

School of Life and Medical Sciences

Title of Programme: Master of Regulatory Science (Pharmaceuticals and Devices)

Programme Code: LMREGSM

# Programme Specification

This programme specification is relevant to students entering:  
26 September 2018

Associate Dean of School (Academic Quality Assurance):  
Dr Stefanie Schmeer



Signature

A programme specification is a collection of key information about a programme of study (or course). It identifies the aims and learning outcomes of the programme, lists the modules that make up each stage (or year) of the programme, and the teaching, learning and assessment methods used by teaching staff. It also describes the structure of the programme, its progression requirements and any programme-specific regulations. This information is therefore useful to potential students to help them choose the right programme of study, to current students on the programme, and to staff teaching and administering the programme.

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#### Summary of amendments to the programme

Date	Section	Amendment
26.03.18	1	Module Code amended from 6LMS0116 to 6LMS0154 for Management and Corporate Finance

If you have any queries regarding the changes please email [AQO@herts.ac.uk](mailto:AQO@herts.ac.uk)

# Programme Specification Master of Regulatory Science (Pharmaceuticals and Devices)

This programme specification (PS) is designed for prospective students, enrolled students, academic staff and potential employers. It provides a concise summary of the main features of the programme and the intended learning outcomes that a typical student might reasonably be expected to achieve and demonstrate if he/she takes full advantage of the learning opportunities that are provided. More detailed information on the teaching, learning and assessment methods, learning outcomes and content for each module can be found in Definitive Module Documents (DMDs) and Module Guides.

## Section 1

<b>Awarding Institution/Body</b>	University of Hertfordshire
<b>Teaching Institution</b>	University of Hertfordshire
<b>University/partner campuses</b>	College Lane
<b>Programme accredited by</b>	Not applicable
<b>Final Award</b>	Integrated Master
<b>All Final Award titles</b>	Regulatory Science (Pharmaceuticals & Devices)
<b>FHEQ level of award</b>	7
<b>UCAS code(s)</b>	F290
<b>Language of Delivery</b>	English

### A. Programme Rationale

- This is a pioneering and distinctive programme which has been designed with extensive input from external stakeholders within the pharmaceutical and medical devices industry.
- World renowned experts in the industry are involved in delivering this innovative programme.
- As pharmaceutical and devices regulation is becoming increasingly complex across all geographic regions there is an urgent need to train individuals with appropriate skills in such disciplines at an undergraduate level. It is these individuals who will be best positioned to work within and manage the complex regulatory environment of the future, without compromising the quality of patient safety and care.
- The fourth year work placement (Residency Placement and Research Project) is a particular strength of the programme and ensures that students are prepared to meet the challenges of today's pharmaceutical/device regulatory environment and its market place.
- This model will give the student command of their skills as a practitioner bringing tangible added value to their work environment and enhancing their employability opportunities.
- The University of Hertfordshire is specifically equipped to ensure the success of such a residency programme through an extensive healthcare, insurance, recruitment, government and industry network. Through strong international academic links, UH is also in a unique position of hosting a culturally and vocationally diverse composition of students. In this sense, the programme hopes to reflect the endeavour and spirit of globalisation, a concept valued and shared by academia and business enterprises alike.

- There has been a strong interest from the stakeholders (i.e. Pharmaceutical industry, regulatory authorities, contract research organisations, health technology assessment agencies, devices industry and professional organisations) in the programme. Such interest on the part of the potential employers should give confidence to the graduates of this programme in terms of their employability in such a dynamic field.

## B. Educational Aims of the Programme

The programme has been devised in accordance with the University's graduate attributes of programmes of study as set out in [UPR TL03](#).

### Additionally this programme aims to:

- enable students to develop the high level knowledge, practical and transferable skills appropriate to the registration and maintenance of pharmaceutical/device products with respect to quality, safety and efficacy.

## C. Intended Learning Outcomes

The programme provides opportunities for students to develop and demonstrate knowledge and understanding, skills and other attributes in the following areas. The programme outcomes are referenced the Frameworks for Higher Education Qualifications of UK Degree-Awarding Bodies (2014), and relate to the typical student. Additionally, the SEEC Credit Level Descriptors for Further and Higher Education (2016) have been used as a guiding framework for curriculum design.

Knowledge and Understanding of:	Teaching/learning methods & strategies	Assessment
<p>Successful students will be able to:</p> <p>A1-understand and apply the fundamental chemical and biological principles on which pharmaceutical development is based;</p> <p>A2-understand the molecular basis of the discovery, design, synthesis and mode of action of drugs;</p> <p>A3-apply an understanding of microbiology and immunology to the preparation and supply of sterile medicines and the control of sterility in pharmaceutical manufacture and storage;</p>	<p>Acquisition of knowledge and understanding (A1-A7) is through a combination of lectures, laboratory classes, workshops throughout the course, as well as the project and the industrial training experience.</p> <p>Throughout, the learner is encouraged to undertake independent study both to supplement and consolidate what is being taught/learnt and to broaden their individual knowledge and understanding of the subject.</p> <p>Acquisition of A1 is introduced through all level 4 modules, specifically the <i>Foundations of</i></p>	<p>Knowledge and understanding are assessed through a combination of laboratory reports, seminars, group work, problem solving, interpretive exercises, written assignments, the project and unseen examinations (A1-A7).</p> <p>The individual performance in the <i>Residency Placement</i> module (A8) is assessed by assignments (essay and wiki) as well as the portfolio during the module</p>

A4-apply the principles of medicinal, analytical and process chemistry to drug design, synthesis and manufacture;

A5-understand the principles of pharmacokinetics, product formulation, and delivery route underlying the optimization of drug administration;

A6 – understand the main analytical techniques and instrumentation used in pharmaceutical dosage form development and testing.

A7 – develop a deep and systematic understanding of the regulations governing pharmaceutical product development

A8- crystallise the theoretical knowledge of regulatory requirements during the Residency Placement in the UK or overseas

*Pharmaceutical Chemistry, Biology and Biochemistry, and Human Physiology and Pharmacology* modules. It is further built upon throughout levels 5 and 6.

A2 is covered in *Foundations of Pharmaceutical Chemistry, Human Physiology and Pharmacology, Pharmacology, Methods in Drug Design* and all level 6 modules. Students are introduced to the principles behind drug design in level 4, knowledge is consolidated and contextualised during workshops and the complexity of the topics in built on during levels 5 and 6

A3 is covered in *Human Physiology and Pharmacology* and more specifically in *Dosage Form Design and Manufacture* at level 5. Students are able apply the knowledge gained in lectures in tablet manufacturing laboratory classes

A4 is covered in the specialist level 5 modules, *Methods in Drug Design* and *Dosage Form Design and Manufacture*.

A5 is achieved through the *Pharmacology* and *Dosage Form Design and Manufacture* modules.

A6 is primarily achieved through the two analytical modules (*Fundamentals of Analytical Chemistry* and *Advanced Analytical Techniques and Quality Assurance*). Students actively participate in a number of practical classes to ensure that they understand this element. Whilst working in industry during the *Residency Placement* and *Research Project*, the student will

continue to learn about this outcome in a real-life setting

A7 is introduced early on in the course where the regulations are integrated into all modules, but specifically in the level 5 & 6 module *Advanced Analytical Techniques and Quality assurance*, where EU regulatory submission & approval process, advanced pharmaceutical regulations (strategy and control for a new active substance in both nonclinical and clinical development are taught. Students are then able to strengthen their understanding within the industry setting in the module *Residency Placement*. The subject is introduced in level 4 and students understanding will be developed further in level 7 whilst working within the industry and completing specified tasks within their portfolio. The *Research Project* module will allow the student to continue to independently develop this knowledge to a deeper level.

Acquisition of A8 is achieved in the industrial placement year (*Residency placement* and *Research Project*) in the UK or abroad.

Intellectual skills - able to:	Teaching/learning methods & strategies	Assessment
<p>Successful students will be able to:</p> <p>B1-understand the ethical implications of their work;</p> <p>B2-execute and report a research project in order to develop the necessary skills for independent research and critical/reflective thinking;</p> <p>B3-apply theoretical concepts to the study of</p>	<p>Intellectual skills are developed through various activities and exercises throughout the programme. Specifically students are given a firm grounding in ethical practices in science (B1) throughout level 4 with issues further developed specific to regulatory science in the level 6 modules.</p> <p>B2 is predominantly achieved through the <i>Research Project</i> module at level 7.</p>	<p>B1 and B3 are assessed in laboratory reports, written assignments and the work in the industry <i>Residency Placement</i> module.</p> <p>B2 is assessed through the production of a dissertation and poster presentation in the project module at level 7.</p> <p>B4 and B5 are assessed through laboratory reports, unseen tests, examinations, interpretive exercises,</p>

<p>pharmaceutical development and evaluate the relationship between theory and practice;</p> <p>B4-develop and demonstrate an understanding of the nature and importance of timely ethical decision-making.</p> <p>B5-demonstrate at a level appropriate to the award, a critical approach in enquiry and a readiness to test hypotheses, interpret scientific data and evaluate published literature.</p>	<p>The relationship of theory to practice (B3) strengthens the learning experience of the students and is achieved throughout all modules and very specifically is the basis of the placement year.</p> <p>Workshops throughout all modules form the basis for B4, which is also supplemented through the personal academic tutors and specifically applied to clinical research in the level 6 module <i>Leadership and Strategic Management in Regulatory Affairs</i>.</p> <p>To acquire B5 statistical analysis is introduced in <i>Human Physiology and Pharmacology</i> at level 4, and reinforced and strengthened through the workshops in the <i>Research Project</i> module at level 7. Critique and evaluation of scientific data is introduced in level 5 and developed throughout level 7 modules most noticeably the <i>Project</i>.</p> <p>Throughout, the learner is encouraged to develop intellectual skills further by independent study</p>	<p>seminars, vivas and the project.</p>
<p>Practical skills - able to:</p>	<p>Teaching/learning methods &amp; strategies</p>	<p>Assessment</p>
<p>Successful students will be able to:</p> <p>C1-acquire appropriate laboratory skills, including safe working practices where relevant;</p> <p>C2-acquire appropriate analytical instrumentation skills;</p> <p>C3-acquire appropriate documentation and record keeping skills</p> <p>C4–design research project and analyse and interpret data.</p>	<p>Practical skills are developed through all modules in the programme, most of which contain a high practical component which is a significant strength of the course. Laboratory skills (C1) are built up during level 4 and 5 and consolidated in the level 7 <i>Project</i>.</p> <p>Analytical skills (C2) are specifically introduced in the <i>Fundamentals of Analytical Chemistry</i> module at level 4, developed through the <i>Advanced Analytical Techniques and Quality Assurance</i> module at level 5 and</p>	<p>Assessment of practical skills and attributes is by both formative and summative assessment in laboratory classes and assessed practicals; laboratory reports, interpretative exercises, group work and the research project.</p>

	<p>reinforced in the <i>Research Project</i> at level 7.</p> <p>C3 and C4 are developed throughout all practical components of the course, with C4 particularly a key component of the level 7 <i>Project</i> module.</p> <p>Data analysis is introduced through assignments at level 4 in the <i>Human Physiology and Pharmacology</i> module and further developed in the level 5 module <i>Pharmacology</i>.</p>	
Transferable skills - able to:	Teaching/learning methods & strategies	Assessment
<p>Successful students will be able to:</p> <p>D1-communicate effectively both orally and in written form</p> <p>D2-use effectively a range of information sources</p> <p>D3-organise and present intellectual argument commensurate with the level of award</p> <p>D4-work effectively both alone, and as part of a team</p> <p>D5-Demonstrate numeracy and manipulate, analyse and present data</p> <p>D6-develop the skills required for continued self-managed professional development</p> <p>D7- Demonstrate the ability to identify and solve complex problems and undertake suitable investigations</p>	<p>Transferable skills are developed throughout all modules on the programme, specifically acquisition of D1 is introduced through exercises in level 4 such as laboratory reports and assignments; seminars, presentations and group work, developed throughout level 5 and further enhanced through the group working scenarios in level 6. This will be further reinforced during the industry placement and research project (viva and poster presentation) at level 7.</p> <p>Acquisition of D2 is through induction classes at all three levels and in lectures, Workshops and problem solving exercises in levels 4, 5 and 6. Higher level skills are obtained and demonstrated through the planning and conduct of the <i>Research Project</i> and the industry placement module at level 7. In both these level 7 modules, information seeking will be facilitated by the research project academic tutor and industry mentor.</p> <p>The teaching of D3 is initiated in <i>Biology and Biochemistry</i> with exercises on report writing; during year 1, personal academic tutors give feedback on written assignments and practical reports</p>	<p>Testing of D1, D2 and D3 is through a combination of essays, abstracts, laboratory reports, posters, seminars, group reports, the assignment report and written examinations throughout the course. Performance in these skills is monitored by personal academic tutors. D4 is assessed formatively by feedback in the laboratory, workshops and personal tutor groups and summatively in individual and group reports, poster presentations and the research project dissertation. Testing of this skill is a major component of the assessment of the final year. D5 (numeracy) is assessed through many of the laboratory assessments, particularly in modules such as <i>Biology and Biochemistry</i>, <i>Fundamentals of analytical Chemistry</i> and <i>Advanced Analytical Techniques</i> and <i>Quality assurance</i>, and the <i>Project</i></p> <p>D6 is assessed through the residency placement report and through the research project.</p>

from a number of modules to facilitate the development of skills; seminars at level 6 and in the *Research Project* module and the *Research Project* itself make a significant contribution to the development of this skill.

The acquisition of D4 is throughout all the practical components of the programme where students are required to work alone or as part of a team and in some modules, to carry out group assignments. This will be particularly developed and demonstrated in the group work of the level 6 modules.

The acquisition of D5 (numeracy) is initiated in lectures, workshops and class exercises in all modules at level 4 and is developed and reinforced throughout the programme in laboratory classes, workshops, personal academic tutor meetings and the research project.

Students have access to mathematics drop in sessions.

The development of self-management skills (D6) is facilitated and monitored by personal academic tutors involving discussion of skills relevant to successful performance on the degree and future employability.

The placement year makes significant contributions to the attainment of this skill.

Throughout, the learner is encouraged to develop transferable skills by maintaining a record of evidence and completing a personal development plan.

D7 - In the *Global Pharmaceutical and Devices Regulatory Requirements* module and *Strategic Planning and*

D7 is assessed during contextualised written work in the *Global Pharmaceutical and Devices Regulatory requirements* module and *Strategic Planning and Product Life Management* module. This skill is further developed and assessed during the written tasks in the *Residency Placement* module and students will also demonstrate this skill whilst undertaking independent research in the *Research Project* module

*Product Life Management* modules, experts in the field have developed and designed teaching material to case examples from industry to illustrate the importance of critical thinking and methodical step wise process to resolve pertinent issues. The theory behind this will be discussed in lectures and students will have the opportunity to develop and practise these skills in the workshop setting using case studies.

## D. Programme Structures, Features, Levels, Modules, and Credits

The programme is offered in full time (4 years) mode and leads to the award of a Master of Regulatory Science (Pharmaceuticals and Devices). Entry is at level 4 with A-level or equivalent qualifications, but is possible at level 5 or 6 with suitable qualifications (HND or successful completion of level 4/5 of comparable basic science degrees elsewhere). Such cases will be referred to the Programme Leader to assess the equivalency of the accumulated modules and the student's experience to that of the MReg Sci curriculum. The intake is normally semester A (September).

### Professional and Statutory Regulatory Bodies

n/a

### Work-Based Learning including sandwich programmes

#### **Industry Placement Year in the UK or Abroad**

A designated 4-year programme including a full year (3 semester) of industry placement leads to a University award in "integrated master" mode and the word "Master" appears on the award certificate. In order for the programme to lead to an award in the "Integrated Master" mode, the student must undertake a period of approved work experience (regulatory organisation Residency Placement and Research Project) of not less than 32 weeks excluding holidays, during Year 4. The placement will normally be completed within the United Kingdom, but there is also an option to complete this abroad at approved partner institutions/organisations. Progress of the student's training is monitored by visits from the University's academic staff. Students will be required to document this period of work in accordance with the guidelines produced by the Department of Pharmacy, Pharmacology and Postgraduate Medicine. Subject to the requirements of the employer, an enhanced Disclosure and Barring Service check may be required before a student can be offered a placement.

Prior to the commencement of the 4<sup>th</sup> year the student and Programme Officers from UH and the host institution/organisation will agree a learning contract and mode of assessment which is standardised and applies to all host organisations and students. The programme provided by the host institution/organisation, will consist of the Residency Placement (hands on experience in pharmaceutical/device regulatory environment) and a Research Project on topics related to regulatory science. The student must confirm his or

her intention to complete the fourth year abroad during the first term of study at Level 6. This will enable a place to be negotiated at a host institution/organisation and the study programme to be arranged and agreed. Only a limited number of places exist per organisation and they will be made available on a competitive basis. Selection will take into account the student's academic performance on the programme. Alternatively, the student may propose, in writing, a host institution/organisation with which the University of Hertfordshire does not have a prior agreement.

### Programme Structure

The programme structure and progression information below (Table 1a and 1b) is provided for the award of a Master of Regulatory Science. Any interim awards are identified in Table 1b. The Programme Learning Outcomes detailed above are developed and assessed through the constituent modules. Table 2 (in section 2) identifies where each learning outcome is assessed.

Table 1a Outline Programme Structure

**Mode of study** Full time

**Entry point** Semester A

#### Level 4 Master of Regulatory Science (Pharmaceuticals and Devices)

	Module Code	Credit Points	Language of Delivery	% Examination	% Coursework	% Practical	Semesters
<b>Compulsory Modules</b>							
Module Title							
Foundations of Pharmaceutical Chemistry	4LMS0111	30	English	50	50	0	AB
Fundamentals of Analytical Chemistry	4LMS0110	30	English	50	50	0	AB
Human Physiology and Pharmacology	4LMS0002	30	English	0	100	0	AB
Biology and Biochemistry	4LMS0112	30	English	50	50	0	AB

Progression to level 5 requires a minimum of 120 credits at level 4

#### Level 5 Master of Regulatory Science (Pharmaceuticals and Devices)

	Module Code	Credit Points	Language of Delivery	% Examination	% Coursework	% Practical	Semesters
<b>Compulsory Modules</b>							
Module Title							
Dosage Form Design and Manufacture	5LMS0024	30	English	50	50	0	AB

Advanced Analytical Techniques and Quality Assurance	5LMS0058	30	English	50	50	0	AB
Methods in Drug Design	5LMS0059	30	English	50	50	0	AB
Pharmacology	5LMS0025	30	English	50	50	0	AB

### Level 6 Master of Regulatory Science (Pharmaceuticals and Devices)

Module Title	Module Code	Credit Points	Language of Delivery	% Examination	% Coursework	% Practical	Semesters
<b>Compulsory Modules</b>							
Introduction to Epidemiology and Pharmacoepidemiology	6LMS0111	15	English	40	60	0	A
Global Pharmaceutical and Devices Regulatory Requirements	6LMS0112	45	English	30	70	0	AB
Introduction to Health Technology Assessment (HTA)	6LMS0113	15	English	40	60	0	A
Clinical Development	6LMS0114	15	English	40	60	0	A
Strategic Planning and Product Life Management	6LMS0115	15	English	30	70	0	B
Management and Corporate Finance	6LMS0154	15	English	30	70	0	B

### Level 7 Master of Regulatory Science (Pharmaceuticals and Devices)

Module Title	Module Code	Credit Points	Language of Delivery	% Examination	% Coursework	% Practical	Semesters
<b>Compulsory Modules</b>							
Residency Placement	7LMS0212	60	English	0	100	0	CA
Research Project	7LMS0213	60	English	0	100	0	AB

Progression to level 6 normally requires 240 credits with a minimum of 120 credits at level 5  
Progression to level 7 normally requires 360 credits with a minimum of 120 credits at level 6

The award of a Master of Regulatory Science (Pharmaceuticals and Devices) degree requires 480 credit points with a minimum of 120 at level 7 including the Project (7LMS0213).

### Degree classification

The University has approved structure and assessment regulations common to all programmes. Full details are provided in [UPR AS14](#), Section D.

**Table 1b Final and interim awards available**

The programme provides the following final and interim awards:

Final Award	Award Title	Minimum requirements	Available at end of (normally):	Programme Learning Outcomes developed (see above)
Integrated Master	Master of Regulatory Science (Pharmaceuticals and Devices)	480 credits, 120 at level 4. 120 at level 5, 120 at level 6 and 120 at level 7	Level 7	All programme learning outcomes (see Table 2)

Interim Award	Award Title	Minimum requirements	Available at end of (normally)	Programme Learning Outcomes developed (see above)
BSc (Hons) Pharmaceutical Studies	BSc (Hons) Pharmaceutical Studies	360 credit points including 240 at Levels 6/5 of which at least 120 must be at Level 6 or 7	Level 6, 7	A1, A2, A3, A4, A5, A6, B1,B2,B3, B4,B5,C1,C2,C3,C4, C5, D1, D2,D3, D4,D5, D6,D7
BSc Pharmaceutical Studies	BSc Pharmaceutical Studies	300 credit points including 180 at level 6/5 of which 60 must be at level 6 or 7	Level 6,7	A1, A2, A3, A4, A5, A6, B1,B2,B3, B4,B5,C1,C2,C3,C4, C5, D1, D2,D3, D4,D5, D6
Diploma of Higher Education		240 credit points including at least 120 at level 5	Level 5,6	See UPR AS11, section 13: <a href="http://sitem.herts.ac.uk/secreg/upr/AS11.htm">http://sitem.herts.ac.uk/secreg/upr/AS11.htm</a>
Certificate of Higher Education		120 credit points at level 4	Level 4,5	See UPR AS11, section 13: <a href="http://sitem.herts.ac.uk/secreg/upr/AS11.htm">http://sitem.herts.ac.uk/secreg/upr/AS11.htm</a>
University Certificate		45 credit points at level 4	4,5	See UPR AS11, section 13: <a href="http://sitem.herts.ac.uk/secreg/upr/AS11.htm">http://sitem.herts.ac.uk/secreg/upr/AS11.htm</a>

## Programme-specific assessment regulations

The programme is compliant with the University's academic regulations (in particular, [UPR AS11](#), [UPR AS12/UPR AS13](#) and [UPR AS14](#)) with the exception of those listed below, which have been specifically approved by the University:

None

Further points of clarification and interpretation relevant to this specific programme are given below:

- Progression from level 4 to level 5 requires a minimum of 120 credits at level 4
- Progression from level 5 to level 6 requires 240 credits, a minimum of 120 credits from level 5 and 120 credits from level 4
- Progression from level 6 to level 7 requires 360 credits, a minimum of 120 credits from level 6, 120 credits from level 5 and 120 credits from level 4

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## E. Management of Programme & Support for student learning.

### Management

The programme is managed by;

- Dean of School of Life and Medical Sciences
- Associate Dean of School (AQA)
- Head of Department of Pharmacy, Pharmacology and Postgraduate Medicine
- A Programme Leader who is responsible for the day-to-day management of the programme
- An Admissions Tutor with specific responsibility for open days and selection
- A designated administrator to deal with day-to-day administration associated with the programme
- Module co-ordinators who are responsible for individual modules
- A Placement Tutor to assist with the procurement of placements
- A programme committee, the membership of which includes:
  - The Programme Leader (Chair)
  - Programme Administrator (Clerk)
  - Associate Dean (AQA) (Ex-officio)
  - Head of Department
  - Pharmaceutical Science Programme Leader
  - Head of Division Pharmaceutical Chemistry
  - Head of Division Pharmacology
  - Head of Division Biosciences
  - Module co-ordinators
  - Admissions tutor
  - Placements tutor
  - Stakeholders Representative
  - IH representative
  - Representative of the technical staff
  - Teaching staff with a substantial input to the programme
  - Student representative

## Support

Students are supported by:

- An induction week at the beginning of each academic session
- Overseas orientation
- StudyNet and Canvas, a versatile online interactive intranet and learning environment
- Access to extensive digital and print collections of information resources
- Attractive modern study environments in 2 learning resource centres
- A substantial student centre that provides advice on issues such as finance, University regulations, legal matters, accommodation, international student support, etc
- Office of the Dean of students, incorporating Chaplaincy, Counselling and nursery
- Medical centre
- A mathematics drop in centre
- University disability advisors
- An equal opportunities officer
- The Students' Union
- Guided student-centred learning on StudyNet module sites
- A Careers, Enterprise and Employment service for all current students and graduates

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## F. Other sources of information

In addition to this Programme Specification, the University publishes guidance to registered students on the programme and its constituent modules:

- A Programme (or Student) Handbook;
- A Definitive Module Document (DMD) for each constituent module;
- A Module Guide for each constituent module.
- University of Hertfordshire Course website:  
<http://www.herts.ac.uk/courses/>
- QAA Benchmark Statement website:  
<http://www.qaa.ac.uk/assuring-standards-and-quality/the-quality-code/subject-benchmark-statements>
- Frameworks for Higher Education Qualifications of UK Degree-Awarding Bodies (2014)  
[The Frameworks for Higher Education Qualifications of UK Degree-Awarding Bodies](#)
- SEEC Credit Level Descriptors for Further and Higher Education 2010:  
<http://www.seec.org.uk/wp-content/uploads/2013/seec-files/SEEC%20Level%20Descriptors%202010.pdf>
- External Quality Review report website:  
[http://www.qaa.ac.uk/reviews-and-reports/provider?UKPRN=10007147#.VCFXlha\\_hSU](http://www.qaa.ac.uk/reviews-and-reports/provider?UKPRN=10007147#.VCFXlha_hSU)
- UNISTATS website:  
<http://www.unistats.com/>
- University of Hertfordshire Academic Quality website:  
(StudyNet → Staff → Department Lists → Academic Quality Office)
- Structure & Assessment Regulations - Undergraduate & Taught Postgraduate Programmes, UPR AS14:  
<http://sitem.herts.ac.uk/segreg/upr/AS14.htm>
- Learning and Teaching Policy and Graduate Attributes, UPR TL03:  
<http://sitem.herts.ac.uk/segreg/upr/TL03.htm>
- Admissions - Undergraduate & Taught Postgraduate Students, UPR SA03:  
<http://sitem.herts.ac.uk/segreg/upr/SA03.htm>
- Academic Quality, UPR AS17:  
<http://sitem.herts.ac.uk/segreg/upr/AS17.htm>

Index of UPRs for students:

[http://sitem.herts.ac.uk/secreg/upr\\_azlist\\_info.htm](http://sitem.herts.ac.uk/secreg/upr_azlist_info.htm)

- Information on Programme and Module External Examiners  
<http://www.studynet1.herts.ac.uk/ptl/common/studentcentre.nsf/Teaching+Documents/184A221E5EECA6B780257A5C00250BA9?OpenDocument>
- School procedure with respect to a student's complaints regarding quality of learning experience whilst on practice and work placement:  
<http://sitem.herts.ac.uk/secreg/documents/General/2016-02-01-LMS-Practice%20Complaints%20Policy.pdf>
- School information on Disclosure and Barring Procedure  
<http://sitem.herts.ac.uk/secreg/School-specific%20LMS%20Policies%20and%20Regs.htm>
- School confidentiality policy  
<http://sitem.herts.ac.uk/secreg/documents/General/2016-02-01-LMS-Confidentiality%20Policy.pdf>

The [Herts Handbook](#) is an introduction to the academic, social, cultural and sporting services and opportunities available at the University of Hertfordshire, and includes the Student Charter and Student Code of Conduct.

As a condition of registration, all students of the University of Hertfordshire are required to comply with the University's rules, regulations and procedures. These are published in a series of documents called 'University Policies and Regulations' (UPRs). The University requires that all students consult these documents which are available on-line, on the UPR web site, at: <http://www.herts.ac.uk/secreg/upr/>. In particular, [UPR SA07](#) 'Regulations and Advice for Students' Particular Attention - Index' provides information on the UPRs that contain the academic regulations of particular relevance for undergraduate and taught postgraduate students.

The UK Quality Assurance Agency for Higher Education (QAA) has confirmed the quality and standards of provision at the University of Hertfordshire. A key part of QAA's role is to review and report on how universities maintain their academic standards and quality, to inform students and the wider public. The team of QAA reviewers visited the University of Hertfordshire in 2015/16 and judged that its academic standards, the quality and enhancement of its students' learning experience, and the quality of information about this learning experience all meet UK expectations. In other words, the University meets national requirements for standards and quality. The QAA's report can be accessed at: <http://www.qaa.ac.uk/reviews-and-reports/provider?UKPRN=10007147#.V-KHajXy0nE>

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## G. Entry requirements

The normal entry requirements for the programme are:

112 UCAS points with a minimum of a grade C in GCE A Level Chemistry plus at least one other Science subject at GCE A level or equivalent.

Plus GCSE English language, mathematics and dual science (or Biology and Chemistry) at grade 4 or above (grade C or above under the old grading system).

Equivalent qualifications will be considered on an individual basis, such as the Access to HE Certificate, BTEC or approved equivalent.

BTEC Extended Diploma in Applied Science with a minimum DMM profile to include a minimum of 6 chemistry-titled units at merit or above. Access to Science Diploma with a merit profile in 45 credits at Level 3, 12 of which must be in Chemistry titled modules with a minimum of merit grade.

An International Baccalaureate offer would require 112 points from a minimum of 2 HL subjects at H4 or above to include chemistry and one other Science (with the remaining points to come from a combination of HL, SL and Core).

All students from non-majority English speaking countries require proof of English language proficiency. The following qualifications and grades will be considered: GCSE English language at grade 4 or above (grade A-C in the old grading structure), or IELTS 6.5 (with no less than 6.0 in any band).

Whilst there is no general requirement for an Enhanced Disclosure and Barring Service (DBS) check, some placement providers may require a satisfactory Disclosure and Barring Service check prior to students being accepted onto a placement. International students would require equivalent checks to be made in this situation. Students who have been resident outside the United Kingdom during the last 5 years will need to get a declaration (in English) from the Police in the country where they have been living stating that they have not committed any crimes.

The programme is subject to the University's Principles, Policies and Regulations for the Admission of Students to Undergraduate and Taught Postgraduate Programmes (in [UPR SA03](#)), along with associated procedures. These will take account of University policy and guidelines for assessing accredited prior certificated learning (APCL) and accredited prior experiential learning (APEL).

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If you would like this information in an alternative format please contact: The programme administrator

If you wish to receive a copy of the latest Programme Annual Monitoring and Evaluation Report (AMER) and/or the External Examiner's Report for the programme, please email a request to [aqo@herts.ac.uk](mailto:aqo@herts.ac.uk)

## Master of Regulatory Science (Pharmaceuticals and Devices)

### Table 2: Development of Programme Learning Outcomes in the Constituent Modules

This map identifies where the programme learning outcomes are assessed in the constituent modules. It provides (i) an aid to academic staff in understanding how individual modules contribute to the programme aims (ii) a checklist for quality control purposes and (iii) a means to help students monitor their own learning, personal and professional development as the programme progresses.

			Programme Learning Outcomes (as identified in section 1 and the following page)																							
			Knowledge & Understanding								Intellectual Skills					Practical Skills				Transferable Skills						
	Module Title	Module Code	A1	A2	A3	A4	A5	A6	A7	A8	B1	B2	B3	B4	B5	C1	C2	C3	C4	D1	D2	D3	D4	D5	D6	D7
L 4	Foundations of Pharmaceutical Chemistry	4LMS0111	X	X		X					X				X	X		X	X	X	X		X	X		
	Fundamentals of Analytic Chemistry	4LMS0110	X			X		X			X					X	X	X	X		X		X	X		
	Human Physiology & Pharmacology	4LMS0002	X												X	X		X	X	X	X	X	X	X		
	Biology and Biochemistry	4LMS0112	X	X	X						X					X			X					X		
L 5	Dosage Form Design and Manufacture	5LMS0024	X	X	X		X	X	X		X		X		X	X	X	X	x	X	X	X	X	X		
	Advanced Analytical Techniques & Quality Assurance	5LMS0058	X			X		X	X		X		X		X	X	X	X	X	X	X	X	X	X		
	Methods in Drug Design	5LMS0059	X	X		X	X	X			X	X	X		X	X		X	X	X	X	X	X		X	
	Pharmacology	5LMS0025	X	X			X				X		X		X	X		X	X	X		X		X		
L 6	Introduction to Epidemiology and Pharmacoepidemiology	6LMS0111							X				X	X	X			X	X	X	X	X	X	X	X	
	Introduction to Health Technology Assessment (HTA)	6LMS0113							X				X	X	X			X	X	X	X	X	X	X	X	
	Clinical Development	6LMS0114							X				X	X	X			X	X	X	X	X	X	X	X	
	Global Pharmaceutical & Devices Regulatory Requirements	6LMS0112							X				X	X	X			X	X	X	X	X	X	X	X	X
L 7	Strategic Planning & Product Life Cycle Management	6LMS0115							X				X	X	X			X	X	X	X	X	X	X	X	X
	Management and Corporate Finance	6LMS0154							X				X	X	X			X	X	X	X	X	X	X	X	
L 7	Residency Placement	7LMS0212	X						X	X	X	X	X	X	X			X		X	X	X	X	X	X	X
	Research Project	7LMS0213	X						X	X	X	X	X	X	X			X		X	X	X	X	X	X	X

## Key to Programme Learning Outcomes

### Knowledge and Understanding

- A1. understand and apply the fundamental chemical and biological principles on which pharmaceutical sciences is based;
- A2. understand the molecular basis of the discovery, design, synthesis and mode of action of drugs;
- A3. apply an understanding of microbiology and immunology to the preparation and supply of sterile medicines and the control of sterility in pharmaceutical manufacture and storage;
- A4. apply the principles of medicinal, analytical and process chemistry to drug design, synthesis and manufacture
- A5. understand the principles of pharmacokinetics, product formulation, and delivery route underlying the optimization of drug administration;
- A6. understand the main analytical techniques and instrumentation used in pharmaceutical dosage form development and testing.
- A7. be familiar with and able to apply the regulations governing pharmaceutical product development and devices
- A8. Crystallise the theoretical knowledge of regulatory requirements during a work placement in the UK or overseas

### Intellectual Skills

- B1. understand the ethical implications of their work
- B2. execute and report a research project in order to develop the necessary skills for independent research
- B3. apply theoretical concepts to the study of pharmaceutical regulatory science and evaluate the relationship between theory and practice
- B4. develop and demonstrate an understanding of the nature and importance of timely ethical decision-making
- B5. demonstrate at a level appropriate to the award, a critical approach in enquiry and a readiness to test hypotheses, interpret scientific data and evaluate published literature

### Practical Skills

- C1. acquire appropriate laboratory skills, including safe working practices where relevant
- C2. acquire appropriate analytical instrumentation skills
- C3. acquire appropriate documentation and record keeping skills
- C4. design research project, analyse and interpret results.

### Transferable Skills

- D1. communicate effectively using a variety of formats
- D2. use effectively a range of information sources
- D3. organise and present intellectual argument commensurate with the level of award
- D4. work effectively both alone, and as part of a team
- D5. Demonstrate numeracy and manipulate, analyse and present data
- D6. Develop the skills required for continued self-managed PD
- D7. Demonstrate the ability to identify and solve complex problems and undertake suitable investigations



## Section 2

### Programme management

<b>Relevant QAA subject benchmarking statements</b>	None
<b>Date of validation/last periodic review</b>	April 17
<b>Date of production/ last revision of PS</b>	N/A
<b>Relevant intakes</b>	All students entering September 2018
<b>Administrative School</b>	School of Life and Medical Sciences

Table 3 Course structure

Course details					
Course code	Course description			JACS	
LMREGSM	Master of Regulatory Science (Pharmaceutical and Devices)			F290	
Course Instances					
Instances code	Intake	Stream	Instances Year	Location :	Mode of study
MSPHA1F	A	<i>Master of Regulatory Science (Pharmaceutical and Devices)</i>	1	Hatfield	Full-time
MSPHA2F	A	<i>Master of Regulatory Science (Pharmaceutical and Devices)</i>	2	Hatfield	Full-time
MSPHA3F	A	<i>Master of Regulatory Science (Pharmaceutical and Devices)</i>	3	Hatfield	Full-time
MSPHA4F-1	A	<i>Master of Regulatory Science (Pharmaceutical and Devices)</i>	4	Hatfield	Full-time
MSPHA4F-2	A	<i>Master of Regulatory Science (Pharmaceutical and Devices)</i>	4	Hatfield	Full-time