

Programme Specification (PG)

Awarding body / institution:	Queen Mary University of London
Teaching institution:	Queen Mary University of London
Name of final award and title:	MSc in Clinical Drug Development FT Distance Learning (January start)
Name of interim award(s):	PGDip/PGCert,
Duration of study / period of registration:	1 Year Full Time
Queen Mary programme code(s):	PSCDD - B2D1& B2S4
QAA Benchmark Group:	
FHEQ Level of Award:	Level 7
Programme accredited by:	
Date Programme Specification approved:	28/11/2023 via Chair' Action
Responsible School / Institute:	William Harvey Research Institute

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

William Harvey Research Institute

Collaborative institution(s) / organisation(s) involved in delivering 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 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 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, 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 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).

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 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.

For the delivery of the distance learning programme, students will have comprehensive study materials provided online. With the recent infrastructure investment by QMUL, the new technologies (e.g. QMPlus, Teams, Eco360) which allows them to discuss and exchange ideas, share knowledge as well as to review the lecture sessions in their own time and at their own pace.

A note on distance learning:

The institute is aware of the difficulties some students face in finding the time and funding to come to London to study. Being unable to come to London for an extended period need no longer be a barrier to obtaining an excellent qualification. The course and assessment protocols would be maintained to ensure that students achieve the same standard as those on the London-based course. The difference being the mode of delivery for the distance learning students will involve online teaching platform. Access to a computer and internet will be essential. Studying via distance learning would provide an attractive option for those with financial constraints, commitments to work or family, or lack of local access to higher education. Lectures are recorded through Echo 360, and uploaded along with lecture slides and relevant materials onto QMPlus.

Teaching methods employed during this 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 learning environment.

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

- 1) Lectures – These lectures will be delivered by members of the course faculty with occasional ‘guest lectures’ for selected topics.
- 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 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.

Dissertation

The candidates will submit a written dissertation on a subject in which they have been supervised. All assignments/dissertation will be double marked by the experts teaching on particular topics.

How is the programme structured?

Please specify the structure of the programme diets for all variants of the programme (e.g. full-time, part-time - if applicable). The description should be sufficiently detailed to fully define the structure of the diet.

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).

Module Titles:

Drug Discovery and Pre-Clinical Research and 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

Programme is offered Full time.

*If you are undertaking the Full time programme- all the listed modules have to be taken in one year.

Academic Year of Study FT - Year 1

Module Title	Module Code	Credits	Level	Module Selection Status	Academic Year of Study	Semester
Drug Discovery and Pre-Clinical Research and Development	WHRM990	15	7	Compulsory	1	Semester 1
Toxicology: from Molecules to Man	WHRM991	15	7	Compulsory	1	Semester 1
Clinical Study Design	WHRM992	15	7	Compulsory	1	Semester 1
Practical Aspects of Clinical Research & Early Drug Development	WHRM993	15	7	Compulsory	1	Semester 2
Ethics & Regulation in Clinical Research	WHRM994	15	7	Compulsory	1	Semester 2
Data Management: The Interpretation of Statistics & Pharmacokinetics	WHRM995	15	7	Compulsory	1	Semester 2
Specific Topics in Clinical Trial Design	WHRM999	30	7	Compulsory	1	Semester 3
Health and Pharmaco-Economics	WHRM996	15	7	Compulsory	1	Semester 1
Pharmaceutical & Healthcare Marketing	WHRM997	15	7	Compulsory	1	Semester 3
Dissertation	WHRM998	30	7	Core	1	Semesters 1-3

What are the entry requirements?

Criteria for admission to the programme:
 A 2:2 or above at undergraduate level in a related subject from a recognised academic institution is required for entry.
 Entry level guidelines for English Language IELTS Academic: 6.5 overall including 6.0 in Writing and Speaking, and 5.5 in Reading and Listening.

How will the quality of the programme be managed and enhanced? How do we listen to 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.

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.

All distance learning students complete online feedback forms.

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

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 of student experience on the course.

What academic support is available?

In addition to Staff-student liaison, all students are allocated a personal tutor who can be contacted during office hours via Teams. The role of the personal tutor is to advise the student on any issues relating to the academic aspects of the course that 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 an Institute level Committee is responsible for ongoing management of the Programmes.

Programme-specific rules and facts

How inclusive is the programme for all students, including those with disabilities?

Queen Mary has a central Disability and Dyslexia Service (DDS) that offers support for all students with disabilities, specific learning difficulties and mental health issues.

Students can access advice, guidance and support in the following areas:

- Finding out if you have a specific learning difficulty like dyslexia
- Applying for funding through the Disabled Students' Allowance (DSA)
- Arranging DSA assessments if need
- Specialist one-to-one "study skills" tuition
- Ensuring access to course materials in alternative formats (e.g. Braille)
- Providing educational support workers (e.g. note-takers, readers, library assistants)
- Mentoring support for students with mental health issues and conditions on the autistic spectrum.

To access the online services at QMUL visit the link below.
<https://dds.qmul.ac.uk>

Links with employers, placement opportunities and transferable skills

Student employment prospects: The employers, which in this case include healthcare research organisations, and the NHS, etc will greatly benefit from having students who successfully completed this MSc. With the modernisation of medical education and the fact that the education and training of staff involved in healthcare has not kept pace with the scientific and regulatory changes that have occurred recently, this MSc course will help accelerate understanding and improve knowledge that is essential for building confidence and experience.

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

Programme Specification Approval

Person completing Programme Specification:

Dr Dunja Aksentijevic/Dr Nina Ravic

Person responsible for management of programme:

Dr Dunja Aksentijevic

Date Programme Specification produced / amended by School / Institute Education Committee:

12/11/2023 (for Jan 2024)

Date Programme Specification approved by Taught Programmes Board:

28/11/2023 via Chair' Action