

CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ

Autumn Examinations 2014

Module Title: Quality Management Systems (CA)

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 Examiner: **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 Hours

Sitting: Autumn 2014

<p>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.</p>
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Q1. COMPULSORY QUESTION.

Answer **four** of the following:

- (a) Briefly outline the theories of the “original quality gurus”.
- (b) List and briefly explain the seven principles of HACCP.
- (c) Explain what a control chart is and what it can be used for.
- (d) Explain the DMADV methodology.
- (e) Explain what LEAN manufacturing is.

(4 x 10 marks)

Q2.

- (a) Explain the four levels of evolution of Total quality management (TQM). **(6 marks)**
- (b) List three reasons why documentation is important in industry. **(6 marks)**
- (c) List three basic prerequisite programs that are required before a HACCP system can be implemented. **(3 marks)**
- (d) In relation to laboratory information management systems (LIMS), explain what change control is. **(5 marks)**
- (e) Explain why a company might use a combination of LEAN and Sigma to reduce defects? **(4 marks)**
- (f) Outline the three basic elements of risk analysis. **(6 marks)**

Q3.

- (a) Define what is meant by current good manufacturing practice (cGMP) and explain the rationale for GMP. **(5 marks)**
- (b) List the seven types of waste in an organization. **(4 marks)**
- (c) Explain the difference between qualitative and quantitative risk assessment **(4 marks)**
- (d) Name three pieces of core functionality associated with laboratory processing phases that appear in most LIMS. **(3 marks)**
- (e) Explain the difference between a LIMS thick client and a LIMS thin client. **(4 marks)**
- (f) In relation to HACCP, explain what a critical control point is. **(4 marks)**
- (g) Explain the two types of variation that can be found in production processes. **(6 marks)**

Q4.

Give a comprehensive explanation of **each** of the following:

- (a) GLP
- (b) Poka Yoke
- (c) 5S
- (d) Variation in production processes
- (e) Kaizen event
- (f) Ishikawa diagrams

(6 x 5 marks)