

Cork Institute of Technology

Bachelor of Science (Honours) in Applied Biosciences (ACCS) - Award

(NFQ - Level 8)

Summer 2006

Quality Management Systems

(Time: 3 Hours)

Answer one question from each of Section A, B, C and D. Each question carries equal marks.

Use separate answer books for each section and mark the question attempted

Examiners : Mr E. Fitzgerald

Ms. A Ward

Ms. A Murphy

Dr. T. Beresford

Section A

- Q1. A small percentage of new entrepreneurs succeed in Ireland's competitive consumer marketplace.
Discuss the reasons why entrepreneurs succeed, to include financial and non-financial supports available to them. Outline the main barriers in Ireland that prevent the success of most entrepreneurs. Use examples you are familiar with to support your answer.
(25 marks)
- Q2. "Knowing consumer's needs and filling these needs is the main reason why new food and pharmaceutical businesses succeed in Ireland's competitive marketplace". Discuss this statement using examples you are familiar with.
(25 marks)

Section B

- Q3. “The successful manager understands the social, legal and financial environment in which the organisation operates and manages the organisation accordingly.” Discuss. (25 marks)
- Q4. Describe the different styles of management of a bio-science manufacturing plant. Comment on which style you think is most appropriate for the various stakeholders in the company. (25 marks)

Section C

- Q5. Describe the ways in which organisations try to ensure that the goods and services they provide meet the needs of their customers. (25 marks)
- Q6. Discuss the obligations on the persons responsible for product release to ensure that no product which might be harmful to customers is not released for sale. How would you approach risk management in this context? (25 marks)

Section D

- Q7. Write an overview of the current Good Manufacturing Practices (cGMP) regulations as they apply to the pharmaceutical manufacturing industry. In your answer, discuss the key recommendations proposed by the FDA for the integration of the quality management system model into existing cGMP programs. (25 marks)
- Q8. ‘Quality Management System principles can be used as a framework to guide an organisation towards improved performance’.
Discuss this statement under the following headings:
- (a) Quality Improvement tools
 - (b) The Process Approach to quality management (25 marks)