1. **Title of the module**

LABS415: GCP

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 4

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 Describe what clinical research is.

8.2 Understand the purpose of Good Clinical Practice (GCP) and the protection of clinical research subjects.

8.3 Give a historical perspective of GCP.

8.4 Understand the basic principles of, and the regulations associated with, GCP.

8.5 Give an overview of good laboratory practice (GLP) and good manufacturing practice (GMP).

8.6 Briefly describe the research approval process in the EU.

8.7 Demonstrate knowledge of sponsors, investigators and ethics committees associated with clinical research.

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

9.1 Work and communicate effectively with others.

9.2 Analyse, evaluate and correctly interpret data

9.3 Present and communicate data effectively

9.4 Demonstrate the ability to obtain and use information from a variety of sources as part of self-directed learning.

9.5 Manage their time and use their organisation skills within the context of self-directed learning.

1. **A synopsis of the curriculum**

This module provides an insight into GCP. It describes what clinical research is, the purpose of GCP and gives a historical perspective of GCP. It also covers the basic principles of GCP, including the protection of clinical research subjects, the International Conference on Harmonisation (ICH) GCP guidelines, the sponsors, Investigators and ethics committees associated with clinical research, and the declaration of Helsinki. The key regulations in the USA, Japan, Europe and the EU are compared and the research approval process in the EU is described. It also gives an overview of good laboratory practice (GLP) and good manufacturing practice (GMP).

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

Hulley, S.B. (2013) Designing Clinical Research. Wolters Kluwer/Lippincott Williams and Wilkins.

Matthews, J.R. (2018) Historical and ethical issues in trial design. Henry Stewart Talks.

1. **Learning and teaching methods**

Blended distance learning:

 Contact Hours: 132 hours

 Private Study Hours: 18 hours

 Total Study Time: 150 hours

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

Two coursework assignments (Essays; 500 words each) and a portfolio

Weighting:

Essay assignment 1 30%

MCQ in class exam (closed book) 30%

Portfolio 40% - composed of 5 individual assignments where topics are applied to the workplace (this is made up of the following;

 WP1: GCP/Discuss the relationship between GLP and GCP principles (Venn diagram). 15%
WP2- GCP/ Choose a drug, explain its mode of action and design a clinical trial (Essay).30%
WP3- GMP/ Choosing one of the following drugs (paracetamol, codeine, mabs), describe its manufacturing process and how it complies with GMP (Essay). 20%
WP4: Short presentations. See Summer School 15%
WP5: Poster. See Summer School 20%)

The weighted average for both the overall coursework and the overall exam component must be of a pass standard.

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 | 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** |
| Teaching | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** |  |
| Work based experience |  | **x** | **x** | **x** |  |  | **x** | **x** | **x** | **x** | **x** |
| **Assessment method** |  |  |  |  |  |  |  |  |  |  |  |
| Essay 1 (500 words) | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** |
| Essay 2 (500 words) | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** |
| Portfolio | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** |
| MCQ | **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**

International vocation is an important part of Applied Bioscience. With regards to the intended learning outcomes, in particular 8.4, 8.6, and 8.7, the target learning outcomes within this module are applicable worldwide as part of the universal principles of clinical practice. 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. Furthermore, it has been developed with global employers to have an international focus.

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**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 |
|  |  |  |  |  |