Paper 6, CRIBS
Question 1

(a) (i) An eco-audit is a quick and simple way of determining environmental impact focusing only on estimating carbon footprint or energy consumption (unlike an LCA, which covers far more factors and is much more complicated and time-consuming to carry out). To do an eco-audit we need to calculate the energy required (carbon footprint) for every stage of the lifecycle of the product: materials production; product manufacture and assembly; use; disposal. Transport between all lifecycle stages must be included. Data can be plugged into a database (e.g. CES Eco-selector database) to find energies.

The steps will be:

compile a bill of materials for the product;

identify manufacturing operations for each component;

estimate energy usage in use phase (mainly maintenance and repair);

estimate end-of-life energy usage (recycling, re-use, disposal);

estimate transport energy usage between all stages (mode of transport, distances).

The energy usage results are partitioned into the four lifecycle phases and presented as a bar chart. The results show greatest energy usage (95%) comes from materials production.

Assumptions:

System boundaries are important, and you should always be aware of this aspect when doing any carbon footprint analysis. The software package will make assumptions about system boundaries: CES explains exactly what it does, and makes sensible decisions for you.

There may be some uncertainty about exactly what materials, manufacturing operations and modes of transport are used (and these may vary over time). Data for the repairs and maintenance in the use phase must be gathered from installations in the field, and may be variable in quality. End-of-life treatment happens 20-25 years after turbine installation, so there may have been advances from current technologies.

Carbon equivalent and energy consumption are related, but are influenced by the carbon intensity of the energy source (e.g. renewable or fossil fuel). This means that geographical locations of operations need to be known, because different countries have different energy generation balances.

(ii) The turbine generates electricity, so the energy payback period is the time taken for it to generate enough electricity to cover the whole lifetime energy consumption of the turbine. It will be typically less than one year.

(iii) Both concrete and steel are resource-intensive to produce and have large carbon footprints. Concrete is the cheapest and most efficient material for the foundations, and at present there is no obvious substitute. At end of life concrete cannot be recycled, but can be downcycled (broken up to make aggregate). It is not hazardous waste.

Steel is likely to be the cheapest material for the tower. At end of life steel can be economically and effectively recycled, so there is some environmental benefit at that stage (a significant proportion of recycled steel will be included already in the embodied energy for the steel).

Alternative lower-impact materials for the tower might be possible (e.g. bamboo has been proposed in China) but are unlikely to be major players.

Improved efficiencies may come from advances in processing for both concrete and steel.

(b) (i) With individual ownership, many cars are unused a lot of the time. Schemes such as car pools, car rentals (e.g. Zipcars) increase intensity of usage and reduce the number of cars that need to be manufactured. PSS schemes involve ownership of vehicles remaining with (typically) the manufacturer, which then provides the customer with a fully-functioning vehicle and takes responsibility for maintenance and end-of-life disposal. This means that the manufacturer has full control over the lifecycle of all parts, and has the possibility of using closed-loop cycles, including repair and modular replacement of parts. The environmental benefits can be significant in increasing recycling and re-use, so reducing production of parts. There is also greater incentive to design for long lifetime and for low-impact end-of-life processes.

(ii)

Taxation:

Congestion charges for cities (individual vehicles pay a charge to enter the zone, perhaps at certain times of day). Normally effective at reducing vehicle usage (so long as effective public transport exists), but only while the charges are in place.

Fuel taxes. High taxes on petrol and diesel already act as disincentive to individual car use. (Even without taxation, high electricity prices are also a disincentive for electric vehicles, although the cost is currently typically a bit lower). Reducing public transport costs (subsidies, a sort of negative taxation!) may in some situations increase usage.

Moral suasion:

The aim of this approach is to make people want to ‘do the right thing’, typically by making it easy, fun, cheaper.

Public transport: Provide excellent information, such as readily accessible route information and bus stops which tell you when the next bus is coming. Reasonable costs and easy payment such as pre-payment card (e.g. London Oyster card).

Walking and cycling: Good infrastructure, such as pavements and pedestrian crossings; cycle racks and cycle routes. Information about journey times: ‘it’s quicker by bike / on foot’

Wellbeing is increasingly used as an incentive for encouraging exercise.

An excellent answer will cover all key points thoroughly, explain the concepts clearly, show knowledge of the material and provide critical assessment of all aspects.

An average answer will address most of the important points, but some may not be fully explained. The discussion should demonstrate basic understanding of the underlying principles.

A weak answer may omit important information and show only partial understanding of some of the concepts.

(a)(i) Weaker answers showed little knowledge about what is meant by an eco-audit, and wrote generally about LCA. Most appreciated that the materials stage would dominate, but there was a surprising amount of muddle with some stating that transport would dominate.

A number of answers wrote only about the blades, which are a small part of the assembly.

(ii) The energy payback period is for the whole turbine lifecycle, not just the production stage. Most did not estimate a payback period.

(b)(i) There was some confusion with car-sharing schemes, aimed at multiple occupancy of vehicles, which are not part of PSS (though could be incorporated in some cases).

(ii) Most were able to produce relevant examples of taxation. Moral suasion was less well-understood, and was mistakenly believed by some to be a weak strategy based on in-your-face advertising aimed at appealing to peoples’ consciences. At best, moral suasion can be quite subtle, and importantly it makes it easy for people to ‘do the right thing’ by making this the cheapest and easiest path to take.

Question 2

2 (a) (i) This question gives the candidates an opportunity to draw upon a range of considerations from across the lecture content. This has not been addressed in the class before but the question is asking the candidate to review the process of taking a device to market and highlight the challenges faced when it is a reused device rather than a new device. A basic answer will note 3-4 challenges through very brief descriptions or bullet points, a good answer will give clear explanations of 3-4 different challenges, and an excellent answer will provide detail on 4. A strong answer should show an understanding that the term medical device covers a very wide range of products, with a range of regulatory classifications and made from a wide range of materials, with the challenges depending on these parameters. It is asked that candidates include examples of medical devices to help support their answer.

It is anticipated that the challenges will likely be from the following categories:

Regulatory challenges

An excellent answer will link this question to the recent change in medical device regulations that allow for reprocessing of single-use devices. In such cases, the firm reprocessing the device takes on the role of the manufacturer and all of their responsibilities. This could be broken down into a wide range of challenges, including, the firm would need to be responsible for the regulatory approval process or conformity assessment.

Depending on the classification, the firm would then be responsible for showing conformity to the required levels of sterilisation, biocompatibility, and product performance (i.e. clinical data).

The firm may need to ensure there are new UDIs added to the devices related to this manufacturing process because of the recent drive towards traceability in the recent regulations.

The firm would be responsible for any required post-market surveillance of the reprocessed devices. There will be a very complex situation for adverse event responsibility and recall responsibility.

Materials

The use, disposal, sorting, and sterilisation processes may have an effect on the material properties. The firm would need to consider how to know the number of times a product has been re-used and the effect it has on the required properties.

The firm may need a range of different sterilisation techniques to ensure they can successfully sterilise all of the materials they encounter (or alternatively, limit their re-processing to a selection). Another challenge will be the validation of sterilisation with a system that is taking a range of materials from different, unknown sources.

Processing steps

These may be specific process challenges linked to the points above about validated packaging, sterilisation, Quality Management System implementation.

2 (a) (ii) This is a very new sterilisation technique not discussed in the lectures, which was being developed during the pandemic. Sterilisation techniques used within a conformity assessment normally have an associated international standard related to their use. A strong answer would

describe briefly the complexity of putting a standard together and note that this would have to happen and be approved to have a process that is readily adopted into medical device manufacturing.
Each sterilisation technique has a known most-resistant organism, or sterilisation indicators to help manufacturers know that it is functioning as required. As a completely new process, this may not be known and would make it challenging to adopt.
Additional points may be around compatibility with different material types, understanding penetration depth in products, or the ability to sterilise wafter packaging.
It is anticipated that candidates will note that it may not yet be fully understood and we would need to understand how it is leading to sterilisation.
A basic, acceptable answer will note two challenges in brief bullet points, whereas a strong answer will show a clear understanding of two challenges faced when trying to make a new sterilisation technique reliable and validated so it can be used in manufacturing.

2 (b) (i) It is anticipated that candidates describe clearly the formation of a structured scaffold, the introduction of the appropriate cells, medium and growth factors, the cell growth and forming of tissue throughout the scaffold, with the cells using this as a structure to guide them, that the cell proliferation occurs within a controlled environment bioreactor, and the eventual quality control checks before implantation. A basic answer will note very briefly in bullet-point form a label for 3-4 steps step, whereas a strong answer will show a clear understanding what is happening at each of any 4 steps.

2 (b) (ii) A basic answer will briefly note two considerations, whereas a strong answer will show a clear understanding of the link between the consideration and the final successful tissue engineered product.
As a manufacturing consideration, it would be good to note selection of an appropriate manufacturing technique, that allows the creation of a sufficiently porous bioceramic material to enable tissue growth. Other manufacturing-related considerations are acceptable, such as the checking of the influence of scaffold fabrication and sterilisation on the properties of the bioceramic, or on the biocompatibility.

In terms of material properties, it will be important to note that there are different bioceramics, such as HA and TCP, that have different properties and so there will need to be careful selection for this application. There may be mechanical property requirements for the product and it is known that synthetic bioceramics are more brittle.
Another key consideration is the rate of dissolution of the scaffold. In tissue engineering, the scaffold eventually dissolves to leave only the pure tissue, but this must happen at the right time to ensure full growth.

Question 3

3 (a) This example firm is selected because they will be dealing with emerging technology scale-up challenges. The first two parts are more basic understanding or definitions, whereas the second two parts require candidates to integrate their knowledge from across the lectures to draw conclusions on this example.

3 (a) (i) A basic answer will note that the gate is a decision point for a project, where the technology is developed to a certain stage, it is assessed, and then it is taken further towards production or stopped completely.
A stronger answer will note the deliverables that have been agreed at the last gate are assessed by a cross-functional management team, specifically those responsible for the resources needed at the next stage. There will be pre-agreed criteria for the assessment. An excellent answer would give examples of standard criteria (technical feasibility, strategic fit, etc.). Decisions are often Go, Kill, Hold, and Recycle, with a good answer conveying a good understanding of these and somewhere noting that deliverables and timings are agreed for the next gate if the answer is Go. Ideally, a strong answer would give details around any 4 different aspects of the gate

3 (a) (ii) When explaining TRLs and MRLS, a strong answer will note that these are terms for communicating the inherent risk associated with the development of a technology or the manufacturing of a technology. For TRLs it is anticipated that candidates will note that they are a systematic way of assessing the maturity of a technology, allowing comparison of different technology types and an understanding of their inherent risk. It would be good to note that they go from 1-9, a very basic technology research stage to commercialisation of an integrated, packaged technology. For MRLs, it is important that it is clear that this is for measuring and communicating manufacturing risks and that these levels have a range of considerations or threads. A strong answer will note that underpinning an MRL is communication about these threads, and a couple of examples may be given. A brief description of the level scale and milestones would be expected in an outstanding answer.

3 (a) (iii) This question is looking for candidates to reflect on the relative strengths and weaknesses of each tool and to highlight specifically where the combination is effective. For example, the standard Phase-Gate approach is not generally used for emerging technology scale-up, where there is a lot of uncertainty about the technologies being used. For this reason, combining with TRLs may be very useful because you can at each stage communicate the associated technology-based risks and track them. In a similar way, TRLs are not very helpful at keeping track of the wide range of manufacturing related risks of new technologies and so are often used hand-in-hand with MRLs to ensure both sets of risks can be monitored and communicated. An outstanding answer may use the

example of the Genome initiative which has created a similar framework to look at advanced material scale-up.

3 (a) (iv) There are two likely approaches to this answer, both equally valid. The first is to turn to the Technology Phase-Gate approach. If this is suggested, a strong answer would explain clearly the key aspects, such as:
The increase in number of steps at the earlier stage of the phase-gate process to allow for early-stage technology research, development, proof-of-concept development, and downselection.
The unknown number of gates, because it can be divided up as required as technology develops, there are new discoveries.
Other details are also acceptable.
The second likely approach is to consider breaking down the framework into specific dimensions of scale-up, in which case at least 2 examples are anticipated in a strong answer. These dimensions can be sector specific, or be quite generic (value chain, business, process, and technology). This has proven helpful in many sectors already.

3 (b) Explain the role of government in supporting emerging technology scale-up, referring to examples within your answer where possible. [30]

The role of government is to put policies in place that will help improve the national economy through ensuring a smooth process to commercialise research. This may be to ensure better industry engagement with research, or how research can ask more industry-relevant questions in suitable facilities. Candidates may describe this more in terms of navigating the Valley of Death, which is also acceptable if explained clearly. This may also lead to identifying that government can invest in capabilities and facilities that help overcome technical risks around the product or production, with examples of recent initiatives given as part of a strong answer. More specifically, candidates may note the importance of the government to fund non-proprietary technologies (product and process, generic and infra-technological) because of the much broader impact these investments have across industry, delivering platform technologies and shared databases or measurement tools.
It is expected that candidates will also refer to the role of government in delivering policy documents, which will guide researchers and industry towards specific emerging technology strengths, with examples provided and explained in terms of the 8 great technologies, the engineering grand challenges, or the synthetic biology UK roadmap.
A basic answer will briefly note 2-3 points, a strong answer will describe each very clearly and refer to specific examples.