

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. Discuss Good Manufacturing Practices (GMP) regulations as they apply to the pharmaceutical industry under the following headings:

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|-------------------------------------|------------|
| (i) General GMP requirements | (10 marks) |
| (ii) Documents and document control | (7 marks) |
| (iii) Method validation | (8 marks) |

Q2. Statistical process control can be defined as a simple effective approach to problem solving and process improvement.

Write a short essay on the importance of SPC design and implementation in a total quality management system.

(25 marks)

Section B

- Q3. (a) A company manufacturing a pharmaceutical product has fixed costs of €485,000.
The selling price of the product is €7.75 and the unit variable cost is €5.90.
- (i) Calculate the unit break even point. (3 marks)
 - (ii) If the selling price was increased by 12%, 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 decreased by 15% and the variable cost increased by 10%? (4 marks)
- (b) Describe, giving examples, the main sources of start up finance available to businesses in Ireland. (9 marks)
- (c) Discuss the main push and pull factors which can stimulate a potential entrepreneur into setting up a business venture. (6 marks)
- Q4. The correct blend or combination of the 4 Ps in the marketing mix is vital for a food or pharmaceutical business to compete successfully in the market place in Ireland today. Discuss this statement using examples with which you are familiar to support your answer. (25 marks)

Section C

- Q5. Discuss the effective leadership of a large food processing company. (25 marks)
- Q6. Write notes on the following:
- (a) Quality manual.
 - (b) International quality standards.
 - (c) Quality policies. (25 marks)

Section D

- Q7. Write concise notes on two techniques with which you are familiar for hazard identification. (20 marks)
- Q8. Write an essay on the implementation of a risk management strategy, for a food or biopharmaceutical production facility, paying particular attention to the various stages in the process. (20 marks)