1. **Title of the module**

LABS507 GxP

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

Digital and Lifelong Learning

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 course(s) of study to which the module contributes**

FdSc and BSc (Hons) in Applied Bioscience

FdSc and BSc (Hons) in Applied Chemical Sciences

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

8.1 Demonstrate a critical understanding of well-established pharmaceutical/industry GxP requirements (e.g. WHO principles, OECD regulations).

8.2 Apply the relevant GxP legislation, to their own work environment and to well defined contexts (e.g. toxicology studies and trials for human therapies).

8.3 Demonstrate how the GCP principles apply to the clinical trial activities (e.g informed consent, welfare and safety to patients), including pharmacovigilance (risk management).

8.4 Demonstrate knowledge and critical understanding of audits in quality management and carry out an internal compliance audit in accordance with the legislative requirements.

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

9.1 Analyse, evaluate and correctly interpret data.

9.2 Present and communicate data effectively.

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

9.4 Display time-management and organisational skills within the context of self-directed learning.

1. **A synopsis of the curriculum**

Basic Introduction to GxP

Good Laboratory Practices (GLP)

Good Manufacturing Practices (GMP)

Reasons for validation

Good Aseptic Practices (GAP)

Good Clinical Practices (GCP)

Risk-Based Compliance

Quality Audits

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

Long (2012) Good Laboratory Practice roles and responsibilities. Henry Stewart Talks.

Rules and guidance for pharmaceutical manufacturers and distributors (Orange Guide) (2015) London: Pharmaceutical Press, 9th edition.

Cingi & Cemal (2017) Quick guide to good clinical practice: how to meet international quality standard in clinical research. Springer.

Inspection and Standards Division of the Medicines and Healthcare products Regulatory Agency (2017) Rules and guidance for pharmaceutical manufacturers and distributors. London: Pharmaceutical Press.

1. **Learning and teaching methods**

Blended distance learning:

 Contact hours: 120 hours

 Private Study Time: 30 hours

 Total Learning Time: 150 hours

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

Portfolio and two coursework assignments

Weighting:

2 Essay Assignments 40% (20% each)

Portfolio 60% - composed of 5 individual assignments where topics are applied to the workplace

The pass mark for this module is 40%.  All assessments must be passed.

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 | 9.1 | 9.2 | 9.3 | 9.4 |
| **Learning/ teaching method** |  |  |  |  |  |  |  |  |
| **Private Study** | **X** | **X** | **X** | **X** | **X** | **X** | **X** | **X** |
| **Teaching** | **X** | **X** | **X** | **X** |  | **X** | **X** |  |
| **Work based expirience** |  |  |  |  |  | **X** | **X** | **X** |
|  |  |  |  |  |  |  |  |  |
| **Assessment method** |  |  |  |  |  |  |  |  |
| **Portfolio** | **X** | **X** | **X** |  | **X** | **X** | **X** |  |
|  |  |  |  |  |  |  |  |  |
| **2 Assignments** |  |  | **X** | **X** | **X** | **X** | **X** |  |
| *-* |  |  |  |  |  |  |  |  |

1. **Inclusive module design**

The Division/Collaborative Partner *(delete as applicable)* 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. All of the intended learning outcomes for this module cover key universal principles for good practice in laboratory, clinical, manufacturing, and pharmaceutical areas of Applied Bioscience worldwide. 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.

**If the module is part of a course in a Partner College or Validated Institution, please complete sections 18 and 19. If the module is not part of a course in a Partner College or Validated Institution these sections can be deleted.**

1. **Partner College/Validated Institution**
2. **University Division responsible for the course**

**DIVISIONAL 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) |
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