible for the production of a number of Expert Reports on a range of companies in support of potential AIM flotations. His academic background is in Xenobiotic Metabolism, with a PhD from Birmingham University and a BSc in Chemistry and Biochemistry from St Andrews. He is a recognised conference speaker having being invited to present on various aspects of Partnering and Due Diligence.

KEITH WILLIAMS  Keith is a Global Product Director with 30 years experience in both clinical development and coordination of development programs, having experience of all stages from research through to product launch and life cycle management. Earlier career demonstrated expertise in cystic fibrosis, meningitis, haematology, oncology, rheumatoid arthritis, urinary incontinence and cardiovascular drugs, along with paediatric studies and patent exclusivity. More recently has led multi-functional global teams in the pre-clinical development of antimicrobials.

MARK WILSON  Mark Wilson has worked for GlaxoSmithKline and its predecessor companies for 16 years and has experience of both manufacturing and development in relation to primary processing, secondary processing and large-scale antibiotic production. He has worked in a licensing role for several years and has negotiated and managed hundreds of collaborative development deals for a technology incubator within GSK that is focussed on novel secondary processing approaches. In relation to compound licensing, he has been an expert pharmaceutics reviewer on several due diligence visits, has co-drafted internal guidelines on negotiation approaches with regard to manufacturing and pre-clinical development activities, and has advised on such matters on approximately 30 major compound licence negotiations.
FREQUENTLY ASKED QUESTIONS

HOW DID THE CONCEPT FOR THE COURSE EVOLVE?

The course was developed by the Education Board of the Pharmaceutical Licensing Group UK Ltd (PLG), the professional association for people involved in business development and licensing. The PLG has been running professional training courses since 1994 and the development of a distance learning formal qualification was a natural development from its Introductory and Masterclass training courses.

The PLG Education Board, consists of Professor Bill Dawson [previously Technology Acquisition Director of Lilly], Roger Davies [formerly Business Development Director at Bioglan and Mundipharma] and Sharon Finch [CEO Medius Associates Ltd]. The design of the modules involved broad consultation with both academics and industry major pharma companies such as AstraZeneca, Merck, Pfizer et al. Once the course outline had been designated, industry module leaders were appointed to determine the precise content of each module.

CAN I PURCHASE AND STUDY INDIVIDUAL MODULES ONLY?

Yes, any of the PLG modules can be bought and studied as part of your personal development training without studying for a Diploma, Certificate or MSc qualification. Individual modules can be purchased via the PLG online store.

WHEN DO THE MODULES START?

The PLG modules can be studies at any time suitable to the applicant. It is expected that each module will be taken in sequence, not in parallel. If working towards a certificate, diploma or full MSc, it is strongly recommended that Module 1 (Introductory) is studied first, as it provides a useful framework for the course and also provides familiarisation with distance learning.

HOW LONG WILL EACH MODULE TAKE?

It is anticipated that each module can take up to four (4) months to complete, however it could be possible to finish the entire eight (8) modules in two years and then there is the additional 600 hour project (dissertation) required to complete the MSc. There is a time limit of nine (9) months to submit Formal Assignments and 1 year to complete the module (including marking); 4 years to complete the Diploma (8 modules); and 5 years for the complete MSc.

WHAT ARE THE COURSE MATERIALS LIKE?

At present the course materials are printed workbooks, supported by backup materials available on line. Some of the assignments may also be run on an interactive basis. Students will have full access to the facilities on the PLG Masters website, including access to the MSD Library for reference materials.

HOW IS THE DIRECTED LEARNING AND DIRECT CONTACT HOURS ORGANISED?

Directed Learning and direct contact hours have been arranged to take account of the fact that most people will be studying on a distance basis. There are seventy (70) hours directed learning achieved via studying the course module materials (hard copy files and CDs), there is then a further seventy (70) hours private study required for reading around the subject matter, private research and the time required to complete the assignments.

The assignments will vary from module to module, reflecting the nature of the subject but all assignments will be relevant to day-to-day business development and licensing activities. Direct contact time will be in the form of 3-4 hour teleconference calls with tutors of individual modules. In addition there are annual workshops for the individual modules, held in London usually during the first week of December.
WHAT ARE THE ACADEMIC COURSE REQUIREMENTS?

Access to study is open to all. There are no special entry requirements if you want to study just individual modules as part of your personal development programme.

All modules require some work and experience within the industry of not less than 3 years.

To study for a Postgraduate Diploma or the MSc degree you should have a relevant degree level qualification. If you do not already have the required qualifications to study for the Postgraduate Diploma, you can join this programme when you have proved your ability by earning four module credits.

Students whose first language is not English require a minimum IELTS overall score 6.5 and 6.0 in writing, or TOEFL 575 (paper-based) 230 (computer-based) or 90 (internet based).

IS CPD REQUIRED IN BUSINESS DEVELOPMENT AND LICENSING?

So far, CPD (Continuous Professional Development) is recognised in the legal profession but is not a formal requirement in pharmaceutical business development. Most companies recognise the need for continuing professional development but do not insist on a formal programme of training.

WHAT ARE THE RESPONSIBILITIES OF THE REGISTERED STUDENTS?

If studying for the Postgraduate Diploma or the MSc degree, each individual will be registered as a student of the University. There are tutors and mentors allocated to each student to assist them with their study programme. It is for individuals to pursue the course at their own pace. Each student has the option of enrolling for a single module, the whole MSc course, the Certificate (four modules) or the Diploma (eight modules).
COURSE MODULE OUTLINES

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.
APPLICATION AND GUIDANCE NOTES

HOW DO I APPLY?
Application details and supporting documentation can be downloaded from The University of Manchester Postgraduate website:
http://www.manchester.ac.uk/postgraduate/taughtdegrees/courses/atoz/02310/pharmaceutical-industrial-advanced-training-piat/

APPLICATIONS MUST INCLUDE:

1. Two satisfactory references, on official headed paper which also must be signed and dated (if applying for MSc or Diploma)
2. A copy of your degree certificate(s)
3. Evidence that you have achieved the required level of proficiency in the English language if English is not your first language
4. Confirmation of Funding (including your company’s VAT number)

CONTACTS:

Linda Sterrett
PLG Course Administrator
PLG Masters
47 Upfield
Croydon
CR0 5DR
U.K.

linda@plgmasters.com
Tel: +44 (0) 20 8654 6040
Fax: +44 (0) 20 8654 6046

Isabelle McGilvray
PIAT, School of Pharmacy & Pharmaceutical Sciences
The University of Manchester
Room 1.19f, Stopford Building
Oxford Road
Manchester M13 9PT
U.K.

piat@manchester.ac.uk
Tel: +44 (0) 161 275 1797
Fax: +44 (0) 161 275 1799

www.plgmasters.com

www.mhs.manchester.ac.uk/postgraduate/programmes/taughtmasters/piat/
THE UNIVERSITY OF MANCHESTER

Pharmaceutical Industry Advanced Training (PIAT)

The School of Pharmacy and Pharmaceutical Sciences is dedicated to excellence and innovation in research and teaching. In the latest Research Assessment Exercise in 2001 – a comprehensive national evaluation of research carried out in all UK universities – the School achieved a top score of 5*. The School’s teaching was awarded the maximum possible score of 24 points for its undergraduate programme by an independent, nationally appointed subject review panel. The School is also consistently ranked as one of the best in the country by the newspaper league tables.

This high standing reflects the high quality and commitment of the School’s academic and support staff. The School gains enormously from its position, unique within the UK, as part of a faculty comprising all the health professions, and from being part of the one of the largest universities in Europe, with excellent schools in the biological, physical and social sciences. It also benefits by having strong links with industry.

The School of Pharmacy is marked out by its commitment to advance training and research in all aspects of the design, development and use of medicines, for the benefit of patients.

It is an exciting time for the School in its work on the design and development of medicines, with rapid advances arising out of the human genome programme, in chemistry, material science and informatics. There is the prospect as never before of tailoring medicines to the individual patient.

THE PHARMACEUTICAL LICENSING GROUP

The Pharmaceutical Licensing Group (PLG) has been established for over 30 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!