

Cork Institute of Technology

Bachelor of Science (Honours) in Applied BioSciences – Award

(NFQ – Level 8)

Autumn 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 B. Walsh
Ms. A Ward
Ms. A Murphy
Mr. S. McCarthy
Dr. T. Beresford

Section A

- Q1. Write concise notes on the methods available for the identification of hazards associated with food or biopharmaceutical products. (25 marks)
- Q2. HACCP is a systematic approach to product safety especially for food and biopharmaceutical products. Outline the purpose and principles of this system. (25 marks)

Section B

- Q3. (a) A company manufacturing a pharmaceutical product has fixed costs of €685,000. The selling price of the product is €6.10 and the unit variable cost is €4.50.
- (i) Calculate the unit break even point. (3 marks)
 - (ii) If the selling price was decreased by 15%, how many units would need to be sold to break even. (3 marks)
 - (iii) What level of profits would be made if the selling price was increased by 10% and the variable cost decreased by 20%? (4 marks)
- (b) Discuss the main level of managerial levels that can exist in food and pharmaceuticals companies. Discuss in details the main skills that are required by each managerial level. (15 marks)

- Q4. Discuss in detail the role of market research for food and pharmaceutical companies in Ireland. Discuss how the findings of market research can be used to enable a company to compete successfully in the market place. Use examples with which you are familiar to support your answer.
- (25 marks)

Section C

- Q5. Write concise notes on the following:
- (a) Company quality plans.
 - (b) Effective managerial leadership.
- (25 marks)
- Q6. Review the ISO9000 under the headings:
- (a) Management elements.
 - (b) Direct process elements.
 - (c) Support elements.
- (25 marks)

Section D

- Q7. Write an account of current Good Manufacturing Practice (cGMP) compliance requirements for the pharmaceutical industry.
In your answer briefly comment on the importance of method validation regulations to the analytical laboratory.
- (25 marks)
- Q8. Statistical Process control is the application of appropriate statistical tools to processes for continual improvement in the quality of products and services.
Discuss this statement.
Comment on the role of the Deming cycle as a method of achieving never ending improvement. .
- (25 marks)