

## Programme Specification

Awarding Body/Institution	Queen Mary, University of London
Teaching Institution	Queen Mary, University of London
Name of Final Award and Programme Title	PG Dip Clinical Drug Development (B2D1/B2D2) MSc Clinical Drug Development (B2S1/B2S2)
Name of Interim Award(s)	
Duration of Study / Period of Registration	1 Year Full Time, 2-4 Years Part Time
QM Programme Code / UCAS Code(s)	B2D1, B2D2, B2S1, B2S2
QAA Benchmark Group	
FHEQ Level of Award	Level 7
Programme Accredited by	
Date Programme Specification Approved	27 Sep 2012
Responsible School / Institute	William Harvey Research Institute

Schools which will also be involved in teaching part of the programme

William Harvey Research Institute

Institution(s) other than Queen Mary that will provide some teaching for the programme

N/A

### Programme Outline

The development of drugs has transformed from peripheral activities, carried out on an ad hoc basis to core activities that require trained, professional staff. However, the education and training of staff involved in drug development has not kept pace with the scientific and regulatory changes that have occurred recently. The pharmaceutical industry moves rapidly and a highly skilled personnel are required in order to adapt to this environment.

The aim of the Distance Learning (DL) PGDip/MSc in Clinical Drug Development course is to provide students with a multi-disciplinary perspective to facilitate their skills. This course is designed for individuals who need an understanding of the drug development process, and provides a detailed picture of the complex and highly interrelated activities required for the development cycle for drugs and biologics, from the process of discovery to successful commercialisation.

The United Kingdom pharmaceutical industry faces one of the greatest challenges in attracting and retaining quality personnel. Moreover, in the current economic climate, demand for highly specialised employees with Postgraduate rather than Graduate Degrees is ever increasing. The DL PGDip/MSc in Clinical Drug Development course provides participants with the opportunities to increase the likelihood of getting into the hard to enter and highly competitive pharmaceutical environment. With the economic growth in the BRIC countries (Brazil, Russia India and China) the pharmaceutical and biotech industry is

shifting research and development towards these regions. This has created a demand for skilled professionals with the knowledge and expertise needed. The DL PGDip/MSc in Clinical Drug Development provides students the edge that pharmaceutical industry requires. It also empowers the professionals working within the field with the skills and understanding required for fast progression within the industry and contract research organisations (CRO-s).

This programme has been running at QMUL for over ten years and the this application uses all the modules of the current course but seeks approval to offer them externally by distance learning.

## Aims of the Programme

The aim of the course is to provide participants with a multi disciplinary perspective to facilitate the skills of post graduate students. It is intended that the course will provide a valuable opportunity for both British and overseas students who wish to gain more experience in understanding the clinical drug development process and obtain a higher degree before entering a career in the pharmaceutical environment.

## What Will You Be Expected to Achieve?

When completing the DL PGDip/MSc in Clinical Drug Development students will be expected to achieve the following learning outcomes.

### Academic Content:

A 1	To critically evaluate the appropriateness of different approaches and demonstrate an understanding of how drugs are "discovered"
A 2	Demonstrate a deep and systematic understanding of the role of pharmacokinetics in candidate optimisation
A 3	Understand need for animal toxicity testing and appreciate and manage the ethical dilemmas involved
A 4	Understand the role of the various methods available for assessing toxicity.
A 5	Demonstrate an understanding of the financial factors and evaluate the constraints that apply to drug testing and development
A 6	Understand the role of the various regulatory procedures involved in drug development
A 7	Display an awareness of the strengths, weaknesses and utilization of specific study designs.
A 8	Maintain an objective approach to choice of study design
A 9	Appreciate the role of guidelines in regulating and guiding research studies
A 10	Understand the process of "first in man" studies
A 11	Design simple single dose and repeat dose studies

Disciplinary Skills - able to:	
B 1	Display an awareness of the scientific needs to support the drug discovery process.
B 2	Understand pre clinical studies compliment phase 1 to 4 studies in man.
B 3	Appreciate the need for optimisation in drug discovery and preclinical development
B 4	Maintain an objective approach to the physiochemical and in vivo characteristics required for candidate selection.
B 5	Display an awareness of the strengths, weaknesses and utilization of specific toxicology testing techniques.
B 6	Appreciate the need for research, an evidence base, and reflective practice when making professional judgements about drug toxicity.
B 7	Demonstrate initiative and originality in problem solving

Attributes:	
C 1	Can act autonomously in planning and implementing tasks at a professional or equivalent level
C 2	Demonstrate appropriate and comprehensive practical and theoretical skills as well as advanced communication expertise- allowing decision making in complex and unpredictable situations
C 3	Demonstrate autonomy in self directed learning and realise their scope of practice

## How Will You Learn?

One of the major strengths of the course lies in the fact that the teaching staff consist of not only institute members but also involves top professionals working in the pharmaceutical industry and CRO-s. Our exceptional expert "panel" of internal as well as external lecturers is actively engaged with the course. Members of the WHRI who are teaching on our course are invaluable assets to the progression of the students on the course as they are not only intellectually stimulating them, but engaging them as self-directed learners, and more closely connecting them to the university and college as a community.

Teaching methods employed during this DL PGDip/MSc course consists of lectures from the William Harvey Research Institute staff and outside experts, using well-established classic teaching methods in order to create a stimulating and effective online distance learning environment.

The taught course will be delivered online via the virtual learning platform.

\* Overall course information, including student handbook and timetables, will be distributed through Moodle.

\* Induction material and a welcome chat room session and / or online discussion thread will be set up at the start of the first term between the distance learning students and the Programme Director.

\* A variety of teaching strategies will be employed, most of which will be delivered via Moodle.

\* Each module is presented on-line as:

- Summary of the module
- Aims and Objectives

- Plan for assessment

\* Additional one-to-one tutorials with individual students will be arranged if required

\* Library facilities. All students registered on the course will have access to the college on-line library facilities. This gives access to a large number of relevant journals. Students will have access to other academic literature and journals via their QMUL log-on in the same way as on-site students.

The topics for the module outlined in the syllabus will be delivered using a variety of methods to include:

1) Lectures – with audio soundtrack (captured using specialised software such as ECO 360 or similar.) These lectures will be delivered by members of the course faculty with occasional 'guest lectures' for selected topics. Both types of lecture will be captured and presented in the same way.

2) Podcasts. Some of the taught material may be delivered by podcast. In addition some of the exercises (for example guided reading, critical appraisal, guidelines review) may be introduced by podcast together with instructions for the exercise. This material will be presented in audio files (MP3 format) with, where relevant, linked paper-based reading material.

3) Lecture notes and document reading material (word documents and PDF.) Topics will also be covered in the form of guided reading – with a reading list or short series of scientific papers to read followed by questions or exercises.

4) Online Seminars / Tutorials. Some topics may be covered in real-time online seminars, delivered by Skype (or similar technology). These will be based around a topic or around a series of relevant articles from scientific journals. The organisation of such synchronous support by voice / video seminars will depend on the proportion and location of overseas students in order to circumvent any difficulties posed by differences in time zones.

5) Online reading lists, linked where possible, to the journals in which the papers appear.

Moreover, students are also involved in using new technologies (eg Moodle, Facebook, Skype) which allow students to discuss and exchange ideas, share knowledge as well as to review the lecture sessions in their own time and at their own pace.

The programme aim is to create an environment in which all participants have the opportunity to learn and explore issues and ideas in depth, from a variety of viewpoints.

## How Will You Be Assessed?

• Students will be assessed based on online submitted written assignments. The course team evaluates the progression of students on their written assignments, maintaining the highest quality of work as well as achieving the course learning objectives.

### Format

The final mark will have the following components

- Continuous assessment (module assignment).
- Dissertation

### Continuous assessment (module assignment)

For the continuous assessment mark, candidates will be assessed throughout the year in the form of objective assessment by written assignment.

### Dissertation

The candidates will submit a written dissertation on a subject in which they have been supervised. The format of the dissertation will usually be literature or policy based. A viva on the dissertation may be required for borderline candidates. This will take place at the final board of Examiners meeting

All assignments will be double marked by the experts teaching on particular topics.

## How is the Programme Structured?

The modular nature of the courses is designed to fit in with the needs of those students who are in full time employment. The taught element of the modules is delivered in three-day blocks every four to six weeks (approximately). For an MSc award 10 modules in total.

Module Titles:

Drug Discovery & Pre-Clinical Research & Development

Toxicology: From Molecules to Man

Clinical Study Design

Practical Aspects of Clinical Research & Early Drug Development

Ethics & Regulation in Clinical Research

Data Management: The Interpretation of Statistics & Pharmacokinetics

Specific Topics in Clinical Trial Design and Elective Project

Health and Pharmaco-Economics

Pharmaceutical & Healthcare Marketing

Dissertation

## Academic Year of Study 1

Module Title	Module Code	Credits	Level	Module Selection Status	Academic Year of Study	Semester
Drug Discovery & Pre-Clinical Research & Development		15	7	Compulsory	1	Semester 1
Toxicology: From Molecules to Man		15	7	Compulsory	1	Semester 1
Clinical Study Design		15	7	Compulsory	1	Semester 1
Practical Aspects of Clinical Research & Early Drug Development		15	7	Compulsory	1	Semester 2
Ethics & Regulation in Clinical Research		15	7	Compulsory	1	Semester 2
Data Management: The Interpretation of Statistics & Pharmacokinetics		15	7	Compulsory	1	Semester 2

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Module Title	Module Code	Credits	Level	Module Selection Status	Academic Year of Study	Semester
Specific Topics in Clinical Trial Design and Elective Project		30	7	Compulsory	1	Semester 3
Health and Pharmaco-Economics		15	7	Compulsory	1	Semester 3
Pharmaceutical & Healthcare Marketing		15	7	Compulsory	1	Semester 3
Dissertation		30	7	Compulsory	1	Semester 3

### What Are the Entry Requirements?

Criteria for admission to the programme:

Candidates should have a degree or equivalent in an appropriate subject from an approved educational establishment.

Or

Professional qualifications or sufficient experience to satisfy the head of division and course director of the applicants fitness to pursue the course of study. The postgraduate diploma will be a prerequisite to enter the MSc in most cases.

Also prospective students would either need to be in employment or be able to produce agreeing project supervision by a suitable supervisor.

Entry level guidelines for English Language

An ILESTS score of  $\geq 6.5$  or a TOEFL score of  $\geq 600$  is required for this course.

### How Do We Listen and Act on Your Feedback?

Students on our course are never seen as "silent partners" in the enterprise of improving teaching. One way their voices can be heard is through completion of feedback forms for each module. The feedback forms gain the students views on the clarity, style of presentation, course material, stimulation and an overall rating of the lectures (please see example of a feedback form below). Student feedback is discussed with the lecturer and is encouraged to make necessary changes following student suggestions.

Module

Lecturer Name

Class

Please rate the following aspects on a scale of 1 (awful) to 5 (excellent)

Clarity (1-5)

Lecture Style (1-5)

Course Material (1-5)

Stimulation (1-5)

Overall rating (1-5)

Specific comments:

All students are in a regular contact with members of the course team. Pastoral as well as academic support is offered on a regular basis. Students are encouraged to contact course team members via email or by phone.

Assessment of effectiveness of student support mechanisms is evaluated with the following means:

- Continuous feedback to the students. Student feedback is an extremely important mechanism to facilitate the students learning experience. Feedback is offered on drafts of coursework and academic progress following formative and summative assessment.
- Staff-student liaison. Students are encouraged to keep in regular contact with the course team members to convey their experience and comments and to seek any advice or help they may need.
- Assessment of action on student feedback.

Continuous student feedback throughout the year is an essential tool with a view to maintain as well as to improve the quality and student experience of the course.

Changes implemented following student feedback 2009-2011

- Additional lectures by the learning services team were incorporated into the timetable to give students experience from qualified staff (eg. EndNote training, medical and scientific writing).

## Academic Support

In addition to Staff-student liaison, all students are allocated a personal tutor who can be contacted during office hours. The role of the personal tutor is to advise the student on any issues relating to the academic aspects of the course that the student may wish to raise. A senior tutor is also available for consultation if their own tutors are not available or if for any reason unsuitable. Also Institute level Committee will be created responsible for ongoing management of the Programmes.

## Programme-specific Rules and Facts

## Specific Support for Disabled Students

As the programme is distance learning in format it becomes readily available to disabled students who under normal circumstances would find it difficult to relocate to London.

## Links With Employers, Placement Opportunities and Transferable Skills

Student Employment Prospects: The employers, which include the pharmaceutical industry, NHS, etc will greatly benefit from having students who successfully completed this PGDip/MSc. With the modernisation of medical education and the fact the education and training of staff involved in drug development has not kept pace with the scientific and regulatory changes that

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have occurred recently, this PGDip/MSc course will help accelerate understanding and improve knowledge that is essential for building confidence and experience.

PGDip/MSc graduates in Clinical Drug Development will be well prepared for employment in any area of clinical drug development, clinical trial design as well as clinical trial management. This includes careers within pharmaceutical or Biotech companies, clinical research organisations (CROs), Universities as well as the Clinical Research Networks. In addition opportunities are possible within regulatory organisations worldwide working within post-market surveillance by bringing together information from different sources to evaluate the safety of newly marketed pharmaceuticals, and similarly in medical writing for medical journals.

The Institute and Centre work with the students to identify suitable opportunities and supports the job application process. Graduates continue the 'Queen Mary experience' after they leave by keeping in touch with the course team, colleagues and friends.

The program supports post graduates seeking careers in clinical trial design and clinical trial management within the pharmaceutical industry in the following key areas:

- Drug Design
- Pharmaceutical Analysis
- Drug safety and pharmacovigilance
- Clinical trial management e.g. (clinical research associates)
- Pharmaco- economics
- Marketing
- Regulatory Affairs
- Quality Assurance
- Medical Writing
- Medical Sales

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## Programme Specification Approval

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**Person completing Programme Specification**

Professor Atholl Johnston

**Person responsible for management of programme**

Professor Atholl Johnston

**Date Programme Specification produced/amended by School Learning and Teaching Committee**

**Date Programme Specification approved by Taught Programmes Board**

27 Sep 2012