1. **Title of the module**

LABS517 Document Management, Quality Management Systems and Biological Sample Management

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 Make appropriate use of the essential documents associated with clinical research and their functions, according to the international conference on harmonisation (ICH) good clinical practice (GCP) guidelines and trail master files (TMF).

8.2 Understand the well-established requirements for archiving.

8.3 Apply the concepts and principles in quality assurance in clinical research.

8.4 Apply the concepts and principles associated with standard operating procedures (SOPS) and critically understand their role in upholding regulations.

8.5 Demonstrate knowledge and critical understanding of the well-established principles within compliance reports and regulatory authority inspections.

8.6 Understand what a biological sample is and how to comply with the applicable rules and laws for the collection, storage, and future use, of biological samples of clinical research subjects.

8.7 Critically evaluate the pros and cons of central and local laboratories.

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

1. **A synopsis of the curriculum**

The module gives an introduction into document management, quality management systems and biological sample management. It looks at the essential documents associated with clinical research and their functions, according to section 8 of the ICH GCP guidelines, and TMF. It also looks at the requirements for archiving, quality assurance and its role in clinical research (including continuous improvement), quality control checks, SOPS and their role in upholding regulations, compliance reports, and regulatory authority inspections. It also looks at the definition of a biological sample, and compliance with the applicable rules and laws for the collection, storage, and future use, of biological samples of clinical research subjects. Furthermore, it looks at the pros and cons of central vs local laboratories.

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

Husovich, M. E. (2019) Process Management Framework: Guidance to Successful Implementation of Process in Clinical Development. Therapeutic Innovation & Regulatory Science. Jan 2019, Vol. 53 Issue 1, p25-35. 11p.

Suprin, M. (2019) Quality Risk Management framework: Guidance for Successful Implementation of Risk Management in Clinical Development. Therapeutic Innovation & Regulatory Science. Jan 2019, Vol. 53 Issue 1, p36-44. 9p.

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 this module is 40%.

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** | **x** | **x** | **x** |
| **Assessment method** |  |  |  |  |  |  |  |  |  |  |  |  |
| Essay (750 words) | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** |
| Portfolio | **x** |  | **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**

Document management, quality management systems and biological sample management is applicable to international organisations and is important in international scientific discovery. With regards to the intended learning outcomes, in particular 8.1, 8.3, 8.4, and 8.5, the target learning outcomes within this module are applicable worldwide as part of the universal principles associated with clinical research. 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.

**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 |
|  |  |  |  |  |