MSc Drug Discovery Programmes

MSc Drug Discovery and Development
MSc Drug Discovery and Pharma Management

Programme Handbook

2015/16
Disclaimer

Every effort has been made to ensure that the information in this Handbook is correct at the time of going to press (September 2015). UCL reserves the right to make amendments to the information contained in this Handbook as a result of unforeseen events or circumstances beyond UCL's control or if deemed reasonably necessary by UCL.

This handbook is deemed to be the definitive version of information for all students on this taught programme of study.

In the event that amendments are made, UCL shall take reasonable steps to notify students as soon as possible.
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Welcome from the Programme Team

Welcome to the UCL School of Pharmacy and congratulations on gaining a place to study here on the MSc Drug Discovery Pathways. These programmes are designed for graduates in science-based subjects who wish to prepare for PhD-level research or pursue a career in the pharmaceutical industry or a government regulatory body.

There are two programmes offered which share a number of core modules:

- MSc Drug Discovery and Development
- MSc Drug Discovery and Pharma management

The *MSc Drug Discovery and Development* provides a broad overview of the drug discovery and development process with hands-on experience of molecular modelling and computer-based drug design, analytical and synthetic techniques, and novel aspects of drug discovery science.

The *MSc Drug Discovery and Pharma management* combines a broad overview of the drug discovery and development process with a deeper insight into the regulatory and commercial aspects of management in the pharmaceutical industry, entrepreneurship and business development.

Completing an MSc in 12 months is a challenge, particularly for international students who are studying in a foreign language. Moving to a new country, leaving behind family and friends can be overwhelming. Good time management and practising and improving your English will help you cope with the demands of the programme. You must also read this handbook carefully and keep it for reference throughout the year. Your tutors at the School and at the placement site are here to mentor and to support you, so if you have any problems or queries do come and talk to one of us.

We wish you good luck with your studies and look forward to getting to know you over the coming year.

Dr Mike Munday (Director), Dr Rosemary Smyth (Deputy Director)
The Programme Team
MSc Drug Discovery Pathways
1. General Information

1.1 PROGRAMME HANDBOOK

This Programme Handbook provides an introduction to the programme and contains the key information you need about the programme of study. Amongst other things, this handbook covers the curriculum, teaching and learning, administrative procedures, key personnel and assessment.

This handbook should be read in conjunction with the School Student Handbook which provides information about School staff, academic regulations and policies and administrative procedures.

The Handbook is relevant to you throughout your studies. There will inevitably be some changes during your time with us, possibly in relation to the teaching staff, programme content and assessment patterns and we shall keep you informed of any important changes. However, you should make sure that you keep up to date by reading our communications, checking the notice boards, reading your emails and browsing Moodle and the School and UCL Websites.

More detailed information on UCL procedures and policies in relation to students can be found on the UCL website at the following link: www.ucl.ac.uk/current-students. You can also find important on the School website here: www.ucl.ac.uk/pharmacy/current-students. Students are expected to be fully aware of procedures but, if in any doubt, please enquire at the Student and Academic Support Office (known as the School Office – SASO).

We hope you find this handbook useful. It is revised every year to include new information and to make it easier to use. If you have any comments about the handbook or suggestions for improving the information provided, please forward your comments to the School Office (SASO) (email sop.saso@ucl.ac.uk).
1.2 PROGRAMME STAFF

Programme Team
Most academic members of the Pharmaceutical and Biological Chemistry staff contribute to the MSc in Drug Discovery along with external experts from business and industry.

Programme Director
Dr Mike Munday
Room: G12
Tel: 020 7753 5875
Email: mike.munday@ucl.ac.uk

Deputy Programme Manager
Dr Rosemary Smyth
Room: 432
Tel: 020 7753 5950
Email: r.smyth@ucl.ac.uk

Academic Staff

<table>
<thead>
<tr>
<th>Name</th>
<th>Position and Affiliation</th>
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<tbody>
<tr>
<td>Dr Mike Munday</td>
<td>Programme Director, Senior Lecturer</td>
</tr>
<tr>
<td>Dr Rosemary Smyth</td>
<td>Deputy Programme Director</td>
</tr>
<tr>
<td>Professor Simon Gibbons</td>
<td>Head of Department, Professor in Phytochemistry</td>
</tr>
<tr>
<td>Professor Oscar Della Pasqua</td>
<td>Professor in Clinical Pharmacology</td>
</tr>
<tr>
<td>Professor Paul Fish</td>
<td>Chair of Medicinal Chemistry</td>
</tr>
<tr>
<td>Professor Stephen Neidle</td>
<td>Director of Centre for Cancer Medicines</td>
</tr>
<tr>
<td>Professor Nigel Ratcliffe</td>
<td>Visiting Professor, ex-VP Reg. Aftrs, AstraZeneca</td>
</tr>
<tr>
<td>Professor Anne Stephenson</td>
<td>Emeritus Professor of Molecular Neuroscience</td>
</tr>
<tr>
<td>Professor Klara Valko</td>
<td>Senior Investigator, GlaxoSmithKline</td>
</tr>
<tr>
<td>Professor Mire Zlohol</td>
<td>Visiting Professor of Chemistry</td>
</tr>
<tr>
<td>Professor Frank Kozielecki</td>
<td>Professor Chemical Biology</td>
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<tr>
<td>Dr Richard Angell</td>
<td>Leader Drug Discovery Research</td>
</tr>
<tr>
<td>Dr Mike Brownleader</td>
<td>CEO Generon, UK, Visiting Lecturer</td>
</tr>
<tr>
<td>Dr Shozeb Haider</td>
<td>Lecturer in Structure Based Drug Design</td>
</tr>
<tr>
<td>Dr Jess Healy</td>
<td>Lecturer in Chemical Biology</td>
</tr>
<tr>
<td>Dr Steve Hilton</td>
<td>Lecturer in Chemistry</td>
</tr>
<tr>
<td>Dr Colin James</td>
<td>Molecular Modelling</td>
</tr>
<tr>
<td>Dr Gary Parkinson</td>
<td>Senior Lecturer in Structural Biology &amp; Chemistry</td>
</tr>
<tr>
<td>Dr Paul Stapleton</td>
<td>Academic Fellow</td>
</tr>
<tr>
<td>Dr Sab Takhar</td>
<td>Clinical Director GSK, Visiting Lecturer</td>
</tr>
<tr>
<td>Dr Geoff Wells</td>
<td>Lecturer in Chemistry</td>
</tr>
<tr>
<td>Dr Andy Wilderspin</td>
<td>Senior Lecturer in Pharmaceutical Biochemistry</td>
</tr>
<tr>
<td>Dr Min Yang</td>
<td>Lecturer in Mass Spectrometry</td>
</tr>
<tr>
<td>Dr Phil Holt</td>
<td>Visiting Lecturer, ex-Global Prod Director, AstraZ</td>
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1.3 PROGRAMME ADMINISTRATION

The School Office (SASO) is the main administrative hub for your programme of study and is located in Room G11, Brunswick Square.

**Opening Hours and Contact Information**

<table>
<thead>
<tr>
<th>Hours</th>
<th>09.00 to 17.00 (Monday-Friday)</th>
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</thead>
<tbody>
<tr>
<td>Location</td>
<td>Room G11, Brunswick Square</td>
</tr>
<tr>
<td>Tel/Fax</td>
<td>+44 (0) 20 7753 5831</td>
</tr>
<tr>
<td>Fax</td>
<td>+44 (0) 20 7753 5829</td>
</tr>
<tr>
<td>E-mail</td>
<td><a href="mailto:sop.saso@ucl.ac.uk">sop.saso@ucl.ac.uk</a></td>
</tr>
</tbody>
</table>

You may also need to visit the UCL Student Centre on some occasions and further information can be found here: [www.ucl.ac.uk/current-students/student-centre](http://www.ucl.ac.uk/current-students/student-centre)

**Postgraduate Programmes Manager**

Rosemary provides general support on academic and welfare matters for students on the full-time postgraduate programmes at the School (MSc and MRes).

Dr Rosemary Smyth
Room: 432
Tel: 020 7753 5950
Email: r.smyth@ucl.ac.uk

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END OF SECTION 1
2. Programme Information

2.1 PROGRAMME DETAILS

Awards: MSc Drug Discovery and Development
MSc Drug Discovery and Pharma Management

Awarded by: University College London

Department: Pharmaceutical and Biological Chemistry

Length and Mode: 1 year full-time

Credits: 180 credits at Level 7

ECTS: 72 ECTS

Programme Director: Dr Mike Munday

Deputy Programme Director: Dr Rosemary Smyth

Teaching site
UCL School of Pharmacy
29/39 Brunswick Square
London WC1N 1AX
UK
Tel: 020 7753 5800
Fax: 020 7753 5829

2.2 THE MSc DRUG DISCOVERY PROGRAMMES

MSc Drug Discovery and Development
The MSc in Drug Discovery and Development is a 12 month full-time taught postgraduate programme intended for those who wish to prepare for PhD-level research or pursue a career in the pharmaceutical industry or a government regulatory body. The degree programme provides a broad overview of the drug discovery and development process, with hands-on experience of molecular modelling and computer-based drug design, and analytical and synthetic techniques.

The programme exposes students to modern platforms for drug discovery and methods of drug synthesis and includes lectures and seminars from industry-based scientists and visits to
industrial and biotechnological research laboratories. It covers marketing, licensing and the regulatory affairs that form an integral part of the development process. Students choose two specialised modules in drug discovery science in the second part of the programme from:

- PHAYG023 New Drug Targets in the Central Nervous System
- PHAYG025 Anticancer Personalised Medicines
- PHAYG028 Pharmacogenomics, adverse drug reactions and biomarkers
- PHAYG031 Advanced Structure-Based Drug Design.

Programme Structure
The MSc programme is designed to allow participants to gain a broad overview of drug discovery and development. This includes an insight into the methodology employed in identification of lead compounds, drug synthesis and development. The preparation for market and post-market surveillance and the analytical techniques required throughout are studied. Students gain an in-depth knowledge of individual examples of drug development throughout and specialize in selected areas towards the end of the programme, culminating with a laboratory research project chosen in one of these areas.

MSc Drug Discovery and Pharma Management
The MSc in Drug Discovery and Pharma Management is a 12 month full-time taught postgraduate programme intended for graduates in science-based subjects who wish to pursue a career in the pharmaceutical or biotechnology industry with a management or business development role. This degree programme combines a broad overview of the drug discovery and development process with a deeper insight into the regulatory and commercial aspects of management in the pharmaceutical industry.

The model for drug discovery in the pharmaceutical industry is changing. “Me too” products, may no longer be commercially viable. Pricing of new products and market access is becoming more difficult. Today major companies are looking for more innovation from outside their own laboratories. AstraZeneca are publicly stating that they expect to buy 40% of their science externally in future. Merck and Pfizer say their growth will be from small product deals or acquisition of smaller enterprises. In this environment research scientists can be involved in evaluating the business potential of their science as well as generating the science itself. There will be real opportunities for business development and scientific enterprise.

This programme contains the science core of the MSc in Drug Discovery plus introductory and advanced level modules addressing Business Management. It is led by Dr Mike Munday (UCL School of Pharmacy), Dr Nigel Ratcliffe (visiting Professor and former Vice President Regulatory and Commercial Affairs, AstraZeneca) and Dr Phil Holt (visiting lecturer and former Global Product Director, AstraZeneca). The degree provides a broad overview of the drug discovery and development process from drug target validation through the identification of lead compounds and their pre-clinical and clinical development into active drugs and medicines. The programme covers marketing, licensing and regulatory affairs but specialises in management training and awareness and Strategic Partnering and Business Development skills.
Programme Structure

The programme outlines the molecular basis of disease and the identification and validation of drug targets. It investigates the various approaches to the identification of lead compounds and their development into active drug candidates. The degree programme exposes students to modern platforms for drug discovery and methods of drug synthesis and includes lectures from industry-based scientists and visits to industrial and biotechnological research laboratories. Students gain hands-on experience of molecular modeling and computer-based drug design, and analytical and synthetic techniques. The approach of the pharmaceutical industry to pre-clinical development, clinical pharmacology, clinical trials, marketing, licensing and regulatory affairs form an integral part of the drug development process that is studied.


The programme culminates in a business development project based on an aspect of science from drug discovery that will be supervised by academic scientists and business managers and can be carried out in the UCL School of Pharmacy or as an extramural placement in industry.

2.3 MASTER’S LEVEL DESCRIPTORS

Master’s level awards are set at Level 7 of the Framework for Higher Education Qualifications in England, Wales and Northern Ireland (FHEQ) published by the Quality Assurance Agency for Higher Education (QAA). Descriptors for the Level 7 qualification are in two parts – (1) what each student must demonstrate in order to gain the award, and (2) the wider abilities that the typical student is expected to develop.

The MSc degree is awarded to students who have demonstrated:

1. Systematic understanding of knowledge and skills required in the application of pharmaceutical care.
2. Critical awareness of current problems and/or new insights in pharmacy practice.
3. Comprehensive understanding of techniques applied to advanced scholarship in pharmaceutics, which include problem solving skills, evaluation, research methods and data analysis.
4. Originality in the application of knowledge, together with a practical understanding of how established techniques of research and enquiry are used to create and interpret knowledge in pharmaceutics.
5. Conceptual understanding that enables the student to:
   • Evaluate critically current research and advanced scholarship in the discipline, and
   • Evaluate methodologies and develop critiques of them and, where appropriate, to propose new hypotheses.

Typically, holders of the MSc degree will be able to:

1. Deal with complex issues both systemically and creatively, make sound judgments in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences;
2. Demonstrate self-direction and originality in tackling and solving problems, and act autonomously in planning and implementing tasks at a professional or equivalent level;
3. Continue to advance their knowledge and understanding through continuing professional development, and
4. Develop new skills to an advanced level in pharmaceutics.

and will have:

5. The qualities and transferable skills necessary for employment requiring:
   • The exercise of initiative and personal responsibility; decision-making in complex and unpredictable situations, and
   • The independent learning ability required for continuing professional development.

2.4 LEARNING AND TEACHING METHODS

Teaching methods are varied and include lectures, seminars, small group work, coursework, oral and poster presentations and individual project work. National experts in the area of natural product science contribute to the degree programme. Class size varies from 8 - 30 students depending on the teaching format.

Some lectures and seminars are shared with the MSc in Pharmacognosy and fourth year students on the Master of Pharmacy degree. This is because the material is highly relevant and pertinent to the Drug Discovery programmes, however there is a separate tutorial programme for MSc students which are held weekly throughout the two terms.

END OF SECTION 2
3. Modules

3.1 MODULE CHOICE

The list of taught modules may change from year to year to reflect changes in the research areas of the staff and to ensure that the syllabus covers the latest research developments in the pharmaceutical sciences. Every effort is made to inform students of any changes before the programme starts.

Within the first two weeks of term 1 you must log onto the PORTICO Student Database in order to enrol for your modules. PORTICO can be found at the following link: https://evision.ucl.ac.uk/urd/sits.urd/run/siw_lgn

MSc Drug Discovery and Development

Students take 3 core modules and 2 optional modules (total of 120 credits)

**Term 1 – Students take 3 core modules (total of 90 credits):**

- PHAYG029 The Process of Drug Discovery (TPODD 1) 30 credits
- PHAYG030 The Process of Drug Development (TPODD 2) 30 credits
- PHAYG057 Modern Aspects of Drug Discovery 30 credits

**Term 2 – Students choose 2 out of 4 optional modules (total of 30 credits):**

- PHAYG023 New Drug Targets in the CNS 15 credits
- PHAYG025 Anticancer Personalised Medicines 15 credits
- PHAYG028 Pharmacogenomics, adverse drug reactions & biomarkers 15 credits
- PHAYG031 Advanced Structure-Based Drug Design 15 credits

**Term 2 & 3 – Students take the core research module:**

- PHAYGX97 Dissertation - MSc Drug Discovery 60 credits
MSc Drug Discovery and Pharma Management

Students take 4 core modules (total of 120 credits)

**Term 1 – Students take 3 core modules (total of 90 credits):**

- **PHAYG029** The Process of Drug Discovery (TPODD 1) 30 credits
- **PHAYG030** The Process of Drug Development (TPODD 2) 30 credits
- **PHAYG057** Modern Aspects of Drug Discovery 30 credits

**Term 2 – Students take 2 core modules (total of 30 credits):**

- **PHAYG033** Pharma Management 30 credits

**Term 2 & 3 – Students take the core research module:**

- **PHAYGX97** Dissertation - MSc Drug Discovery 60 credits

### 3.2 MODULE OUTLINES

This handbook contains brief outlines of the modules which are available for the MSc Drug Discovery pathways. You will receive more detailed Module Outlines at the start of the module and the content may be slightly different to the information published here. This is because staff are constantly updating their teaching in light of developments in current research and new thinking.

The modules are listed in Module Code order by type:

(i) Core Modules

- **PHAYG029** The Process of Drug Discovery (TPODD 1) 30 credits
- **PHAYG030** The Process of Drug Development (TPODD 2) 30 credits
- **PHAYG033** Pharma Management 30 credits
- **PHAYG057** Modern Aspects of Drug Discovery 30 credits

(ii) Optional Modules (MSc Drug Discovery and Development only)

- **PHAYG023** New Drug Targets in the CNS 15 credits
- **PHAYG025** Anticancer Personalised Medicines 15 credits
- **PHAYG028** Pharmacogenomics, adverse drug reactions & biomarkers 15 credits
- **PHAYG031** Advanced Structure-Based Drug Design 15 credits
(i) **Core Modules**

**PHAYG029  THE PROCESS OF DRUG DISCOVERY (TPODD1) – 30 credits**

*Module Leader: Dr Mike Munday*

This module is the core of the whole degree programme and follows the process of drug discovery and development and runs throughout the first and second terms. It introduces the basis of the pharmaceutical industry through examining previous successes and current methods of drug discovery. The module includes:

**Introduction to the molecular basis of disease, identification and validation of drug targets** *(Dr M Munday)*

The molecular basis of disease is considered with examples of infection, genetic and multifactorial clinical conditions and the mechanism of action of certain drugs in their therapy. There is a detailed revision of basic macromolecular structure and the types of cellular components that constitute drug targets. This section examines the identification of drug targets and the genomic approaches to the validation of drug targets.

**Drug Discovery and Lead Identification** *(Dr M Munday; Prof P Fish; Prof S Neidle; Dr G Wells)*

The identification of drugs for human use has a long and fascinating history with its origins in witchcraft and magic through to the present time where techniques such as computer modeling, combinatorial synthesis and high-throughput screening are used. This section begins with a discussion of how ancient civilizations utilized a combination of witchcraft, magic and materials extracted from plants, animal and humans to attempt (usually unsuccessfully) to cure diseases. A number of natural products with genuine therapeutic activity such as salacin from willow bark (as an anti-inflammatory) and honey (as an antibacterial) were discovered in this period and will be described in more detail. Discussions will then move to a later period where chemical techniques, although in their infancy, were used to isolate and structurally elucidate well known natural products such as the major plant alkaloids. Discussion will then move to more modern times describing how modern drug leads are identified by a number of different techniques including combinations of molecular modeling, combinatorial libraries and high-throughput screening. The delivery of this module is supplemented by keynote lectures from academic and industrial experts with personal examples of drug discovery successes.

**Advances in synthetic chemistry** *(Prof P Fish; Dr R Angell; Dr G Wells; Prof F Kozielski; Dr J Healy)*

Key themes of the application of modern synthetic methods in medicinal chemistry and drug discovery are covered in this section. Chemical-synthetic techniques that are utilized in the preparation of compounds for use in the chemical genetic approach will be discussed; importance will be given to the generation of novel natural product-like or -derived compound libraries. Topics include reaction mechanisms and asymmetric synthesis, combinatorial chemistry, pericyclic and multicomponent reactions, solid phase and microwave chemistry, and chemistry in flow.
High Throughput Screening of Compound and Natural product Libraries
(Dr A Wilderspin; Dr M Munday)
This section examines the types, molecular basis and technical procedures of biochemical and cell-based bioassays. Understanding the automation of the HTS process and the importance of bioinformatics and data processing in identification of lead compounds is an important component.

Molecular Modeling and Structure Based Design
(Dr G Parkinson; Dr C James; Prof S Neidle; Dr S Haider)
This section is designed to introduce the student to the principles and practice of modern drug discovery. The course will provide an awareness of rational drug design, based on understanding the three-dimensional structures and physicochemical properties of drugs and receptors. There is considerable “hands on” experience of computational chemistry and computer-based molecular modeling. This section will cover modeling drug/receptor interactions with the emphasis on molecular mechanisms, molecular dynamics simulations and homology modeling. Other topics will be selected from: conformational sampling, macromolecular folding, structural bioinformatics, receptor-based and ligand-based design and docking methods, in silico screening of libraries, semi-empirical and ab-initio methods, QSAR methods, molecular diversity, design of combinatorial libraries of drug-like molecules, macromolecular and chemical databases

PHAYG030 THE PROCESS OF DRUG DEVELOPMENT (TPODD2) – 30 credits

Physicochemical Properties of Drugs (Absorption, Distribution Metabolism)
(Prof Klara Valko, GSK)
This section provides understanding of the physicochemical properties of molecules that can be used for compound selection at the early discovery stage. Students will study the traditional and newer high throughput methods for the determination of lipophilicity, solubility and pKa values and get an insight of the in silico calculations of these properties using software packages. Students will gain an understanding of how physicochemical properties influence cell permeability, oral absorption, protein binding, and blood/brain barrier distributions by discussion of various predictive models published in the literature. Course content includes: Discussion and practical demonstrations of methods for lipophilicity determination (octanol/water partition, chromatographic hydrophobicity index, micellar electrokinetic chromatography). Discussion and demonstration of methods for solubility determinations and their automation. Practical determinations of pKa values. Commercially available instruments with various levels of automation.


**Preclinical Development**  
*Dr G Meneses-Lorente, Roche; Dr M Munday, Dr R Smyth: Prof O Della Pasqua, Dr V Birault, GSK, Prof F Kozielski*)  
This section covers phase 1 and phase 2 drug metabolism and factors that affect these processes. This includes chemical modification and the use of prodrugs to protect from metabolism. The industrial approach to Clinical Pharmacology is covered by Dr G Meneses-Lorente (Roche). The use of preclinical toxicology studies which are necessary before the drug can be administered to humans will be discussed in detail.

**Clinical Development**  
*Dr R Williams & Dr S Nabarro, CRUK; Dr S Takhar, Roche; Dr K Sheikh*)  
The choice, preparation for and execution of the four phases of clinical trials are investigated. External experts from Celgene (Dr S Takhar), CRUK (Dr R Williams) plus Quintiles and the NHS discuss a variety of issues and expertise.

**Regulatory Affairs, Commercial Affairs and Intellectual Property**  
*Prof Nigel Ratcliffe, ex-Vice President Regulatory Affairs, AstraZeneca; Mr P Bhartiya, MHRA; Dr R Waters, Director Reg Affairs, Allergan*)  
Discovering lead compounds and then developing them towards a marketable product are only the first two components of a very complex and expensive process. Once a lead compound has been suitably developed it then has to be tested extensively in animals before going into the first human clinical trials. If it successfully completes these trials, then the company has to apply for a license to market the product from the appropriate Government agency e.g. FDA in the USA, MHRA (Medicines and Healthcare products Regulatory Agency, formally the MCA) in the UK. Before granting a license, these agencies will require extensive evidence that the product is efficacious and safe i.e. has a positive risk/benefit ratio. Even after a product license (e.g. a Marketing Authorization in the UK) is granted, the Government agencies of all countries in the developed world operate a Post Marketing Surveillance system supported by many different types of health workers, including doctors, pharmacists and nurses who report any adverse drug effects. If it becomes evident that in the larger general population the risk/benefit ratio is larger than anticipated, then the MA can be withdrawn.

It is crucial that Intellectual Property (known as IP) surrounding novel drug products are protected by processes such as filing patents and registering trademarks. Once protection is in place, a company that may have spent many millions discovering and developing a product can then freely market it for approximately 20 years in the countries in which it is protected without fear of other manufacturers marketing a similar or generic product. Once patent protection has lapsed, then other companies are free to market generic versions of the products. This section will describe in detail all aspects of the IP protection process. It will discuss the recent trends for large pharmaceutical companies to merge into large international
conglomerates, and for the formation of numerous small start-up biotechnology companies often based around academic programmes of research. These changes have transformed the pharmaceutical industry in the last 10 years with a trend towards new lead molecules being discovered, predominantly by smaller companies which then license their IP to the larger merged pharmaceutical companies. Many of the latter focus more on lead development, clinical trials and marketing than lead discovery.

PHAYG033  PHARMA MANAGEMENT 1 (30 credits)

Module Leader: Dr Phil Holt,

This module will cover the following key areas:

(i) The team approach to Research and Clinical Development. The module will discuss the important input from:
   • Clinical Development
   • Intellectual property.
   • Commercial Teams.

(ii) Global Regulatory Affairs and the different steps involved:
   • Regulatory Objectives
   • Regulatory Agencies.
   • Global Regulatory Package.
   • Global Process
   • Hearings and approvals
   • What does an approval provide
   • Risk Management and post approval obligations.

(iii) Considerations to be taken into account when commercialising a product:
   • What is the market?
   • How do you design a product for a market?
   • How do you launch your product?

(iv) How is a Pharmaceutical Company Structured?
   • Functions within the company, the governance and obligations?
   • What is the current Pharmaceutical environment? How is it changing?
   • Industrial relations. Investor relations.
   • Strategic Partnering and Business development. How is it run?
   • Searching for products. Initial evaluation
   • Due Diligence. The teams involved
   • Financial analysis
   • Introduction to all parameters studies. PYS, IRR eIRR NPV eNPV ROI etc.
   • The Business case. Compilation and delivery of the Business case.
   • Media Training, Communication Skills
   • Disclosure Committees
(v) Product and Science Due Diligence.
- Where DD fits in the process
- What the initial assessments will have told you and what the difference is here between early evaluation and Due Diligence
- What the team looks like
- What e rooms are, what paper rooms are like
- How a team is formed, who sits on the team and why?
- Where a bench scientist may sit, what they will be doing
- What is the meeting like, who does what?
- What are you looking for, what interactions do you have with their scientists
- Who rights the report, who takes notes? What's the legal standing of the reports? What do you do with the report?
- The kind of issues you find, what are the problems? What to look for
- What to consider as an employee in Discovery? One day someone may undertake DD on your work

(vi) Clinical Development
- Study types, Phase 1, 2 and 3
- The requirements pre tox for commencement of each phase
- Multi-disciplinary teams. The role the scientist may play in metabolite identification, sample analysis etc.
- Centre selection
- Advisory board, Safety Board
- Regulatory clearance
- Ethics boards
- Use of contract organisations
- Data interpretation, audits

(vii) Introduction to Financial Evaluation of Science and Product Evaluation
- The Financial Director in a Strategic Partnering and Business Development Team, what role do they play?
- A financial business case. What do you look for, what parameters do you study, what are the terms and what do they mean
- What information do you need for a business case?
- Who do you need to influence?
- What measures would make a business case approvable, i.e. what are the acceptable limits for a pre-clinical, phase 1, phase 2 opportunity etc.?
- Venture capital, what does this mean? How does it work?
- Basic Financial parameters

(viii) Entrepreneurship and the challenges of setting up a company
- Small and medium enterprises
- Spin out and commercialising research
- Biotech industry
- Raising Funds
This module introduces an overview of the pipeline of drug discovery and explores some themes that cover specific examples of drug discovery stories, techniques used in the analysis of drugs and their targets and the structure of the industry responsible for this process and the challenges that it faces.

The module is divided into three themes: ‘Drug Discovery Case Studies’ describes the discovery of beta blockers and GPCR drugs and targets (Dr Munday); inhibitors of protein-protein interactions (Dr Wells); retrosynthesis of drug molecules (Dr Hilton); enzymes as drug targets (Dr Wilderspin); antibiotics and the search for new antibiotic medicines (Dr Stapleton).

The theme ‘Techniques in Drug Discovery’ explains the use of HPLC (Prof Valko, GSK), mass spectrometry (Dr Smyth), NMR in the investigation of drug molecules (Dr Hilton) and the use of X-ray crystallography (Dr Parkinson), electrophoresis and immunochemistry (Dr Munday) and the state of the art modern technology used in the investigation of drugs and drug targets.

The theme ‘Pharmaceutical Industry and New Technologies’ describes the structure of large pharma and the small and medium enterprises involved (Dr Holt, ex-AstraZeneca); the challenges faced by the pharma industry (Prof Ratcliffe, ex-Astra); the opportunity for biotechnology and business development (Dr Gergely Toth, Garderam Therapeutics); the rise in biopharmaceuticals and biosimilars that form a major part of new therapeutic technology (Dr Munday/Dr Wilderspin). The module draws upon the experience of external teachers who are professionals in the pharma industry.
(ii) **Optional Modules**

**PHAYG023  NEW DRUG TARGETS IN THE CNS (15 credits)**  
*Module Leader: Prof Anne Stephenson*

Neurotransmitter receptor proteins are a major target for drug action within the central nervous system (CNS). CNS drug discovery programmes have been revolutionized during the last ten years with the realization that rather than a single neurotransmitter receptor existing per neurotransmitter, multiple highly homologous neurotransmitter receptor subtypes exist for each inhibitory and excitatory neurotransmitter. Therefore, the challenge is to develop receptor subtype-selective therapeutic compounds with the hope that this new generation of drugs will have unique and selective therapeutic properties while reducing unwanted adverse effects. In this module students will initially study the biochemical basis for receptor heterogeneity. Next, case studies of subtype-selective drugs currently undergoing clinical trial will be presented including such examples as an NR2B NMDA receptor-selective ligands for the treatment of neuropathic pain, and GABA_\alpha_ receptor subunit-specific drugs for certain neuroses including anxiety. A further component of the module will focus on CNS therapeutic targets likely to be important in the next few years.

**PHAYG025  ANTICANCER PERSONALISED MEDICINES (15 credits)**  
*Module Leader: Dr Geoff Wells*

Cancer represents a collection of over 200 distinct diseases and is second only to heart disease as the cause of premature death in the Western world. Cancer is treated by surgery whenever possible, but there is often follow-up treatment with radiotherapy or chemotherapy, and the latter are sometimes used without surgery, either singly or in combination. Although there are a large number of cancer chemotherapeutic agents in current use, many of these cause unpleasant side effects and there is a need to develop novel agents with higher selectivity and less toxicity. This module begins with an overview of the various different classes of anticancer agents, focusing on their strengths and weaknesses. It will then discuss the various new approaches to cancer chemotherapy still in development that seek to reduce toxicity by enhancing selectivity. Examples will include the kinase inhibitors, anti-angiogenics, gene-targeting approaches and antibody targeted strategies such as ADEPT. The module will provide a background to the emerging role of personalized medicine and patient stratification in cancer therapy. Aspects of tumour diversity and heterogeneity, personalized medicines and preventative therapies will be investigated. The module will be enhanced by guest lectures from practising oncologists, medics and experts in anticancer drug development from the pharmaceutical industry.
PHAYG028 PHARMACOGENOMICS, ADVERSE DRUG REACTIONS & BIOMARKERS

Module Leader: Dr Rosemary Smyth

A biomarker is a characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or pharmacological responses to a therapeutic intervention. The identification of disease and toxicity is an area of significant interest and much research is focused on identifying biomarkers for the initial stages of disease or toxic insult, thus paving the way for future development of new drug targets and early diagnosis and treatment. This module will pay particular attention to the current and newly developed techniques employed in the identification of biomarkers. The use of proteomic techniques such as mass spectrometry for biomarker discovery will be studied in depth as well the methods used to determine post-translational modifications such as glycosylation, which is especially important since many tumour biomarkers are glycosylated. The use of metabolomics in biomarker discovery will be explored.

The second part of this module addresses the individual responses of patients to drugs as a result of genomic variation in the form of SNPs, microsatellite repeats and CNVs in genes coding for drug metabolizing enzymes, drug transporters and drug targets. This is the basis of pharmacogenomics and explains not only variability in patient response but also many of the adverse drug reactions. This module will provide students with a detailed understanding of methodologies under development and in use which enable processing of the vast quantity of new information becoming available from genomic interrogation. Examples of these new technologies will be described that enable extremely rapid, efficient and cost–minimizing interrogation of the genome for new drug targets. The development of personalized medicines is a goal of pharmacogenomics and these are increasingly developed in conjunction with companion diagnostics. A range of approaches will illustrate diagnostic pharmacogenomic-based high-throughput screening and microarray methodologies.

PHAYG031 ADVANCED STRUCTURE BASED DRUG DESIGN (15 credits)

Module Leader: Dr Shozeb Haider

The module will focus on the current methods in the computer aided drug design. Modeling drug/receptor interactions will be covered in detail, including predicting protein structure, homology modeling and molecular docking. Other topics will be selected from: conformational sampling, fragment based drug design, receptor-based de novo design and ligand-based drug design. Through hands-on experience, students will gain a more complete understanding of drug design process.

END OF SECTION 3
4. Research Project

4.1 PHAYGX97 DISSERTATION - MSc DRUG DISCOVERY PATHWAYS

A major component of the MSc programme is the research project.

Students in the MSc Drug Discovery and Development programme are expected to pursue a scientific research project that could be laboratory-based or achieved through computer modelling/database interrogation. Students will have a choice of projects and every attempt will be made to accommodate their preferences to work in specific drug discovery areas (for example: chemical synthesis, biochemistry and drug targets, pharmaceutical analysis of drug properties, pharmacology, natural product etc). Projects can be carried out in laboratories at the School of Pharmacy, with other academics within UCL, in industry with our industrial partners, in other universities and institutions in the UK or possible even abroad. Assessment of the project by dissertation and oral presentation is carried out by academics in the teaching team.

Students in the MSc Drug Discovery and Pharma Management programme are expected to pursue a research project that could be an investigation of management aspects of the pharma industry, or could be the development of a business case for bringing science or a product to market, or could be a comparison of regulatory requirements or business development between different countries, or could be an investigation/audit of processes within a small or medium sized pharma or biotech company.

Students are encouraged to develop their own ideas and strategies in discussion with their supervisors and wherever possible the project will be linked to an existing pharma or biotech company.

Assessment of the project by dissertation and oral presentation is carried out by academics in the teaching team.

END OF SECTION 4
5. Assessment and Regulations

5.1 PROGRAMME REGULATIONS

The full Programme Regulations for Taught Postgraduate Programmes can be found on the UCL website at the link below. Students must also read the information contained in the School Student Handbook. We have included a brief summary of the main regulations in this handbook; however students must read the regulations in full.

http://www.ucl.ac.uk/ras/acad_regs

Coursework
Students must complete a number of formative and summative assignments. Formative assignments give feedback to students on their performance but do not count towards final marks (however, it may still be a requirement to complete these). Marks for summative assignments do count towards the final mark for each module. The minimum pass mark is 50%.

Examinations
Students will normally take written examinations for term 1 modules in January and written examinations for term 2 modules in April-June. Resit examinations are normally held in the last week of August or the first week of September and will be of the same format and duration as term 1 and 2 examinations. The minimum pass mark for examinations is 50%.

Overall module marks
Your overall mark for each module will be made up of your coursework and exam marks (see below for details). Most modules are assessed by 33% coursework and 67% examination, except for PHAYG032 (Methods of Analysis) where the assessment is 50% coursework and 50% exam.

Aggregation
To pass a module you must obtain overall at least 50%, including a coursework mark of 50% at minimum. If you achieve between 40% and 50% in your exam and your overall module mark calculates at over 50% then you are permitted to pass the module.

Resits
The regulations permit students a first opportunity at an assessment and one resit opportunity only (at the discretion of the Board of Examiners). No further opportunities are permitted. The higher of the marks achieved at the first attempt and the re-sit attempt will apply. Students cannot resit modules which they have passed.

Condoning
Please refer to the Post Graduate Taught Academic Regulations, Section 3 (3.2.4)

https://www.ucl.ac.uk/srs/academic-regulations
Final Degree Mark
The overall pass mark for the award of the MSc is 50%. The final degree mark is calculated on the average module marks weighted according to the number of credits they carry. The Master’s degree is worth 180 credits in total so a 30 credit module would contribute 30/180 to the final mark.

Criteria for the Award of Pass, Merit and Distinction
Please refer to the Post Graduate Taught Academic Regulations, Section 2 (2.10.6) https://www.ucl.ac.uk/srs/academic-regulations

5.2 ASSESSMENT STRUCTURE

All modules are assessed by coursework and an examination at the end of the module. The contribution of exam and coursework marks to final overall module mark will be exams = 67% and coursework = 33%

PHAYG057 MODERN ASPECTS OF DRUG DISCOVERY:

Exam: (4 questions from 6 in 3hr) 1 question from each of 3 themes plus free choice for 4th question
Coursework: A case study, one worksheet per week for first 3 weeks. Open book report to be written in week 5. (Dr Munday)

PHAYG029 THE PROCESS OF DRUG DISCOVERY (TPODD 1)

Exam: (2 from 4 questions in 2hr)
Coursework: Write up of practical classes (Dr Smyth) (40%)
Molecular Modelling portfolio – in class (Dr James) (20%)
Profiling Assays for HTS – a scientific poster explaining a technique and its use in Lead Compound Identification (Dr Wilderspin and Dr Munday) (40%)

PHAYG030 THE PROCESS OF DRUG DEVELOPMENT (TPODD2)

Exam: (2 from 4 questions in 2hr)
Coursework: MCQ test on basic chemistry (from blackboard notes) (Dr Smyth) (15%)
Chemical Calculations test (Dr Munday) (15%)
Analysis of Clinical Trial Data (Dr Munday) (40%)
Data Handling and Interpretation – open book exercise (Dr Munday) (30%)

PHAYG033 PHARMA MANAGEMENT

Exam: (2 from 4 questions in 2hr)

PHAYG023,025,028,031 OPTIONAL SCIENCE MODULES (2 per student)
Exam: (1 from 2 questions in each module in 1hr. Therefore, 2 questions in 2hr).
Coursework: Report on background and interpretation of research publication.

PHAYGX97 Research Project (60 credits) - Dissertation and Oral Presentation
Module Assessment (Core and Option modules)

<table>
<thead>
<tr>
<th>Assessment Component</th>
<th>Pass Mark</th>
<th>Weighting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coursework</td>
<td>50%</td>
<td>33%</td>
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<tr>
<td>Unseen written examination</td>
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</table>

Module Assessment (PHAYGX97 Dissertation)

<table>
<thead>
<tr>
<th>Assessment Component</th>
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</thead>
<tbody>
<tr>
<td>Written report and Oral presentation</td>
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<td>100%</td>
</tr>
</tbody>
</table>

5.3 SCHEME OF AWARD

The scheme or award sets out the individual assessment components and their relative weighting. Students will be subject to the scheme of award in effect at the time they start the programme. The MSc is worth 180 credits. His is comprised of 120 credits of taught modules and a 60 credit dissertation.

**MSc in Drug Discovery and Development**

The MSc comprises the following weighted assessment components:

<table>
<thead>
<tr>
<th>Module</th>
<th>Marks</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHAYG057 Modern Aspects of Drug Discovery</td>
<td>100</td>
<td>30</td>
</tr>
<tr>
<td>PHAYG029 The Process of Drug Discovery &amp; Clinical Development 1</td>
<td>100</td>
<td>30</td>
</tr>
<tr>
<td>PHAYG030 The Process of Drug Discovery &amp; Clinical Development 2</td>
<td>100</td>
<td>30</td>
</tr>
<tr>
<td>Option 1 Optional module 1 (15 credits)</td>
<td>100</td>
<td>15</td>
</tr>
<tr>
<td>Option 2 Optional module 2 (15 credits)</td>
<td>100</td>
<td>15</td>
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<tr>
<td>PHAYGX97 Dissertation - MSc Drug Discovery Pathways</td>
<td>100</td>
<td>60</td>
</tr>
</tbody>
</table>

**MSc in Drug Discovery and Pharma Management**

The MSc comprises the following weighted assessment components:

<table>
<thead>
<tr>
<th>Module</th>
<th>Marks</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHAYG057 Modern Aspects of Drug Discovery</td>
<td>100</td>
<td>30</td>
</tr>
<tr>
<td>PHAYG029 The Process of Drug Discovery &amp; Clinical Development 1</td>
<td>100</td>
<td>30</td>
</tr>
<tr>
<td>PHAYG030 The Process of Drug Discovery &amp; Clinical Development 2</td>
<td>100</td>
<td>30</td>
</tr>
<tr>
<td>PHAYG033 Pharma Management 1</td>
<td>100</td>
<td>15</td>
</tr>
<tr>
<td>PHAYG034 Pharma Management 2</td>
<td>100</td>
<td>15</td>
</tr>
<tr>
<td>PHAYGX97 Dissertation - MSc Drug Discovery Pathways</td>
<td>100</td>
<td>60</td>
</tr>
</tbody>
</table>

END OF SECTION 5
Appendix 1: Academic Calendar

The MSc is a full-time, twelve-month programme. Students should not plan any activities to interfere with the 9:00am – 5:00pm schedule, Monday to Friday for the entirety of the programme.

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>Induction Week</td>
<td>28 September 2015</td>
</tr>
<tr>
<td><strong>Term 1 Starts</strong></td>
<td>28 September 2015</td>
</tr>
<tr>
<td>Classes start</td>
<td>28 September 2015</td>
</tr>
<tr>
<td>Term Ends</td>
<td>18 December 2015</td>
</tr>
<tr>
<td><strong>Term 2 Starts</strong></td>
<td>11 January 2016</td>
</tr>
<tr>
<td>Examination period</td>
<td>11 – 15 January 2015</td>
</tr>
<tr>
<td>Begin Project Work</td>
<td>End of March 2016</td>
</tr>
<tr>
<td>Term 2 Ends</td>
<td>24 March 2016</td>
</tr>
<tr>
<td><strong>Term 3 Starts</strong></td>
<td>25 April 2016</td>
</tr>
<tr>
<td>Research Project Starts</td>
<td>May 2016</td>
</tr>
<tr>
<td>Examination Period</td>
<td>April – June 2016</td>
</tr>
<tr>
<td>Deadline for Project Submission</td>
<td>Early September 2016</td>
</tr>
</tbody>
</table>

**Important Notes**

1. UCL School of Pharmacy reserves the right to change these dates if necessary. The School will inform students of any changes.
2. Students must ensure that they are available to attend all classes throughout the terms.
3. Students on full-time Taught Master’s programmes study for a full calendar year. Therefore students are expected to study beyond the end of the third term to prepare their dissertation in time for submission in September.