

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

**Semester 1 Examinations 2013/2014**

**Module Title: Industrial Biotechnology**

**Module Code: BIOT 7003**

**School: Science**

**Programme Title:**

Bachelor of Science Applied Biosciences& Biotechnology – Year 3

Bachelor of Science (Honours) in Analytical Chemistry with Quality Assurance – Year 3

Bachelor of Science Analytical and Pharmaceutical Chemistry – Year 3

**Programme Code: SBIBI\_7\_Y3**  
**SCHQA\_8\_Y3**  
**SCHEM\_7\_Y3**

**External Examiner(s): Dr Gillian Gardiner**

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

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

**Duration: 2 Hours**

**Sitting: Winter 2013/2014**

**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) Write a brief description of the role of the FDA as a regulatory authority for the Biotechnology industry in ensuring the safety and efficacy of drugs. (12 marks)
- (b) Discuss the purpose of validation and the areas within a process that require validation. (13 marks)
- Q2 Write descriptive notes on each of the following:
- (a) The use of perfusion in a mammalian cell fermentation (5 marks)
- (b) The advantages and disadvantages of a batch system (6 marks)
- (c) Typical STR bioreactor construction (6 marks)
- (d) Cleaning, sterility, heat transfer, and foaming in a typical STR (8 marks)
- Q3 Discuss the Monitoring and Control of a fermentation process producing a protein drug.
- Discuss the different parameters that will be measured and explain the effect of these parameters on protein products. (25 marks)
- Q4 (a) Water is a vital ingredient in a biotechnology process.
- Discuss the use of water and the categories of water that are used in Biotechnology Production. (10 marks)
- (b) Discuss the process of constructing a mammalian cell bank and its continuous use and storage. (15 marks)
- Q5 Discuss the importance of clean rooms in the manufacture of a drug that cannot be terminally sterilized. Mention the different classifications of clean rooms, sources of contamination, contamination control and clean room monitoring. (25 marks)
- Q6 (a) The contamination by viruses is a major concern in the production of Biopharmaceutical drugs by mammalian cell lines. Discuss this statement and how this is dealt with in the Industry. (10 marks)
- (b) Write an overview of the steps involved in the downstream processing of a monoclonal antibody. (15 marks)