

Title of Programme: MSc in Pharmacovigilance

Programme Code: HHPV

Programme Specification

This programme specification is relevant to students entering:
01 September 2024

Associate Dean of School (Academic Quality Assurance):
Sherael Webley



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 PgC/PgD/MSc in 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 and online
Programme accredited by	Not Applicable
Final Award (Qualification)	PgCert/PgDip/MSc
All Final Award titles	Postgraduate Certificate in Pharmacovigilance
(Qualification and Subject)	Postgraduate Diploma in Pharmacovigilance Masters in Pharmacovigilance
FHEQ level of award	7

A. Programme Rationale

This part-time postgraduate programme in Pharmacovigilance is designed for full-time employed professionals within drug safety.

The programme, in collaboration with Pharmaceutical Industry and PIPA (Pharmaceutical Information and Pharmacovigilance Association), has international recognition as an established provider of Pharmacovigilance education with academic accreditation, focusing on European Union and United Kingdom Regulations/Guidelines, yet providing a rounded global context.

You will gain knowledge and skills in evaluating sources of pharmacovigilance data, identifying potential signals by understanding biological processes behind adverse drug reactions, assessing medicine risk management, and labelling requirements, and understanding regulations and guidelines shaping pre- and post-authorisation development, and pharmacoepidemiologic studies.

A faculty of expert speakers and project supervisors provide you with latest Pharmacovigilance thinking; working in small groups to evaluate real-world case examples, share your experiences and network.

The programme offers flexibility to fit in with your busy working life. You will attend a 3-day block teaching, per module which is delivered online and in-person simultaneously, during a working day in United Kingdom time-zone. There must be a minimum of 6 students who attend regularly to in-person for this delivery method if there not more than 6 students the whole module will be delivered online.

You can enroll any time during the year and will enter the next scheduled module; the eight modules are taught in 2 -year taught cycle and you can take up to 4 modules per year. It is delivered online and in-person, with eight taught modules and a MSc project to be completed within 5 academic years.

B. Educational Aims of the Programme

Diversity and Inclusion

Our programmes are purposefully designed to enable all students to engage meaningfully with the curriculum by being accessible and representative. We will support students to shape their learning experience, removing barriers and enabling them to succeed. The curriculum explicitly includes multiple and representative

perspectives, valuing collective identities and individual diversity. Learning, teaching and assessment activities help students to understand how they can enhance outcomes both for themselves and for others. All students belong to a learning community, and during their studies we really want to hear their voices, encourage them to listen to others, and express themselves.

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:

- promote 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 and skills 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.

Graduate Attributes

Our graduates will be capable and professional, creative and enterprising, and will build their social and global awareness throughout. In addition to their subject expertise and proficiency, as a University of Hertfordshire graduate, they will be:

- Professionally focused
- Globally minded
- Sustainability driven
- Digitally capable and confident
- Inclusive and collaborative
- Evidence based and ethical.

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 (2021) 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-A8).	Knowledge and understanding are assessed through use a combination of coursework elements including data interpretation problem solving, Multiple Response Question & short answer online tests, group presentations, group debates, decision making
A2-Spontaneous and unstructured reporting, including an appreciation of the advantages and	Throughout, the learner is encouraged to undertake	

<p>B3-Analyse and critically evaluate experimental, pharmacoepidemiological data and adverse drug experiences.</p> <p>B4-Analyse and critically evaluate regulations and guidelines in Pharmacovigilance processes.</p> <p>B5-Apply knowledge with critical awareness to the design of processes to implement Pharmacovigilance regulations and guidelines and business practices.</p> <p>B6-Critically analyse and interpret information and draw conclusions in the context of a hypothesis being tested.</p>	<p>Throughout, the learner is encouraged to develop intellectual skills further by independent study.</p> <p>Acquisition of B6 is through the Project module where students undertake an in-depth research study.</p>	<p>B6 is assessed through the research project written report and an oral presentation.</p>
<p>Practical skills:</p>	<p>Teaching/learning methods & strategies</p>	<p>Assessment</p>
<p>C1-Undertake causality assessments and evaluate reports, scientific and clinical papers.</p> <p>C2-Design and evaluate Pharmacovigilance working processes.</p> <p>C3-Undertake a risk benefit analysis of a product.</p> <p>C4-Operate in complex and unpredictable and specialized contexts and have an overview of good practice.</p> <p>C5-Demonstrate initiative and personal responsibility.</p> <p>C6-Use information technology effectively.</p>	<p>Practical skills are developed through case studies (C1) group work (C1, C2) module assignment exercises (C1-C6).</p>	<p>Practical skills are assessed through written reports (C1-C6).</p>
<p>Transferable skills:</p>	<p>Teaching/learning methods & strategies</p>	<p>Assessment</p>

D1-Communicate effectively both orally and in writing.	Transferable skills are developed through developed through formative group workshops, summative written assignments, group presentations/debates, project work (D1-7).	Transferable skills are assessed through a range of assignments built into the curriculum, assignments and the project (D1-6) including viva voce and presentations.
D2-Present and support an extended argument.		
D3-Demonstrate self-direction and originality in solving problems and act autonomously in planning and implementing tasks.	Throughout, the learner is encouraged to develop transferable skills by maintaining a record of evidence and completing a personal development plan.	
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 effectively 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 (a maximum of 6 years with approval) and leads to the award of MSc in Pharmacovigilance. Intake is normally in Semester A (September) and B (February).

Professional and Statutory Regulatory Bodies

No accreditation.

Work-Based Learning, including Sandwich Programmes

Not applicable.

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 years under special circumstances). Each taught module consists of: (i) pre-course reading (6 weeks) (ii) 3-day taught component including 2 assignments and (iii) a post module assignment due approximately 6 weeks after taught session. The 8 taught modules can be completed within 2 years.

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

Compulsory Modules Module Title	Module Code	Credit Points	% Test	% Examination	% Coursework	% Practical	Semesters
Principles of Pharmacovigilance*	7LMS2018	15	0	0	100	0	B
Adverse Drug Reactions by Major Body Systems I	7LMS2019	15	0	0	100	0	B
Pharmacovigilance Regulations and Guidelines*	7LMS0255	15	0	0	100	0	A
Drug Safety in Clinical Trials	7LMS0256	15	0	0	100	0	A
Adverse Drug Reactions by Major Body Systems II	7LMS0257	15	0	0	100	0	B
Management and Reporting of Pharmacovigilance Data	7LMS0258	15	0	0	100	0	B
Pharmacoepidemiology	7LMS2020	15	0	0	100	0	A
Risk Management and Labelling	7LMS2021	15	0	0	100	0	A
Project	7LMS0259	60	0	0	100	0	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 an Postgraduate Diploma in Pharmacovigilance requires 120 credit points passed at level 7 (excluding 7LMS0259)..

The award of an Postgraduate 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	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.

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:

- There are no external validating body for this programme.

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

- A pass in 7LMS2018 (Principles of Pharmacovigilance) and 7LMS0255 (Regulations and Guidelines in Pharmacovigilance) is required for all awards.
- It is expected that students attend all three days during the 3-day teaching block, and to be present during the timetabled assignments. The timetable is released 6 weeks prior to the taught session.
- The maximum period within which a student may gain an award on the programme is 5 years from their date of registration, however student may be permitted a 6th year with approval under special circumstances.
- To enrol onto the project module students must have completed 120 credits, including both compulsory modules.

E. Management of Programme & Support for student 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.
- The Programme Leader, who is responsible for advising students on the programme as a whole and chairing the programme committee.
- An Admissions Tutor, who is responsible for selection of students.
- A designated administration team to deal with day-to-day administration associated with the modules in 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 on programme committees.

Support

Students are supported by:

- An induction week at the beginning of each new academic session.
- Overseas Orientation.
- You will have a Personal Tutor who will be an important point of contact, able to help you gain a good understanding of the School and programme you are studying.
- A substantial Student Centre that provides advice on issues such as finance, University regulations, legal matters, accommodation, international student support, etc.
- Office of Dean of Students, Student Wellbeing (incorporating Counselling, Mental Health and Disability Support), Chaplaincy, and Day Nursery.
- A versatile on-line inter-active intranet and learning environment.
- Guided student-centred learning on Canvas module sites.
- Access to extensive digital and print collections of information resources.
- Attractive modern study environments in 2 Learning Resources Centres.
- Student Success Hubs, which include a Mathematics Drop-in Centre.
- Medical Centre.
- University Disability Advisors.
- Careers and Employment.
- Hertfordshire Student's Union.
- Dedicated programme site.

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 dedicated programme site
- A Definitive Module Document (DMD) 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/>.

G. Entry requirements

Academic Requirements

The normal entry requirements for the programme are:

- at least 6 months experience in full-time Pharmacovigilance work **and** at least one of the following:
- 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 nursing, veterinary science, medicine or dentistry or
- a first- or second-class Honours Degree in disciplines that would be judged as equivalent to the above.

English Language Requirements

All international students are required to demonstrate an English Language International English Language Testing System (IELTS): Score of 6.5 (with no less than 5.5 in any band) for postgraduate.

Alternative permitted evidence is located: <https://www.herts.ac.uk/international/new-international-students/international-apply-now/international-entry-requirements>.

Non-standard applications

The school will consider non-standard applications who can demonstrate that they have **relevant** work experience for at least 3 years, via a Curriculum Vitae and/or LinkedIn profile. A substantial personal statement (approximately 300-500 words) and/or video presentation as to why you want to study the programme, what you hope to gain from the course, and where this will help your career.

This personal assessment will be assessed on the following criteria:

1. insight into the demands of the course,
2. ability to reflect critically on own experience and how the course will impact their career pathway.

A reference letter from a current or previous manager or HR department, or person in a position of authority is required as supporting evidence.

Current Tariff Entry Point Requirements

For current entry tariff point requirements, please refer to the relevant page for the Course on the University website or on the online prospectus.

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:
icaq@herts.ac.uk

If you wish to receive a copy of the latest External Examiner's Report for the programme, please email a request to aqo@herts.ac.uk

PgC/PgD/MSc in 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	A9	B1	B2	B3	B4	B5	B6	C1	C2	C3	C4	C5	C6	D1	D2	D3	D4	D5	D6	D7	
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	x
ADRs by Major Body Systems I	7LMS2019			x		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	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	x
ADRs by Major Body Systems II	7LMS0257			x		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	x
Pharmacoepidemiology	7LMS2020				x	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	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	x	x

KEY TO PROGRAMME LEARNING OUTCOMES

Knowledge and Understanding	Practical Skills
A1. Principles of pharmacovigilance from the development of the science to its place in the pre-and post-marketing environment.	C1. Undertake causality assessments and evaluate reports, scientific and clinical papers.
A2. Spontaneous reporting including an appreciation of the advantages and limitations with regard to identification and clarification of drug safety issues.	C2. Design and evaluate pharmacovigilance working processes.
A3. The factors and mechanisms of adverse drug reactions.	C3. Undertake a risk benefit analysis of a product.
A4. Pharmacovigilance regulations and guidelines underpinning pharmacovigilance requirements in UK, Europe, USA and other pharmaceutical markets worldwide.	C4. Operate in complex and unpredictable and specialized contexts and have an overview of good practice.
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.	C5. Demonstrate initiative and personal responsibility.
A6. Risk management and strategies to minimise risk.	C6. Use information technology effectively.
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.	
Intellectual Skills	Transferable Skills
B1. Critically appraise the factors leading to the withdrawal of a selected drug from the market.	D1. Communicate effectively both orally and in writing.
B2. Critically assess case reports effectively and to put them into perspective in terms of safety signals/alerts.	D2. Present and support an extended argument.
B3. Analyse and critically evaluate experimental, pharmacoepidemiological data and adverse drug experiences.	D3. Demonstrate self-direction and originality in solving problems and act autonomously in planning and implementing tasks.
B4. Analyse and critically evaluate regulations and guidelines in Pharmacovigilance processes.	D4. Demonstrate skills in searching medical and scientific literature.
B5. Apply knowledge with critical awareness to the design of processes to implement Pharmacovigilance regulations and guidelines and business practices.	D5. Manage information.
B6. Critically analyse and interpret information and draw conclusions in the context of a hypothesis being tested.	D6. Able to reflect on their own and peers work

	D7. Work effectively in small groups.
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Table 3: Development of Graduate Attributes in the Constituent Modules

This map identifies where the Graduate Attributes are delivered in the constituent modules. It provides (i) an aid to academic staff in understanding how individual modules contribute to the development of the Graduate Attributes (ii) a checklist for quality control purposes and (iii) a means to help students monitor their own personal and professional development as the programme progresses. [Note that there is no requirement for the Graduate Attributes to be assessed through these modules]

D = Delivered

Module Title	Module Code	Professionally Focused	Globally Minded	Sustainability Driven	Digitally capable & confident	Inclusive and collaborative	Evidenced based and Ethical
Principles of Pharmacovigilance	7LMS2018	D	D	D	D	D	D
ADRs by Major Body Systems I	7LMS2019	D	D	D	D	D	D
Pharmacovigilance Regulation and Guidelines	7LMS0255	D	D	D	D	D	D
Drug Safety in Clinical Trials	7LMS0256	D	D	D	D	D	D
ADRs by Major Body Systems II	7LMS0257	D	D	D	D	D	D
Management and Reporting of Pharmacovigilance Data	7LMS0258	D	D	D	D	D	D
Pharmacoepidemiology	7LMS2020	D	D	D	D	D	D
Risk Management and Labelling	7LMS2021	D	D	D	D	D	D
Project	7LMS0259	D	D	D	D	D	D

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	2023
Relevant to level/cohort	Level 7 entering Choose an item.
Administrative School	School of Life and Medical Sciences
Language of Delivery	English

Table 4 Course structure

Course details			
Course Code	Course Description	HECOS	UCAS
HHPV	MSc Pharmacovigilance	100250 100%	Not Applicable
LMPVPGC	PgCert Pharmacovigilance	100250 100%	Not Applicable
LMPVPGD	PgDip Pharmacovigilance	100250 100%	Not Applicable