CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ

Autumn Examinations 2009/10

Module Title: Quality Management Systems II C/A

Module Code: BIOT7004

School: Science

Programme Title: **BSc. in Applied Biosciences & Biotechnology**
BSc. in Food Science & Technology

Programme Code: **SBIBI_7_Y3**
SFSTE_7_Y3

External Examiner(s): Prof. Gary Walsh
Internal Examiner(s): Anne Ward, Anna Murphy

Instructions: Answer TWO questions from Section A and TWO questions from Section B

Duration: 2hr

Sitting: Autumn 2010

Requirements for this examination:

Note to Candidates: Please check the Programme Title and the Module Title to ensure that you have received the correct examination paper.
If in doubt please contact an Invigilator.

Section A

Q1. Write an overview of documentation in a total quality management system.

In your answer outline the main elements of each of the following types of documentation:

(a) Instructional documents

(b) Records and Reports

(25 marks)

Q2. Discuss the general requirements of current Good Manufacturing Practice (cGMP) regulations for the pharmaceutical industry. (25 marks)

Q3. Write an essay on **either** of the following:

(a) ISO9001:2008 international standards

OR

(b) Six Sigma system as an important quality improvement technique.

(25 marks)

SECTION B

Q4(a) Discuss the applications of a LIMS system in a Quality Control Laboratory of a food or pharmaceutical company. (8 marks)

(b) Write a brief note on the risk control step/stage of the risk management process. (7 marks)

(c) During the develoment of the HACCP plan in a food or pharmaceutical company, discuss the benefits of drawing up a flow diagram of the production of a product and describe how this flow diagram can be confirmed. (10 marks)

Q5(a) Write a brief note on Critical Limits in relation to HACCP to include:

(i) A definition of Critical Limits

(ii) Difference between a critical limit and a target limit

(iii) Examples of critical limits for physical, chemical and microbiological hazards. (9 marks)

(b) Discuss the functions of the World Trade Organisation in relation to Free Trade development world wide. (7 marks)

(c) Describe briefly the function of the Verification stage of HACCP. Discuss the main methods of verifying a HACCP plan in a food or pharmaceutical industry. (9 marks)

Q6(a) Describe how a commercial LIMS system such as Laura 4 meets the requirements of a regulatory laboratory. (7 marks)

(b) Write a brief note on Critical Control Points (CCPs) in relation to HACCP to include the CCP Decision Tree. (8 marks)

(c) Define the term Risk. Distinguish between Qualitative Risk Assessment and Quantitative Risk Assessment to include an example of each. (10 marks)