

CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ

Autumn Examinations 2015

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

External Examiner: Dr. Tom O'Connor

Internal Examiner: Dr. Máire Begley

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 2015

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 what LEAN manufacturing is.
- (b) Explain why documentation is important in industry.
- (c) Describe 2 tools that can be used for process analysis.
- (d) Outline the 3 basic elements of risk analysis.
- (e) Explain the DMAIC methodology.
- (f) Explain what GMP is and outline the 5 general GMP requirements.

(4 x 10 marks)

Q2. Explain each of the following with the aid of a diagram:

- (a) Control chart
- (b) Ishikawa diagram
- (c) The evolution of Total Quality Management (TQM)

(3 x 10 marks)

Q3.

- (a) List 3 pieces of core functionality associated with a LIMS system. **(3 marks)**
- (b) Outline the benefits of a LIMS system to the food sector. **(7 marks)**
- (c) Explain the difference between a LIMS thick client and thin client. **(10 marks)**
- (d) Explain what a LIMS validation plan is. **(10 marks)**

Q4. Give a comprehensive explanation of each of the following:

- (a) 5 Whys
- (b) 5 S
- (c) Takt time
- (d) Kanban
- (e) Poka yoke
- (f) PDCA cycle

(6 x 5 marks)