CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ

Autumn Examinations 2014-2015

Module Title: Industrial Biotechnology

Module Code: **BIOT 7003**

School: Science

Programme Title: BSc Applied Biosciences& Biotechnology
BSc (Hons) in Analytical Chemistry with Quality Assurance
BSc Analytical and Pharmaceutical Chemistry

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 2015

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) Microbial fermentations were the forerunner to modern Pharmaceutical Biotechnology. Discuss Industrial Microbial fermentations and the developments that led to the production of modern Biopharmaceuticals.
(Use examples of traditional and modern products in your answer)

(17 marks)

(b) List and briefly describe the basic principles required to establish a new Biotechnology facility. (8 marks)

Q2 (a) Explain what each of the following terms mean and discuss the advantages and disadvantages of each.

- **Batch**
- **Fed batch**
- **Continuous systems**
- **Fermentation**

(18 marks)

(b) Explain how Microcarriers are used for the growth of anchorage dependant mammalian cells. (7 marks)

Q3. 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)

Q4. The removal of viruses in the production of pharmaceutical drugs is part of the downstream process. Discuss using the following headings:

- Sources of Viral contamination
- Viral clearance in the downstream processing
- Regulatory requirements
- Virus detection

(25 marks)

Q5. Write notes on each of the following:

(a) Construction of a cell bank (8 marks)

(b) Microbial fermentation media (9 marks)

(c) Cell disruption techniques in downstream processing (8 marks)

Q6 Write a descriptive account of the steps involved in developing and gaining approval from the FDA to market a new pharmaceutical drug. (25 marks)