1. **Title of the module**

LABS518 Pharmacovigilance

1. **School or partner institution which will be responsible for management of the module**

Centre for Higher and Degree Apprenticeships

1. **The level of the module (Level 4, Level 5, Level 6 or Level 7)**

Level 5

1. **The number of credits and the ECTS value which the module represents**

15 credits (7.5 ECTs)

1. **Which term(s) the module is to be taught in (or other teaching pattern)**

Flexible delivery model

Autumn and/or Spring and/or Summer

1. **Prerequisite and co-requisite modules**

N/A

1. **The programmes of study to which the module contributes**

BSc (Hons) in Applied Bioscience

FdSc in Applied Bioscience

1. **The intended subject specific learning outcomes.
On successfully completing the module students will be able to:**

8.1 Understand the safety signals, event reporting, the steps of case processing, the process of ensuring a valid case, serious criteria definitions, grading, medical reviews and the fundamentals of effective query raising, that are associated with pharmacovigilance (PV).

8.2 Assess safety information from laboratory alerts, pregnancy reports, overdose reports and protocol-specific reports.

8.3 Produce accurate report narratives, and raise and resolve case queries with investigators or other reporters.

8.4 Understand how to convert coding verbatim medical terms into MedDRA terms and coding trade medical product names into generic names.

8.5 Understand the protection of subject confidentiality, and make appropriate use of the use of safety databases, safety reporting, event detection and reconciliation, event reporting, regulatory requirements and other expedited safety reports according to specific procedures and local regulations.

8.6 Critically evaluate the role of the qualified person for PV.

8.7 Demonstrate knowledge and critical understanding of the process of gathering, advising and acting on local regulatory intelligence.

1. **The intended generic learning outcomes.
On successfully completing the module students will be able to:**

9.1 Develop and demonstrate an ability to work and communicate effectively with others.

9.2 Analyse, evaluate and correctly interpret data.

9.3 Present and communicate data effectively.

9.4 Obtain and use information from a variety of sources as part of self-directed learning.

9.5 Demonstrate time-management and organisational skills within the context of self-directed learning.

1. **A synopsis of the curriculum**

The module provides an introduction to pharmacovigilance (PV). It looks at the safety signals, event reporting, steps of case processing, the process of ensuring a valid case, serious criteria definitions, grading, medical reviews and the fundamentals of effective query raising, that are associated with PV. It also looks at how to assess safety information from laboratory alerts, pregnancy reports, overdose reports and protocol-specific reports and how to produce accurate report narratives, and raise and resolve case queries with investigators or other reporters. It also looks at how to convert coding verbatim medical terms into MedDRA terms and coding trade medical product names into generic names. Furthermore, it covers the protection of subject confidentiality, the use of safety databases, safety reporting, event detection and reconciliation, event reporting, regulatory requirements and other expedited safety reports according to specific procedures and local regulations. It also looks at the role of the qualified person for PV and the process of gathering, advising, and acting on local regulatory intelligence.

1. **Reading list (Indicative list, current at time of publication. Reading lists will be published annually)**

Walker R. and Whittlesea C. (2012) Clinical Pharmacy and Therapeutics. Churchill Livingstone.

Gad S. (2011) Safety Evaluation of Pharmaceutical and Medical Devices International regulatory guide. Springer

1. **Learning and teaching methods**

Blended distance learning:

 Contact Hours: 100 hours

 Private Study Time: 50 hours

 Total Learning Time: 150 hours

1. **Assessment methods**
	1. Main assessment methods

Coursework assignment (essay; 750 words) and a portfolio

Weighting:

Essay Assignment 50%

Portfolio 50% - composed of 5 individual assignments where topics are applied to the workplace

The pass mark for each individual assessment is 40%.  All assessments must be passed in order to pass the module.

13.2 Reassessment methods

Like for like

1. ***Map of module learning outcomes (sections 8 & 9) to learning and teaching methods (section12) and methods of assessment (section 13)***

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Module learning outcome** | 8.1 | 8.2 | 8.3 | 8.4 | 8.5 | 8.6 | 8.7 | 9.1 | 9.2 | 9.3 | 9.4 | 9.5 |
| **Learning/ teaching method** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Private Study** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** |
| Teaching | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** |  |
| Work based experience |  | **x** |  |  | **x** |  |  | **x** | **x** | **x** | **x** | **x** |
| **Assessment method** |  |  |  |  |  |  |  |  |  |  |  |  |
| Essay (750 words) | **x** |  |  |  | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** |
| Portfolio |  | **x** | **x** | **x** |  |  | **x** | **x** | **x** | **x** | **x** | **x** |

1. **Inclusive module design**

The School/Collaborative Partner recognises and has embedded the expectations of current equality legislation, by ensuring that the module is as accessible as possible by design. Additional alternative arrangements for students with Inclusive Learning Plans (ILPs)/declared disabilities will be made on an individual basis, in consultation with the relevant policies and support services.

The inclusive practices in the guidance (see Annex B Appendix A) have been considered in order to support all students in the following areas:

a) Accessible resources and curriculum

b) Learning, teaching and assessment methods

1. **Campus(es) or centre(s) where module will be delivered**

Blended distance learning – delivered from Medway or Canterbury campus

1. **Internationalisation**

Good PV practice is important in all organisations concerning pharmaceutical products for the safety of patients. With regards to the intended learning outcomes, in particular 8.5, the target learning outcomes within this module are applicable worldwide as part of the universal principles of pharmacovigilance. With regard to subject content, the material within the syllabus is applied to a wide range of international contexts, where it draws on and compares current standards and regulations across Europe. The monitoring and safety of authorised pharmaceutical products is important internationally and current PV regulations have international implications for institutions and organisations manufacturing and producing pharmaceutical products. Furthermore, this module has been developed with global employers to have an international focus.

**FACULTIES SUPPORT OFFICE USE ONLY**

**Revision record – all revisions must be recorded in the grid and full details of the change retained in the appropriate committee records.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date approved | Major/minor revision | Start date of delivery of revised version | Section revised | Impacts PLOs (Q6&7 cover sheet) |
| 05/10/20 | Minor | Sep 20 | 13 | No |
|  |  |  |  |  |