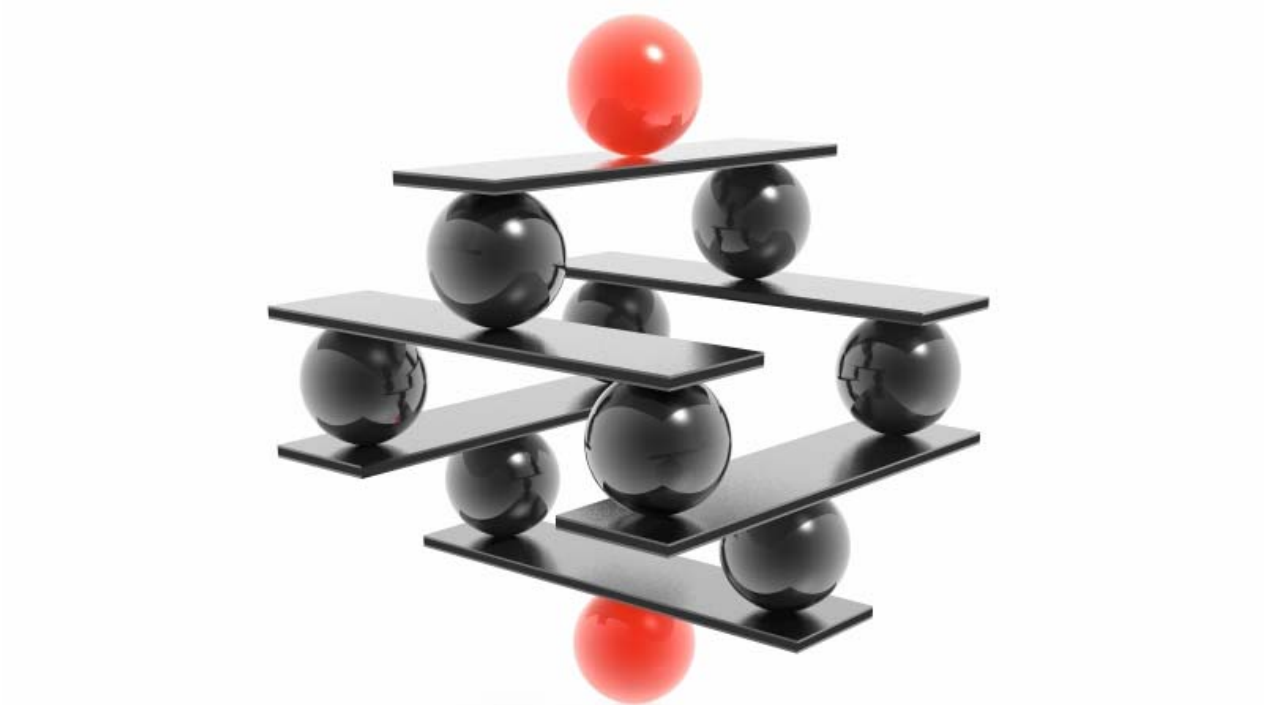
MANCHESTER 1824
The University of Manchester

MSc, Diploma or Certificate in Pharmaceutical Business Development & Licensing



COURSE PROSPECTUS

PLG
pharmaceutical licensing group

providing continuous professional development

CONTENTS

MSC, DIPLOMA OR CERTIFICATE IN PHARMACEUTICAL BUSINESS DEVELOPMENT & LICENSING

The Pharmaceutical Licensing Group in conjunction with the University of Manchester runs a modular distance learning course which can result in an award of an MSc, Diploma or Certificate in Business Development in the healthcare industry.

This course offers a range of modules which can be studied sequentially to secure a full MSc qualification (eight modules completed in four years, plus an extra year for dissertation), a Diploma (eight modules completed in four years) or a Certificate (four units completed in two years).

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, students need to succeed in 4 modules from a choice of 8 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

FREQUENTLY ASKED QUESTIONS

HOW DID THE CONCEPT FOR THE COURSE ARISE?

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, specialist module leaders from industry and the profession were appointed to write and teach the precise content of each module.

WHAT ARE MY OPTIONS TO STUDY?

Students have two options, either to register with the University of Manchester to study for a Postgraduate Certificate, Diploma or MSc, or purchase individual modules for CPD (Continual Professional Development) via the PLG Masters website.

DO I RECEIVE TEACHING SUPPORT IF I BUY AN INDIVIDUAL MODULE FOR CPD

Yes, purchase of an individual module has the same teaching support as for modules purchased for a University qualification.

WHEN DO THE MODULES START?

If working towards a Certificate, Diploma or full MSc the student needs to be registered with the University of Manchester where the student intake is in April and October each year. Purchase of individual modules for CPD can be made at any time.

HOW LONG WILL EACH MODULE TAKE?

It is anticipated that each module can take approx. 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 9 months to submit Formal Assignments and 1 year to complete each module (including marking); 4 years to complete the Diploma (8 modules); and 5 years for the complete MSc.

WHAT ARE THE COURSE MATERIALS LIKE?

The course materials are available for all students on the PLG Masters website as pdf documents, with supporting materials in Microsoft Excel, Word or Powerpoint files. Students registered with the UoM also receive a printed workbook.

Students will have access to the module support materials on the PLG Masters website, including access to the PLG Library for reference materials. Students registered with the University of Manchester also have access to the University of Manchester library.

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 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 Certificate, Diploma or the MSc degree you should have a relevant degree level qualification. If you do not already have the required qualifications, 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).

IF I BUY A CPD MODULE, CAN I AT A LATER DATE GO ONTO STUDY FOR A CERTIFICATE, DIPLOMA OR MSC AS A STUDENT OF THE UNIVERSITY OF MANCHESTER?

Yes, provided that you pass the Formal Assignment on the modules purchased and do not buy more than 3 individual modules and within 3 years. Passed formal assignments will count towards your University of Manchester qualification (Certificate, Diploma or MSc.)

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 GUIDANCE

HOW DO I APPLY?

To apply for a full MSc, Diploma or Certificate from the University of Manchester, complete and submit an online application via the University of Manchester's PIAT website:

https://www.bmh.manchester.ac.uk/pharmacy/study/masters/piat/?pg=4#course

The page includes overview of the courses, entry requirements, application and selection and full course details. Choose application and selection to begin the online application process.

To apply for individual CPD modules, individual modules can be purchased online via the PLG website:

http://plg-group.com/training/master-of-science-msc/how-to-apply/

CONTACTS:

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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 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!