

**CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ**

Semester 1 Examinations 2016/2017

Module Title: Industrial Biotechnology

Module Code: BIOT 7003

School: Science

Programme Title: BSc Applied Biosciences& Biotechnology

Programme Code: CR_SBIBI_7_Y3

External Examiner(s):Dr Brendan O Donnell

Internal Examiner(s):Ms Margaret Lane

Instructions: Answer 4 Questions.All questions carry equal marks.

Duration:2 hours

Sitting: Winter 2016/2017

Requirements for this examination:

Note to Candidates: Please check the Programme Title and the Module Title to ensure that you have received the correct examination paper.
If in doubt please contact an Invigilator.

Q1. (a) Describe the Lactose operon and explain how the lactose promoter could be used to control the production of a heterologous protein in a bacterial cell. (10 marks)

(b) Discuss the advantages and disadvantages of using Bacterial and Mammalian cells for the production of biopharmaceuticals. (15 marks)

2(a) Bioreactors may vary in their design. Discuss the criteria that must be considered when designing a bioreactor. (5 marks)

(b) Describe each of the following types of Bioreactors and indicate why a particular bioreactor might be used for a specific process.

Bubble Column

Airlift loop

Fluidized bed

Packed bed

Wave bag

(20 marks)

3. Write detailed account of the methods used in a Biotechnology company to ensure (by detecting its presence) that pharmaceutical injectable drugs do not contain endotoxin. (25 marks)

4. Write an account of the use of each of the following in the production a biopharmaceutical.

(a) Microcarriers (5 marks)

(b) Fed batch operation (10 marks)

(c) Continuous operation including perfusion. (10 marks)

5. Following downstream purification of a drug product, the resulting API must be formulated.

(a) Explain the purpose and process of formulation. (12 marks)

(b) Describe the final product fill and labelling and packing of the drug. (13 marks)

6. (a) Describe the role of the FDA in the regulation of the production of biopharmaceuticals.
(8 marks)

(b) Describe the stages involved in drug discovery, development and approval by the FDA.
(17 marks)