

Faculty of Life Sciences

Programme Specification

Programme title: Pharmaceutical Technology and Medicines Control

Academic Year:	2018-19
Degree Awarding Body:	University of Bradford
Partner(s), delivery organisation or support provider (if appropriate):	N/A
Final and interim award(s):	[Framework for Higher Education Qualifications level 7] MA/MSc Postgraduate Diploma Postgraduate Certificate
Programme accredited by (if appropriate):	N/A
Programme duration:	1 year full-time
QAA Subject benchmark statement(s):	N/A
Date of Senate Approval:	
Date last confirmed and/or minor modification approved by Faculty Board	Oct 2017

Introduction

This programme is designed to continue the University of Bradford's long track record of developing innovative curricula in line with the needs of world-wide industry. The pharmaceutical industry is growing at a considerable pace, globally, and due to changing business dynamics, innovative pharmaceutical processing technologies are gaining importance. The increasing significance of technologies for manufacturing advanced drug delivery systems and the need to comply with stringent regulatory requirements has raised demand for a workforce with specialist skills in the area of pharmaceutical technology.

The programme will enable students to gain a wide perspective of pharmaceutical sciences that covers pharmaceutical formulation development with foundation knowledge of processing technologies. This

provides advanced theoretical knowledge and laboratory skills of the sciences related to a pharmaceutical sciences discipline with the focus on the development and production of medicines. This leads to an emphasis in the programme on clinical trial processes and procedures needed for licensing and regulation.

Medicine control is an important element of this programme. It encompasses drug regulations, drug licensing, managing drug supply, drug procurement, drug testing and safety. It will enable students to develop key knowledge of structured enforcement and inspection standards through the application of quality assurance. Students will learn the principles of quality assurance and regulatory systems for the production of high-quality medicines by the pharmaceutical industry. Students will also gain knowledge and skills related to pharmacovigilance, including the safe and proper use of medicines.

The interdisciplinary postgraduate programme in Pharmaceutical Technology and Medicines Control has been developed taking into consideration the requirements of the global pharmaceutical industry and the strong infrastructure and expertise available across the Faculty of Life Sciences and Engineering Design & Technology. The course structure is modular and the programme delivered over 52 weeks. The taught components are run over two semesters (September to January then late-January to May), with the research project taking place between May and August. In the first semester, the students take three modules (which constitute 60 credits) and in the second semester, they take three modules worth 60 credits. The research project is worth 60 credits. The programme will progress from structured learning led by lectures and practical through more seminar based learning to an individual research based dissertation and project.

This programme will be hosted by the School of Pharmacy and Medical Sciences which is situated on the main University campus. The programme is interdisciplinary in structure and will be supported by the University's Analytical Centre. The programme will provide students with an exposure to and understanding of pharmaceutical technologies, delivery systems, drug regulation and process analytics.

Programme Aims

The programme is intended to:

- provide an opportunity to develop a comprehensive understanding and knowledge in the area of pharmaceutical formulation development and its underpinning science and processes.

- develop an understanding of the application of analytical techniques in pharmaceutical formulation development.
- provide an insight into regulatory requirements for licensing pharmaceuticals and application of Process Analytical Technologies (PAT) in process development and the manufacture of pharmaceuticals.
- provide students with knowledge and understanding of quality assurance and managing drug supply which can support the availability of quality of medicines.
- provide an opportunity to develop a conceptual understanding that enables the student to evaluate critically current research and, where appropriate, to propose new hypotheses.
- develop transferable skills including scientific literature searching and evaluating, reporting and presenting scientific information.

Programme Learning Outcomes

To be eligible for the award of Postgraduate Certificate at FHEQ level 7, students will be able to:

- LO1 deal with complex issues related to pharmaceutical formulation and processing technologies both systematically and creatively.
- LO2 understand and evaluate the application of different processes and techniques in preformulation and formulation development.
- LO3 evaluate the application of analytical techniques for the characterisation of the physico-chemical properties of drug substances.
- LO4 assess and evaluate with critical awareness the principle of the pharmaceutical quality system, which ensures the availability of quality affordable medicines.
- LO5 demonstrate a clear understanding of current regulatory procedures in the licensing of medicines, and regulatory issues with reference to case studies.
- LO6 demonstrate the qualities and transferable skills required to exercise initiative and personal responsibility and decision making in complex and unpredictable situations.

Additionally, to be eligible for the award of Postgraduate Diploma at FHEQ level 7, students will be able to:

- LO7 understand and evaluate the application of different techniques in process analytics.
- LO8 critically evaluate scientific literature and communicate scientific information both in writing and orally.
- LO9 demonstrate independent learning and the critical thinking ability required for continuing professional development.

Additionally, to be eligible for the award of Degree of Master at FHEQ level 7, students will be able to:

- LO10 demonstrate originality in application of knowledge, together with practical understanding of research techniques in an area within the pharmaceutical sciences.
- LO11 demonstrate self-direction and originality in implementing a research project; employ appropriate experimental approaches and report their findings in relation to current research knowledge and understanding.

Curriculum

Postgraduate Certificate

FHEQ Level	Module Title	Core/ Option/ Elective	Credits	Study Period	Module Code
6	Fundamentals of Drug Delivery	Optional	20	1	PHA6005-B
7	Science of Solid Dosage Forms & Advanced Pharmaceutical Technologies	Core	20	1	PHA7007-B
7	Solid Analysis	Optional	20	1	CFS7026-B
7	Quality Assurance and Medicine Safety	Core	20	1	PHA7051-B

Students will be eligible to exit with the award of Postgraduate Certificate if they have successfully completed 60 credits and achieved the award learning outcomes.

Postgraduate Diploma

FHEQ Level	Module Title	Core/ Option/ Elective	Credits	Study Period	Module Code
7	Critical Appraisal of a Current Topic in Pharmaceutical Sciences	Core	20	2	PHA7005-B
7	Process Analytical Technologies (PAT) & Quality by Design (QbD)	Core	20	2	PHA7050-B
7	Separation Science and Mass Spectrometry*	Optional	20	2	CFS7027-B
7	Imaging*	Optional	20	2	CFS7028-B
7	Management of Global Pharmaceutical Supply	Optional	20	2	PHA7049-B

Students must select one of the modules marked *, if they have not taken Solid Analysis in semester 1.

Students will be eligible to exit with the award of Postgraduate Diploma if they have successfully completed at least 120 credits and achieved the award learning outcomes.

Degree of Master

FHEQ Level	Module Title	Core/ Option/ Elective	Credits	Study Period	Module Code
7	Research Project	Core	60	3	PHA7011-E

Students will be eligible for the award of Degree of Master if they have successfully completed at least 180 credits and achieved the award learning outcomes.

Learning and Teaching Strategy

The teaching and learning strategy takes into consideration the programme and modules and the nature of the subject, with the expectation that the students will take responsibility for their learning as they develop their academic skills. A wide variety of teaching and learning methods across modules to suit different students' learning styles and appropriate to the learning outcomes of the individual modules are employed throughout the programme, and are supported by the virtual learning environment, provided by the University.

The students will be offered extended induction workshops throughout the first semester, for the necessary support to help them to make a smooth transition into the Framework for Higher Education Qualifications (FHEQ) Level 7 in the United Kingdom. As part of these workshops, students will be exposed at an early stage of their studies to an enquiry based group task. Also, they will be introduced to self-reflection for continuing professional development (CPD) and strategies for reflective practice and will select activities to reflect on what they have learnt and how it will influence them in future (For more details on these workshops and other support that is available for students, see programme handbook).

The range of teaching and learning methods used across modules will facilitate participatory learning. These methods include formal lectures, laboratory practical sessions, critical appraisal, coursework assignments, presentations and workshop sessions. Lectures, tutorials and seminars will identify and develop new subject-specific skills and systematic understanding, which the students will apply in their research project. In face-to-face sessions concepts, principles and theories will be introduced and explored in lectures and discussed in tutorials by working through examples, with lab sessions to enhance collaborative experiences where students work with each other and the tutor to complete the lab exercises. These skills will be further developed through workshop sessions where students get the opportunity to work in small groups and also to participate in a course-based journal club where a number of recent research articles are discussed and presented in teams of two. Self-directed research based learning is also a key element of subject skills development.

Throughout the programme, we make use of case studies so that students can apply their theoretical understanding to real-world issues. They will be engaged on a range of realistic group tasks that provide a real environment in which team skills can be practised and developed. These tasks include real industrial case studies that require a practical solution applying scientific knowledge which are considered authentic, as they mimic the way problems are solved in real-world settings. Additionally, the tasks are designed around technical and scientific knowledge that researchers use in employment, for example running journal clubs, workshops and research talks.

In this programme, critical thinking and analytical skills are applied across all modules including the Critical Appraisal module and MSc dissertation projects. This will help the students to develop an independent enquiry, based on established research techniques, that critically evaluates and interprets advanced research and scholarships linked to the pharmaceutical

sciences field and demonstrates conceptual understanding and originality that contributes to knowledge in the discipline.

Student choice is important in developing ownership of their learning and fostering deep learning. The structure of the programme offers them the opportunity to study more specialised topics selected from a range of options. However, students must select one of the modules marked with asterisk (*) in the curriculum to give them hands-on use of advanced characterisation equipment. Students may indicate their choice of study subject by the third week of the study period.

The methods implemented in developing the students' practical skills include demonstrations and practical sessions linked with the taught modules. Students will also design formulations, use analytical techniques, develop skills in using software applications and use control and measuring instruments under supervision during the initial phase of their research projects.

MSc students undertaking a dissertation are expected to independently design, conduct, and report on a research project under the supervision of a tutor. The dissertation is a key part of the course as it accounts for one-third of the programme credits. The dissertation element brings together the knowledge and skills learnt throughout the programme and gives students the opportunity to build on a topic of particular interest within the pharmaceutical sciences field. It also allows them to further enhance their critical evaluation skills of the recent research developments in the pharmaceutical sciences and the ability to synthesize and evaluate the literature. This further allows students to acquire specialised knowledge and high-level research skills.

We invite industrial speakers to this programme on a regular basis. They present seminars on the most pressing topics within drug development in the industry and real case studies on the challenges in the drug development of some of their products. The students will have the opportunity to present their dissertation projects to industrial scientists, which enables them to communicate their research to a wider audience including researchers from the University. Besides, there will be an opportunity to attend industrial visits.

The learning outcomes (LOs) are embedded in the curriculum design of the specific modules and are detailed below:

- LO1 and LO2 are mainly developed in Fundamentals of Drug Delivery and Science of Solid Dosage Forms & Advanced Pharmaceutical Technologies modules.

- LO3 will be developed in Solid Analysis, Separation Science and Mass Spectrometry, and Quality Assurance and Medicine Safety modules.
- The modules of advanced analytical techniques and Quality Assurance and Medicine Safety module provide an opportunity for students to integrate their knowledge of formulation development and processing, and achieve LO2 and LO7.
- The Critical Appraisal module and research project along with laboratory experimental exercises and case studies work, will allow the students to develop their intellectual skills to accomplish LO8 to LO11.
- Development of transferable skills (LO6) should occur throughout the programme. It will mainly occur through preparation and presentation of critiques, project reports, laboratory reports and seminars. Implementation of the research project, in the third semester, will provide the students with an opportunity to learn about effective planning, time management, interpersonal skills and professional responsibility.
- The teaching and learning methods implemented to engage students in developing their knowledge and understanding as mentioned in LO1 through LO5 and LO7, include formal lectures (including those visiting lectures from pharmaceutical companies), laboratory coursework, small group discussions, syndicate workshops, project work, directed learning and individual work.
The MSc Research Project will allow students to demonstrate all skills and knowledge developed through the year, and it is required to demonstrate the achievement of LO10-11.

Assessment Strategy

Modules are assessed by a variety of means including essays, exams, laboratory reports, presentations (oral and poster) including journal club presentations, written critical review, case study report and a dissertation. Formative feedback is provided on all modules, for instance, students receive written formative feedback on the first report in Fundamentals of Drug Delivery, and Science of Solid Dosage Form & Advanced Pharmaceutical Technologies modules. They also receive written formative feedback on a draft of the critical appraisal report and dissertation. The students will have the opportunity to deliver a formative presentation in Quality Assurance and Medicine Safety, and Process Analytical Technologies (PAT) & Quality by Design (QbD) modules. On the other hand, assessment deadlines for all modules are carefully planned to ensure a balanced and manageable

workload throughout the semesters. Additionally, assessment deadlines are recorded in the programme handbook, which is released to students on the induction day.

The students will have some choice in their assessment methods. For example, they can select optional modules that apply different assessment methods. The students will also have the choice to present their dissertation work either as an oral or poster presentation. They will also be provided with the marking scheme for the report course work, presentation and dissertation beforehand and they are encouraged to make themselves familiar with it before starting their assignments.

The various assessment methods across modules are designed to reflect the range of learning outcomes in the programme and to allow the students to demonstrate their knowledge and achievement:

- The methods of assessment to assess the students' knowledge and understanding in LO1 to LO5 and LO7 will include written examination, critical review, case study report, evaluation of project reports, presentations including journal club presentation and experimental coursework.
- The methods of assessment of the ability to evaluate critically current research and advanced scholarship in the discipline include presentation of a critique of published research articles and experimental coursework, and most importantly, the MSc dissertation (outcomes LO8 to 11).
- The methods of assessment of practical skills include verbal or written feedback on laboratory work linked with the taught modules. The presentation and appropriate use, understanding and analysis of these methods will be assessed through the MSc dissertation.
- The final MSc project is assessed by dissertation and presentation (oral or poster) and allows students to demonstrate achievement of all learning outcomes developed throughout the programme, and more specifically, achievement of LO10-11 required for the MSc degree.
- The methods of assessment of transferable skills (LO 6) are built into the structure of the examinations, case studies, and research or project work.

Assessment Regulations

This Programme conforms to the standard University Regulations which are available at the following link:

<http://www.bradford.ac.uk/agpo/ordinances-and-regulations/>

Admission Requirements

The University welcomes applications from all potential students and most important in the decision to offer a place is our assessment of a candidate's potential to benefit from their studies and of their ability to succeed on this particular programme. Consideration of applications will be based on a combination of formal academic qualifications and other relevant experience.

The standard entry requirements for the programme are as follows:

As a general guideline, acceptance on the Masters programme requires a first degree at Honours or equivalent (2:2) in a relevant area such as Biological Sciences, Chemistry, Pharmacy, Pharmacology or Pharmaceutical Sciences.

Applicants whose native language is not English will also have to pass a test in English approved by the University. The following qualification is acceptable as satisfying this requirement:

- The International English Language Testing Service Test (IELTS) administered by the British Council is the test which is preferred by the University. Applicants must achieve an Overall Band of at least 6.0, with at least 5.5 in each of the four sub-tests. Testing facilities are available at most British Council overseas offices. When taking the test, applicants should ask for a copy of their Test Report Form to be sent to the University.

Further information can be found at:

<https://www.bradford.ac.uk/international/your-application/english-language-requirements/>.

Applications are welcome from students with non-standard qualifications or mature students (those over 21 years of age on entry) with significant relevant experience.

Recognition of Prior Learning

If applicants have prior certificated learning or professional experience which may be equivalent to parts of this programme, the University has procedures to evaluate and recognise this learning in order to provide applicants with exemptions from specified modules or parts of the programme.

Minor Modification Schedule

Version Number	Brief description of Modification	Date of Approval (Faculty Board)
1		