CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ

Autumn Examinations 2012

Module Title: Validation Science

Reassessment of a 100 % Continuous Assessment Module

Module Code:	MANU7007
School:	Engineering
Programme Title(s):	Bachelor of Science in Good Manufacturing Practice and Technology Bachelor of Science (Honours) Pharmaceutical Biotechnology Bachelor of Science (Honours) Nutrition and Health Science
Programmes Code(s):	SGMPE_7_Y3 SPHBI_8_Y2 SNHSC_8_Y2 SCISY_8_Y3 SINEN_8_Y3 SNHSC_8_Y2 SPHYS_7_Y3
External Examiner(s):	Dr Stephen Fitzpatrick Ms Bernadette Whelan
Internal Examiner(s):	Dr Ann Toebes
Instructions:	Question 1 is compulsory. Answer 2 questions from Questions 2, 3 and 4.
Duration:	2 hours
Sitting:	Autumn 2012

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. If in doubt please contact an Invigilator.

Q1. **Answer 8 of the following 10 parts.** Marks

(a) Explain the term '*Good Manufacturing Practice'* (5 marks)

(b) List 5 principles of *Good Manufacturing Practice*. (5 marks)

(c) Define the term *'validation'*. (5 marks)

(d) Explain why validation is necessary in pharmaceutical and biopharmaceutical manufacturing operations.

(e) Identify **2** regulatory bodies that inspect pharmaceutical and biopharmaceutical manufacturing facilities in Ireland to ensure validation is adequately performed. (5 marks)

(f) List the steps in the validation of a piece of equipment and describe what is involved in each step. (5 marks)

(g) P&ID (piping and instrumentation diagrams) are important design drawings. Identify **2** items of information included in them. (5 marks)

(h) A Validation Master Plan (VMP) documents the company's approach to validation projects. List 5 elements of a comprehensive VMP. (5 marks)

(i) Draw a flow diagram outlining the steps in quality risk management. (5 marks)

(j) Describe a tool that is often used in the implementation of quality risk management. (5 marks)

Total (40 marks)

Q2. Process Validation is provides documented evidence "that the manufacturing process when operated within established parameters, can perform effectively and reproducibly to produce a medicinal product meetings its predetermined specifications and quality attributes". *Source: Annex 15, EU Guide to GMP*

(a) Explain the following terms mentioned above and give an example of each:

(i) Parameters

(ii) Quality attributes

(b) Process Validation may be performed at different stages during the product lifecycle. Identify the different types of process validation and explain why each may be performed.

Total (30 marks)

Q3. (a) During in-line filter validation identify 5 parameters that are reviewed during the Design Qualification stage. (5 marks)

(b) Describe the purpose of the bubble point test and how it differs from the bacterial challenge test. (10 marks)

(c) Explain how media fills are performed during the validation of an aseptic manufacturing process. (5 marks)

Total (30 marks)

Q4. (a) Draw a diagram of an autoclave and describe how it is operated. (15 marks)

(b) Explain how an autoclave is validated. In your answer include the validation steps and documentation required. (15 marks)

Total (30 marks)