**METIIA – Paper 6, 2017 - Cribs**

**Question 1, Part a**

'Green' is an imprecise term, which can be interpreted in various ways. Answers can explore what is implied by a 'green' company: typically, there will be mention of triple bottom line accounting (e.g. environment, finance, social).

Motivation may typically be driven by:

Philanthropy (desire to 'do good'): benefit may be mainly social, but there can be environmental benefit in some cases.

Social or environmental responsibility – which may be local (e.g. to local community), or broader, perhaps global.

Legislation: e.g. emissions controls; WEEE directive.

Business advantage: opening up markets where environmental restrictions are in place, e.g. ISO14001 Accreditation; RoHS, WEEE. Advantage may be short, medium or long-term.

Future-proofing and risk management: in anticipation of changes in legislation, or projected materials or energy shortages.

Examples of some specific business measures that could be used to illustrate answers, with their main implications, include:

**Maximise material and energy efficiency** *(Do more with less resources, generating less waste, emissions and pollution)* [financial advantage, see e.g. McKinsey abatement charts indicating that the first stage of 'going green' saves money; plus environmental advantage]

**Create value from waste** *(Turn waste streams, emissions and discarded products into feed stocks for other products and processes)* [Financial mainly; some environmental]

**Use renewable resources** *(Use of renewable materials and energy sources rather than finite non-renewable resources)* [Environmental, but also has financial implications because it improves risk management and future-proofing]

**Deliver functionality, rather than ownership** *(Provide services that satisfy users' needs without having to own physical products)* [Dematerialisation, reduction in amount of manufactured goods, so ultimately environmental]

**Adopt a stewardship role** *(Proactively engaging with all stakeholders to ensure their long-term health and well-being)* [Social]

**Re-purpose the business for society/environment** *(Focusing the business on delivering social and environmental benefits, rather than economic profit maximization)* [Social]

**Integrate the business more fully with other stakeholders** *(Including community, employees, partners, etc. through more collaborative approaches)* [Social]

**Question 1, Part b, (i):** Zero waste to landfill

Toyota has been used as a case study for this, and examples are found in other manufacturers such as JLR. Most of the measures are all, however, generically applicable.

Eliminate as much waste as possible through changes to process or design: this is the 'reduce' part of the 3Rs of waste. Then move all unavoidable waste up the waste hierarchy. Least good is disposal (landfill or incineration); 'other recovery' includes incineration with energy recovery; 'recycling' has variable value for different materials; 're-use' is the best end-of-life option.

Cultural changes needed (all employees to 'buy in' to requirement that waste must be reduced and that landfill is unacceptable), as well as technical fixes.

Reducing waste may involve changes to process (e.g. improve quality control to reduce off-specification scrap waste; refine processes to produce less waste such as electrostatic paint application rather than unfocused spray; use low-waste powder forming processes rather than casting) or design (e.g. exploring 'design for manufacture' may help). Moving up the waste hierarchy away from landfill may involve looking for outlets to receive waste materials for recycling, e.g. sourcing markets for polymer scrap. Re-use may apply not only to production materials (e.g. closed loop material reuse for polymer injection moulding scrap) but also to production equipment (refurbish machines rather than buying new).

Environmental consequences: Landfill of inert materials is neutral, but moving to increased recycling/reuse may lead to reduction in the amount of virgin material being produced which is beneficial.

Financial: Reduce landfill costs (gate fees/tonne). Scrap for recycling may have value so can be sold. Equipment re-use: reduce new equipment costs.

**Question 1, Part b, (ii):** Product Service Systems

Replace product with a service. For the automotive industry, implementation could involve the manufacturer retaining ownership of the vehicle and leasing it out. The company can take responsibility for maintenance, and will take back the product at end-of-life. Flexible lease plans: customers have a vehicle that matches their lifestyle requirements at any time without needing to buy/sell.

Environmental consequences: Possibly fewer cars needed (more sharing of product; more durable product), but main consequences are during service and at end-of-life in retaining ownership of car parts enabling re-use or refurbishment whenever possible, and maximizing recycling when it isn't.

Financial: PSS is a fundamentally different business model: the company sells a service not a product. The product may still exist, but might be made by someone else, or the product may be eliminated altogether. Various types of PSS can be made to work profitably, but this is not automatically true. In the automotive industry, we might expect that the manufacturers continue to make their vehicles.

**Question 2, Part a, (i)**

Devices are classified based on the device risks and the vulnerability of the human body to the use of the device. The higher the risk, the more likely the product can do harm. This is a graduated system of control. A very good explanation would describe this clearly with the help of examples. There are several reasons for this classification approach. First and more important is for the benefit of the patient. Greater reassurance needs to be given if the risk is greater and it is therefore important to identify these higher risk devices. Secondly, this approach helps the manufacturer control costs while ensuring the appropriate precautions are in place for a given device. Thirdly, classification also guides regulatory bodies and enables them to see which products require their focused efforts.

There were a range of differences noted in the answers between EU and US classification procedures. Most candidates noted the different categorisation. Also, the EU sets rules for self-assessment by the medical device manufacturer. These are part of the Medical Device Directive. The set of 18 rules lead the manufacturer to a very clear decision as to the classification. The US sets classification through precedence, using a searchable database controlled by the FDA. This means breakthrough products need to follow a different regulatory path to those of incremental change.

**Question 2, Part a, (ii)**

The core point to this answer is that bioethics is the study of ethics applied to biosystems. However, a strong answer should include some additional detail to show a full understanding. For example, it is helpful to identify that “Ethics” is a system of moral values, for a broad population or society or that bioethics concerns the moral, legal, political, and social issues raised by medicine, biomedical research, clinical care and life sciences technologies.

For the next part, it was not necessary to know the names of the different international studies, inquiries or report, it was just important to describe the three selected principles from any such activities. It was also acceptable to include multiple principles from the same study. The cribs show examples of possible selections below, but all answers were considered, whether from the module or additional reading.

The Nuremberg Code is a set of research ethics regarding principles for human experimentation and there are 10 guidelines. The first is the key guideline, and noted by many of the cohort, that the voluntary consent of the human subject is essential. Consent is detailed further by “Disclosure”, the communication of relevant information by the clinician and its comprehension by the patient. The patient needs to have the ability or capacity to understand this information and the consequences of decisions taken. Also, the patient must have the right to come to a decision freely.

Declaration of Helsinki led to the key point that subjects should not be put at a disadvantage with respect to medical care. Some of the key points include (i) research with humans should be based on the results from laboratory and animal experimentation, (ii) research protocols should be reviewed by an independent committee prior to initiation, (iii) research should be conducted by medically/scientifically qualified individuals and (iv) risks should not exceed benefits.

The Belmont Report led to three principles and these were also used within several the answers. The first is “Respect for persons” and requires that the choices of autonomous individuals be respected and that people who are incapable of making their own choices be protected. The second principle is “Beneficence” and requires that participation in research be associated with a favourable balance of potential benefits and harms. It is important to show an understanding that this is a balance. The final principle is “Justice” and requires that researchers must not exploit vulnerable people or exclude without good reason eligible candidates who may benefit from participation in a study.

Excellent answers identified three different principles and conveyed a clear understanding of the main points in each.

**Question 2, Part a, (iii)**

It was noted in most cases that "Cyto" refers to the cell and toxicity can be considered as cell death, cell damage, the slowing in growth of a cell population or a change in cell metabolism.

This is measured because medical device manufacturers need to consider biocompatibility and one element of this is biosafety (The exclusion of severe deleterious effects of a biomaterial on an organism). This includes cytotoxicity, mutagenicity, carcinogenicity, pyrogenicity, irritation, etc.] Another more specific reason to measure is that often within the medical device manufacturing standards, manufacturers must show compliance by conforming to specific cytotoxicity standards, such as ISO 10993-5 "Tests for Cytotoxicity—In Vitro methods". Cytotoxicity testing is usually the first in a series of evaluations because a poor result can stop the process and allow for material improvement at an early stage.

Cytotoxicity tests may be required if the device was not already used extensively in the same application, if the device specifically requires testing for biocompatibility because of standards and if the supplier can't provide a certification for biocompatibility. Some noted that if there are changes in sterilisation or processing, cytotoxicity testing may be needed.

<u>Example of measurement includes:</u>

Testing new biomaterial - Cytotoxicity tests emphasize

- Direct contact with the material,
- Diffusion of toxins through a gel layer
- Exposure of a cell layer to a liquid that has been exposed to the material of interest ("fluid extract").
- Cells are watched in culture for a limited period, i.e. 3 days and thus the results are indicative only of short term implantation.

A general description of the testing and conveying an understanding of the process is required, rather than a detailed answer that includes all points noted above.

**Question 2, Part b, (i)**

This question asks for a description of the benefits and challenges associated with two material types in implanted medical devices. Very strong answers not only identify these characteristics but describe them clearly, showing a good understanding. A selection of some of the possible answers are included below,

**Polymers:**

<u>Benefits</u>

A very wide range of mechanical, chemical and physical properties are accessible with polymers. An answer could include details about the key controls of such properties (functional groups, molecular weight, level of cross-linking, level of crystallinity, etc.)

Polymers can achieve excellent transparency, which is not feasible with most other materials (other than some ceramics). This is due to the amorphous nature of many glassy polymers and is useful for permanent optical implants.

Polymer implants can be designed to have a controlled rate of degradation. This can be used both as a means of removing a tissue engineering scaffold, for avoiding additional surgery through slow degradation of internal sutures or in a separate application for controlled release of pharmaceuticals.

Challenges

Degradation can also be a challenge, due to a change in mechanical properties that is not always beneficial.

Polymers used in implanted devices can wear quite rapidly and release particulates around the body.

Some polymers can be very challenging to fabricate into the required shapes, e.g. UHMWPE.

**Ceramics:**

Benefits

Ceramics can include oxides, nitrides, carbides as the non-metallic component. There are also carbon or silicate ceramics and a grouping known as bioceramics, Answers can refer to any type linked to implantation.

For example, ceramics can be used in the femoral head of total hip replacements. They can withstand very significant compressive forces. Ceramics also have excellent wear properties and lubricity.

These materials are highly resistant to corrosion but bioceramics can be designed to be bioresorbable and so is less permanent for tissue engineering applications.

Challenges

A few of the challenges include, for example, the fact that ceramics are not ductile and so can be sensitive to catastrophic failure. Metals and polymers, however, can accommodate through deformation. Ceramics have a very low tolerance for stress concentrations. And have particularly poor tensile strength (compared with their compressive stress.

Biocompatibility of some carbon ceramics is now also uncertain.

Ceramics are especially difficult to machine into shape and into the right surface finish.

**Question 2, Part b, (ii)**

Systematic use of information about each individual patient to select or optimise the patient's preventative and therapeutic care

- Usually associated with genome-based knowledge for targeted treatment
- Genome-based knowledge not as useful for repair of critical tissue damage
- Personalised medicine can also include tissue engineering.

An example provided in lectures Molecular biology --> identifying bio markers to rationalise and individualise treatment

e.g. Mammaprint: Individualized metastasis risk assessment for breast cancer patients

- 70 critical genes identified and tested for using microarray chip
- Such in-vitro diagnostic tests to (i) identify presence of biomarkers or (ii) predict response to targeted therapy

**Question 2, Part b, (iii)**

As "two approaches" were requested, rather than two techniques, almost all answers considered top-down and bottom-up fabrication. However, two detailed descriptions of different nanomanufacturing techniques is also acceptable.

**Top-down manufacturing** uses traditional approaches to machining and fabrication (i.e. mostly subtractive). New tools are required to produce nanoscale structures when machining

and these include electron, x-ray, UV lithography. Lithography technique could be described here, including the mask, exposure to radiation, removal of thin polymer film and deposition of other functional materials. Nanoimprint lithography and direct-writing subtractive manufacturing by laser, gallium- or ion-beam fabrication are also valid examples to include or describe.

**Bottom-up manufacturing** relies on the spontaneous assembly of components into the shapes/structures you want. This takes advantage of surface tension forces and intermolecular forces that find their minimum energy in certain configurations. Molecules or small particles pack together in a pre-defined way and lead to nano and microstructures. These forces are dominant at the nanoscale and in some cases microscale. We design the molecular building blocks that then assemble into desired structures. This is inspired by biological systems, which are mostly driven by self-assembly, e.g. protein folding, nucleic acid complexes, plasma membrane formation, cytoskeleton assembly, etc.

A definition of personalised medicine was not requested, but for clarity it is normally defined as systematic use of information about each individual patient to select or optimise the patient's preventative and therapeutic care. It is usually associated with genome-based knowledge for targeted treatment, repair of tissue damage and tissue engineering among other applications. The most common examples of nanomanufacturing supporting this was through microfluidic sensors or lab-on-chip devices for diagnosing diseases or for mapping out the genome. An example of Mammaprint was accepted if it was clear that the reason was for the high-density arrays of sensing zones to highlight an individualized metastasis risk assessment for breast cancer patients. Acoustic sensors with MEMS devices, personalised drug delivery and many other examples were acceptable for this second part of the question.

**Question 3, Part a**

For each example company provided, it is important to give an impression of the level of product variants they were producing and the level of throughput. Very strong answers would also identify if these were constant or if there were levels of uncertainty and fluctuation.

*Some example points about British Steel:* The key variants are steel beams, billet and wire. There is a high-volume throughput (approx. 500,000 tonnes/yr) and few variants. Most of the products are made to order and on average there is a lead time of 6-8 weeks. The products are tracked throughout the process. British Steel operate continuous manufacturing to ensure the blast furnaces and the forming areas remain efficient. Production is set up by schedulers, who dictate the time and route of material/product flow. When the level of orders is not sufficient to maintain a continuous production, then parts are made for stock and sold to distributers, who take on the responsibility of selling it to end users. This is feasible because of the low variety. The layout is limited in flexibility and a result of historical developments and so covers an unnecessarily large site and is not optimised. The operations are capital intensive but not labour intensive, due to the general level of automation. In terms of their suppliers, it was noted in the answers that while coal is imported globally (Vancouver example given), otherwise they try to use locally sourced materials to reduce transport costs. This leads to a very large on-site storage of materials and inventory. The main cost reduction approach is through Lean and it is focused on reducing their waste flows. Many of which are recycled or sold. There are also low volumes of bespoke products. The lead times for these are considerably longer, require changeovers and flexibility in the lines.

*Some example points about Mars:*

High volume, there are a small range of variants, certainly not as high as observed in some companies (e.g. SMC) There is also a real volatility in demand. The operation is 24 hours a day, 7 days a week and there are 9 production lines in use at the factory in Slough. The production lines operate in semi-continuous mode and have very low flexibility, only running economically when manufacturing large runs. The combination of high volume, relatively low variety is ideal for automation, which Mars has employed. The challenge in demand prediction, means Mars must work closely with the customer but they still have the finished goods stored in the factory for around 2 weeks. The low variety in terms of the common raw ingredient of coca, means they are highly sensitive to fluctuations in price. The setup chosen to deal with the volume/variety position means there is therefore high pressure to remain efficient and so there are Kanban techniques in use in the packaging and raw materials areas and continuous improvement teams in each division.

These give an example of the kinds of points that are useful to convey. Any of the visited companies could have been included, based on the information provided in the company visit and operations management presentations and the cohort’s experiences within this module.

**Question 3, Part b:**

(b) This question guides the candidate to identify a sector where sustainability has been considered and the companies have been implementing sustainable approaches to manufacturing. The companies visited need to be named and the observations relating to sustainability included in the answer. The layout of the question was not important in terms of separating actions from reasons, it was just important that they were explained in sufficient detail within the question.

For example, the most often used example was the fast-moving consumer goods sector, which included visits to Hain Daniels and Mars. However, other answers used aerospace, primary processing and electromechanical sectors.

In the case of the most often used example, Mars were noted to have shown a very thorough approach to sustainable manufacturing. They have already achieved their target of sending zero waste to landfill, to reduce costs. Their local area is “water-stressed” and so they are aiming to cut water usage by 25% (currently managed 17%). It was noted by many that because they are a family-owned business, they have more flexibility to make longer term investments than public companies and the family are keen to make Mars more sustainable. One aspect is making the cocoa raw material more sustainable because they rely on this crop so completely. The crop is very disease prone and so Mars are funding significant levels of research on making them more resilient. Also, they aim to get all cocoa from certified sources by 2020. In addition, Mars have invested very heavily in a wind farm in Scotland and now sources its energy from this sustainable approach. Apart from the reasons above, the cohort mentioned the importance of consumer choice with FMCGs and that promoting this sustainable message will be beneficial for the brand.

In the case of Hain Daniels, they are also managing waste and energy carefully. They also have achieved their target of no waste to landfill due to cost reasons. Their approach has been to collect waste that is not possible to recycle and firstly to try and use it in the anaerobic digester they have invested in on site. This produces 80-90% of their electricity and is ideal because of the organic nature of their waste. Some of their waste can’t be recycled or go to the anaerobic digester and this instead is incinerated or used as a filler in concrete. Hain Daniels also invested in a new technology for vacuum boiling their jams. Partly this is to improve their product but also this is a major cost saver due to the significantly lower energy consumption. Finally, a note could be made of their statement to move to entirely sustainable sources of palm oil. This is mainly with a consumer-focus and brand image in mind.

Candidates noted sustainability initiatives in all the sectors and any of the valid examples were accepted.