CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ

Semester 2 Examinations 2010/11

Module Title: Biopharmaceutical Upstream

Module Code: **BIOT 7006**

School: Science

Programme Title: Bachelor of Science (Honours) in Pharmaceutical Biotechnology – Year 2
Bachelor of Science (Honours) in Nutrition and Health Science – Year 2

Programme Code: **SPHBI_8_Y2**
SNHSC_8_Y2

External Examiner(s): **Dr. J. Bird**
Internal Examiner(s): **Dr. Rosemary Rea**

Instructions: Answer **any 3** questions below. All questions carry equal marks.

Duration: 2 Hours

Sitting: Summer 2011

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. Compare the advantages and disadvantages of the following expression systems for the production of recombinant biopharmaceutical products:

- *Escherichia coli*
- Yeast
- Animal cells
- Transgenic animals
- Insect cell culture systems

(30 marks)

Q2. The drug discovery and development process is designed to ensure that only those pharmaceutical / biopharmaceutical products that are both safe and effective are brought to market.

I. List the steps involved in the life history of a successful drug.

II. Discuss clinical trials and the role of the regulatory agencies in more detail.

(30 marks)

Q3. Following production of a cell bank cryopreservation is a process used to preserve the cells by cooling to sub-zero temperatures. Discuss this statement using the following headings:

- Risks of cryopreservation
- Main methods to prevent risks
- Storage

(30 marks)

Q4. Media design is an essential part of the fermentation process. Discuss the defined and non-defined nutritional requirements for mammalian cells. Include the use of serum-free media in this discussion.

(30 marks)

Q5. List the general criteria that have to be considered when designing a bioreactor. Discuss five of these in detail.

(30 marks)