

**CORK INSTITUTE OF TECHNOLOGY**  
**INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ**

**Autumn Examinations 2011/12**

**Module Title: Industrial Biotechnology (CA)**

**Module Code:** BIOT7003

**School:** Science & Informatics

**Programme Title:** BSc Applied Biosciences & Biotechnology  
BSc (Hons) Pharmaceutical Biotechnology

**Programme Code:** SBIBI\_7\_Y3  
SPHBI\_8\_Y3

**External Examiner(s):** Dr Don Faller

**Internal Examiner(s):** Ms Margaret Lane

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

**Duration:** 2 hours

**Sitting:** Autumn 2012

**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. Discuss the role of the FDA in drug approval/ regulation. Include in your answer an account of human drug trials. (25 marks)

Q2. Write a descriptive account of the steps involved in the downstream processing of an extra cellular product that will be formulated as an injectable drug. (25 marks)

Q3. Write notes on the following as they apply to the pharmaceutical Biotechnology industry.

Expression systems (8 marks)

Fermentation operating mode (9 marks)

Regulatory requirements regarding viral inactivation and clearance (8 marks)

Q4. 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)

Q5. Discuss the options available when choosing a Bioreactor for an industrial fermentation.

Explain the features of each and the likely cell types that would be grown in each.

(25 marks)

Q6. (a) Explain how cell lines (prokaryotic and eukaryotic) can be preserved in the short and long term.

(15 marks)

(b) Discuss the importance of the LAL test in the pharmaceutical Biotechnology industry.

Write a brief description of the three ways this test can be performed.

(10 marks)