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:
23 September 2019

Associate Dean of School (Academic Quality Assurance):
Philomena Shaughnessy

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.

Summary of amendments to the programme

<table>
<thead>
<tr>
<th>Date</th>
<th>Section</th>
<th>Amendment</th>
</tr>
</thead>
</table>

If you have any queries regarding the changes please email 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

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

<table>
<thead>
<tr>
<th>Knowledge and Understanding of:</th>
<th>Teaching/learning methods &amp; strategies</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful students will be able to:</td>
<td>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.</td>
<td>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).</td>
</tr>
<tr>
<td>A1-understand and apply the fundamental chemical and biological principles on which pharmaceutical development is based;</td>
<td>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.</td>
<td>The individual performance in the Residency Placement module (A8) is assessed by assignments (essay and wiki) as well as the portfolio during the module.</td>
</tr>
<tr>
<td>A2-understand the molecular basis of the discovery, design, synthesis and mode of action of drugs;</td>
<td>Acquisition of A1 is introduced through all level 4 modules, specifically the Foundations of</td>
<td></td>
</tr>
<tr>
<td>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;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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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, 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.

<table>
<thead>
<tr>
<th>Intellectual skills - able to:</th>
<th>Teaching/learning methods &amp; strategies</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful students will be able to:</td>
<td>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.</td>
<td>B1 and B3 are assessed in laboratory reports, written assignments and the work in the industry Residency Placement module. B2 is assessed through the production of a dissertation and poster presentation in the project module at level 7. B4 and B5 are assessed through laboratory reports, unseen tests, examinations, interpretive exercises,</td>
</tr>
<tr>
<td>B1-understand the ethical implications of their work;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B2-execute and report a research project in order to develop the necessary skills for independent research and critical/reflective thinking;</td>
<td></td>
<td></td>
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<tr>
<td>B3-apply theoretical concepts to the study of pharmaceutical</td>
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</tbody>
</table>

Successful students will be able to:

- 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 and critical/reflective thinking;
- B3 - apply theoretical concepts to the study of pharmaceutical
development 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.

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. 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 Leadership and Strategic Management in Regulatory Affairs.

To acquire B5 statistical analysis is introduced in Human Physiology and Pharmacology at level 4, and reinforced and strengthened through the workshops in the Research Project module at level 7. Critique and evaluation of scientific data is introduced in level 5 and developed throughout level 7 modules most noticeably the Project.

Throughout, the learner is encouraged to develop intellectual skills further by independent study.

### Practical skills - able to:

<table>
<thead>
<tr>
<th>Successful students will be able to:</th>
<th>Teaching/learning methods &amp; strategies</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1-acquire appropriate laboratory skills, including safe working practices where relevant;</td>
<td>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 Project. Analytical skills (C2) are specifically introduced in the Fundamentals of Analytical Chemistry module at level 4, developed through the Advanced Analytical Techniques and Quality Assurance module at level 5 and</td>
<td>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.</td>
</tr>
<tr>
<td>C2-acquire appropriate analytical instrumentation skills;</td>
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<td></td>
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<tr>
<td>C3-acquire appropriate documentation and record keeping skills</td>
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<tr>
<td>C4-design research project and analyse and interpret data.</td>
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</tbody>
</table>

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reinforced in the *Research Project* at level 7. C3 and C4 are developed throughout all practical components of the course, with C4 particularly a key component of the level 7 *Project* module. Data analysis is introduced through assignments at level 4 in the *Human Physiology and Pharmacology* module and further developed in the level 5 module *Pharmacology*.

<table>
<thead>
<tr>
<th>Transferable skills - able to:</th>
<th>Teaching/learning methods &amp; strategies</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful students will be able to:</td>
<td>Transferrable 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. 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 <em>Research Project</em> 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. The teaching of D3 is initiated in <em>Biology and Biochemistry</em> with exercises on report writing; during year 1, personal academic tutors give feedback on written assignments and practical reports from a number of modules to</td>
<td>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 <em>Biology and Biochemistry, Fundamentals of analytical Chemistry</em> and <em>Advanced Analytical Techniques and Quality assurance</em>, and the <em>Research Project</em> D6 is assessed through the residency placement report and through the research project.</td>
</tr>
</tbody>
</table>
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 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.

D7 - In the Global Pharmaceutical and Devices Regulatory Requirements module and Strategic Planning and Product Life Management modules, experts in the field have
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 4th 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)

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

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

Level 5 Master of Regulatory Science (Pharmaceuticals and Devices)

<table>
<thead>
<tr>
<th>Compulsory Modules</th>
<th>Module Code</th>
<th>Credit Points</th>
<th>Language of Delivery</th>
<th>% Examination</th>
<th>% Coursework</th>
<th>% Practical</th>
<th>Semesters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosage Form Design and Manufacture</td>
<td>5LMS0024</td>
<td>30</td>
<td>English</td>
<td>50</td>
<td>50</td>
<td>0</td>
<td>AB</td>
</tr>
</tbody>
</table>
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)**

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

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

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

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](http://sitem.herts.ac.uk/secreg/upr/AS14.htm), Section D.

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

The programme provides the following final and interim awards:

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

<table>
<thead>
<tr>
<th>Interim Award</th>
<th>Award Title</th>
<th>Minimum requirements</th>
<th>Available at end of (normally):</th>
<th>Programme Learning Outcomes developed (see above)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSc (Hons) Pharmaceutical Studies</td>
<td>BSc (Hons) Pharmaceutical Studies</td>
<td>360 credit points including 240 at Levels 6/5 of which at least 120 must be at Level 6 or 7</td>
<td>Level 6, 7</td>
<td>A1, A2, A3, A4, A5, A6, B1, B2, B3, B4, B5, C1, C2, C3, C4, C5, D1, D2, D3, D4, D5, D6, D7</td>
</tr>
<tr>
<td>BSc Pharmaceutical Studies</td>
<td>BSc Pharmaceutical Studies</td>
<td>300 credit points including 180 at level 6/5 of which 60 must be at level 6 or 7</td>
<td>Level 6, 7</td>
<td>A1, A2, A3, A4, A5, A6, B1, B2, B3, B4, B5, C1, C2, C3, C4, C5, D1, D2, D3, D4, D5, D6</td>
</tr>
<tr>
<td>Diploma of Higher Education</td>
<td></td>
<td>240 credit points including at least 120 at level 5</td>
<td>Level 5, 6</td>
<td>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></td>
</tr>
</tbody>
</table>
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

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

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/](http://www.herts.ac.uk/courses/)
- 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:
- University of Hertfordshire Academic Quality website:
  (StudyNet → Staff → Department Lists → Academic Quality Office)
- Structure & Assessment Regulations - Undergraduate & Taught Postgraduate Programmes, UPR AS14:
- Learning and Teaching Policy and Graduate Attributes, UPR TL03:
  [http://sitem.herts.ac.uk/secreg/upr/TL03.htm](http://sitem.herts.ac.uk/secreg/upr/TL03.htm)
- Admissions - Undergraduate & Taught Postgraduate Students, UPR SA03:
  [http://sitem.herts.ac.uk/secreg/upr/SA03.htm](http://sitem.herts.ac.uk/secreg/upr/SA03.htm)
- Academic Quality, UPR AS17:
  [http://sitem.herts.ac.uk/secreg/upr/AS17.htm](http://sitem.herts.ac.uk/secreg/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.studyinet1.herts.ac.uk/plt/common/studentcentre.nsf/Teaching+Documents/184A221E5EEC
  A6B7B8257A5C00250BA9?OpenDocument](http://www.studyinet1.herts.ac.uk/plt/common/studentcentre.nsf/Teaching+Documents/184A221E5EEC
  A6B7B8257A5C00250BA9?OpenDocument)
- School procedure with respect to a student’s complaints regarding quality of learning experience whilst
  on practice and work placement:
The Ask Herts website provides information on a wide range of resources and services available at the University of Hertfordshire including academic support, accommodation, fees, funding, visas, wellbeing services and student societies.

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.

In accordance with section 4(5) of the Higher Education and Research Act 2017 (HERA), the UK Office for Students (OfS) has registered the University of Hertfordshire in the register of English higher education providers. The Register can be viewed at: https://www.officeforstudents.org.uk/advice-and-guidance/the-register/the-ofs-register/. Furthermore, the OfS has judged that the University of Hertfordshire delivers consistently outstanding teaching, learning and outcomes for its students. It is of the highest quality found in the UK. Consequently, the University received a Gold award in the 2018 Teaching Excellence and Student Outcomes (TEF) exercise. This award was made in June 2018 and is valid for up to 3 years. The TEF panel's report and conclusions can be accessed at: https://www.officeforstudents.org.uk/advice-and-guidance/teaching/tef-outcomes/#/provider/10007147

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).

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.u
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) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Module Title | Module Code | Knowledge & Understanding | Intellectual Skills | Practical Skills | Transferable Skills |
| | | A1 | A2 | A3 | A4 | A5 | A6 | A7 | A8 | B1 | B2 | B3 | B4 | B5 | C1 | C2 | C3 | C4 | D1 | D2 | D3 | D4 | D5 | D6 | D7 |
| Foundations of Pharmaceutical Chemistry | 4LMS0111 | X | X | X | X | X | X | X | X | X | X | X | X | X | 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 | X | X | X | 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 | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Biology and Biochemistry | 4LMS0112 | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Dosage Form Design and Manufacture | 5LMS0024 | X | X | X | X | X | X | X | 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 | 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 | X | X | X | X | X | X | X | X |
| Pharmacology | 5LMS0025 | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Introduction to Epidemiology and Pharmacoepidemiology | 6LMS0111 | X | X | X | X | X | X | X | X | X | X | X | X | X | 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 | X | 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 | X | 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 | X | X | X | X | X | X | X | X | X | X | X | X |
| Strategic Planning & Product Life Cycle Management | 6LMS0115 | X | X | X | X | X | X | X | X | X | X | X | X | 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 | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Residency Placement | 7LMS0212 | X | X | X | X | X | X | X | X | X | 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 | X | X | X | X | X | X | X | X | X |

Bachelor’s Programme Specification / December 2018 / AS Review Date June 2018
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

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.

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

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

| Relevant QAA subject benchmarking statements | None |
| Date of validation/last periodic review | April 17 |
| Date of production/last revision of PS | March 2018 |
| Relevant Intakes | All students entering September 2019 |
| Administrative School | School of Life and Medical Sciences |

Table 3 Course structure

<table>
<thead>
<tr>
<th>Course code</th>
<th>Course description</th>
<th>JACS / HECOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>LMREGSM</td>
<td>Master of Regulatory Science (Pharmaceutical and Devices)</td>
<td>F290 / 100225</td>
</tr>
</tbody>
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