CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ

Autumn Examinations 2011/2012

Module Title: Quality Management Systems II (CA)

Module Code:	BIOT7004
School:	Science & Informatics
Programme Title:	BSc in Applied Biosciences & Biotechnology – Award BSc in Food Science & Technology – Award BSc (Hons) Nutrition & Health Science – Year 3 BSc (Hons) Pharmaceutical Biotechnology – Year 3
Programme Code:	SBIBI_7_Y3 SFSTE_7_Y3 SNHSC_8_Y3 SPHBI_8_Y3
External Examiner(s):	Dr Anne Nelson, Dr Alison Gallagher, Dr Jerry Bird
Internal Examiner(s):	Ms Maire Begley, 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 2012

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) Explain what a "lean process" is and list the seven types of waste in an organization.

(6 marks)

(b) Briefly explain what HACCP is and list the seven principles of HACCP.

(6 marks)

(c) Explain how a control chart can be used to examine the capability of a process.

(6 marks)

(d) Describe the two types of variation that can be found in production processes.

(7 marks)

Q2.

(a) Explain what an SOP is and list four benefits/uses of SOPs.

(6 marks)

(b) Briefly explain the following two tools that can be used within Lean operations: 5S and poka yoke.

(6 marks)

(c) Explain the DMAIC methodology than can be used for Six Sigma projects.

(6 marks)

(d) In relation to HACCP, explain what a critical control point and critical limits are.

(7 marks)

Q3.

(a) Explain what the PDCA cycle is.

(6 marks)

(b) List three reasons why documentation is important in business and explain what steps can be taken to control documents.

(6 marks)

(c) Define the term risk and explain with the use of examples the difference between qualitative and quantitative risk assessment.

(6 marks)

(d) Define what is meant by good manufacturing practice (cGMP) and list four reasons why GMP is needed.

(7 marks)

Section B

Q.4 (a) Discuss the applications of a LIMS system in a Research Laboratory of a food or pharmaceutical company. (6 marks)

(b) Define the term Protectionism in relation to Trade. (3 marks)

(c) Describe in detail two forms of protectionism that you are familiar with. (8 marks)

(d) Write a detailed note on the mass or flow production process to include applications in food, nutritional or pharmaceutical industries. (8 marks)

Q.5 (a) Describe briefly the main hardware and software requirements of a LIMS system. (8 marks)

(b) In relation to world trade, describe briefly what is meant by free trade. (2 marks)

(c) Write a note on a free trade area/trading bloc that you are familiar with. (7 marks)

(d) Write a detailed note on the batch production process to include applications in food, nutritional or pharmaceutical industries. (8 marks)

Q.6 (a) Describe how a commercial LIMS system such as Laura 4 or Debra 5 meets the requirements of a regulatory laboratory. (7 marks)

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

(c) Describe in detail the main factors that influence the choice of manufacturing process that a particular company will use in production. (7 marks)

(d) Describe briefly the term “change control” in relation to validation of a LIMS system. (4 marks)