Crib

1. (a) 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 is included.

The steps will be:

Compile a bill of materials for the product;
identify manufacturing operations for each component;
estimate energy usage in use phase;
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 eco-audit methodology is to focus on the phase with the largest energy in order to gain the biggest impact reduction. Greendox should however look at all phases and see where energy gains can be made; the actions that it takes should be informed by the relative totals in each phase.
The results are expected to show greatest energy usage in materials production and in the use stage.
The eco-audit will not explicitly account for Greendox factory operations. Energies for the manufacturing operations will include an 'overhead' for an average factory, but Greendox may be able to make significant improvements to not only the manufacturing side but also to the 'office' side of the company (e.g. heating, lighting).

An excellent answer will cover main points and provide an insightful critical assessment of the appropriateness of an eco-audit for this. Weaker answers may miss important points and analysis may be inaccurate.

(b) Biggest savings will be from waste reduction:
tight quality control on manufacture quality to reduce failure rates;
optimize material and other resource usage (including water);
optimize energy for manufacturing operations (e.g. machine switch-off).
The company should also look at any improvements in upstream and downstream supply chains, including transportation methods and packaging.

An excellent answer will produce a prioritized list of measures and discuss their relative importance. Weaker answers may not prioritise correctly and may cover a limited range of factors.

(c) The product will be in service for 10 years, so will use significant energy and supplies (paper, toner). Greendox can make the machine energy-efficient, including automatic switch-off. Toner (ink) typically comes in cartridges, and

there is potential for reducing material wastage by design, e.g. making them re-usable. Paper usage reduction: have double-sided as machine default; use default machine settings to promote electronic copies rather than paper copies (Xerox has done this).

An excellent answer will look at all lifetime issues and suggest improvements. Weaker answers may focus just on a single factor such as operating energy.

(d) Command and Control is an example of "Direct regulation" which is the dominant method of environmental regulation in most countries, enforced by fines and by imposing taxes

•Pollution control; emissions targets

•Management of common property resources e.g. fishing regulations

The aim might be to tax at levels which cover abatement cost (i.e. cost to society of pollution reduction)

Tax to raise revenue for government to improve environment, or to put additional facilities in place (e.g. waste disposal)

Tax to raise revenue to cover costs of research/environmental projects (e.g. Biffa landfill tax used to fund research)

These legislative techniques are effective, but don't change attitudes. Remove the tax or penalty, and people revert to previous behaviour. Permanent change can happen if the desired outcome is easier of cheaper than the undesirable behaviour. For example, with urban 'congestion charges' the introduction of cheap and effective public transport can encourage people away from driving their own vehicles.

Moral Suasion: Aims to manipulate culture without exerting force. Providing information about environmental consequences of behaviour is a central mechanism. Popular with governments and corporations because they are seen to be encouraging people to do the morally correct thing, but avoid criticism of how this is being achieved.

e.g.

•Finance of campaigns to raise public awareness
•Product-labelling requirements
•Voluntary agreements by emissions sources on emissions targets
•Subsidising research and development for alternative technologies
•Finance of basic research

Effective when the campaign is tuned to culture or to other popular movements, but again people will generally do 'the right thing' only if it's easy.

An excellent answer will provide good definitions and examples, together with full discussion of their effectiveness. Weaker answers may provide only partial answers and lack accurate and insightful discussion.

2 **(a) (i)** The example of using calcium phosphate bioceramics in bone repair applications was noted very briefly, and the mixing of one type of calcium phosphate into a polymer matrix was noted as a type of ceramic composite. However, there is sufficient information in the question to guide the candidate to draw upon reasons from what they learnt about polymers, bioceramics and composites. There are 4 areas the answers are likely to cover, in terms of reasons:
(1) Making materials that have similar properties to bone
(2) Using materials that will have biocompatibility for injection/implantation
(3) Designing materials that will encourage growth or repair of natural bone
(4) Using source materials that have controllable rates of dissolution so they are gradually replaced by the natural bone

As part of **reason 1** the candidate may note that ceramics are normally very strong in compression and poor in tension. They are also noted as having low tolerance for stress concentrations. The exception is a porous bioceramic, which also has poor compressive strength. To avoid brittle behaviour and increase elasticity, the ceramic and polymer may be combined as a composite. The candidate may note that the mechanical properties of polymers can be controlled by the chain length, level of cross-linking and/or crystallinity. The candidate may also refer to composites and note that mechanical properties can be controlled by changing the nature of the discontinuous phase (particulate, fibrous, laminate) and the scale.
Reason 2 may consider ease of selecting materials that are biocompatible. There are a number of biocompatible polymers (PMMA, PLA, UHMWPE, etc.) discussed and bioceramics (Hydroxy Apatite, Tricalcium Phosphate maybe referred to more often as HA and TCP). Also, these materials are already in implanted medical devices and so will be more straight forward to approve.
Reason 3 will most likely focus on the bioceramic because TCP and HA (types of bioceramics) are known to osteoconductive or bioactive (forming bone-like calcium phosphate on the surface) to promote and form a direct bond with bone. An example was given of making the material porous so the bone grows into pores before the scaffold dissolves.
Reason 4 may include notes on the bioceramics and polymers having controlled dissolution. The bioceramics have slightly different degradation rates from each other. Polymers can be carefully designed to degrade at a required rate. This will allow the scaffold to dissolve as the bone grows to fill the void in the fracture. Additional reasons may be the ease of manufacturing such materials, i.e. the known chemical and process route. An excellent answer would convey 4 very different reasons clearly, with examples of materials. An acceptable answer would describe 2.

(a) (ii) There are a number of reasons to choose gamma radiation, but for an excellent answer it is important to link the reasons back to the product at least twice. Overall, it is expected that 4 reasons are noted for an acceptable answer

1. For example: sterilisation by gamma radiation penetrates through primary and secondary packaging. This product is within a syringe, which in turn is within a plastic pouch. It is not going to be feasible use steam to penetrate through to the ceramic/polymer mix. While ethylene oxide is known to be used through certain

packaging materials, it would be very difficult to design something that will allow it to pass into the syringe and formulation, and also be removed afterwards. This formulation is the compound that will be implanted into the patient so the answer should note it is likely this is the most important part to ensure is sterile. This means high energy radiation is the likely solution, which can pass through all of the components

2. As there is a polymer in the composite, and the viscosity will be very important to the behaviour and flow, it is likely going to be very sensitive to being raised over 120^{o}C by methods such as steam sterilisation. Gamma radiation does not lead to temperature increases. It is likely the company would have carried out tests to ensure the key properties had not changed.
3. Gamma radiation is a very common technique and so it would be quite straight forward to find a third party to sterilise this product needed.
4. This technique leaves no toxic residue or contamination on the product and so allows immediate sterilisation and release.
5. There are known ways of validating the dose, with dosimeters, and so it will be straight forward to know the product has been exposed to the correct level of radiation.
6. This is known as an economical and reliable technique, and it is possible that the company decided it was important to sterilise in the shipping packaging to ensure everything was sterilised.

(a) (iii) The definitions from the lectures are given below, but it is not expected verbatim, rather a clear indication that the candidate understands "*performance*" is a measure in the EU of the device and not all of the additional external influences that can determine if it produces the desired therapeutic, diagnostic result. "Effectiveness" is measuring the effect on the patient, and so taking into account a broader set of influencing factors other than just the device itself.

Performance (EU): The action of a device with reference to its intended use when correctly applied.
Performance does not refer to the outcome. The outcome may be influenced by other factors.

Effectiveness (US): The extent to which a specific intervention, procedure, regimen of service, when deployed in the field, does what it is intended to do for a defined population.

(b) (i) It is important for a full answer that the candidate identifies that the device can be anything in a range of different forms i.e. a machine, apparatus, material, appliance etc. Showing this understanding through examples is also acceptable.
It should be noted that a device refers to a range of different actions such as diagnosis, prevention, monitoring, treatment.
It is important to note the principal action is not as a drug or pharmaceutical agent.

In addition, it may be noted that a medical device can also refer to in-vitro diagnostics, active medical devices, active implantable medical devices, custom-

made devices, accessories intended to be used with the device and software with a medical purpose.
An additional point may be that devices are classified and have a graduated system of control based on vulnerability of the human body and device risks.
The use of examples is important to show a clear understanding of any or all of these points.

(b) (ii) An outstanding answer will identify that these are competing influences to determine the overall degradation behaviour. The rate of water diffusion into a polymer will determine if hydrolysis can occur only at the outer surface or within the bulk.
The rate of hydrolysis will determine if degradation happens shortly after the water interacts with the polymer or much later, for example after it has diffused through the bulk.
In short, a fast hydrolysis rate and slow diffusion will lead to surface erosion, whereas the slow hydrolysis and rapid diffusion will lead to bulk erosion.
Diagrams explaining this are acceptable as long as the concept is clearly conveyed.

It may also be noted that water diffusion is linked to the concentration gradient and also porosity, geometry as well as basic chemistry. Hydrolysis rates are also mainly driven by the material chemistry.

b(iii) There are trends that can be considered at the hospital level (patient surveillance, real-time location systems, connected equipment), in a GP clinic (lap-on-chip devices, handheld medical technologies), across a community (mobility, supply chain logistics, automated kiosks), in the home (home medical devices, activity monitoring, digital assistants), and on the body (wearables, smart devices, smart implants).

Alternatively, the answer may address specific examples in detail such as:
Cloud solutions for healthcare: Cloud-based clinical applications can access medical records, provide health information exchange, and provide population health management solutions. Examples include Whole Foods and Amazon, investing in this area.
Cognitive computing accesses enormous quantities of data for analysis to gain new insights. An example is the IBM Watson platform. This is already applied in oncology.
Care Management Solutions, where Alphabet are investing in technologies that will enhance drug discovery and improve chronic disease management.

3. **(a) (i)**
A good answer will note the definition about the translation of an innovation into a market. A very good answer will communicate some additional information to clarify this is about taking innovations from the lab to manufacturing, or the journey from design and prototyping to early production runs and full-scale manufacturing. A full answer will note that scale-up can refer to the scale up of a firm. There is a definition that scale-ups are enterprises with average annualised growth in employees (or in

turnover) greater than 20 per cent a year over a three-year period, and with 10 more employees at the beginning of the observation period.

The second part of this questions should communicate clearly that they understand what is meant by the different dimensions of scale-up and also why they need to be considered. From the publications noted and the discussions in the lectures, there are different aspects of scaling up or different "journeys" to get the product to full scale manufaturing. Examples include Value Chain scale-up, Business scale-up, Process scale-up and Technology development scale-up. These examples, or possibly examples from other frameworks, such as the Critical Path Initiative are all acceptable. These dimensions or aspects are all influenced by developments in each other as the technology moves closer to full scale manufacturing. This may be explained through examples, e.g. as a product that incorporates carbon nanotubes scales up to full manufacturing, the value chain dimension will need to manage how suppliers can scale-up carbon nanotube manufacturing without changing the functionality.

(ii) It was noted in the lectures that it is now being considered that "countries that can build powerful links between laboratory research and new manufacturing will be able to derive full benefit from their innovative capabilities". There is also a national economic advantage from domestic industries making the transition between technology life cycles faster /more efficiently than competitors. These benefits or advantages are often related to the capability to generate economic growth. Emerging technology 'scale-up' is especially challenging because there is technological risk associated with a potentially wide range of technologies and tools. The technical competencies required to address the risks faced during scale-up may not be within the firm or university and in fact may be distributed across a range of private and public sector organisations. It is important for governments therefore to put facilities or capabilities in place to align technology de-risking with skills development, operations management development, etc.

Examples include (1) the HVM Catapult and Tools and (2)Services for Synthetic Biology (both in UK), or (3) Materials Genome Initiative and (4) National Network for Manufacturing Innovation (both in US).

An acceptable answer will note two appropriate examples but a strong answer is expected to describe each example briefly and a full answer must link these back to the role of government:
E.g. The HVM Catapult is an example of an institute funded through government initiatives that act as an intermediate R&D centre to enable pilot-scale or manufacturing-like demonstration as innovations move from prototype to full-scale manufacturing. These are used for university-led projects as well as industry innovations or start-ups during the scale-up journey. While such centres help with the scale-up process, they are not affordable investments for any one stakeholder.

(b) (i) The concept of Technology Readiness was developed as a risk assessment process for incorporating new technology into mission-critical systems in NASA. This has been translated to general emerging technology development and scale-up since its inception in the 1980s to help manage projects that involve a "technology push". The Technology Readiness Level scale is a sequence of defined categories of development activity used to characterise the maturity of a novel technology. It is a consistent

comparison of maturity between different types of technology and most importantly are used as a communication tool among stakeholders to understand the estimated level of maturity. An acceptable answer will note that this is a a tool to measure the level of maturity, however a strong answer will note that it is a risk assessment process and communication tool.

It is often important to consider Manufacturing Readiness at the same time as Technology Readiness because while TRLs communicate the development of the ability of a technology to deliver its function, MRLs are more focused on ensuring the capability to produce a final and integrated product. It has been noted that TRLs are more open to interpretation when examining the move to manufacturing. Key threads, such as the assessment of required personnel and skills, the ability of the design to meet the user requirements, the capabilities and capacity of manufacturing facilities or suppliers, are important manufacturing related risks. A strong answer will give a couple of examples from the 9 threads noted in the lectures.

(ii) There is an investment by governments in technologies and research from TRL 1-4 by universities or public bodies. This does not directly target specific private enterprises. The Private Sector invest in innovation and development from approximately TRL 6 and above. Investment in lower TRLs by the Private Sector is seen as risky and unlikely to lead to a product without significant additional research and investment. Also, there is a chance this would benefit competitors. This leads to a gap that is considered the Valley of Death, where there is a lack of investment in the transition between public and private sectors.
A sketch of Investment against TRL is also acceptable if correctly labelled and clearly identifying a valley where there is a lack of investment. A full answer would show an understanding that this valley is a product technology investment risk as well as a production technology investment risk & 'Infra-technology investment risk.

While there have been investments to try and ensure this translation can be improved, there are a few trends that are making scale-up more difficult. These include:

Private sector investment may be inhibited from supporting emerging product technology R&D or process technology R&D because there is an increasing risk of not getting a return on investment. This is linked to the increasing complexity of product applications and the accumulation of technical risks. Also, firm 'specialisation' in limited sets of technology applications can lead to a lack of core competencies to solve industrialisation challenges. Finally, it was discussed in lectures that accelerating technology/product life cycles lead to a shorter 'window of opportunity' to get a strong return on investment. Any two trends can be noted with a brief explanation required for a full answer.