CRIBS

Question 1

(a) An eco-audit is used to determine the relative impacts of the five different stages in the lifecycle of the product: material, manufacture, transport, use and disposal, looking typically at a limited number of impact factors (often only energy use, or CO2 footprint). The company should use the information to identify which aspects of the lifecycle of the product will give the biggest eco-hits for energy minimisation, so informing design decisions.

(b) (i) The most significant phase is likely to be the duty cycle (the use phase), so design should focus on energy minimisation in use. The next most significant phase is probably materials. This can be reduced mainly by increasing product lifetime (so reducing the need to make machines); use of recycled material can help too. The UK factory may help minimise transport costs (assuming machines are sold in UK).

(ii) Use phase: Features should include automatically switching off, or to a very low-energy standby mode. Other default modes should include double-sided copying.

Modular design can allow machines to be repaired easily, or refurbished or reconditioned at end-of-life. This lifetime extension significantly reduces end-of-life impacts, but does require that the infrastructure for reconditioning is set up properly from the start (see iii).

Choice of materials and manufacturing processes are inter-related, and there may not be much scope for innovation. Materials decisions influence end-of-life: metal is readily recycled and generates revenue; plastic is not. The electronics manufacture has potential for high eco-impact; design decisions also influence end-of-life possibilities.

(iii) Use phase: It is safest to assume that users will not have much awareness of environmental aspects, so the product design should make it as easy as possible for this to happen without user input.

End-of-life: If machines or machine parts are to be brought back to the factory for refurbishment (as happens at Xerox, one of the case studies in the lecture notes) then there are implications for:

logistics (getting machines back at end-of-life);

factory design, to include refurbishment operations;

perhaps business models, moving to Product Service System with machine leasing rather than ownership.

(c) Space heating is the most significant energy use for buildings. Good insulation in office buildings; consider appropriate heating levels for factory operations. Lighting: automatic switch-off when not in use. Machines: automatic switch-off or low-energy standby mode when not in use.

Question 2 – Part a - i.

"A material intended to interface with biological systems to evaluate, treat, augment or replace any tissue, organ or function in the body."

Categories of materials in medical devices/implants:
Bio-inert: all of historic implants - no cells or living components
Hybrid: combined implants with both cellular and materials components, potentially also including drug elements, as for use in tissue engineering and regenerative medicine.
Biological: transplants - has a cost in terms of immune reaction

Examples may include a range of polymers, metals, ceramics or composites discussed in lectures.
An excellent answer should give examples.

Question 2 – Part a - ii.

1. Tissue engineering scaffolds
   - Description should include a description of the role of the scaffold as the structural element during cell proliferation and tissue growth. The benefits include reducing the number of invasive surgeries and enabling growth of a range of different tissues through material and geometry choices. Notes should be made of typical materials.
2. Drug delivery
   - Description should highlight how the dosage can be controlled by the degradation rate, with a clear benefit being the slow, controlled release rates feasible. Some mention of mechanisms will allow differentiation of excellent answers. Example applications should be mentioned along with materials.

Question 2 – Part a - iii.

Bulk erosion
The answer should note the rapid diffusion of water, the relatively slow hydrolysis rate and therefore the bulk change in molecular weight without changing the overall geometry, until it all breaks down.

Surface erosion
The answer should note the relatively slow diffusion of water and rapid hydrolysis, leading to a breakdown of polymer from the outside surfaces. The overall geometry changes, while the molecular weight of the remaining polymer is not modified.
Diagrams can be used for an equivalent description.

If switching from a bulk erosion to a surface erosion system, it needs to be spotted that either the diffusion rate needs to decrease or the hydrolysis rate needs to increase (or both). It is very likely the polymer itself will need to be changed. The most important factor to consider that will determine how easy a system is to break down is how hydrolysable are the bonds in the polymer system. This basic chemistry can be tuned by designing the appropriate polymer and an example was given in lectures of combining PGA and PLA in differing amounts. The second most important factor after basic chemistry is the geometry and how easy it is for water molecules to access the polymer.

Increasing the crystallinity, including hydrophobic side chains, decreasing porosity or moving from glassy to rubbery state will lead to higher likelihood of surface erosion.
An excellent answer should briefly note the key differences between the two types of erosion and then quickly identify the key **chemical** and **structural** considerations.

Question 2 – Part b - i.

Quality system requirements result in Good Manufacturing Practice (GMP), reducing non-conforming products.
Critical for manufacturers to conform with quality system standards.
Quality systems represent a preventative approach to assuring medical device quality versus the previous reactive approach by inspection and rejection at the end of the manufacturing line. Prevention has been proven to be more efficient and cost effective in controlling manufacturing processes and maintaining medical device quality.
Quality System: Organizational structure, responsibilities, procedures, processes and resources needed to implement quality management.
Regulations for quality systems covers: methods, facilities, controls used by the manufacturer in the design, manufacture, packaging, labelling, storage, installation, servicing and post-market handling of medical devices.
U.S. (FDA Quality System Regulation / Good Manufacturing Practice)
E.U. (ISO13485)

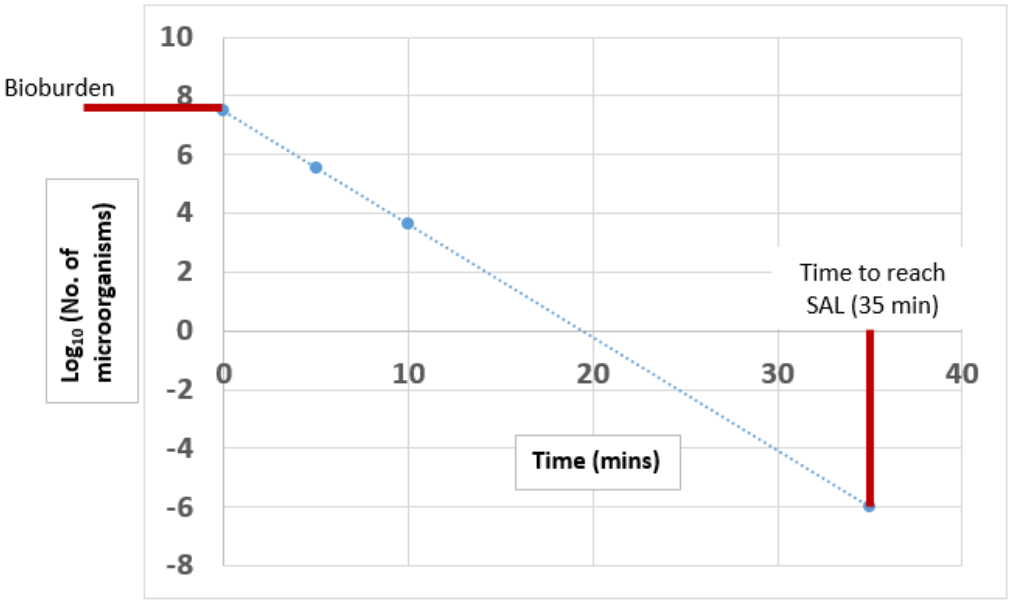
The Quality Management System will cover the standards that need to be adhered to for sterilisation technique implementation.
Up to manufacturer to validate sterilisation
Essential as part of ISO 13485 clearance
"ISO 14937 Sterilization of healthcare products – general requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical device."
The manufacturer must also comply with all standards relating to sterilisation technique
Must validate under actual manufacturing conditions and in final packaging configuration

Question 2 – Part b - iii.

It should be noted that the time to reach the SAL is in fact 35 minutes ($42 \times \frac{100}{120}$).

We then have three points that can be graphed using $\log_{10}$ (no. of microorganisms) against time (minutes).

Time (mins)	No. of microorganisms	$\log_{10}$ (No. of microorganisms)
5	3.55E+05	5.55
10	4.47E+03	3.65
35	1.00E-06	-6.00



If the SAL is placed at the point (35, -6), then the other two points are graphed and a linear extrapolation to the y-axis allows us to find the bioburden or level of contamination at time = 0 min. Bioburden is therefore $10^{7.5}$ or 3.16×10^7 microorganisms**.**

Some answers may use a simple mathematical extrapolation because they know it is linear. This is acceptable also as long as the workings are shown.

Question 3

3. (a) (i)

Examples

Tata Steel: innovating with niche, customised steels to try and differentiate themselves from the bulk steel market and its competition with China.

Rolls Royce: Rubber nose cone with sufficient vibration to prevent ice formation. Fan blades made from composites that are safer when a fracture occurs as containment is a key issue. Compressor: Very small tolerance for this part at the blade/disk interface (+ or -10 micrometres). At the moment they use a conventional disk with mechanically fixed blades but in the future they are planning on using Integrally Bladed Disk (BLISK) which gets rid of the interface and allows a weight reduction of 30% at the expense of higher weight.

McLaren: Cold stamped aluminium bodywork to reduce price and allow optimal appearance. Carbon fibre in chassis for weight reduction.

SMC: Maintaining competitiveness. 6% of turnover reinvested in R&D. Embracing industry 4.0 & internet of things. £1bn ongoing investment. 400 new Mazaks worldwide. This was

linked to deskilling workforce by having lots of CNC machines which once programmed with various operations need little input.

Hain Daniels: Using vacuum boiling for jam manufacturing to reduce energy consumption.

Other examples will be considered valid if described in sufficient detail.

3. (a) (ii)

This second part focuses on materials and expects an opinion about sectors based on evidence picked up during the visits. It is expected that the student will note where sectors rely on material innovations, such as aerospace and automotive and where sectors rely on using standard materials, electrical or electromechanical.

The students may also refer to relative R&D investment in the sectors to back up their argument as this was presented by a number of the groups. Examples given include R&D being boosted in an attempt to increase revenue through innovations, such as in Tata Steel, Rolls Royce. However, FMCG have decreased research and focused on product improvements.

3 (b)

Question 3 – Part b

Possible examples points that may be raised.
1. Tata
No outsourcing, primary process.

2: JLR
Buy in most of the components but this leads to a highly complex supply challenge, that is outsourced to DHL.

3: McLaren
All outsourced components. Adding value in design and assembly.

4: Rolls Royce
Significant in-house manufacturing, 30% of components. E.g. fan blade and compressor. All assembled in-house.

5: Marshalls
Outsource production for convenience or requirements.

6: Briton
Final assembly is the added value so they purchase all the components.

7: Nemco
Adding value by assembly so all components bought in.

8: MK
They outsource laser cutting, as well as PVD or plating or any unusual requests or finishes. In addition to these, more complex electronics such as touch sensor light switches in the latest range are outsourced. Moulding is done in house.

9: SMC
Outsource a complex manifold bonding to Japan but other than that everything made in house.

10: Hain Daniels
Outsource packaging and some of the smaller volume products.

11: P&G:
Outsource all packaging. Key is in the design and then innovation is in the R&D / formulation / marketing.

Outstanding answers should draw conclusions from these comparisons, e.g.:
The key added value for some companies is the product inside the packaging and the design of the packaging and so the companies outsource other elements of the manufacturing. Companies keep activities in house when they feel there is a strategic advantage to it and control can be maintained. The outsourcing is done for reasons of cost and strategy about where the value will be added by the company. Outsourcing is avoided where the brand would be put at risk through errors (e.g. Rolls Royce). A good level of detail is expected in each example.