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GAILLIMH

NATIONAL UNIVERSITY OF IRELAND
GALWAY

SPRING EXAMINATIONS 2000

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. Answer all parts.

- (a) Define what is meant by a patent. Explain the significance of the key phrases of your definition.
- (b) Who gets to benefit from a patented invention and why? When an inventor is filing for a patent he/she can opt to file with a number of different bodies. Explain briefly what the options are and what motivates the choice.
- (c) During a program of process/product development what additional documents are required to safeguard patentability? What are the key features and the significance of these documents?

2. Answer (a) and (b)

- (a) Discuss the importance of a Validation Master Plan (VMP) in the context of how a firm organises its validation work.
- (b) What are the most important features of a validation master plan?

3. Answer (a) and (b).

- (a) "The Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations, 1994 places most of the emphasis for its implementation on the employer." Discuss this statement.
- (b) Briefly discuss the role of Material Safety Data Sheets in activities involving the use of hazardous chemicals/substances.

4. Give a brief overview description of the Medical Device Directive. Explain the importance of Annex I of the directive. Indicate what steps are necessary for a manufacturer to obtain CE qualification for its products and outline the main qualification approaches indicated in the directive.

5. Answer either (a) or (b)

(a) Discuss the importance of a quality system for industries involved in the manufacture of medical devices and/or pharmaceutical products. Include key elements, QC/QA/QE, auditing and the Medical Device Directive in your discussion

or

(b) Discuss product monitoring and sampling in the medical device/pharmaceutical industries. Include types of sampling, AQL/LTPD, distributions, and statistical methods.