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OLLSCOIL NA hÉIREANN
GAILLIMH

NATIONAL UNIVERSITY OF IRELAND
GALWAY

SPRING EXAMINATIONS 2001

M.Sc. in BIOMEDICAL SCIENCE

EP515: Product Development, Validation, and Regulation

Prof. T.J. Glynn
Prof. M. J. Hynes

Time allowed : **Two** hours.

Answer three questions.

1. (a) Describe the process of concept evaluation in product development. Include in your answer the motivations behind the process, its general features, and details of how two mechanisms work

   (b) Define what is meant by a patent, explaining the significance of the key phrases of the definition. Describe briefly the sections in a patent application and outline the general features of the process of filing and the grant of a patent.

2. Give a brief overview account of the Medical Device Directive. What is the purpose of the Essential Requirements listed in Annex I and how should these requirements be addressed in developing and manufacturing a medical device. Explain the term *vigilance* in the context of the directive.

3. "Validation is the means by which members of industries selling into regulated markets demonstrate to themselves, to government regulators and to the general public that they have taken and are taking the best possible actions to secure the integrity of their products."

   Discuss this statement.

4. What is process validation?

   Discuss the various steps that must be taken to ensure that a specific process will consistently produce a product meeting predetermined specifications and quality attributes. You may wish to refer to three types of process validation in your answer.

[PTO]

5. Answer **one** of the following

(a) Define AND discuss the qualification of products by medical device manufacturers. Include reference to qualification approaches, reasons for qualifying products, regulatory/quality system requirements, and international standards.

(b) Discuss the importance of quality systems in the manufacture of healthcare products. Include reference to key elements, QC/QA/QE methodology, compliance, failure of quality systems.

(c) Discuss product sampling and monitoring. Make reference where necessary to statistical methods.
Include reference to representation, process characterisation, types of acceptance sampling, and the normal distribution.