

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

**Autumn Examinations 2012/13**

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| <b>Module Title:      Industrial Biotechnology</b> |
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**Module Code:**      **BIOT7003**

**School:**      Science & Informatics

**Programme Title:**

Bachelor of Science in Applied Biosciences & Biotechnology – Year 3

Bachelor of Science (Honours) in Pharmaceutical 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**  
                              **SPHBI\_8\_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 2012/2013

**Requirements for this examination:**

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| <p><b>Note to Candidates:</b> Please check the Programme Title and the Module Title to ensure that you have received the correct examination paper.<br/>If in doubt please contact an Invigilator.</p> |
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Q1 Write a detailed account of Clean rooms and their use in pharmaceutical biotechnology processes.  
In your answer mention classes of clean rooms, areas of use, maintaining the required standards in clean rooms and monitoring of cleanrooms. (25 marks)

Q2 Discuss:

- (a) The role of the FDA as a regulatory authority in pharmaceutical biotechnology processes. (16 marks)
- (b) Clinical trials. (9 marks)

Q3 Describe the steps involved in the downstream processing of an extracellular heterologous protein following fermentation. (25 marks)

Q4. Describe and discuss the advantages and disadvantages of the various operating modes that can be used to run a fermentation. (25 marks)

Q5 Write descriptive notes on the following as they apply to the pharmaceutical biotechnology industry.

- (a) Validation
- (b) Water
- (c) Endotoxin testing (25 marks)

Q6 Discuss the term Industrial Biotechnology with specific reference to

- Traditional Biotechnology Processes
- Modern Pharmaceutical Processes
- Development of a Biotechnology facility

Use relevant examples to illustrate your answer. (25 marks)