Paper 6 CRIB SHEET

Question 1

a) i) To perform an eco-audit we need to calculate the energy required, which is analogous to the carbon footprint, for every stage of the lifecycle of the product: material production, product manufacture, product use, and product disposal. Transport between all lifecycle stages is also calculated and can be included as a separate 'stage' of the lifecycle. Traditionally, the eco-audit methodology focuses on the phase with the largest energy usage in order to maximize impact reduction, however, the company should look at all phases to see where energy gains can be made.

The steps in an eco-audit are:
1. Compile a bill of materials for the product
2. Calculate energy used in the manufacturing operations for each component (all manufacturing steps)
3. Estimate the energy used in the 'product use' phase
4. Estimate the end-of-life energy use (recycling, re-use, disposal)
5. Estimate the energy used for transport between all stages (mode of transport, distances).

The results are expected to show greatest energy usage in materials production, with manufacture and transport coming in second and third (most likely). Depending on whether the bottle is recycled, the disposal phase may even be negative.

a) ii)
Reduce the unnecessary use of materials, energy, and time

In the Lean Manufacturing protocol, all of the following are considered wastes:
Unnecessary transport – material are being moved without needing to
Material or product defects – poor feedstock, or poor manufacturing processes
Waiting time in the product line – poorly designed manufacturing line
Inappropriate processing - poorly designed manufacturing line
Excess component / material inventory – storing more material than is needed, using extra space
Overproduction – storing more product than is needed, using extra space
Unnecessary Motion
Untapped human potential – employees are not able to share their great ideas
Inappropriate systems – business is doing unnecessary tasks
Energy and water loss – inefficient machines or systems
Material loss – material degrades or is damaged, or is wasted in production process
Service and office time wasted – taking away time from employees with other tasks
Customer time used unnecessarily – needing too much from the customer to fulfil an order
Customer loss – losing customers to competitors

In assessing financial implications, use may be made of McKinsey Abatement Cost Curves These present the cost of measures aimed at reducing greenhouse gas emissions, presented in order of increasing cost. The width of the bars tells us the abatement potential: the amount of CO2 that could be saved by implementing each of the measures. The measures on the left all have negative cost (i.e. present opportunities to save money as well as improving environmental performance). Many of these are to do with reducing waste (mainly of energy).

The measures on the right require capital investment and so cost money up-front, but this is where the biggest opportunities for reducing CO2 emissions are to be found.

Specific examples: material and manufacturing quality to reduce off spec products, to minimize material inventory and reduce overproduction, improve manufacturing equipment efficiency, changing to LED lights and turn off equipment when not in use, or reduce unnecessary space heating.

a) iii)
Re-use:
Re-using products saves energy/waste by eliminating product disposal, material production and manufacture/delivery stages
- water can be re-circulated for reuse
- pallets can be re-used (Can be logistically complex)
- storage containers for goods and components can also be re-use containers
- in the office, re-usable cups, glasses, mugs and plates can be used, rather than disposable
- machines can be fixed and reconditioned

Recycling
Recycling eliminates the product disposal stage. It reduces the material production impact, as less fresh material is produced, which means less mining, and also means that only part of the material production process is necessary for the recycled material. Minimum impact recycling (material re-use) eliminates the material production stage.
- off-spec product
- packaging materials in the factory
- wastes from the office, such as bottles and paper

The McKinsey curves may again be useful here.

The financial ranking of measures for a plastic bottle factory is likely to be quite similar as the environmental ranking: Reuse of materials such as pallets and storage containers, followed by recycling of off-spec product, and then ‘office’ functions.

b) Moral Suasion aims to manipulate culture without exerting force. It is frequently implemented by providing data about environmental impacts of consumer or company behaviour. Typically, governments and corporations like this method because they are seen to be encouraging people to do the morally correct thing, but don’t have to worry about the specific implementation. It is often effective when the campaign is in tune with popular movements or the cultural zeitgeist but can be less effective if the ‘right thing’ is challenging or a lot of work.

Some examples of implementing this for recycling bottles would be:
• Financing campaigns to raise public awareness about the impact of plastic pollution
• Product-labeling requirements about the amount of energy needed to create the bottle
• Subsidising research and development for plastic bottle alternatives

Command and Control is an type of “Direct regulation” which is the dominant method of environmental regulation in most countries, where governments prescribe rules or laws which are enforced by fines and by imposing taxes. These legislative techniques are effective in

changing behaviour, but don't change attitudes. If the tax or penalty is removed, people often revert to previous behaviour, unless the penalty was used to change material conditions.

Some examples of implementing this for recycling bottles would be:
• charging a tax on bottles which can be recovered if they are recycled
• making littering of bottles illegal

Answer standards:
Basic answers: Demonstrate understanding of the underlying concepts. May demonstrate lack of knowledge and understanding of some important factors. Examples may be inappropriate. The discussion may be superficial and inaccurate.
Strong answers: Good depth of knowledge and understanding. Will cover the key environmental aspects and provide adequate discussion with pertinent examples discussed with accuracy.
Best answers: Detailed descriptions and analysis. Demonstrate understanding of the more subtle tensions in the environmental assessments. Examples will draw on experience from many different parts of the course together with the student's own observations. The discussion will be critical and insightful.

Question 2 - CRIB

(a) (i) A basic answer would note the classification is based on a rating of vulnerability of the user to harm. A good answer would expand to note that there are regulations in the EU and US that dictate the classification and that it is the whole responsibility of the manufacturer to ensure that the classification is decided correctly. A strong answer will provide additional details regarding the guidelines provided by the EU to help the manufacturer decide on the classification, such as a series of questions where the manufacturer can follow a documented pathway to a classification. In the US there is a database that allows the manufacturer to search for similar devices and it is acceptable to classify based on precedent. However, for very new medical devices, this is not feasible, and a separate process is required. It was covered in the lectures that when devices are especially complex because the are at the boundary between medicines and devices, then the regional Competent Authority can be consulted for advice.

(a) (ii) This answer is only asking for the candidate to consider the example of a Class III device. It is assessed by looking at the three sections, namely biocompatibility, sterilisation and clinical evaluation and is focused on European regulatory approval only. A basic answer will give one key piece of information about each aspect, a good answer will have a more detailed explanation of each. A strong answer will have 3-4 points as part of that clear explanation.
In biocompatibility, it is anticipated that the candidates will note that when changing the manufacturing approach of the device, there is the potential to introduce contamination, changes in material properties or different sterilisation techniques, that may change the response of cells to the product and so biocompatibility tests would need to be carried out for this version of the product. If the sensor is part of the device that makes contact with tissue, this is especially important and then the candidate will comment on how to select materials for compatibility. If, however, they assume it is a part of the device that is not in contact with tissue, then it is a standard repeat of the tests carried out during first approval. They will hopefully also give examples of testing for cytotoxicity, irritation, etc. For sterilisation, the new device that has been added in can't be degraded due to the sterilisation technique and so the function and material properties will need to be tested along with the general considerations of efficacy, cost, suitable sterilisation batch sizes (and many other aspects). In terms of clinical evaluation, the candidate would be anticipated to discuss the likelihood that significant in-vitro testing would have to be carried out and simulations of the product use, to validate the data and usage. Also, because it is class III, it may be required to carry out clinical investigation (trials) to complete the approval process.

(a) (iii) This question is giving the candidate an opportunity to discuss the potential to capture data for machine learning / AI purposes. They may also discuss an opportunity for redesigning the probe so it is compatible with surgical robotics. Alternatively, they may talk about linking to connected devices. Each has an appropriate area for discussion with a focus on at least one of the devices and links to the future of health and care. A basic answer would recognise one link to a trend and give a brief introduction. A good answer would expand upon one or two trends with more detail. A strong answer would link to three trends very clearly.

(b) (i) This question is prompting the candidate to consider what material to use and how to balance diffusion of water into the bead with hydrolysis of the bonds (or rate of dissolution) to ensure rapid swelling to allow drug out but slow breakup, and so over time it may become less mechanically robust, but it will hold its shape for as long as possible. The alternative is faster hydrolysis or dissolution and slower diffusion, and it will constantly shrink from the outside while releasing the drug. A basic answer will give a brief understanding of this balance without considering the material. A good answer will give a show a more detailed understanding of the

balance while also giving more detail about polymers and how they are tuned. A strong answer will consider polymers and bioceramics, explain how to control their degradation and link to the answers above.

(b) (ii) With a move to cells and cell therapy, the candidate can explore any of a range of topics, including a need to find a different way to ensure sterility of the beads, as sterilisation can't happen while biological components are within. They will need to consider the change in regulatory pathway with a specific regulation that covers cell and gene therapies. They may also refer to ethical, biocompatibility, or other challenges. A basic answer will give a very brief note about the challenge. A strong answer will explain the answer in a bit more detail, whereas a strong answer will clearly explain the challenge and link back to the application.

Paper 6 Question 3 - CRIB

(a) There are two levels of this question clearly noted. There are marks allocated for clear explanations of the terms and also marks in describing how they contribute to the 'translation of an innovation into a market' (which is the short definition for scale-up). A basic answer will note that a generic or platform technology is a core technology that is developed into a product and an infra-technology or infrastructural technology is a supporting technology that helps it get there. However a good answer will give more details about each or examples to show an understanding. A strong answer will also show how the link together in an overall system to translate the generic technology into a proprietary technology, which then is commercialised.

(b) A basic answer will show a good understanding of MRLs and the fact that there is a scale that progresses towards full launch of a product. A good answer will show very clear understanding of the levels, how the manufacturing readiness threads contribute to the measurement of levels, and how the series of targeted questions help a manufacturer score where they are. A very strong answer would also make a link to milestones.

(c) There are a range of dimensions discussed throughout the lectures and any two will be accepted. The most common to discuss will be business and value chain dimensions. A basic answer will give a definition of each. A good answer will give a more detailed explanation with examples and a strong answer will also explain why they are important to track, what are the aspects that need to be considered, and how that links to scale-up. There are a range of frameworks covered in the lectures and any valid dimension will be accepted.

(d) A basic answer will note the role of funding of low TRL/MRL research and the need to fund pathways to translation, to avoid the Valley of Death. A strong answer will discuss the link with policy and give examples of policy documents and their influence on the scale-up infrastructure in UK or US. A strong answer will cover all of these points and link back to the different dimensions of scale-up that have to be managed and highlight the need for the government to put in place capabilities to ensure return on public spending for research.