

MSc course in Pharmaceutical Business Development & Licensing

COURSE PROSPECTUS

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MSC COURSE IN PHARMACEUTICAL BUSINESS DEVELOPMENT AND LICENSING

The Pharmaceutical Licensing Group has introduced a new modular text based distance learning MSc in Business Development which is part of the University of Manchester's PIAT programme. This course offers a range of modules, which can be studied independently or sequentially to secure a full MSc qualification.

Course Objective

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

The University 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 Training Ltd is contracted by the PLG to manage and administer its training programmes.

Success options

1 module	CPD recognition
4 modules	PG Certificate
8 modules	Diploma
8 modules + dissertation	MSc

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.

Course content

Module 1	Introduction to the Pharmaceutical Industry
Module 2	Business Development Operations
Module 3	Financial Aspects of Business Development and Licensing
Module 4	Legal Aspects and Intellectual Property Rights
Module 5	Interpersonal Skills and Negotiation
Module 6	Product Marketing and Commercialisation
Module 7	Intellectual Property Rights
Module 8	R&D and Production

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

Frequently Asked Questions

How did the concept for the course arise and who has been involved in the design of the modules?

The course was developed by the Education Board of the Pharmaceutical Licensing Group, 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 Advanced training courses.

The course modules were developed by the PLG Education Board, which 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, Non Exec Chairman of PLG UK]. The design of the modules involved broad consultation with both academics and industry major pharma companies such as AZ, Merck, Pfizer et al. Once the course outline had been designated, industry module leaders were appointed to determine the precise content of each module.

When do the modules start?

It is expected that each module will be taken in sequence, not in parallel; it is strongly recommended that the Introductory module (1) 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?

The course is run as distance learning and it is anticipated that each module can take approx four [4] months to complete. It is therefore 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 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 paper, PDF and CD based but some of the assignments may be run on an interactive basis. Students will have full access to the facilities on the PLG Masters website, including chat rooms, discussion groups and MSD Library for reference materials.

How is the directed learning and direct contact hours organised?

In respect of the direct contact hours, these have been arranged to take account of the fact that most people will be operating on a distance basis. There are seventy [70] hours directed learning achieved via studying the course module materials [hard copy files and CDs], which are despatched to each student on registering for that specific module. 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 and materials for these calls will be sent out in advance.

What are the academic course requirements?

Entry requirements to the course are an appropriate degree or relevant industrial experience of not less than three years.

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 pharma 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?

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

AIM

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

OBJECTIVES

This module aims to provide the foundation knowledge for business development personnel to understand the basic framework of the pharmaceutical industry.

To develop a general awareness of the healthcare industry with emphasis on the role of business development and the contribution made by licensed products to companies' success.

To analyse company strategies and the different roles of business development in the various types of company, both public and private.

To understand the business development operational metrics and norms within companies and the ethics of being a *Partner of Choice*.

MODULE CONTENT

Industry overview and historical perspective

This Unit reviews the growth of the industry from its origins in traditional therapies. It charts the role of pharmacists in the development of the drug industry and the progression from the antibiotic revolution through the emergence of biotechnology to the current trend of industry consolidation.

A major industry? Facts and figures

Unit 2 addresses the economics and statistics underpinning the pharma industry and considers R&D investment and expenditure in depth. The major players, key pharma markets and the importance of blockbuster drugs are reviewed as well as the role of the generics industry in delivering cost effective medication to the masses. The role of government and industry organisations such as ABPI, JPMA is also considered.

The structure of healthcare systems

The finances behind the markets are reviewed in Unit 3 with the role of mechanisms for control of healthcare expenditure via NICE, pharmacoeconomics and the fourth hurdle. The influence of non-governmental organisations [NGOs] and patient advocacy groups are assessed.

Drug Discovery

Are there any remaining unmet therapeutic needs? This Unit studies the current aims of drug discovery and issues around testing and safety and the ethics of using animals in research. The Human Genome Project and the role of genomics and informatics are also evaluated.

Clinical development

Unit 5 addresses the costs of clinical development and the need for paediatric trials. Study design, clinical trial ethics, safety assessment of marketed medicines and health economics are considered. The current drive for outsourcing of clinical trials and transparency is also considered.

Regulatory Issues

The role and organisation of the MHRA, EMEA and FDA

Role of business development : Company strategies and market dynamics

A review of corporate development from start up to mid cap. The potential role of biotech's as engines for R&D. The need for alliances or acquisitions in managing product life cycles and planning the portfolio.

The Industry in the future

Where will the industry go in the future - continuation of mega-mergers? What is the role remaining for mid caps companies? What are the new market trends, are there any more new niche markets? Disease trends – the emergence of AIDS, SARS, the next flu pandemic. Cost containment measures, the role of the public, direct to consumer and internet marketing.



Module 2 :

BUSINESS DEVELOPMENT OPERATIONS

AIM

- To introduce the framework for the development and manufacture of medicinal products on an international level.
- To understand the relevant regulatory processes which are applicable to medicinal products in the United Kingdom to that of the relevant European Union Directives.
- To provide an appreciation of the role of business development within the corporate structure

OBJECTIVES

On completion of this module the student should be able to:

- assess and evaluate the management of due diligence systems

MODULE CONTENT

Introduction and Overview of the Licensing Process

This unit considers the corporate culture, strategy and attitudes.

An appreciation of the role of business development within the corporate structure, business development fit with corporate strategy, reporting relationships of business development and relationships to other functions e.g. research, medical and commercial. The basic partnering process – terminology, definitions and scope of the licence : research aspects, products and technologies. Standard operating procedures for in-house operation of the licensing function. Company attitudes and the metrics of success.

Due Diligence

Operations - planning the process; selecting the team, team roles and essential skills : building the team. Planning the timetable, defining the objective and identifying key decision points. Finding major issues and the optimal position; alternative strategies. Triage and resourcing for the entire process. Communications and use of checklists.

Intellectual Property Rights , Legal and Corporate due diligence

Security of the rights, which hold the most relevance – patents, trademarks, copyright, know how. Duration of rights, SPCs, enforcement and infringement . Freedom to use. Confidentiality and ownership. Product liability.

Scientific and regulatory due diligence

Questioning the scientific rationale, the quality of the data package. Clinical and development strategy, regulatory hurdles. Formulation and manufacturing, issues around drug delivery.

Commercial and Financial due diligence

Establishing the market potential and undertaking competitor assessment. Agreeing a baseline for valuation of products / technologies and the financial assessment of the opportunity. Employing risk assessment. Reviewing the financial impact of different deal structures and adjusting the package to accommodate risk. Targets and benchmarking

Regulatory Affairs

The role and organisation of the MHRA, EMEA, VMD, DMRC. Basic process, compliance, inspections.

Manufacturing

Optimisation of process, pilot scale, paper trials, batch to batch consistency, CoGs and potential for savings. Inspections of premises, security of supply. Access to know how.

Technology Transfer

The role of the due diligence process, deployment and use of checklists. Science and enabling technology, delivery technologies. Monoclonal antibodies and gene technology

Technology transfer from academia and biotech companies to majors.

The Academic : Industry interface. Science, technology, product or validation or any combination. Company:company interface. Big Pharma:SME; SME:Big Pharma; either:niche

Alliance Management

The emergence of Alliance Management in major companies. The process of implementation, critical path analysis, successful project management and review of experiences. Managing failure when problems occur. Auditing the success of agreements and the licensing function. Applying performance criteria, termination of agreements



Module 3 :

FINANCIAL ASPECTS OF BUSINESS DEVELOPMENT & LICENSING

AIM

- 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

On completion of this module the student should be able to:

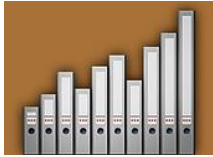
- Recognise the key components of published corporate financial information and distinguish between their principal functions whilst reviewing the key conceptual issues which underpin the production of the information;
- Undertake a range of calculations to demonstrate the financial strengths and weaknesses 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 CONTENT

As for all of the modules, the assignments will be directly related to the business development role and will include proposals of financial deal terms for case studies as viewed from the buyers/licensees and sellers/licensors perspectives.

This module will cover the following areas : -

- Basic financial concepts including profit and loss account, balance sheet, cash flow and funding, financial performance ratios, accounting standards and their effect, tax and currency.
- Financial modelling together with sales forecasting techniques for different types of deals, pharmaceutical pricing systems, cost of goods (including full versus marginal costing), operating costs (including sales and marketing, production and R&D), amortisation and depreciation, tax considerations, working capital and capital expenditure, cash flow, discount rates and terminal values.
- Financial deal terms for different types of deals from the viewpoint of both the buyer and seller, public and private company considerations, upfront and milestone payments including conditionality, sales threshold payments, R&D funding and third party costs, royalties, equity investment and loans
- Valuation methods and management of risk, overview of valuation methods, asset acquisition and disposal valuations, payback, discounted cash flow, net present value and internal rate of return, overview of risk management, multiple scenarios, Monte Carlo analysis, decision analysis, option valuations, share of deal value between each side
- Other financially related deal terms, net sales definitions, performance measurements, hardship clauses, audit provisions, supply and currency, termination and buy back provisions
- Trends in deal values and real life examples of company and product/asset acquisitions and disposals, patent and platform technology and drug delivery licensing, early stage product licensing and co-development, clinical stage product licensing and co-development, distribution, co-promotion and co-marketing and generic deals, joint ventures and profit sharing deals.



Module 4 :

LEGAL ISSUES IN BUSINESS DEVELOPMENT CONTRACTS

AIM

- To provide an insight into applicable legislation.
- To understand the relevant legislation applicable to medicinal products in the United Kingdom to that of the relevant European Union Directives.
- To provide an appreciation of the basic legal concepts English and European legislation

OBJECTIVES

On completion of this module the student should be able to relate applicable European legislation to medicinal products produced in the UK

MODULE CONTENT

Types of Agreements

This section reviews the ranges of agreements deployed in business development :

- Confidentiality Disclosure Agreements - key clauses – parties, housekeeping
- Material Transfer Agreements - Standard clauses
- Collaboration agreements - key clauses
- Intellectual Property – foreground and background rights, joint patents,
- Definitions of scientific success, Lambert agreements
- Contract research and outsourcing - standard clauses and deliverables
- Option agreements and pre agreement commitments : their use to manage risk in early stage partnering.
- Standard formats, letters of intent in particular binding and non-binding elements
- Supply and distribution agreements; wholesale dealers and importers legislation.
- Standard terms, floor prices and exchange provisions
- Licence agreements : grant of rights, Intellectual Property Rights, strategy and management and commercial terms

Contract Issues

This section addresses key areas for contract negotiation.

- Product liability - who holds liability?
- Insurance and paper trails to manufacturers.
- Pharmacovigilance
- Performance issues - what are the commonly used performance criteria for R&D and in the marketplace. How these can be measured and enforced
- National, Regional and Global considerations – variations in local law and the choice of law in contracts
- Competition Law - EU competition law, in particular articles 81 and 82 and the implications of these in licensing agreements.
- Block exemptions and the measurement of market share.
- Fines and penalties and US antitrust law.
- Product Divestment
- Technology transfer;
- Intellectual Property strategy and management.



Module 5 :

NEGOTIATION AND INTERPERSONAL SKILLS

AIM

- To provide an introduction to negotiating business development deals in the pharmaceutical and biotech industry
- To provide an insight into behavioural models
- To develop an understanding of communication techniques

OBJECTIVES

On completion of this module the student should be able to:

- engage in negotiations
- understand basic behavioural models
- communications

MODULE CONTENT

- Managing the Negotiating Process including Internal Negotiations
- Negotiating Techniques and Behaviour
- Negotiating Media
- Cross Border Negotiations



Module 6:

MARKETING AND COMMERCIALISATION

AIM

- 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

To provide an introduction to the principles of commercialisation in the pharmaceutical industry and an appreciation of the marketing practices in Europe, the USA and the Rest of the World markets.

To provide an insight into legislation and codes of practice applicable to the marketing of pharmaceutical products and understand the framework for manufacture and 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.

MODULE CONTENT

Introduction

Global marketing, corporate spend on sales and marketing, deployment and typical size of sales forces.

Contribution made by in licensed products. Constraints on advertising, codes of practice. Comparison of US and European practices. Emergence and value of rest of world markets, accessing global markets.

Marketing Strategy

Criticality of successful product launches and brand management strategies. Current practices in life cycle management including evergreening, development of new formulations and presentations, extending indications. Market intelligence and competition analysis. The range of forecasting data sources, strengths and weaknesses of various sources. Forecasting scenarios including the strength and weighting of key assumptions.

Marketing media

The role of the sales force and its importance to maximising return on product investment. Effective sales force sizes and costs, call rates, the required levels of investment in sales and marketing.

This unit will also include a review of the types of sales force deployed including the use of mirror sales forces and support by additional contract sales forces.

The role of advertising in product marketing, levels of spend on advertising and promotion, launch campaigns and advertising through the product life cycle will be addressed.

The role of support literature, journal & direct-to-consumer advertising and media relations is reviewed. Other key issues such as sampling, mailings and e-promotion, media and e detailing are also included as well as the increasing importance of public relations.

Business Development - Commercial deals

Principles of portfolio analysis – balancing the local portfolio and the flow of products from corporate sources [both R&D and in licensing]. This unit will also include an introduction to the role of strategic the value of alliances and a detailed review of key deal types used to maximise sales of products such as Co-marketing/ Co-promotion and Product Fostering. Product licensing, product acquisition and product divestment will also be addressed.

Distribution and other industry issues

In this unit the value and importance of supply and distribution agreements to reach into rest of the world markets will be reviewed. Accessing distribution channels, wholesale dealers and importers will also be addressed. Key factors such as parallel imports and pricing and reimbursement issues such as NICE, PPRS and reference pricing will be considered in detail. The impact of generics and biogenerics and parallel imports on life cycle management will also be reviewed.



Module 7 :

INTELLECTUAL PROPERTY

AIM

This module introduces the concept of intellectual property and reviews the strategic issues that companies face as part of their intellectual asset management. It also reviews the legislative framework and the key intellectual property treaties on an international basis.

In this Unit, students will gain an appreciation of the value and relevance of know how as a key part of a company's IPR portfolio. This Unit reviews the role of trade marks in pharmaceuticals. In addition, the procedures for filing, prosecution and maintenance are addressed

OBJECTIVES

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

MODULE CONTENT

IPRs

This section considers the importance of IP as the basic currency of licensing deals.

- Intellectual Property - understanding the legal basis of IPRs.
- IP Strategy : national, regional and global considerations, ring fencing and developing IP portfolios

Patents

- The main patent systems of the world - PCT, EP, US, JP
- Filing, prosecution and grant procedures and associated costs
- Enforcement; inventor ship and ownership

Trade marks

- The value of brands; filing procedures and costs
- Know how – the importance in early stage deals, confidentiality
- Design and copyright in packaging and PILs



Module 8 :

RESEARCH & DEVELOPMENT AND PRODUCTION

AIM

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 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 have 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.

MODULE CONTENT

Molecular Development

- HTS
- Lead optimisation
- Exploring SARs
- Identifying the lead
- Pilot scale manufacture
- Manufacturing of NCEs – developing new synthetic pathways

Pre clinical development

- Toxicology
- ADME
- Animal models
- Other pre clinical studies

Regulatory Affairs

- Regulatory issues in the USA
- Regulatory matters in Japan
- Regulatory issues in RoW.

Clinical Development

- Phase I development
- Phase II development
- Phase III development
- Choosing comparator products for phase III
- Phase IV studies
- ADR reporting
- Pharmacovigilance agreements

Pharmaceutical Development

- Developing a viable formulation
- Stability studies and accelerated studies.
- Overage and filling.

Manufacturing and Logistics Issues

- Batch to batch consistency
- Acceptable commercial yields
- Manufacturing of biologicals – contamination
- Quality control procedures
- Developing manufacturing and product specifications
- Cold chain supply
- Distribution logistics
- Warehousing
- Technical agreements

APPLICATION AND GUIDANCE NOTES

How do I apply?

It is vital that you read and understand all of the information for your chosen course of study before you apply. When you have done this you are ready to start filling in the application.

Application forms and supporting notes can be downloaded from the PLG Masters Website or The University of Manchester Post graduate website :

www.plgmasters.com

www.manchester.ac.uk/piat

Or you can request a printed copy from Linda Sterrett at **info@plgmasters.com**

Every application must include :

1. Copies of degree certificates and official transcripts of previous study
2. Evidence of English language ability (if appropriate). Please note, if any documents are in a language other than English, you will need to provide official translations
3. Two references. Download referee form from websites above

Full applications should be sent to either :

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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 Training 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 600 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 we deliver more than 300+ years of business development experience!