

Cork Institute of Technology

Bachelor of Science (Honours) in Applied BioSciences – Award

(NFQ – Level 8)

December 2005

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 B. Walsh

Mr S. McCarthy

Ms. A Ward

Ms. A Murphy

Dr. T. Beresford

Section A

- Q1. Using a case study with which you are familiar critically evaluate the efficacy of Root Cause Analysis (RCA) as a technique for hazard identification. (25 marks)
- Q2. Write concise notes on the principles of Risk Assessment for illness caused by food-borne biological agents (25 marks)

Section B

- Q3. (a) Discuss how an organisation can use the promotion tool within its marketing mix as a means of initiating consumer recognition for their product and maintaining consumer awareness. Use examples with which you are familiar to support your answer. (17 marks)
- (b) Discuss the benefits of branding for a manufacturing organisation. Use examples with which you are familiar to support your answer. (8 marks)

- Q4. (a) A company manufacturing a pharmaceutical product has fixed costs of €300,000. The selling price of the product is €4.90 and the unit variable cost is €2.65.
- (i) Calculate the unit break even point (3 marks)
 - (ii) If the selling price of the product was decreased by 20% how many units would the company be required to sell to not make a loss. (3 marks)
 - (b) Discuss in detail the main functions of managers in an organisation. (10 Marks)
 - (c) Discuss the main funding sources available to entrepreneurs in Ireland. (9 marks)

Section C

- Q5. Write concise notes on the following:
- (a) Effective managerial leadership
 - (b) International quality standards
 - (c) Good company quality policies (25 marks)
- Q6. Discuss the total quality management of a small to medium sized food enterprise. (25 marks)

Section D

- Q7. Discuss the essential elements of process validation as they apply to both prospective and retrospective process validation systems in the pharmaceutical industry. (25 marks)
- Q8. (a) Write an essay on new methodologies currently being implemented in disciplined quality improvement systems. (15 marks)
- (b) Discuss the influence of these quality improvement methodologies and increasing the process performance level on reducing the cost of poor quality. (10 marks)