

**CORK INSTITUTE OF TECHNOLOGY  
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ**

**Autumn Examinations 2011**

**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

**External Examiner(s):** Dr Oliver Joyce

**Internal Examiner(s):** Dr Ann Toebe

**Instructions:** Question 1 is compulsory.  
Answer 2 questions from Questions 2, 3 and 4.

**Duration:** 2 hours

**Sitting:** Autumn 2011

**Requirements for this examination:**

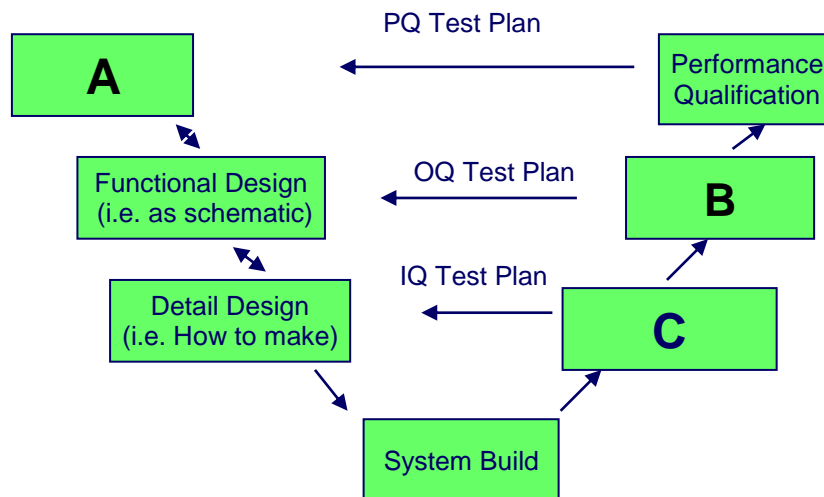
**Note to Candidates:** Please check the Programme Title and the Module Title to ensure that you have received the correct examination. If in doubt please contact an Invigilator.

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

- (a) Define validation. (5 marks)
- (b) Explain why validation is a necessary part of Quality Assurance in a GMP (good manufacturing practice) compliant organisation. (5 marks)
- (c) Identify **2** regulatory bodies that inspect pharmaceutical and biopharmaceutical manufacturing facilities in Ireland to ensure validation is adequately performed. (5 marks)
- (d) Identify the different steps in a Pharmaceutical Product Lifecycle, beginning with drug discovery. (5 marks)
- (e) Explain the function of the International Conference on Harmonisation. (5 marks)
- (f) Describe **2** activities performed during active commissioning of a piece of equipment. (5 marks)
- (g) P&ID (piping and instrumentation diagrams) are important design drawings. Identify **2** items of information included in them. (5 marks)
- (h) Explain the meaning of the terms “FAT” and SAT” in connection with commissioning and validation. (5 marks)
- (i) Describe the purpose of a User Requirement Specification (URS). (5 marks)
- (j) All new equipment in a pharmaceutical or medical device production process undergoes a System Impact Assessment before validation. Explain the purpose of this assessment. (5 marks)

**Total (40 marks)**

Q2. The diagram below is a V-model for equipment validation.



- (a) Identify Steps A, B and C on the above diagram. (6 marks)
- (b) Give **3** examples of checks that are performed during Step C for new equipment. (9 marks)
- (c) Give **3** examples of checks that are performed during Step B. (9 marks)
- (d) Give **2** examples of checks that may be performed during the Performance Qualification of a freezer for storage of product. (6 marks)

**Total (30 marks)**

- Q3. (a) Explain the purpose of Quality Risk Management and why it is used in validation. (5 marks)
- (b) Draw a diagram, identifying and explaining the steps of the quality risk management process as laid out in ICH Q9. (20 marks)
- (c) Explain how the risk management tool, *Failure Mode, Effects and Criticality Analysis (FMECA)*, is used. (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)**