

**Module Title: Quality Management Systems (CA module)**

**Module Code:** BIOT7004

**School:** Science and Informatics

**Programme title:** BSc in Applied Biosciences & Biotechnology  
BSc in Food Science & Technology  
BSc (Hons) Nutrition & Health Science  
BSc (Hons) Pharmaceutical Biotechnology

**Programme Code:** SBIBI\_7\_Y3  
SFSTE\_7\_Y3  
SNHSC\_8\_Y3  
SPHBI\_8\_Y3

**Internal Examiner:** Dr. Máire Begley

**External Examiners:** Prof. Torres Sweeney

**Instructions:** Answer Question one and two other questions.

Q1 is worth 40 marks. All other questions carry equal marks (30 marks).

**Duration:** 2 hrs

**Sitting:** Autumn 2013

**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.

**Q1. COMPULSORY QUESTION.**

Answer **four** of the following:

- (a) Explain the four levels of evolution of Total quality management (TQM).
- (b) Explain why documentation is important in industry.
- (c) Briefly describe three tools used to develop a foundation of LEAN thinking in the day to day operations of an industry.
- (d) Explain the DMAIC methodology.
- (e) List and briefly explain the seven principles of HACCP.
- (f) Briefly explain what a Laboratory Information Management Systems (LIMS) is and outline the benefits of such a system.

**(4 x 10 marks)**

## **Q2.**

- (a) Explain what is meant by Total Quality Management (TQM). **(6 marks)**
- (b) Explain what an SOP is and list 4 uses of SOPs in industry. **(6 marks)**
- (c) Define what is meant by current good manufacturing practice (cGMP) and explain the rationale for GMP. **(6 marks)**
- (d) List the seven types of waste in an organization. **(4 marks)**
- (e) Explain the difference between qualitative and quantitative risk assessment **(4 marks)**
- (f) Name three pieces of core functionality associated with laboratory processing phases that appear in most laboratory information management systems (LIMS). **(4 marks)**

## **Q3.**

- (a) Explain what each of the following quality gurus are best remembered for: Crosby, Deming, Ishikawa, Juran and Taguchi.
- (b) List three ways in which documents can be controlled in an organisation.
- (c) Explain what Poka Yoke is.
- (d) Explain what 5S is.
- (e) In relation to HACCP, explain what a critical control point is.
- (f) Explain the difference between a LIMS thick client and a LIMS thin client.

**(6 x 5 marks)**

## **Q4.**

- (a) Explain with the aid of diagrams what control charts and Ishakawa diagrams are and explain their use in industry. **(9 marks)**
- (b) Explain the two types of variation that can be found in production processes. **(6 marks)**
- (c) Define what good laboratory practice (GLP) is. **(5 marks)**
- (d) List three basic prerequisite programs that are required before a HACCP system can be implemented. **(5 marks)**
- (e) In relation to LIMS, explain what change control is. **(5 marks)**