**CORK INSTITUTE OF TECHNOLOGY**
**INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ**

# Module Title: Regulatory Affairs & Compliance (CA)

**Module Code: BIOT8002**

**School:** Science

**Programme Title:** B.Sc. (hons) in Pharmaceutical Biotechnology

B.Sc. (hons) in Herbal Science

**Programme Code:** **SPHB1 8 Y4**
**SHERB 8 Y4**

**External Examiner(s):** Dr. Cormac Gahan
**Internal Examiner(s):** Anne Ward

**Instructions:** Answer **FOUR** questions only All questions carry equal marks.

**Duration: 2 hr**

**Sitting: Autumn 2014**

**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.

Q1. Write an account of cGMP regulation in the pharmaceutical industry. In your answer, outline the general cGMP requirements with specific reference to the relevant regulatory documentation.

Q2. In relation to documentation, write an overview of **ONE** of the following:

(i) Good Documentation Practice (GDP)

(ii) Standard Operating Procedures (SOPs)

(iii) Quality System Manual

Q3. Write a short account of **ONE** of the following:

(i) Process Validation

(ii) Method Validation

(iii) Process Analytical Technology (PAT)

In your answer reference the relevant regulatory documentation

Q4. Lean manufacturing can be defined as ' the ability to achieve more with less resource by the continuous elimination of waste' Discuss this statement. (25 marks)

Q5. Discuss the importance of six sigma as a key quality improvement initiative in business today under the following headings:

(i) Basic methodologies (10 marks)

(ii) Quality management methods used in six sigma (10 marks)

(iii) Six sigma roles (5 marks)

Q6. (a) Define what is a process (5 marks)

(b) Outline the seven basic tools in statistical process control (15 marks)

(c) How would you assess the process capability index? (5 marks)