
Friday 9 May 2025 9:00 to 10:40

Paper 6

MODULE 3P10: CONTEMPORARY ISSUES IN MANUFACTURING

*Answer **all** questions.*

All questions carry the same number of marks.

*The **approximate** percentage of marks allocated to each part of a question is indicated in the right margin.*

Write your candidate number not your name on the cover sheet and at the top of each answer booklet.

Use a separate answer booklet for each question.

STATIONERY REQUIREMENTS

8 page answer booklet x 3

Rough work pad

SPECIAL REQUIREMENTS TO BE SUPPLIED FOR THIS EXAM

CUED approved calculator allowed

Engineering Data Book

10 minutes reading time is allowed for this paper at the start of the exam.

You may not start to read the questions printed on the subsequent pages of this question paper until instructed to do so.

You may not remove any stationery from the Examination Room.

Question 1

(a) A company which manufactures plastic drink bottles is interested in minimising their environmental footprint.

- (i) Describe how you would carry out an *eco-audit* for this product across its entire lifecycle. Discuss what information you need in order to conduct the eco-audit and describe what you would expect to find.

[35%]

- (ii) Describe how the company could minimise its environmental impact using four examples from the *Lean Manufacturing Protocol*, considering everything that takes place on the company site, including in-house manufacturing operations and the operation of the buildings and offices. Discuss the trade-offs between the environmental and economic impacts in each of the four examples.

[20%]

- (iii) How can the *Reuse* and *Recycle* aspects of the *Three R's* to minimise material and energy waste be implemented to reduce the environmental impact of the on-site operation of the company? Provide two examples of each, discussing the trade-offs between the environmental and economic impacts.

[20%]

- (b) Describe *moral suasion* and *command and control* instruments for minimising environmental impacts through changing people's attitudes and behaviours. Discuss how these instruments can be used to change behaviours with reference to the recycling of plastic bottles.

[25%]

Question 2

(a) A medical device manufacturing firm decided to integrate force sensors and data transmitters into their existing medical device products. They will start with crutches and the data will help clinical staff track patient recovery. Next, force sensors and data transmitters will be integrated into their neurosurgery tools. For example, surgeons can insert a thin probe into the brain to analyse a tumour and the new capability will help surgeons monitor the forces exerted when inserting the probe, to minimise damage to healthy tissue.

(i) Crutches and neurosurgery probes have different classifications under medical device regulations (Class I and Class III respectively). Explain how the classification of a medical device is decided, for both European and U.S. regulations.

[15%]

(ii) This manufacturer is selling both products into the European market. The crutches are Class 1 medical devices and require minimal tests to meet regulatory requirements. However, tests are required for the newly updated neurosurgery probe, a Class III medical device. Describe how you would deliver suitable levels of confidence for this device in terms of biocompatibility, sterilisation and clinical evaluation.

[40%]

(iii) Discuss whether the integration of these new force sensing and data transmission capabilities is likely to help product sales, based on your knowledge of medical technology trends.

[15%]

(b) The same medical device manufacturing firm wants to start making small spherical beads that would be surgically implanted next to tumours. These would be designed to degrade slowly and release the drug over the course of three months.

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- (i) Explain how you would select an appropriate material for these small implants so that they maintain their physical size and shape for as long as possible, while slowly releasing the drug. Include in your answer examples of possible materials you could select.

[20%]

- (ii) Describe any one challenge the manufacturer would face if they decided to use the beads to deliver biological cells to the tumour instead of a drug, as part of a cell or gene therapy.

[10%]

Question 3

- (a) Explain what is meant by each of the terms *generic technologies* and *infra-technologies*. Include in your explanations the role they play when translating an innovation into a market. [25%]
- (b) Explain the role of *Manufacturing Readiness Levels* and how they are measured when scaling up innovative technologies. [25%]
- (c) It is important to track progress in both technology and production process dimensions when translating an innovation into a market. Describe any two other dimensions that may be important during this translation. [25%]
- (d) Explain what is the role of government in supporting emerging technology scale-up, using examples to support your answer. [25%]

END OF PAPER

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