GX653

OLLSCOIL NA hÉIREANN
The National University of Ireland

National University of Ireland, Galway.

Trinity Examinations, 1998/99

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. Describe the main components of the three primary cleanroom standards :
(i) BS-5295,
(ii) FS-209, and
(iii) ISO
(20)

2. Within a cleanroom, many disciplines must be followed to ensure that the product is not contaminated. Each cleanroom must produce its own written procedures, suitable for that room. It may be useful to have these 'do's and don'ts' posted in the change or cleanroom area. Draw up a list of "disciplines" that must be adhered to for personal working in cleanrooms. These procedures should not consider the choice of cleanroom garments, wipes, masks, gloves or similar items used in the cleanroom.
(20)

SECTION B

3. Write an essay on water-borne diseases. Discuss in your answer the epidemiology of the major diseases that are transmitted via the aqueous vector system.
(20)

4(a) Compare and contrast the use of ionising radiation or ethylene oxide gas for sterilisation.
(10)

(b) If you were setting up a plant in the west of Ireland for the manufacture of sterile surgical implants (e.g. plastic catheters) which of these systems would you use and why ?
(10)

SECTION C

5(a) Describe, using relevant diagrams, the Rapid Exchange and Over the Wire Balloon Dilation Cardiovascular Product Designs. **(8)**

(b) What is meant by the terms 'Crossability' and 'Efficiency' ? **(4)**

(c) When designing any healthcare product a series of design inputs are considered. With reference to a PTCA balloon catheter, list some of the design inputs which must be considered relating to the inflation balloon and the catheter shaft. Suggest a manufacturing flow chart for an OTW balloon catheter. **(8)**

6(a) Heat Welding is a process used to join two plastic materials together. Outline the validation steps that must be carried out to install this equipment. **(6)**

(b) List other types of joining processes that are used in the healthcare industry giving examples of use. What are the critical parameters ? **(6)**

(c) List all relevant Balloon Stenting Surgical Techniques – single and bifurcation. With the aid of diagrams, describe the surgical procedure for any two implantation techniques. **(8)**

7(a) List the primary components that constitute an orthopaedic hip implant. **(6)**

(b) With regard to two of these components, list the design inputs that should be considered. Suggest a manufacturing flow chart for an orthopaedic stem. **(6)**

(c) Carry out a Design FMEA on a femoral stem component. Show that you understand the principle of a working FMEA document and the engineering design/biomechanics of an orthopaedic stem. You should list approximately five potential failure modes. **(8)**

8(a) What do you understand by the term 'Validation' ? List reasons why equipment/processes should be validated. **(6)**

(b) Considering <u>one</u> of the following processes complete a Process FMEA :
(i) Resistance Welding, <u>or</u>
(ii) Injection Moulding.
You should list approximately five potential failure modes. **(8)**

(c) Outline the validation steps that must be completed to validate the machine chosen above. Prepare a draft Validation Protocol. **(6)**