1. **Title of the module**

LABS414: Advanced Therapies: R&D to Market

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 Understand the basic principles involved in advanced therapies.

8.2 Apply the underlying concepts and principles associated with in gene therapy, cell therapy, and tissue engineering.

8.3 Understand the basics concepts involved in the development of viral vectors, tissue engineering, and cell therapy.

8.4 Demonstrate knowledge of the underlying concepts and principles associated with manufacture and industrialisaton of advanced therapies.

8.5 Understand the key concepts associated with commercialisation, clinical aspects, and regulation of advanced therapies.

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**

The module provides an insight into advanced therapies and advanced therapy medicinal products (ATMPs). It covers the basic principles and key tools, associated with advanced therapies (gene therapy, cell therapy, and tissue engineering), and their application and development. It also covers the manufacturing and industrialisaton of advanced therapies, and their commercialisation, and regulation. This will include:

* The use of various vectors in advanced therapies
* The techniques involved in advanced therapies
* Specific examples of ATMPs
* The clinical relevance of ATMPs
* Delivery methods of various advanced therapies
* Upstream and downstream processes
* Reasons for failure
* Scale and costs
* Commercial opportunities
* Good manufacturing practice (GMP) and good clinical practice (GCP) basics
* Relevant regulation and legislation

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

Giacca, M. (2010) Gene Therapy. Springer Milan.

Pallua, N. (2011) Tissue Engineering From Lab to Clinic. Springer Berlin Heidelberg.

Baharvand, H. (2013). Regenerative Medicine and Cell Therapy. Humana Press.

1. **Learning and teaching methods**

Blended distance learning:

Contact Hours: 120 hours

Private Study Hours: 30 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%

Essay assignment 2 30%

Portfolio 40% - composed of 5 individual assignments where topics are applied to the workplace

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** |

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 and 8.5, the target learning outcomes within this module are applicable worldwide as part of the universal principles of advanced therapies, within the pharmaceutical industry. 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. This is important as ATMPs are developed and produced internationally and those that are placed on the market in the EU must be regulated and have authorisation. 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 |
|  |  |  |  |  |