

**CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ**

Autumn Examinations 2009/10

Industrial Biotechnology C/A

Module Code: BIOT7003

School: Science

Programme Title: BSc in Applied Biosciences & Biotechnology

Programme Code: SBIBI_7_Y3

External Examiner(s): Dr Gary Walsh
Internal Examiner(s): Ms Margaret Lane

Instructions: Answer 4 Questions.

Duration: 2 hours

Sitting: Autumn 2010

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. In the context of a mammalian cell fermentation discuss the possible options in terms of:

- (a) Bioreactor design
- (b) Media
- (c) Operating systems

That could be used to produce a therapeutic protein. (25 marks)

Q2. Discuss the use of clean rooms in the biotechnology industry.

In your answer consider :

- (a) purpose of clean rooms
- (b) Clean room classification
- (c) Contamination control in a clean room
- (d) Clean areas of importance for sterile manufacture
- (e) Clean room monitoring (25 marks)

Q 3 (a) Using a flow diagram explain the stages in the development of a biotechnology facility. In your answer refer to the economic considerations in developing a Biological process. (10 marks)

(b) Discuss the different cell types (using specific examples) that are used in a Biotechnology processes. Give advantages and disadvantages of each. (15 marks)

Q 4 Write descriptive notes on each of the following:

Fermentation scale up

Culture maintenance

Cell Banking

Pyrogens and the LAL test

(25 marks)

Q 5. (a) Write an account of Clinical trials associated with a new Pharmaceutical Drug.

(15 marks)

(b) Write a brief account of one important Regulatory authority involved in the regulation of Pharmaceuticals

(10 marks)

Q 6 Write an explanatory account of Down stream processing.

In your answer mention initial product recovery, concentration and purification of the final product.

(25 marks)