

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 Examiner: Dr. Brendan O' Donnell

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 2016

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.

Write comprehensive notes on **four** of the following:

- (a) Laboratory Information Management Systems (LIMS)
- (b) Standard Operating Procedures (SOPs)
- (c) LEAN Six Sigma
- (d) DMAIC methodology
- (e) PDCA cycle
- (f) The 7 management principles that ISO Quality Management Standards are based on.

(4 x 10 marks)

Q2.

- (a) Explain what statistical process control is. **(5 marks)**
- (b) Explain with the aid of labelled control charts the two types of variation in production process. **(17 marks)**
- (c) Explain with the aid of a labelled diagram the use of Ishikawa diagrams. **(8 marks)**

Q3.

- (a) Explain with the aid of examples the difference between qualitative and quantitative risk assessment. **(6 marks)**
- (b) Outline the 5 preliminary tasks involved in the development of a HACCP plan. **(7 marks)**
- (c) Explain the 7 principles of HACCP. **(17 marks)**

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

- (a) Poka Yoke
- (b) FMEA
- (c) Pareto Chart
- (d) 7 types of waste in an organization
- (e) The rationale for GMP
- (f) LIMS change control

(6 x 5 marks)