**CORK INSTITUTE OF TECHNOLOGY**
**INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ**

**Autumn Examinations 2011**

# Module Title: Quality Management Systems II (CA)

**Module Code:** **BIOT7004**

**School:** Biological Science

**Programme Title:** Bachelor of Science in Food Science & Technology – Year 3
Bachelor of Science in Applied Biosciences & Biotechnology – Year 3
Bachelor of Science (Honours) in Nutrition & Health Science – Year 3
Bachelor of Science (Honours) in Pharmaceutical Biotechnology – Year 3

**Programme Code:** **SFSTE_7_Y3**
**SBIBI_7_Y3**
**SNHSC_8_Y3**
**SPHBI_8_Y3**

**External Examiner(s):** **Dr Anne Nelson, Dr Alison Gallagher, Dr Jerry Bird**
**Internal Examiner(s):** **Ms Anne Ward, Ms Anna Murphy**

**Instructions:** Answer TWQ questions from Section A and TWO question from Section B. Each question carries equal marks.

**Duration:** **2 Hours**

**Sitting:** **Autumn 2011**

**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. (a)Write a brief overview of the eight principles of Quality Management (8 marks)

(b) Outline the important elements of each of the following types of documentation:

(i) Instructional documents (6 marks)

(ii) Records & Reports (5 marks)

(c) Write a brief note on the importance of the process approach in a TQM system. (6 marks)

(25 Marks)

Q2. Write short notes on each of the following:

(a).The main regulators in the pharmaceutical & Medical Devices Industries in Ireland (10 marks)

(b).General current Good Manufacturing Practice (cGMP) requirements (15 marks)

(25 Marks)

Q3. (a) Write an overview of the six sigma system as an important quality improvement technique. (10 marks)

(b) What type of wastes are associated with the lean manufacturing initiative in quality Improvement? (15 marks)

(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. (8 marks)

(c) During the development 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. (9 marks)

(25 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 how risks can be communicated effectively to stakeholders during the risk management process. (9 marks)

(25 Marks)

Q6(a) Describe how a commercial LIMS system such as Laura 4 or Debra 5 meets the requirements of a regulatory laboratory. (8 marks)

(b) Discuss the importance of the HACCP team in developing an effective HACCP plan.

(8 marks)

(c) Define the term Risk. Distinguish between Qualitative Risk Assessment and Quantitative Risk Assessment and include an example of each type of assessment in answer.

(9 marks)

(25 Marks)