

School of Life and Medical Sciences

Title of Programme: MSc/PgD/PgC in Pharmacovigilance

Programme Code: HHPV

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

Date	Section	Amendment
20.2.18	1	Table 2 module codes amended to correspond with Table 1a
13.5.19	1	Table 1b amended to include PgDip and PgCert as exit awards
10.7.19	1D	The requirements for award of PgDip and PgCert given.
12.7.19	Table 1b	The availability of PgCert changed to normally at end of 4 semesters

If you have any queries regarding the changes please email AQO@herts.ac.uk

Programme Specification MSc Pharmacovigilance

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	Fielder Centre/College Lane
Programme accredited by	Not applicable
Final Award (Qualification)	MSc / PGDip / PGCert
All Final Award titles (Qualification and Subject)	Pharmacovigilance
FHEQ level of award	7
Language of Delivery	English

A. Programme Rationale

This part-time postgraduate programme in Pharmacovigilance is delivered in collaboration with members of the Pharmaceutical Industry who contribute to the curriculum and teaching. The programme is designed to recruit personnel who are working in drug safety or pharmacovigilance and has continued to maintain its international recognition as one of two excellent providers of pharmacovigilance and drug safety education in the world. The close collaboration with industry remains one of the strengths of the programme and informs the way in which the degree is delivered. The curriculum is current and aligned with the requirements of the Pharmaceutical Industry for practicing pharmacovigilance personnel. The programme provides a wealth of opportunities to gain a wide range of knowledge and skills related to pharmacovigilance including knowledge and understanding of European and major worldwide Medicines Regulations and the development of skills used to critically evaluate pharmacoepidemiological studies. Emphasis is placed on understanding and implementing pharmacovigilance issues, therefore workshops, case studies and problem based learning activities form an integral part of the teaching method. The programme is based on a core introductory module, Principles of Pharmacovigilance (7LMS0081), followed by seven modules developing key aspects of pharmacovigilance from the pre-clinical to post-authorisation stages of a drug's lifecycle, plus a research project for those undertaking an MSc. Taught modules are delivered as 3-day block teaching sessions with no more than 4 modules being taught per year, thereby providing flexibility for those in full time employment. The programme has an impressive employability record with several of our post-graduates going on to secure more senior positions within the Pharmaceutical Industry.

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:

- engender a continuing and independent approach to learning, encouraging initiative and self-discipline such that students will be able to comprehend, contribute to and apply advances in pharmacovigilance;
- build and improve on students' cognitive skills, including the ability to think logically and independently; to be reflective and critical of scientific hypotheses; to analyse, synthesise and be creative;
- provide not only specialist knowledge but also a perspective of broad intellectual, ethical and social contexts;

- provide a framework for the acquisition of a comprehensive understanding of pharmacovigilance skills applicable to their own research, advanced scholarship and professional practice;
- develop an ability to apply the knowledge (iii above) and skills (iv above) to information in order to inform judgments, develop and advance ideas in the discipline;
- provide opportunities for the continuing development of transferable skills including communication, mathematical analysis where appropriate, use of information technology, problem solving and working as part of a team.

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:	Teaching/learning methods & strategies	Assessment
A1- Principles of pharmacovigilance from the development of the science to its place in the pre-and post-marketing environment.	Acquisition of knowledge and understanding is through a combination of directed reading, lectures, workshops based on real-life examples, problem based exercises and assignments (A1-A7).	For A1 to A7, knowledge and understanding are summatively assessed through a combination of in-course assessments in the form of in-class tests, assignments and workshop based exercises.
A2- Spontaneous reporting, including an appreciation of the advantages and limitations with regard to identification and clarification of drug safety issues.	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.	Poster production and seminar presentations (some of which will include group work) are also used for A1 to A7.
A3- The factors and mechanisms of adverse drug reactions.	For example, A3 is introduced in the module <i>Principles of Pharmacovigilance</i> (7LMS0083) and developed through to the <i>ADRs by Major Body Systems</i> (7LMS0081) module using directed learning and case study exercises.	Within the module <i>Pharmacovigilance Regulations and Guidelines</i> , For A4, (7LMS0081) A4 is assessed mainly through the creation of a PowerPoint presentation and completion of a decision tree exercise.
A4- The Pharmacovigilance regulations and guidelines pertaining to the EU the USA and other major markets.		
A5- The methodologies used in the collection and assessment of adverse drug experience both pre-and post-authorisation to meet regulatory requirements and for the development of the discipline.		
A6- Risk management and strategies to minimise risk		
A7- Communication with patients, healthcare		

professionals, the media and regulatory authorities.		
A8- Ethical implications of their work including data protection and confidentiality.		
Intellectual skills:	Teaching/learning methods & strategies	Assessment
B1- Critically appraise the factors leading to the withdrawal of a selected drug from the market.	Intellectual skills are developed through methods and strategies outlined in section A above.	Intellectual skills B1 to B5 are assessed through analysis of case studies, unseen in-course assessments, assignments and project work.
B2- Critically assess case reports effectively and to put them into perspective in terms of safety signals/alerts.	Analysis, critical evaluation, synthesis and application of information is further developed throughout workshops, in-course exercises, module assignment exercise and project work B1-B5).	
B3- Analysis and critically evaluate experimental, pharmacoepidemiological data and adverse drug experiences.	B5 is mainly acquired in the module <i>Labelling and Risk Management (7LMS0086)</i> through lectures, assessed problem based learning exercises and role play workshops.	
B4- Analyse and critically evaluate regulations and guidelines in Pharmacovigilance processes.	Throughout, the learner is encouraged to develop intellectual skills further by independent study.	
B5- Apply knowledge with critical awareness to the design of processes to implement Pharmacovigilance regulations and guidelines and business practices.		
Practical skills:	Teaching/learning methods & strategies	Assessment
C1-Undertake causality assessments and evaluate reports, scientific and clinical papers.	Practical skills are developed through case studies (C1) group work (C1, C2) post course exercises (C1-C6).	Practical skills are assessed through written reports (C1-C6)
C2- Design and evaluate Pharmacovigilance working processes.	For C2 students are expected to design their own Pharmacovigilance data base following a workshop activity.	
C3--Undertake a risk benefit analysis of a product.	Acquisition of C3 is achieved in a workshop based on risk benefit related cases.	
C4- Operate in complex and unpredictable and specialized contexts and have an overview of good practice.		

C5- Demonstrate initiative and personal responsibility.		
C6- Use information technology effectively.		
Transferable skills:	Teaching/learning methods & strategies	Assessment
D1- Communicate effectively both orally and in writing.	D1-D6 transferable skills are developed through written reports, the <i>Project (7LMS0104)</i> and workshops (D7). Acquisition of D1 is achieved in modules and the project. Acquisition of D2 is through the Project, Case Studies and module assignments. Acquisition of D4 is achieved in the module assignments, ADR based case study workshops and the project. Throughout, the learner is encouraged to develop transferable skills by maintaining a record of evidence.	Transferable skills are assessed through a range of assignments built into the curriculum, coursework assignments and the project (D1-5, D6). For example: <i>Viva voce</i> examinations (D1 and D2); seminar presentations (D1) PBL reports (D1,3,4) and the Project (D1,2, 3, 4, 5).
D2- Present and support an extended argument.		
D3- Demonstrate self-direction and originality in solving problems and act autonomously in planning and implementing tasks.		
D4- Demonstrate skills in searching medical and scientific literature.		
D5- Manage information.		
D6- Is able to reflect on their own work and the work of others.		
D7- Work in small groups.		

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

The programme is offered in part-time mode for between 2-5 academic years (with a maximum of 6 academic years under special circumstances) and leads to the award of an MSc in Pharmacovigilance. Entry is normally at Masters level with good Honours degree qualifications as specified in section F. Intake is normally semesters A (September) and/or B (February).

Professional and Statutory Regulatory Bodies

N/A

Work-Based Learning, including Sandwich Programmes

N/A

Programme Structure

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

Table 1a Outline Programme Structure

Mode of study The programme is offered in part-time mode for between 2-5 academic years (with a maximum of 6 academic years under special circumstances)

Entry point Semester A or Semester B for the structure as outlined.

Compulsory Modules

Module Title	Module Code	Credit Points	Language of Delivery	% Examination	% Coursework	% Practical	Semesters
Principles of Pharmacovigilance*	7LMS0083	15	English	0	100	n/a	B
Adverse Drug Reactions by Major Body Systems I	7LMS0084	15	English	0	100	n/a	B
Pharmacovigilance Regulations and Guidelines*	7LMS0079	15	English	0	100	n/a	A
Drug Safety in Clinical Trials	7LMS0080	15	English	0	100	n/a	A
Adverse Drug Reactions by Major Body Systems II	7LMS0081	15	English	0	100	n/a	B
Management of Pharmacovigilance Data	7LMS0082	15	English	0	100		B
Pharmacoepidemiology	7LMS0085	15	English	0	100	n/a	A
Labelling and Risk Management	7LMS0086	15	English	0	100	n/a	A
Project	7LMS0104	60	English	0	100	n/a	AB

*Compulsory modules that must be passed for any award.

The award of an MSc in Pharmacovigilance requires 180 credit points passed at level 7 including the Masters Project (7LMS0104).

The award of Post Graduate Diploma in Pharmacovigilance requires 120 credit points passed at level 7 excluding the Project (7LMS0104).

The award of Post Graduate Certificate in Pharmacovigilance requires 60 credit points passed at level 7 including the two *compulsory modules.

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)
Masters	Pharmacovigilance	180 credit points including at least 150 at level 7	6 Semesters	All programme learning outcomes
Postgraduate Diploma	Pharmacovigilance	120 credit points, including at least 90 at level 7	4 Semesters	A1, A2, A3, A4, A5, A6, A7, A8, B1, B2, B3, B4, B5, B6, C1, C2, C3, C4, C5, C6, D1, D4, D5, D6, D7
Postgraduate Certificate	Pharmacovigilance	60 credit points, including at least 45 at level 7	4 Semesters	A1, A2, A3, A4, A5, B1, B2, B4, B5, B6, C1, C2, C4, C5, C6, D1, D4, D5, D6, D7.

Interim Award	Award Title	Minimum requirements	Available at end of Level	Programme Learning Outcomes developed (see above)
Postgraduate Diploma	Pharmacovigilance	120 credit points, including at least 90 at level 7	4 Semesters	A1, A2, A3, A4, A5, A6, A7, A8, B1, B2, B3, B4, B5, B6, C1, C2, C3, C4, C5, C6, D1, D4, D5, D6, D7

Postgraduate Certificate	Pharmacovigilance	60 credit points, including at least 45 at level 7	4 Semesters	A1, A2, A3, A4, A5, B1, B2, B4, B5, B6, C1, C2, C4, C5, C6, D1, D4, D5, D6, D7. <i>For untitled awards:</i> See UPR AS11, section 13: http://sitem.herts.ac.uk/secreg/upr/AS11.htm
--------------------------	-------------------	----------------------------------------------------	-------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Masters and Diploma awards can be made "with Distinction" or "with Commendation" where criteria as described in [UPR AS14](#), Section D and the students' handbook are met.

Programme-specific assessment regulations

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

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

- A pass in 7LMS0079 Pharmacovigilance Regulations and Guidelines, to include a minimum grade of 50% in the assessment related to Periodic Safety Update Reports.
- The maximum period within which a student may gain an award is 6 years from their registration on the programme.
- To enrol onto the project module students must have completed all eight taught modules (120 credits).
- To proceed through the programme students cannot normally be referred in more than two modules; continuation on the Programme will be at the discretion of the Board of Examiners.

E. Management of the Programme & Support for students learning

Management

The programme is managed and administered through:

- Head of Department who has responsibility for Pharmacy, Pharmacology and Post-graduate Medicine programmes
- A Programme Leader who is responsible for the day to day management
- An Admissions Tutor, who is responsible for selection
- A designated Programme Administrator to deal with day to day administration associated with the programme
- Module Leaders who are responsible for individual modules
- A programme committee, the membership of which includes, Programme Tutor (Chair), Programme Administrator (secretary) and module leaders
- Student Representatives

Support

Students are supported by:

- An induction session at the beginning of the first module
- An extensive Learning Resources Centre, incorporating a library and computer centre
- A Programme Leader to give academic advice
- Personal tutors to provide pastoral and academic support
- Project tutors
- Module guides providing module information and study guidance
- On-line module information provided via the University's managed learning environment "StudyNet" a University-wide system for study support
- A student handbook
- Comprehensive feedback on assessed assignments
- Student representatives on the Programme Committee

- A substantial Student Centre that provides advice on issues such as finance, University regulations, legal matters etc
- A Mathematics Drop-in Centre
- A Disabled Student Co-ordinator
- An Equal Opportunities Officer
- The Students' Union

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.

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:

- a first or second class Honours Degree in Biosciences, Pharmacy or Biological Chemistry or
- a professional qualification accepted as equivalent to the above or
- a qualification in veterinary science, medicine or dentistry or
- a first or second class Honours Degree in disciplines that would be judged as equivalent to the above and
- at least 6 months experience in full-time Pharmacovigilance work.

All International students are required to demonstrate an English Language capability of IELTS 7.0 (with no less than 6.5 in any band) or equivalent qualification.

Entry requirements- non-standard criteria

Applicants not within the categories described above will be interviewed, by a panel consisting of one academic and one member from industry, in order to establish their suitability based upon the following criteria:

The applicant will be rated on a 5 point scale for their ability to demonstrate:

1. advanced knowledge in the field of pharmacovigilance and how this has been developed during employment.

2. critical awareness of current issues within drug safety, in particular regulatory requirements, adverse event reporting and pharmacoepidemiology.
3. industry experience of a range of pharmacovigilance regulatory processes, illustrating the ability to synthesize, evaluate and interpret pharmacovigilance data.

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 e-mail request to aqo@herts.ac.uk

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

MSc Pharmacovigilance

Table 2: Development of Intended 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	C5	C6	D1	D2	D3	D4	D5	D6	D7	
Principles of Pharmacovigilance	7LMS0083	X	X	X	X	X		X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X		
ADRs by Major Body Systems I	7LMS0084			X		X			X			X	X		X			X	X	X		X	X	X	X	X		
Pharmacovigilance Regulation and Guidelines	7LMS0079	X			X	X					X		X	X	X	X		X	X	X		X	X	X	X	X		
Drug Safety in Clinical Trials	7LMS0080		X		X	X			X	X	X	X	X		X	X		X	X	X		X	X	X	X	X		
ADRs by Major Body Systems II	7LMS0081			X		X			X			X	X		X			X	X	X		X	X	X	X	X		
Management of Pharmacovigilance Data	7LMS0082				X	X	X	X	X			X	X			X		X	X	X	X	X	X	X	X	X	X	
Pharmacoepidemiology	7LMS0085				X	X	X			X	X	X	X	X	X			X	X	X		X	X	X	X	X	X	
Labelling and Risk Management	7LMS0086				X	X	X					X	X	X	X	X	X	X	X	X		X	X	X	X	X		
Project	7LMS0104	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	X	

KEY TO PROGRAMME LEARNING OUTCOMES

Knowledge and Understanding

- A1. Principles of pharmacovigilance from the development of the science to its place in the pre-and post-marketing environment
- A2. Spontaneous reporting including an appreciation of the advantages and limitations with regard to identification and clarification of drug safety issues.
- A3. The factors and mechanisms of adverse drug reactions.
- A4. Pharmacovigilance regulations and guidelines underpinning pharmacovigilance requirements in UK, Europe, USA and other pharmaceutical markets worldwide.
- A5. The methodologies used in the collection and assessment of adverse drug experiences both pre-and post-marketing to meet regulatory requirements and for the development of the discipline.
- A6. Risk management and strategies to minimise risk.
- A7. Communication with patients, healthcare professionals, the media and regulatory authorities.
- A8. Ethical implications of their work including data protection and confidentiality.

Intellectual Skills

- B1. Critically appraise the factors leading to the withdrawal of a selected drug from the market.
- B2. Critically assess case reports effectively and to put them into perspective in terms of safety signals/alerts.
- B3. Analyse and critically evaluate experimental, pharmacoepidemiological data and adverse drug experiences.
- B4. Analyse and critically evaluate regulations and guidelines and pharmacovigilance processes.
- B5. Apply knowledge with critical awareness to the design of processes to implement pharmacovigilance regulations and guidelines and business practices.

Practical Skills

- C1. Undertake causality assessments and evaluate reports, scientific and clinical papers
- C2. Design and evaluate pharmacovigilance working processes
- C3. Undertake a risk benefit analysis of a product
- C4. Operate in complex and unpredictable and specialized contexts and have an overview of good practice
- C5. Demonstrate initiative and personal responsibility
- C6. Use information technology effectively

Transferable Skills

- D1. Communicate effectively both orally and in writing
- D2. Present and support an extended argument
- D3. Demonstrate self-direction and originality in solving problems and act autonomously in planning and implementing tasks
- D4. Demonstrate skills in searching medical, scientific, regulatory and guidance literature
- D5. Manage information
- D6. Is able to reflect on their own work and the work of others
- D7. Work in small groups

Section 2

Programme management

Relevant QAA subject benchmarking statements	None
Type of programme	Taught postgraduate
Date of validation/last periodic review	January 14
Date of production/ last revision of PS	March 2018
Relevant to level/cohort	Level 7 entering September 2019
Administrative School	School of Life and Medical Sciences

Table 3 Course structure

Course details		
Course code	Course description	JACS / HECOS
HHPV LMPVPGC LMPVPGD	MSc Pharmacovigilance PgCert Pharmacovigilance PgDip Pharmacovigilance	B210 / 100250