Cribs for Paper 6 2022

Question 1

(a) (i) Guidance notes.

The relative environmental importance of the different areas will depend on the size of the factory and its operations. Automotive manufacture and assembly involves heavy equipment, high-energy manufacturing operations and a large amount of material usage; quality control is very important. Space heating is generally a big factor. Energy usage of equipment when it's not actually being used for production may be a relatively small factor, depending on the way the factory is set up. Paper and single-use items won't have a big impact, but avoiding waste here can be important to the culture of the company, demonstrating that sustainability is valued.

Quality control in manufacturing operations to reduce number of defective parts so avoiding scrap or the additional resource needed to rework parts.

Main saving: materials usage

Making improvements: May involve more measurement and inspection, improvements to processes or to their operation, operative training.

Environment: Reduce number of parts needing to be made. Environmental impact from reduction in material embodied energy and production operations. Sustainability credibility can be boosted using publicity from reduction in defect rates.

Note that identifying defective parts before assembling is important: if defective parts are introduced into assemblies, the whole assembly may need to be scrapped rather than just the single part.

Finances: Some aspects may be low-cost, such as small adjustments to manufacturing processes and improving working practices. High defect rates may indicate need for new equipment, which could be costly.

Office operations:

Reduce paper usage

Making improvements: enable PDF production rather than hard copy; double-sided printing where hard copy still required. May require purchase of, e.g., new photocopiers. Increase recycling. With all aspects, awareness raising and education will be needed.

Environment: small impact, but changes can be used as a visible indicator of 'sustainability'.

Finances: small reduction in paper costs, and perhaps postage. Offset against any new equipment purchase.

Catering operations

Ban single-use drinking vessels, plates, cutlery. Use durable, washable articles such as glasses, steel cutlery, crockery plates. Environment and finances similar to above.

Equipment energy usage:

Standby/switch off machines when not in use both in manufacturing and office operations.

Making improvements: enable standby mode where possible; switch-off likely to require manual intervention. Requires training and education to ensure practice is followed.

Environment: May have significant impact for manufacturing equipment.

Finances: May give significant savings, for little or no cost.

Space heating:

Making improvements: improve building insulation; set appropriate temperatures. Manual control of heating requires behavioural change. More sophisticated, and effective, automated heating control systems can be used.

Environment: space heating is a big factor for energy consumption, so this can be large (depending on type of building and shop floor environment). The company might consider introducing 'green' heating systems (e.g. ground source heat pump; solar panels), and use this to boost environmental credibility.

Finances: Fuel cost reductions an immediate benefit, and some can be achieved at low cost. Offset against cost of insulation, introduction of automatic controls, new systems.

(ii) Other sustainability aspects

Other measures to reduce energy waste:

Low-energy lighting systems; appropriate lighting levels

Other measures to reduce materials waste:

Don't produce excess parts (order-book and inventory control)

Material-efficient manufacturing operations e.g. sheet steel cutouts can be used for making other parts

Re-usable packing for products (e.g. returnable pallets)

Aim for zero waste-to-landfill

Hazardous materials: Assess usage, and eliminate where possible

Incoming materials: Use local suppliers to avoid transport; consider using recycled materials

Water: look at water usage and possibly introduce recirculating water system

'Green' energy has been mentioned in (i) but could also be brought in here. Moving to renewable energy generation could be considered (solar panels, perhaps wind turbine).

The automotive industry is changing rapidly, moving to low-environmental-impact transport. The company may wish to capitalise on this by emphasising its environmental credentials in any way it can.

Note that 'Sustainability' can also include social aspects, so community involvement could be mentioned.

(**iii) Financial implications.**

McKinsey abatement plots are the main tool that can be used quickly here to assess the likely benefits and costs of any measures. The width of the bars on the charts show the carbon saving from implementing a particular measure, and the height shows the cost (positive or negative).

An energy payback period is particularly relevant to an energy generating system such as a wind turbine, where the time taken to generate the amount of energy required to make the turbine can be measured. The term could be applied loosely for something like an energy-efficient lightbulb, where the energy saved is offset against the energy to manufacture the bulb.

(b) Industrial Symbiosis.

Waste streams from one company are used as raw material input to another.

Example: the Kalundborg network in Denmark, in which around 20 co-located companies and organisations (including the local community) exchange materials, energy, water, creating a virtually zero-waste operation.
To create even a single IS partnership, there needs to be a very close collaboration between the companies.
For this automotive manufacturer, there would need to be an identifiable high-value and fairly high-volume waste stream. A possible application for the waste would need to be found, and a potential industrial partner. The main processes in the factory would vary, but typically would be sheet metal shaping cutting and assembling processes, and then painting/coating of vehicle bodies. The main waste might be scrap metal, which is already readily recycled and with good supporting infrastructure. Other waste streams may possibly be suitable, for example waste paint or chemicals from a coating process, but it's not clear that this sector is an obvious candidate for industrial symbiosis.

Question 2

(i) A basic answer to this first part will indicate that classification is a way of indicating the vulnerability of a person to harm when using the device. A more detailed description will also highlight that the classification is an early step towards device approval for manufacture and helps guide the manufacturer towards the right level of controls required during manufacturing. An excellent answer will also note that classification helps guide the auditing body (or Notified Body) as to which devices need to be examined in detail, and communicate the vulnerability of a person to the patient/user. Additional points may include the different classification levels of devices in US and EU, or examples beyond the one presented here.

The question requests specific points to be raised with regard to EU classification. To address these points, a basic answer will note that the process includes identifying the correct regulation and following the provided guidance and rules to self-assess the classification. A stronger answer would say that in the example provided, this means referring to the Medical Devices Regulation to carry out classification of the implantable device, and the In-vitro Medical Device Regulation for the sensor. An outstanding answer will notice that the software interpreting the results and leading to a medical decision will need to undergo classification and approval also.

(ii) A basic answer will describe 3 considerations very briefly. A good answer will describe all 4 with at least 2 at a more detailed level, and a strong answer will describe any 4 considerations clearly, showing a good understanding of each.

- For example, candidates could discuss the need to ensure voluntary consent for any participant, with a good description of what is meant by consent in terms of bioethics.
- It could be noted that to run a trial they will need to communicate the relevant information to the patient and ensure they understand. This information may include the duration of the study, what it is aiming to achieve, how it will be run, and the potential downsides to participating.
- The research protocol being used will need to be examined and approved by an independent research ethics committee before the study begins.

- It would need to be demonstrated that taking part has a favourable balance of potential benefits compared with potential harms.

There are other potential answers and all will be considered.

(iii) The first part requires only a list and these may include the documenting of the device manufacture, biocompatibility studies or sterilisation of the device, as examples.

A strong answer should explain why standards are useful while referring to the activities noted in the list at the start of the answer. Standards are useful as they ensure the devices are fit for purpose if they are followed. For example, there is a standard for the design and manufacture of medical devices. By following these standards, the manufacturer knows they will successfully pass the audit from the Notified Body. As everyone is being asked to reach the same targets across Europe, it provides equal confidence in the device safety across Europe. Standards give manufacturers all the information and guidance needed regarding the needs of the facilities and controls at the manufacturing site, and also guides on the design, packaging, storage, and post-market handling.
There is a standard for assessing biocompatibility, or biological evaluation, of the medical devices. There are many standards as part of this focusing on particular test types (e.g. leachable substances, cytotoxicity, irritation upon exposure to the devices, etc.) There are many different tests that may need to be carried out, depending on the planned usage. For each use-case, there are different tests that will need to be carried out and standards help ensure that the correct procedures are carried out in the tests.
There are standards linked to sterilisation of healthcare products. There is a general standard that discusses how to characterise the sterilising agent and how to develop and control a sterilisation process. As with biocompatibility, there are further standards on each specific technique (i.e. ethylene oxide, or gamma radiation, etc.). By following these, the firm knows they are providing an approach acceptable within the regulations and will ensure repeatable sterility.

(iv) Any two techniques may be described. It is likely that candidates will refer to UV lithography and imprint lithography. In each case a basic answer will give a brief description, showing some level of understanding of the two techniques. A very good answer will provide details on each, with possible sketches, showing the steps required.
For example, for UV lithography, it will be important to show an understanding. A thin polymer layer deposited on top of the silicon, and the use of a mask and UV source to expose only the areas requiring patterning. The exposed polymer can be developed and washed away. The pattern now exposes the silicon surface only where the intended channel will be positioned. A chemical etch is used to make these channels deeper within the silicon.

(v) Any two challenges can be raised, with a basic answer just noting each briefly and a stronger answer providing more detail and a strong answer linking it clearly to the product. Example challenges that are anticipated being raised include:

- Design or specification of a degradable polymer or bioceramic that will break down only after the time required for the device to be operational. If this happens earlier, there is a danger of a sudden release of the reservoir of drug.

- Following on from this, the degradation would most likely happen with some material swelling first, with diffusion of water into the material, and then degradation reactions. It would be important not to compromise the microfluidic channels through material swelling.
- Very rigorous biocompatibility studies, as the full bulk of the device will break down within the body.
- In addition, the new materials would need to still support the use of photo lithography, imprint lithography, so some alternative channel fabrication technique.

Question 3

(i) This question is focusing on the challenges in taking emerging technologies from an early-stage research phase through to commercialisation.

A good answer would comment on the Valley of Death typically being observed in the regions of these TRL levels. While there is significant research being carried out at low TRL levels, often funding from the private sector is inhibited to bring these technologies forward. A very good answer would convey an understanding about why this is missing, commenting on some of the reasons why the private sector is concerned about the risk of not getting a return on investment, or the high investment required while still at a high level of risk. An excellent answer would highlight that often, progress in these TRL levels needs more developed production technologies and enabling infratechnologies, which can be of significant capital expense. An excellent answer would also comment on the role of government in assisting technology firms in accessing scale-up facilities and capabilities to avoid the capital expense, such as facilities mentioned
in the question. More focused answers about centralising expertise in this complex area are also acceptable.

(ii) The question asks for any four dimensions, so they do not need to come from one example framework. A good answer will explain any four dimensions clearly. A very strong answer would recognise that there are different considerations picked up, depending on the framework, and these were developed based on the sector, so they would pick dimensions clearly related to the example provided of tissue engineering.

There are four common dimensions often discussed: Technology Development, Process/production development, Business scale-up, Value chain scale-up. In the healthcare-focused sectors there are often dimensions looking at demonstrating medical utility, product safety, a regulation journey. These or others are all valid, and any four can be described. It is important to describe clearly and excellent answers will link the dimension back to the example sector.

(iii) A range of risk management tools were covered within the lecture series. The candidates should identify that these are relevant to this situation and describe any two. For example, they may describe the phase-gate management process, the use of manufacturing readiness levels, technology readiness levels, or alternative frameworks that create their

own systems based on a combination of such levels. If describing the phase-gate management process, a strong answer would highlight the need for a modification to be appropriate to high-risk emerging technologies.
A good answer will give a brief description of its key characteristics and benefits. A strong answer will provide more detail about how they are used and important points that need to be considered when implementing them. An excellent answer will link back to the tissue engineering example in the question to show an understanding of their application.

(iv) There are a range of areas that may be raised in the answers. For example, it is likely that candidates will refer to market-related challenges faced by emerging technologies in tissue engineering. There have been cases in the past where overestimation of the market has been an issue for tissue engineering firms. A good answer would note this, while a very good answer would explore one reason why this may happen in detail. An outstanding answer would highlight a few different reasons, such as competition, reimbursement rates, challenges of being accepted by the medical community to ensure products will be used. A second reason may focus on the regulatory uncertainty in the area, complexity as new materials and products emerge, the challenges of ensuring the required clearances, quality control, or the ability of regulatory agencies to understand and approve the product. Additional barriers discussed relate to the technology or production processes but rather than general barriers good answers should specifically focus on the challenges for tissue engineering products.