University of Hertfordshire UH

School of Life and Medical Sciences

Title of Programme: MSc/PgDip /PgCert in Pharmacovigilance

Programme Code: HHPV

Programme Specification

This programme specification is relevant to students entering:
27 September 2021

Acting Associate Dean of School (Academic Quality Assurance):
Naomi Hewitt

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

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 includes an introductory module, the Principles of Pharmacovigilance (7LMS0260), 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. 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- The Pharmacovigilance regulations and guidelines pertaining to the EU the USA and other major markets.	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). 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. For example, A3 is introduced in the module *Principles of Pharmacovigilance* (7LMS0260) and developed through to the *ADRs by Major Body Systems* (7LMS0261) module using directed learning and case study exercises.	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. Poster production and seminar presentations (some of which will include group work) are also used for A1 to A7. Within the module *Pharmacovigilance Regulations and Guidelines* (7LMS0255) A4 is assessed through a critical analysis report and the completion of a section of a pharmacovigilance regulatory document

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.	A8 is primarily achieved through two modules, *Drug Safety in Clinical Trials* (LMS0256) and *Management and Reporting of Pharmacovigilance Data* (LMS0258), through a combination of lectures and workshop activities.	(Periodic Safety Update Report). A8 is assessed through workshop activities and the module written assignments.
A9- Deep and systematic understanding of how to formulate and design a research study to undertake an extended, in-depth study of a selected aspect of research.	Acquisition of A9 is through the *Project* module (7LMS0259) where students are required to undertake an in-depth study on a selected topic from within the scope of the programme.	A9 is assessed through the research project proposal, project written report and an oral presentation.
Intellectual skills:	Teaching/learning methods & strategies	Assessment
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 in Pharmacovigilance processes. B5- Apply knowledge with critical awareness to the design of processes to	Intellectual skills are developed through methods and strategies outlined in section A above. Analysis, critical evaluation, synthesis and application of information is further developed throughout workshops, in-course exercises, module assignment exercise and project work B1-B5). B5 is mainly acquired in the module *Risk Management and Labelling* (7LMS0263) through lectures, assessed problem based learning exercises and role play workshops. Throughout, the learner is encouraged to develop intellectual skills further by independent study.	Intellectual skills B1 to B5 are assessed through analysis of case studies, unseen in-course assessments, assignments and project work.

implement Pharmacovigilance regulations and guidelines and business practices. B6- Critically analyse and interpret information and draw conclusions in the context of a hypothesis being tested.	Acquisition of B6 is through the *Project* module (7LMS0259) where students undertake an in-depth research study.	B6 is assessed through the research project written report and an oral presentation.
Practical skills:	Teaching/learning methods & strategies	Assessment
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.	Practical skills are developed through case studies (C1) group work (C1, C2) module assignment exercises (C1-C6). For C2 students are expected to design their own Pharmacovigilance data base following a workshop activity. Acquisition of C3 is achieved in a workshop based on risk benefit related cases.	Practical skills are assessed through written reports (C1-C6).
Transferable skills:	Teaching/learning methods & strategies	Assessment
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 and scientific literature. D5- Manage information.	D1-D6 transferable skills are developed through written reports, the *Project (7LMS0259)* 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.	Transferable skills are assessed through a range of assignments built into the curriculum, coursework assignments and the project (D1-5, D6). For example: *Viva voce* examinations (D1 and D2); workshop presentations (D1) PBL reports (D1,3,4) and the Project (D1,2, 3, 4, 5). D7 is assessed in workshops associated with the *Management and Reporting of Pharmacovigilance Data* (7LMS0258) and

D6- Is able to reflect on their own work and the work of others. D7- Work effectively in small groups.		*Pharmacoepidemiology* (7LMS0262).

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 in either Semester A or Semester B.

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*	7LMS2018	15	English	0	100	n/a	B
Adverse Drug Reactions by Major Body Systems I	7LMS2019	15	English	0	100	n/a	B
Pharmacovigilance Regulations and Guidelines*	7LMS0255	15	English	0	100	n/a	A
Drug Safety in Clinical Trials	7LMS0256	15	English	0	100	n/a	A
Adverse Drug Reactions by Major Body Systems II	7LMS0257	15	English	0	100	n/a	B
Management and Reporting of Pharmacovigilance Data	7LMS0258	15	English	0	100	n/a	B
Pharmacoepidemiology	7LMS2020	15	English	0	100	n/a	A
Risk Management and Labelling	7LMS2021	15	English	0	100	n/a	A
Project	7LMS0259	60	English	0	100	n/a	A, B

*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 (7LMS0259).
The award of Postgraduate Diploma in Pharmacovigilance requires 120 credit points passed at level 7

excluding the Project (7LMS0259).
The award of Postgraduate Certificate in Pharmacovigilance requires 60 credit points passed at level 7 including the two *compulsory modules.

Table 1b Final and interim awards available

Students may enter directly onto the Masters, Postgraduate Diploma or the Postgraduate Certificate programme. Compulsory modules must be passed for any award. 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	A1, A2, A3, A4, A5, A6, A7, A8, A9, B1, B2, B3, B4, B5, B6, C1, C2, C3, C4, C5, C6, D1, D4, D5, D6, D7
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, 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, 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, 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, C1, C2, C4, C5, C6, D1, D4, D5, D6, D7. *For untitled awards:* 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 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 7LMS0255 Pharmacovigilance Regulations and Guidelines is required for all awards, 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 normally 5 years from their registration on the programme.

- To enrol onto the project module students must have completed 120 credits, including both compulsory modules.

E. Management of the Programme & Support for students learning

Management

The programme is managed and administered through:

- Dean of School
- An Associate Dean of School (Academic Quality)
- A Head of Department
- A Head of Subject Group
- A Programme Leader who is responsible for the day to day programme management
- An Admissions Tutor, who is responsible for selection of students
- A designated programme administration team 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 Leader (Chair), Programme Administrator (Secretary), Module Leaders, student and industry representatives
- 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 provide pastoral and academic support
- Project tutors
- Canvas module sites
- Module guides providing module information and study guidance
- On-line module information provided via the University's managed learning environment "StudyNet Canvas" a University-wide system for study support
- Programme 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:

i. at least 6 months experience in full-time Pharmacovigilance work and at least one of the following:

ii. a first or second class Honours Degree in Biosciences, Pharmacy or Biological Chemistry or
iii. a professional qualification accepted as equivalent to the above or
iv. a qualification in veterinary science, medicine or dentistry or
v. a first or second class Honours Degree in disciplines that would be judged as equivalent to the above.

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 categories ii-v 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	A 1	A 2	A 3	A 4	A 5	A 6	A 7	A 8	A 9	B 1	B 2	B 3	B 4	B 5	B 6	C 1	C 2	C 3	C 4	C 5	C 6	D 1	D 2	D 3	D 4	D 5	D 6	D 7
Principles of Pharmacovigilance	7LMS2018	X	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	7LMS2019			X		X			X				X	X			X			X	X	X	X	X	X	X	X	X	X
Pharmacovigilance Regulation and Guidelines	7LMS0255	X			X	X						X		X	X		X	X		X	X	X		X	X	X	X	X	X
Drug Safety in Clinical Trials	7LMS0256		X		X	X			X		X	X	X	X			X	X		X	X	X		X	X	X	X	X	X
ADRs by Major Body Systems II	7LMS0257			X		X			X				X	X			X			X	X	X		X	X	X	X	X	X
Management and Reporting of Pharmacovigilance Data	7LMS0258				X	X	X	X	X				X	X	X			X		X	X	X	X	X	X	X	X	X	X
Pharmacoepidemiology	7LMS2020				X	X	X				X	X	X	X	X		X			X	X	X		X	X	X	X	X	X
Risk Management and Labelling	7LMS2021				X	X	X	X				X	X	X	X		X	X	X	X	X	X		X	X	X	X	X	X
Project	7LMS0259	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	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.
A9. Deep and systematic understanding of how to formulate and design a research study to undertake an extended, in-depth study of a selected aspect of research.

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.

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.
B6. Critically analyse and interpret information and draw conclusions in the context of a hypothesis being tested.

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	October 19
Date of production/ last revision of PS	March 2021
Relevant to level/cohort	Level 7 entering September 2021
Administrative School	School of Life and Medical Sciences

Table 3 Course structure

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