Cork Institute of Technology

Bachelor of Science (Honours) in Applied Biosciences - Award

December 2004

Quality Management Systems

(Time: 3 Hours)

Answer FOUR questions. Answer ONE question form each of Sections 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
Mr. M. Hickey

Section A

Q1. (a) Write a brief note on FMEA. (3 marks)

(b) Differentiate between FTA and ETA. (4 marks)

(c) Describe the method known as sneak analysis for hazard identification. (9 marks)

(d) Explain hazard analysis in the context of the HACCP system. (9 marks)

Q2. "Hazard study and process validation have different origins and development histories but these two areas now overlap". Discuss possible synergies between these methodologies in the biopharmaceutical industry. (25 marks)

Section B

Q3. A market orientated organisation has a more significant likelihood of succeeding in Ireland's competitive consumer market.
Discuss this statement using examples with which you are familiar to support your answer.
(25 marks)

Q4 (a) A business manufacturing a pharmaceutical product has fixed costs of €230,000. The unit selling price is €6.40 and the unit variable cost is €3.20.

(i) Calculate the unit break even point. (3 marks)

(ii) What level of profit/loss would the business make if it sells 65,000 units? (3 marks)

(iii) Outline the limitations of break even analysis for a business. (3 marks)

(b) Discuss the main push and pull factors which can stimulate a potential entrepreneur into setting up a business venture. (6 marks)

(c) Write a detailed note on the types of state supports available to entrepreneurs in Ireland. Give examples of each type of support available. (10 marks)

Section C

Q5. Write notes on the following:

(a) Good company quality policies

(b) International Quality Standards (25 marks)

Q6. Discuss the effective leadership of a large food processing industry.

(25 marks)

Section D

Q7. Write an essay on the recommendations proposed by the FDA to integrate quality system approaches into existing cGMP programs with the goal of encouraging the adoption of modern and innovative manufacturing technologies in the pharmaceutical industry.

In your answer, discuss both current cGMP regulations and the concepts of modern quality systems. (25 marks)

Q8. Discuss method validation under the following headings:

(i) Method validation of analytical methods

(ii) Types of method validation and pre-qualification requirements

(iii) Calculation of the Cpk index as a method of establishing acceptance criteria in validation studies (25 marks)