METIIA 2023/24 Paper 6 Cribs

Crib Question 1

(a) *Waste reduction, including energy usage*

Waste encompasses materials, water, energy, labour. Waste can arise from all of the following.

Production operations:

Manufacturing operations which are inefficient in terms of energy usage, materials and water usage, labour.

Quality control: High defect rates which may arise from poor control of manufacturing processes and/or poor design.

Inventory control: purchase of correct quantities and types of raw materials and components. Inappropriate and un-needed stock can become waste.

Sales forecasting: Produce only required numbers of goods. Unwanted stock can become waste.

Office operations:

Packaging of goods for sales.

Paper, single-use disposable catering items.

Building operations:

Space heating, water heating. Lighting.

Water usage, for manufacturing as well as everyday usage for building occupants.

For environmental impact measured by carbon footprint, the biggest factors are likely to be space and water heating. Next biggest may be energy-intensive manufacturing operations (e.g. anything involving heat such as injection moulding). If there are high defect rates and poor inventory/sales control then material wastage may also be a major factor. Materials wastage from inefficient manufacturing operations probably next. Office functions will make only a small contribution to carbon footprint, but can be important for embedding a 'sustainability culture' into workers.

The carbon footprint of water and labour may be difficult to quantify.

The environmental impact of energy used (electricity) is very dependent on how the electricity is generated, whether from renewable or non-renewable sources.

(b) The carbon footprint analysis is basically an eco-audit. Need to have quantitative data on all aspects of company operations: materials in and out; waste types and quantities, and its destination (landfill, energy-from-waste, recycling); energy and water usage.

Carbon footprint of materials can be estimated from embodied carbon using databases such as Cambridge Engineering Selector.

Carbon footprint of waste destinations estimated from internet searches

Carbon footprint of electricity and water from supplier data

(c) Discussion of the significance of recommended measures can usefully include reference to McKinsey abatement curves.

Immediate improvements:

Start to introduce environmentally aware culture into the company: worker training (extends into long-term measures as well)

Reduce air temperature to minimum level for worker comfort (no cost, only financial benefit).

Look at scope for reduction in hot water wastage (no cost, only financial benefit).

Switch off machines and lights when not in use (no cost, only financial benefit).

Replace any high-energy lighting (costs, offset by reduction in energy bills)

No single-use catering items (one-off cost of purchase of re-useables, offset by reduction in purchase of single-use items. One-off cost of dishwasher, plus running costs).
Paperless operations (low or no cost, depending on state of IT equipment; financial benefit)
Move to 'green' electricity supplier
Longer-term:
Improve building insulation (costs, offset by reduction in heating bills)
More efficient heating (significant costs, offset by reduction in heating bills)
Replace inefficient or inaccurate machine tools (significant costs, offset by reduction in materials wastage)
Redesign products to reduce defect rates (employee time costs, offset by reduction in materials wastage)
Assess manufacturing operations to look for waste reduction possibilities (employee time costs, offset by reduction in materials wastage)
Introduce training on Lean manufacturing practices
Reduce environmental impact of electricity by installing solar panels (or possibly wind turbine). (Significant costs, offset by reduction in energy bills)

(d) Carbon footprint / global warming potential is easy to understand and can be used as a single metric covering the different target areas. It is therefore suitable for this public-facing website. It does not address other environmental impacts such as those arising from the paint-spraying activity, or any electrical or hazardous waste.

(e) The environmental impact of the company's operations includes what happens outside the factory building. It will be important to set some boundaries to limit the scope of further studies to keep the task to manageable size.
Imported electronic items: Transport, certainly; production of the items themselves could be included. (Significant)
Goods sold from factory: packaging, carbon footprint of transport. (Could be significant)
The operating efficiency of the equipment should be considered (e.g. power consumed in stand-by mode). (Significance varies depending on equipment type, but could be a marketing attribute)
End-of-life of goods sold: look at repair potential, design for re-use, disassembly etc. (Could be significant, and a good marketing attribute)

Crib Question 2
(a) (i) A basic level will note something about materials interfacing with the body. A stronger answer will note interfacing with biological systems, or if not that phrase then something to show an understanding it does not have to be only with the body but it could be interfacing with biological samples, blood, etc. An outstanding answer may also note that they are engineered in some way and link them to a medical purpose, highlighting they may be completely inert, a hybrid of inert and biological, or fully biological in nature. Examples are expected in all answers and these will likely be from devices that use metal, polymer, ceramic or composite biomaterials due to the lecture content, but all answers will be considered.
(a) (ii) A basic answer would note that there are polymers that degrade over time due to exposure to aqueous systems, such as found in the body and so a key aspect would be to select the right polymer chemistry so the backbone or crosslinks degrade at the right rate to release drug contained in the device. A good answer would give more detail about the need to select the right material, through thinking about the level of access of water to the polymer (i.e. through porosity, level of crystallinity, geometry of device), and would note that the polymer chemistry

can be tuned to give the level of control needed. An excellent answer would also note how the structure of the device would need carefully design along with the above to control the relative rates of degradation and diffusion of water into the device. An excellent answer would also clearly link these behaviours to bulk or surface erosion.
(b) This device integrates in-vitro diagnostic medical devices with tissue engineering and it is important that strong answers reflect this by considering challenges in both areas.
A basic answer will note clearly 5 challenges, a good answer will show a basic understanding of 3 and provide more detail about 2, an excellent answer will show a good understanding of all 5 challenges.
Most common challenges include:
Understanding which regulations apply. There are regulations relating to medicines, tissue engineering, and in-vitro medical devices, all of which will need to be carefully consulted to see how it can be dealt with. As this is potentially an entirely new product, it may be noted that regulators may also struggle with this, which will slow the process. If noting regulations, candidates may also mention the challenge of correctly classifying the device (A-D).
There will be challenges in creating an in-vitro medical device because products will need to be sterilised, but this is not feasible for a tissue engineered product because sterilisation will automatically damage the target cells. The challenge will be sterilising the microfluidic device and then assembling it with the tissue engineered product without introducing any contamination.
As this is made with autologous cells, there are no ethical issues but this will mean shipping the cells to a location where they can be integrated into a scaffold, given the required growth factors and nutrients to grow into the required tissue, and then possibly shipped back to the healthcare centre. The candidates can describe a range of challenges relating to the complexity of this supply chain, regarding traceability, cost due to environmental control, level of hazard, etc.
For approval, there may need to be clinical trials to ensure the diagnosis is correct. This may be challenging for tissue engineering products because you would need to compare against a current best practice, but from the description it suggests it is possibly not feasible with sampling at the moment.
There may also be challenges related to the use of a microfluidic device, in terms of manufacturing, quality, inspection, sterilisation, etc.
There are a wide range of challenges and these are all accepted as long as they relate to the device.

(c) (i) This is a short question and a basic answer will note one point, with stronger answers noting 2-3 points. For example, there would be a reduction in cost to the manufacturer as they would not need to go through multiple approval processes. Secondly, there would be a shorter time to market because at the moment it is likely firms will focus on one region at a time. Thirdly, it may be feasible to bring the best of all the different approaches to regulation together to give the optimum balance of speed to patient and safety. All answers will be considered.
(c) (ii) In this short question, only one challenge is required to be described. In this case the number of marks will be linked to the level of understanding conveyed. It is likely that candidates will note the challenge of ensuring there is a qualified expert recruited to the firm responsible for regulatory compliance, or there will be a discussion about the need to include unique identifier codes on products and their components to improve traceability. Again, all answers will be considered but a strong answer will not only note the challenge but give a clear explanation.

Crib Question 3
(i) The key basic answer is that it is a technology (often referred to as generic) that can be applied to many different sectors and applications. It is normally used for technologies at their

proof-of-concept stage prior to developing the technology to fit one application. Because of this they tend to still need significant R&D funding. A strong answer would show this understanding through explanation and examples.

(ii) A basic answer will demonstrate some understanding of different risk management techniques during scale-up. A basic answer would still need to explain two techniques as it is asked how each firm would approach this.
A good answer will link these selected techniques to each firm and give reasons why these risk management differences exist. A strong answer will also give a very clear description of each risk management approach.
In terms of risk management approaches, it is anticipated a description of the stage-gate approach with respect to the established firm, with a clear indication of what is meant by both a stage and a gate. For the spin-out, it is likely that there will be a discussion about the challenges of managing multiple dimensions of scale-up, showing an understanding of what they mean by this, and linking it to development or adoption of a framework. In a strong answer they will talk about Technology Stage Gate methods, as well as tracking TRL and MRL levels, again showing a good understanding of what these mean.

(iii) A very basic answer will highlight that they the start-up needs to consider how to fund development work between TRL4-7, with an explanation of how this links to overcoming the valley of death. A good answer will elaborate on this lack of investment and the more common investment in established technologies to reap the financial benefits. A good answer will also make a link to the need to develop infrastructural technologies in tandem with the platform technology to create a proprietary technology, with descriptions to show a good understanding of any terms used. An excellent answer will link the points made to carrying out work within established scale-up facilities, giving examples of the expertise and facilities they provide and describing how they have been designed by government policy to help with the 'Valley of Death' transition.

(iv) There are a wide range of valid challenges that could be raised from the information given. In terms of the Technology dimension, there needs to be a demonstration that it not only can function in principle, but that it can function as an integrated and packaged product with all the range of technologies that entails. In terms of production, a new nanomaterial may need new production capabilities, which will be a major investment. In terms of business, researchers will be unlikely to have the required operational capability, although strong on the technical. This means they will have a challenge of hiring the right expertise. Depending on how they intend to produce, the value chain may need to innovate. For example, if the nanoparticle production is outsourced, or ingredients required. Also, it is unknown what process technologies will be needed to make the sensor. There may also be a comment on regulatory challenges because this a sensor for toxic gases and so may have regulatory requirements.