UNIVERSITY COLLEGE LONDON

University of London

EXAMINATION FOR INTERNAL STUDENTS

For The Following Qualification:-

M.Sc.

Biochem Eng G24: Integrated Biochemical Engineering Design

COURSE CODE	:	**BENGEG24**
DATE	:	**08-MAY-03**
TIME	:	**10.00**
TIME ALLOWED	:	**3 Hours**

TURN OVER

*Answer **TWO** questions from **PART A** and the question in **PART B**. Only the first **THREE** answers will be marked. The marks are distributed as shown [ ]. The answer to **PART B** should be in a separate answer booklet.*

Part A

1.

i) What is a business plan? [5]

ii) What are the features of a business plan? [10]

iii) What are the specific issues which need to be addressed in a business plan written in the life sciences industry. Illustrate your answer using an example. [10]

2.

Comment on the regulatory issues which need to be addressed in the clinical trials for possible gene therapy. [25]

3.

i) Describe the time scales and costs associated with obtaining a patent in the life sciences sector in UK. [15]

ii) What would result in making a patent void. [10]

Part B

4.

You are required to specify a process flow sheet for the recovery of a labile protein. The protein is expressed as an intracellular product of *E.coli* and has a pI of 6. The final product is to be used as a repeat injectable and it is known that aggregates of the protein will cause severe side reactions.

Devise an appropriate process for this material and tabulate the reasons for the choice of each item of equipment that you select as well as the function that each item will perform. You should also state the typical product specification that your process will deliver and the likely process yield. [30]

The generation of the necessary design data for the specification of the above process needs to be done quickly and you are envisaging the use of scale down methods to assist in this. Provide a brief summary of the salient features of scale down and discuss how the application of this methodology might assist in achieving speed through process development. [20]

END OF PAPER