

CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ

Autumn 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: Autumn 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. Discuss the role of the FDA in drug approval/ regulation. Include in your answer an account of human drug trials. (25 marks)
- Q2. (a) Write an account of the most commonly used expression systems for the production of biotechnology products. Mention the advantages and disadvantages of each expression system. (15 marks)
- (b) Write a brief comparison of bacterial cell media and the media used for mammalian cell culture. Mention the constituents and the methods of sterilization. (10 marks)
- Q3. 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)
- Q4. (a) Discuss the importance of and categories of water used in a pharmaceutical biotechnology process. (10 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. (15 marks)
- Q5. Describe the following types of bioreactors:
Bubble column, Airlift, STR, Packed bed, and Wave bag.
Explain the features of each and the likely cell types that would be grown in each. (25 marks)
- Q6. (a) Describe how a cell bank is constructed. (7 marks)
- (b) Comment on cell bank characterisation and cell bank consistency checks. (8 marks)
- (c) Describe the process used when removing mammalian cells from storage to commence a fermentation. (10 marks)