CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ

Semester 1 Examinations 2015/2016

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
SCHEM_7

External Examiner(s):Dr Brendan O Donnell
Internal Examiner(s):Ms Margaret Lane

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

Duration: **2 hours**

Sitting: Winter 2015/2016

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 importance of cell preservation in an industrial biotechnology process.

In your answer mention

(a) Cell preservation methods (6 marks)

(b) Cell Banking (7 marks)

(c) Cell Characterisation (12 marks)

Q2 (a) Describe the design and construction of a typical Stirred Tank Reactor (STR) used in an industrial setting.

(10 marks)

(b) Describe the steps involved in the preparation of Stirred tank Bioreactor for a fermentation.

(8 marks)

(c) List the advantages of using a STR in the production of Biotechnology Products. (7 marks)

Q3 Discuss the following in the context of downstream processing.

(a) Viral contamination and removal (8 marks)

(b) Regulatory requirements regarding viral inactivation and clearance (7 marks)

(c) Methods for Viral inactivation and clearance, and viral detection. (10 marks)

Q4 Describe each of the following as they would be used in the downstream processing and purification of a monoclonal antibody

(a) Initial Product recovery (8 marks)

(b) Nucleic acid removal (5marks)

(c) Initial product concentration (8 marks)

(d) Protein A chromatography (4 marks)

Q5.Write descriptive notes on the following

(a) Pharmacopeia and monographs (7 marks)

(b) The various grades of water and their uses in Biopharmaceutical industry (8 marks)

(c) Biopharma QC testing and production support (10 marks)

Q6 Write a descriptive account of Clean rooms using the following.

(a) Definition of a clean room as used in biopharmaceutical production (2 marks)

(b) Contamination sources (2 marks)

(c) Clean room classification (7 marks)

(d) Clean room contamination control (8 marks)

(e) Clean room monitoring (6 marks)