GK805

OLLSCOIL NA hÉIREANN
The National University of Ireland

National University of Ireland, Galway.

Michaelmas Examinations, 2002/03

B.E. Degree (Mechanical & Biomedical) Examination

BIOMEDICAL PRODUCTION & ENVIRONMENTAL SERVICES

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Attempt FIVE questions, including at least ONE question from each section.
Use SEPARATE ANSWER BOOKS for each section.
Time Allowed: 3 Hours

SECTION A

1 (a) List the main sources of contamination within a cleanroom and briefly outline how contamination may be controlled (6)

(b) A cleanroom under consideration has an area of $28m^2$. Conformance with the specified airborne particulate cleanliness is to be determined in the operational state. The specified classification of the cleanroom is ISO Class 3, with a specified particle size of 0.3μm.

(i) Calculate the maximum permitted airborne particle concentrations and the minimum number of sampling point locations, according to the ISO standard. Give details of the criteria for selecting an appropriate sampling volume / sampling time. (6)

(ii) At each sampling location, only one single sample of 100 litres is taken. The counts obtained are indicated below. Calculate the upper confidence limit (UCL) and indicate whether the cleanroom conforms to ISO class 4. (8)

Sampling Location	No. of Particles (≥0.3μm)
1	10
2	8
3	4
4	6
5	0
6	8

No. of individual averages (m)	2	3	4	5	6	7-9
t	6.3	2.9	2.4	2.1	2.0	1.9

Table 1: t distribution for the 95% upper confidence limit.

2(a) Define a medical device (2)

(b) Describe the different categories of medical device in terms of:
(1) Duration
(2) Nature of Contact (9)

(c) Discuss the different types of *biological* evaluation tests that should be considered prior to clinical use of a medical device. (9)

SECTION B

3(a) Discuss the use of ethylene oxide in achieving product sterility. How is it applied and what are its advantages and disadvantages to the manufacturer of biomedical devices. (10)

(b) How does this process compare with ionising radiation for the sterilisation of biomedical devices? (10)

4(a) Define the term "disinfectant". (2)

(b) List five features of an ideal disinfectant. (5)

(c) Describe the characteristics (including the mode of action) of four types of disinfectants. (13)

SECTION C

5(a) What do you understand by the term "Quality" as it relates to the design and manufacture of medical devices? What are the four key areas of Quality Management? (6)

(b) What is meant by the following terms?
Validation: Pareto Principle: Cause and effect Diagrams. Provide examples of where you would apply each of these. (6)

(c) As a Packaging Engineer you have been asked to compile a validation protocol for a blister machine. List the critical components of this protocol including all the relevant test methods. (8)

6(a) What is meant by the terms Osteoarthritis and Osteoporosis? (4)

(b) The Charnley Hip System is generally regarded as the benchmark Total Hip Replacement (THR) system against which all other designs are assessed. List the breakthrough features, using diagrams where appropriate, of this hip system. (10)

(c) Describe, using process flow diagrams, the Investment Casting Process used to Manufacture Orthopaedic Femoral Hip components. (6)

7(a) What is Atherosclerotic disease? What does PTCA stand for and describe how a PTCA catheter may be used to treat this disease. (6)

(b) What are the advantages and disadvantages of "Balloon Stenting"? What do you understand by the term "IH"? List the design inputs that should be considered when designing a balloon stent. (8)

(c) Describe the steps that a surgeon would use to implant a self-expanding stent. List two of the major differences between a self expanding stent and a balloon expanded stent? (6)