

Programme Specification

Masters, Postgraduate Diploma, Postgraduate Certificate in Pharmaceutical Development with Business Management

This programme specification applies to students starting the programme from September 2021 onwards.

Information for students: the programme specification is the definitive document summarising the structure and content of your degree programme. It is reviewed and updated every year as part of Keele's Curriculum Annual Review and Development process. The document aims to clarify to potential and current students what you can expect from the study of the subject over the course of your programme.

Names of programme(s) and award title(s)	<p>Master of Science in Pharmaceutical Development with Business Management</p> <p>Postgraduate Diploma in Pharmaceutical Development with Business Management</p> <p>Postgraduate Certificate in Pharmaceutical Development with Business Management</p>
Mode of study	Full time only
Framework of Higher Education Qualification (FHEQ) level of final award	7
Duration:	One year full time

Details of professional, statutory and regulatory body (PSRB) (If appropriate):
<http://www.keele.ac.uk/qa/professionalstatutoryregulatorybodies/>

External Examiner(s): Further information can be found at:
<https://www.keele.ac.uk/qa/externalexaminers/currentexternalexaminers/>

1. What is the philosophy of the Programme?

The overall aim of this programme is to provide you with the knowledge base and an environment to develop the skills and confidence needed in the pharmaceutical, cosmetic or food industry.

The programme will:

- Build on your existing knowledge of chemistry, biology and other pharmaceutical sciences and apply them in a pharmaceutical industry setting
- Provide a comprehensive knowledge of the processes that are involved in product development and bringing a product into market
- Introduce theories and conceptual models for make and buy decisions, transactional costing, buyer-supplier relationship and supply chains and apply them in a pharmaceutical industry setting
- Develop in-depth knowledge of the global social, economic, cultural, political and technological conditions that shape the goals and processes of transnational organisational activity such as those in the pharmaceutical industry
- Provide a thorough grounding in the application and development of key pharmaceutical analysis approaches.

This is an innovative postgraduate programme that combines study of the applied pharmaceutical sciences relating to the development and launch of pharmaceutical products and devices within the context of the structure of the global pharmaceutical industry. The knowledge you learn on the programme can also be applied in the cosmetic, nutraceutical or food industry. It aims to meet the needs of the industry by producing graduates who are pharmaceutically aware, who have the ability to think critically and creatively and who also have significant knowledge and understanding of business and management, thus facilitating the transition to employment and their immediate contribution to the pharmaceutical industry or in the cosmetic or food industry.

Our new multidisciplinary programme will deliver a new generation of potential global industry leaders with a broad, solutions-focused knowledge of the applied pharmaceutical sciences. To achieve this, students on the programme are encouraged to integrate their business management knowledge and skills with their understanding of the pharmaceutical science. The interdisciplinary module PHA-40173 was developed with this in mind and covers the core principles in the pharmaceutical sciences through to product launch and post-market life cycle management. As a graduate of this course you will have the business insight essential in the new model of the pharmaceutical industry to be able to buy and sell science and to participate in, and manage, global product development teams. The emerging markets, notably Brazil, Russia, India, China, Mexico and Turkey (BRIC-MT), are expanding rapidly and have a shortage of qualified local people to deliver. In addition, global regulatory agencies may be interested in recruitment of assessors and inspectors to such new and expanding markets.

Keele Graduate Attributes

Engagement with this programme will enable you to further develop your intellectual, personal and professional capabilities. At Keele, we call these our ten Graduate Attributes and they include independent thinking, synthesizing information, creative problem solving, communicating clearly, and appreciating the social, environmental and global implications of your studies and activities. Whilst you will undoubtedly have already developed these skills and abilities to varying degrees, such existing capabilities can always be deepened and enriched. Our educational programme and learning environment is designed to help you to develop further as a well-rounded postgraduate who is capable of making a positive and valued contribution in a complex and rapidly changing world, whichever spheres of life you engage in during and after your studies at Keele.

Please refer to the programme webpages for a statement of how you can achieve the Keele Graduate Attributes through full engagement in the programme and other educational opportunities at Keele. Further information about the Keele Graduate Attributes can be found here: <http://www.keele.ac.uk/journey/>

2. How is the Programme taught?

This is a full-time programme that will involve face-to-face teaching. The programme is delivered through a variety of learning and teaching activities designed to develop research and professional skills. They include the following:

- Lectures, including those from external speakers
- Workshops
- Oral presentations
- Poster presentations
- Group / team work
- Practical work
- Literature research tasks
- Directed reading
- Independent study
- Independent project
- Use of e-learning / the Keele Learning Environment (KLE, Blackboard)
- One-on-one meetings/discussions with individual research supervisors

Teaching Staff

You can find the teaching and research profiles of the staff that deliver and support this programme on <https://www.keele.ac.uk/pharmacy/staff/> and <https://www.keele.ac.uk/kbs/staff/academicstaff/>.

Academic staff span different disciplines and there are additional guest lecturers from the industry and from our business partners. The academic staff from the School of Pharmacy at Keele teaching on this programme have expertise and interests within pharmaceutical science and the pharmaceutical industry. A number of staff are Fellows of the Higher Education Academy.

3. What is the Structure of the Programme?

The MSc in Pharmaceutical Development with Business Management has been designed as a full-time programme that is completed over one calendar year. The structure and content of this programme has been developed in consultation with experts who have significant experience in the pharmaceutical industry and in collaboration with the Keele Business School (KBS). As a result, the modules have been developed to reflect current education, training and professional development needs.

In the first semester of the programme, you will study two 15-credit modules by KBS and a 30-credit module by the School of Pharmacy as listed in the table in the later part of this section and in the 'Programme Structure and Module Information section' of the programme handbook. We may bring in guest speakers with experience in the pharmaceutical industry to complement the taught content within these modules.

In the second semester of the programme, you will study three modules totalling 60 credits. PHA-40174 Applied Pharmaceutical Analysis (30 credits) will focus on teaching you on how to apply core analytical techniques used in the pharmaceutical industry. You will also study two 15 credit modules that will further your knowledge in the pharmaceutical development process. They are: PHA-40169 Quality by Design and PHA-40190 Development of Biopharmaceuticals.

In the final semester, you will be expected to complete a 60-credit project that can either take place within the state-of-the-art laboratories at Keele University or in partnership with our industrial partners.

Listed below are the modules that you will study on this course:

Semester 1

PHA-40173 Product Development and Management (30 credits)

This interdisciplinary module covers the pharmaceutical development process, from the core principles in pharmaceutical science, through technology, processes and associated tools in product development from launch to post-market life cycle management in the context of appropriate regulatory frameworks.

Modules delivered by Keele Business School (KBS):

MAN-40114 International Business Context (15 credits)

The module offers insight into a range of social, political, economic, technological and cultural processes that shape the goals and processes of international business activities. You will have a critical and solid understanding of basic theories underlying the importance of international trade and investment. You will also be able to apply the theories and background knowledge learned to enhance understanding of current events and their impact.

MAN-40110 International Operations and Supply (15 credits)

The purpose of this module is to explore how international supply chains are designed, managed and controlled, as well as how they might have to adapt for different locations in the world. The module will therefore cover theoretical and strategic concerns on the development of supply chain concepts and operations in practice. Other indicative module content includes: designing business processes, outsourcing and offshoring and supplier selection and development. The learning process is facilitated through lectures, guided reading, videos, worked exercises, and contemporary case studies.

Semester 2

PHA-40174 Applied Pharmaceutical Analysis (30 credits)

This module will focus on the core analytical techniques employed in the pharmaceutical industry. This will include chemical and biological methods applied during the different stages of drug discovery, from research development to manufacturing process.

PHA-40169 Quality By Design (15 credits)

This module will mirror the Quality-by-Design (QbD) process adopted in pharmaceutical formulation and manufacture. It will commence by defining a target product quality profile and, establishing key production parameters and a control protocol for the development processes, will lead students through the QbD processes in a pharmaceutical context.

PHA-40190 Development of Biopharmaceuticals (15 credits)

This module will equip you with the fundamental knowledge and skills required to pursue a career in recombinant protein science. You will gain hands on experience during practical laboratory sessions. You will learn to design and execute an appropriate recombinant protein protocol and validate the quality and quantity of a produced biopharmaceutical.

Semester 3

PHA-40171 Pharmaceutical Development with Business Management Project (60 credits)

Project options range from the core science areas of pharmaceuticals, chemistry, pharmacology, pharmacokinetics, recombinant protein expression, or relevant business-focused projects. We would also allow you to conduct this semester with companies if you are successful in securing your own research/audit position.

The table below summarises the modules on this MSc course with their intended learning outcomes and their principal forms of assessment:

Module	Intended Learning Outcomes	Principal forms of assessment
<i>PHA-40173 Product Development and Management (30 credits)</i>	<p>If you successfully complete this module, you will be able to:</p> <ul style="list-style-type: none"> • determine the appropriate strategies, tools and matrices that can be employed to set out a framework and direction for product development and design this into a programme of product development including product improvement, cost reductions, line extension and new products and manage a portfolio demonstrate an understanding of the applications of market research tools such as secondary research, qualitative vs quantitative, focus groups, customer site visits, ethnography, consumer panels, social media and market testing. 	<ul style="list-style-type: none"> • Portfolio • Oral Presentation • Examination

	<ul style="list-style-type: none"> • assess, compare and critique the various technologies and processes that lead to product development • demonstrate an understanding of product life cycle management by being able to explain and critique the different methodologies used in the different phases of product life cycle (introduction, growth, maturity and decline). • discuss and explain the processes in which environmental, financial and social considerations are integrated into company systems from idea generation to research and development and finally into commercialisation to generate sustainable innovation. • build on, apply and explain the principles of pharmaceutical science that are utilised in the process of product development. 	
<p><i>MAN-40114 International Business Context (15 credits)</i></p>	<p>If you successfully complete this module, you will be able to:</p> <ul style="list-style-type: none"> • critically evaluate the arguments relating to global economic, political, cultural and technological factors that shape international business. • use theories and background knowledge learned to enhance general understanding of current events and their impacts on international business and to formulate critical opinions. 	<ul style="list-style-type: none"> • Literature Review • Group presentation on a case study

	<ul style="list-style-type: none"> • understand and analyse the international environments in which international business decisions are made. 	
<p><i>MAN-40110 International Operations and Supply (15 credits)</i></p>	<p>If you successfully complete this module, you will be able to:</p> <ul style="list-style-type: none"> • position the design, operation and quality management of operations and supply networks within a theoretical and conceptual framework. • interpret theories of decision making and design in operations and supply chain management, including strategic analysis, process optimisation, lean and agile operations, kaizen improvement, make or buy, portfolio management and relationship management, buyer-supplier power, value chains, etc. • analyse the operational requirements when managing operations and supply networks in contemporary international businesses. • reflect critically upon current “best practices” in operations, procurement, supply and logistics. • conceptualise and communicate strategic international operations and supply management issues in a convincing and meaningful way. 	<ul style="list-style-type: none"> • Essay • Group presentation

<p>PHA-40174 Applied Pharmaceutical Analysis (30 credits)</p>	<p>If you successfully complete this module, you will be able to:</p> <ul style="list-style-type: none"> • evaluate and critically appraise the literature on analytical methods within the context of pharmaceutical production and development. • synthesise ideas, communicate with fellow professionals and formulate scientific documentation commensurate with that expected of a professional pharmaceutical scientist. • evaluate and critically appraise methods for pharmaceutical assessment. 	<ul style="list-style-type: none"> • Assignment (constructing a case study + literature review) • Individual viva voce
<p>PHA-40169 Quality By Design (15 credits)</p>	<p>If you successfully complete this module, you will be able to:</p> <ul style="list-style-type: none"> • demonstrate the ability to gather and integrate prior knowledge about active ingredients, excipients and process operations. • design and assess a target product quality profile that will be used by formulators and process engineers as a benchmark for clinical safety and efficacy during product development. • critically appraise a formulation and identify the critical material attributes, critical process parameters and variables that have to be managed/controlled to meet the target product quality profile. • demonstrate the ability to perform risk assessments and prioritise 	<ul style="list-style-type: none"> • Portfolio • Examination

	<p>process parameters, knowledge gaps for further investigation and material attributes for verification.</p> <ul style="list-style-type: none"> design and propose a manufacturing process to produce a product that meets the identified target product quality profile. 	
<p><i>PHA-40190 Development of Biopharmaceuticals (15 credits)</i></p>	<p>If you successfully complete this module, you will be able to:</p> <ul style="list-style-type: none"> apply basic cell biology knowledge relating to DNA and proteins to the production of biological therapeutic agents. design and execute an appropriate recombinant protein production protocol. justify the approach and procedures used to produce and isolate a biopharmaceutical agent. validate and verify the quality and quantity of a produced biopharmaceutical. critically evaluate and interpret experimental results and laboratory protocols. critically evaluate the success or otherwise of the protein production and purification protocol used. 	<ul style="list-style-type: none"> Viva voce Laboratory Report
<p><i>PHA-40171 Pharmaceutical Development with Business Management Project (60 credits)</i></p>	<p>If you successfully complete this module, you will be able to:</p> <ul style="list-style-type: none"> demonstrate an understanding of scientific concepts by applying knowledge and skills relevant to their project to evaluate, interpret and verify data. 	<ul style="list-style-type: none"> Laboratory/audit Project Notebook Project Report Viva voce

	<ul style="list-style-type: none"> • plan, prioritise and implement tasks according to changing workload demands. • demonstrate critical reflection and analysis in the application of knowledge, together with a practical understanding of how established techniques are used to create and interpret knowledge in the subject area. • critically evaluate current research/audit (evidences and findings) and advanced scholarship in the subject area • demonstrate decision-making skills in the planning tasks and interpretation of data • justify, discuss and defend chosen methodologies, interpretation of data and conclusions • design a project strategy to investigate hypotheses/standards/policies, evaluate methodologies and develop critiques of them and where appropriate propose new hypotheses 	
--	---	--

The programme has three exit routes as listed below.

Named awards available:

- Master of Science (MSc) in Pharmaceutical Development with Business Management – 180 credits at Level 7 to include the 60 credit Pharmaceutical Development with Business Management project.

- Postgraduate Diploma (PgD) in Pharmaceutical Development with Business Management - 120 credits at Level 7 to include all taught modules.
- Postgraduate Certificate (PgC) in Pharmaceutical Development with Business Management – 60 credits at Level 7 to include the module “Product Development and Management”.

4. How is the Programme assessed?

A variety of assessment methods are used in this programme. These include coursework-based essays, reports on laboratory- based practicals, essay-based examination, interactive oral presentations, viva and a project report based on the student project.

Clear marking guidelines accompany each mode of assessment where a mark of 50% or above is required to achieve a pass.

Through adoption of the above assessment methods students are given an opportunity to display achievements spanning knowledge and problem-solving abilities, communication and research skills, development of practical skills, and critical thinking.

Formative assessment occurs in a continuous process driven by tutor-led sessions, one-on-one mentoring, and lecturer-led discussions accompanying taught materials

5. What are the typical admission requirements for the programme?

Applicants should have, or expect to achieve, a minimum of an upper second class honours degree in a relevant science subject or an equivalent overseas qualification. In exceptional circumstances students with appropriate professional qualifications and/or work experience may be accepted at the University’s discretion.

International candidates should have an English language qualification of at least IELTS 7.0 (with no subtest lower than 6.5) or equivalent.

6. How are students supported on the programme?

- The relevant Programme Handbook will provide you with key information and guidance on structure, content and assessment, including dates for submission of your assessments for the period of your chosen course, and the dates you have to come to study days at Keele and/or participate in online collaborative learning workshops. You will also be provided with guidance on some study skills.

- Pastoral and Academic support including decisions on module choices and feedback on assessments will be provided by your academic tutor and personal tutor. You will also have access to an Independent Advisor in line with University Student Support Guidance.
- The Programme Manager and Programme Administrator will provide support as appropriate.
- You will have access to our own School of Pharmacy's IT support team as well as Keele's IT Services
- Details of your academic tutor and personal tutor will be provided to you.

7. Learning Resources

The programme is based at Keele University utilising modern teaching facilities available in locations such as the Hornbeam and Jack Ashley Buildings. You will have access to the computer facilities in the Digital Health Hub and laboratories based in the Jack Ashley Building with some taught elements possibly being delivered at the Guy Hilton Research Centre.

You will also have access to the Keele Learning Environment and Library as detailed in the course handbook.

8. Other learning opportunities

You have opportunities to complete your project (Semester 3) at the Guy Hilton Research Centre and with our industrial partners.

9. Quality management and enhancement

The *MSc Pharmaceutical Development with Business Management* Course Management Committee, which comprises all academic staff teaching on the programmes and student representation, is responsible for the day-to-day management of the programmes and reports to the School Education Committee.

To ensure that the MSc programme maintains the highest possible standards and ensures the effective management and continuous enhancement of the quality of learning and teaching, the following procedures are employed:

- Student evaluation of teaching: students have the opportunity to evaluate each module and the programme as a whole. Data from the evaluations is reported at regular course management committee meetings.

- Student-Staff Voice Committee: this is an integral part of the monitoring and review procedures and provides a valuable source of management data for the programme team.
- School Education Committee (SEC) meetings: the Programme Committee reports to the School of Pharmacy's Education Committee. Both committees meet on a regular basis and the SEC is responsible for the continual reviewing and monitoring of quality management and enhancement procedures and activities across the School.
- Peer observation of teaching: the staff responsible for delivering the programme undertake regular peer observation of teaching that is used to identify teaching strengths and areas of development.
- Annual Programme Review; individual modules and the programme as a whole are reviewed and enhanced every year as part of the University's Annual Programme Review process. A range of data is used to inform the annual programme review. It comprises student evaluations, external examiners report and internal programme review and monitoring data.
- The programme will be run in accordance with all applicable policies and will be reviewed as part of the University's Internal Quality Audit process. Each School is normally subject to audit once every five years.
- External Examiners are experienced academics from other universities who are appointed by Senate to each programme. The external examiner has access to all module mark sheets, marked examinations scripts and major pieces of coursework when he/she visits Keele for the final examination board in October.

10. The principles of programme design

The *MSc in Pharmaceutical Development with Business Management* programme is built on the successful industrial collaborations between Keele University's School of Pharmacy and several national or international industries. The associations developed provide an excellent framework in which to train you in those generic and science specific skills that would increase your employability in the pharmaceutical industry. In addition, it gives you an opportunity to contribute to the further development of the collaborative links between Keele and its industrial partners.

In addition to this, *the MSc in Pharmaceutical Development with Business Management* programme is informed by the Learning and Teaching Strategy of Keele University by:

- Promoting research-informed education and evidence-based practice that supports and increasingly diverse student body through critical evaluation of the making/remaking of

Pharmaceutical Science knowledge, development of research skills, and the promotion of international, sustainability and interdisciplinary perspectives in the Pharmacy and Pharmaceutical Science programmes.

- Sustaining and extending approaches to learning that further enhance the employability of Keele graduates and the career destinations they are able to reach through learning and teaching at the research-teaching nexus.

For further information, see www.keele.ac.uk/strategicplan/learningandteachingstrategy

11. Programme Version History

Version History	Date	CHANGES / NOTES
Date first created	18 July 2018	
Revision history	24 th November 2018	Changes made as per advised by QA at scrutiny meeting.
	23 rd January 2019	Changes made as per advised by QA and FLTC
	30 th April 2021	Changes made to reflect changes in module PHA-40174
Date approved by SEC	19 th July 2018	
Date approved by FEC	22 nd February 2019	