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1. (a)
The Kaya identity is
F = P (G/P)(E/G)(F/E) where
F is global CO_2 emissions
P is population
G is GDP, so (G/P) is GDP per capita
E is global energy production, and (E/G) is energy intensity of GDP
F/E is carbon intensity of energy

F can be reduced by:
Population reduction. Voluntary birth control is now part of the debate. Significant potential impact.
G/P: reduce or reverse economic development. Not generally regarded as desirable or feasible.
E/G: reduce demand for energy. Efficiency measures (e.g. reduce waste; more efficient processes) will have the biggest impacts in industry (which consumes 35% of energy), transport (32%), housing and commercial buildings (29%)
F/E: increase low-carbon energy generation. Currently only 7% of energy comes from 'renewable' sources. Renewable vs non-renewable is only part of the energy generation impact picture, though, since (for example) the energy required to build the generation equipment may be very significant.

(b) The steel industry consumes the largest amounts of energy in the manufacture of iron and steel (mining, transport, smelting), processing (heating, forming), and transport (at every stage).
Improvements in efficiency in each stage are feasible. Currently known efficiency measures would allow 40% cut in primary emissions due to technology gains plus 20% de-carbonisation of all energy supply. These projections assume perfect implementation of all technologies.
Significant reductions in the impact of the industry require that less steel is manufactured from ore. Reduction in the amount of steel which is used is one approach, but in the short term this is unlikely to happen (would require huge paradigm shifts in de-materialisation). A more immediate measure would seek to increase not only the amount by also the efficiency of recycling (i.e. changes to the recycling process). At present, recycling involves returning steel to the purification stage of steel manufacture, so the steel is remelted and then re-shaped. This is (and always has been) embedded into the steel manufacture process, and about 40% of 'new' steel is recycled material (higher than any other metal except lead). These processes are energy-intensive. A new approach to recycling would involve re-use without melting (e.g. some construction steel from demolished buildings could be re-used with only minor re-shaping and cutting). Whether this could ever be implemented on any scale is questionable: The logistics would be very complex, and would involve radical changes to the way steel is traded and used. However, the energy benefits are significant.

(c) After the success of the ISO9000 series of quality standards, the International Standards Organization published a comprehensive set of standards for environmental management. This series of standards is designed to cover the whole area of environmental issues for organizations in the global marketplace.

Version: Final

ISO 14001 is not a set of regulations but an internationally recognized standard that defines the criteria for a management system for developing and controlling those aspects of a firm's operations that can have an effect on the environment.
ISO14001accreditation requires an Environmental Policy to be in existence within the organisation, fully supported by senior management, and outlining the policies of the company, not only to the staff but to the public. The policy must be written in non-technical language. It needs to clarify compliance with Environmental Legislation that may affect the organization and stress a commitment to continuous improvement. It should provide an overview of the company's activities on the site and a description of those activities, and a clear picture of the company's operations.
Topics which the Policy might be expected to cover include environmental: management systems, auditing, performance evaluation, labelling. Some companies might refer to product ife cycle assessment and environmental aspects of product standards.

The main arguments put forward for a company seeking first compliance with ISO14001 and then accreditation are related to the media, public recognition and international trading. Improvements in environmental performance should occur, but such moves are rarely driven by altruistic 'green' motives: ultimately, financial aspects dominate most company operations. The media have a powerful voice which can endanger a company:
"In the fish-bowl environment created by the media, it may be in your firm's best interest to take a proactive stance, first toward conformance and then toward certification to ISO 14001. It may not make the media go totally away, but it will provide objective evidence that your management is committed to protecting the environment. Also, from a pure business view, conformance to the requirements of ISO 14001 may provide a competitive marketing advantage. It also provides your firm a proactive approach to risk management.
The majority of the benefits of conformance to ISO 14001 can be realized by a company without going the extra step of certification. However, there are two benefits that can only be realized by certification. These are: entry into controlled markets and public recognition. If you want to do business on an international level, it is likely certification will be a requirement. Even if your business is all domestic, certification and the accompanying public recognition may provide your firm with a marketing advantage. The risk you face is that your competition may obtain this advantage before you do."

Examiner's comments: Most people had engaged well with the material and produced a competent answer for at least one part of the question. The best demonstrated a good critical understanding of many of the issues. Weaker answers had low factual content and relied on emotional responses and general statements.
Marks /20: Max: 18; Min 7 Mean 12.1

2 (a) (i) A tissue engineered implant will typically have the following components: biological cells and a scaffold to support the cells initially. It can also potentially contain a stimulatory chemical component (which can be coupled to the scaffold) such as signalling molecules or growth factors. Autologous cells are those that come from the patient's own body. There are two advantages of this: one, there is no risk of immune rejection from the cells since the body would see them as "familiar" instead of "foreign"; two, there are no ethical quandaries associated with the use of the cells since they do not come from a separate source, who would have to consent to the use of their cells in another patient's body. A potential disadvantage is to the patient himself or herself, in that the cells have to be harvested in a separate procedure and expanded in culture, and there is thus an additional cost to the procedure and potential complications (e.g. infection) at the site of the other surgery.

(ii) There are currently only two types of tissue-engineered products that are FDA/EU approved and commercially available. The first is only peripherally a tissue-engineered product, as it is solely an autologous cell transplant from healthy cartilage within the joint to a defect. Thus, there is no scaffold. The second is monolayer or bilayer skin-like materials, where the cell source is fetal foreskin fibroblasts from donor tissue. The LigaNew product is a hybrid of these two, in that it contains autologous cells but there is a polymer scaffold (as in the skin-type product). As no such product is currently on the market, the challenges associated with commercializing the product are greater. However, the market analyses have shown that the potential is also great and thus this is a high-risk, high-reward prospect.

(iii) Prior to sale of any implant, there is a process of regulatory control that varies depending on the country, although the general conditions of the process are similar. The implant is typically developed in a research environment, where studies are done in vitro and in animal models to assess the biocompatibility and efficacy of the implant. The implant is then brought into limited clinical trials, to test the performance of the implant in a human context. This is regulated closely, for example, in the US, the FDA has to authorize an "investigational device exemption" allowing the device to be implanted into humans without it having been fully approved yet. There is an important review of ethical issues to do with any implant before it is used in the human body. Success in limited clinical trials leads to more extensive clinical trials, and eventually an application to the appropriate regulatory authorities in the US and EU prior to clearance for sale.

The process is different in the US and the UK in both philosophy and in details of execution. The duration and rigor of the examination process for the implant depends on the risk it presents to humans, and the existence of a comparable product in the approved implant market. In the US there are three categories of risk in order of increasing risk: class I, class II and class III. In the EU, class II is subdivided into class 2a and class 2b. Long term implants, as would be expected for this tissue engineered replacement, are high risk and considered class III; further, there is little precedent for the approval of such implants such that the approval process will be more rigorous than that for an established class of medical device.

The philosophical difference between the US and EU is that in the US the implant must be proven to be efficacious (beneficent) while in the EU the emphasis is on safety and process control (non-malificence). The governmental body, the FDA, in the US must approve all implants for sale, while in the EU authority is not centralized but is delegated to a "notified body" which is an independent and private organization with authority to grant the CE mark, which approves the device for sale. The FDA procedure is based in federal regulation while the EU process relates to voluntary standards.

Further, and this is critical, because tissue engineered products contain living cells, the existing medical device regulations—designed for non-living implants and devices—have been found to be insufficient for regulating these products. There are thus new rules in both the US and EU. In the EU the new rules only came into effect in 2008, so they have not been tested or used very much yet!

(b) There are three types of polymer-based drug delivery systems, in order of increasing complexity:

(1) Diffusion-controlled
(2) Swelling-controlled
(3) Erosion-controlled

Diffusion-controlled systems rely on simple diffusion of a drug through polymer and the kinetics are controlled completely by Fick's second law. As such, the drug released is proportional to the square root of the diffusion constant and the square root of time.
There are four sub-cases for diffusion-controlled devices, based on (a) whether the device is monolithic or a "reservoir" system and (b) whether the device is a planar object, such as a patch (nicotine patch) or a spherical object, such as an ingested or implanted microsphere. A further sub-classification is related to whether the drug loading is initially smaller than or larger than the solubility of the drug in the polymer—if larger, some of the drug is present in aggregates and must break up before diffusing out.

Swelling controlled systems are particularly useful when the diffusivity of the drug in the polymer is very low. Water enters the pore spaces in the polymer, opening them up (causing swelling) and the swelling enhances drug diffusion.

Overall the behavior is controlled by two competing diffusivities:
(1) Diffusivity of drug in the polymer (as in diffusion controlled systems, above)
(2) Diffusivity of water in the polymer (to give rise to swelling)

A semi-empirical expression for the drug release shows this enhanced drug release compared with pure diffusion-controlled systems: cumulative drug released M_t = constant*t^n

In pure Fickian diffusion, n = 0.5 as noted above
if swelling enhanced diffusion, n = 0.5 to as high as 1 for the case where the effective diffusivity of the drug in the polymer increases linearly with time, $D = D_0 + constant*t$

In erosion-controlled drug delivery systems, we see an additional parameter added to the two diffusivities, resulting in a complicated system with three key parameters:
1.Diffusivity of drug in the polymer (as in diffusion controlled systems, above)
2.diffusivity of water in the polymer (as in swelling controlled systems, above)
3.hydrolysis reaction rate (k)

The second and third of these, the water diffusivity and the hydrolysis reaction rate, are what trade off to determine whether surface or bulk erosion is dominant. The kinetics of drug delivery are sufficiently complicated in this case to eliminate the potential for simple analytical models of drug delivery, and typically stochastic approaches such as Monte Carlo simulations are used to create drug release-time profiles for erosion-controlled systems.

Examiner's comments:
Most candidates showed good understanding of at least some parts of the question, although the technical detail was a bit thin in places. The section on regulatory approval was particularly well-answered.
Marks /20: Max: 17; Min 3; Mean 11.8

3.

Students were expected to describe the practices observed in the visits to Marshall Aerospace and Rolls-Royce as examples from the Aerospace sector, and in Jaguar Land Rover and Prodrive from the Automotive sector.

HR practices can be grouped under Recruitment and Training, Remuneration, and Employee Relations (see the Generic Visit Themes and Topics document issued as part of the guidelines for student visits).

Table A attached summarises the practices reported in the visit debrief presentations.

In the second part of the question students were asked to consider the extent to which any differences might be company specific or whether there are characteristics relating to the business sector which influence these differences. This requires critical comparative analysis of material reported in the debrief sessions, stepping back from all the detail and trying to see bigger and more generic patterns.

One possible view is given in Table B, see attached This suggests that in the aerospace companies there are strong sectoral influences, principally driven by the need for quality standards, with some company specific differences eg the strong family culture in Marshall. The automotive sector however is very diverse, so sectoral influences are less important and individual company difference are more pronounced.

Examiner's comments:
In describing HR practices, most students wrote about all four companies. Since each student had visited only two out of the four companies they were relying on discussions in the debrief sessions and reports from the other half of the student group. The level of knowledge was generally good, although understandably the facts were generally more secure for companies which the candidates had themselves visited. There was tendency to focus on recruitment and retention – in some cases to the exclusion of all else.
The second part of the question required analytical thought and a level of abstraction which most found difficult. Answers tended to be too focused on specific company operations, and candidates could not say much about sector issues. In many cases, the large company / small company differences were regarded as more significant then sector differences.
Marks /20: Max: 16; Min 8; Mean 11.8

Table A **Describe the HR practices observed in the Aerospace and Automotive companies visited**

Company	Recruitment, training	Remuneration	Employee relations
Aerospace - Marshall	High skills Some increase in semi skilled work Long service – not always a plus! Training focus – incl apprentices Multi skilled, flexible	Not high pay Appraisals and bonus Special deals on cars Conscious of lower labour costs abroad	Shop floor unionised but placid paternalistic
Aerospace – R-R	High skills Formal training schemes Apprentices Graduates Leadership Masters programmes Individual performance management	Annual bonus opportunity Sharesave scheme – Buy shares with bonus and/or salary	Shop floor self directed teams Shift work RRPS determines everything – can be demotivating Corporate story board – interactive group wide briefing
Automotive - Prodrive	Strong brand and profile – high applications Headhunting within the industry for managers	All employees are salaried – to reflect need for totally flexible hours	Highly motivated employees – passionate about motorsport Can do mentality Recent redundancies – loss of Subaru contract
Automotive – Jaguar Land Rover	Multi skill training on shop floor – to cover absences Education available for promotion Still recruiting undergrads and grads No prod staff recruitment in 5 years Non prod days used for training – good morale, avoids lay offs	Issue is coping with down turn – Voluntary redundancy prog Sabbatical programme Pay freeze Reduced working week Non pay rewards – eg test drive new cars	History of poor relations under Ford – Tata more hands off Recognise people are key Strong union - Unite Shop floor chart to register morale issues

Table B Discuss whether the differences observed are a function of the individual company or relate to the sector as a whole.

Aerospace	**Automotive**
Sector ***Strong*** sector influences - Driven by the importance of quality standards, so… Hierarchical structures Bureaucratic processes – traceability Professional training at all levels – high technical content Long time scale Relatively slow pace of work	**Sector** ***Some*** sector similarities both coping with down turn – redundancies JLR more creative in avoiding lay-offs. Poss union influence
Company ***Some*** company differences: Marshall family owned Almost paternalistic culture Several generations from the same family R-R – large corporate More formal schemes	**Company** ***Strong*** company differences Prodrive – Founder influence still strong Employees are highly motivated enthusiasts Easy recruitment Maximum flexibility in working practices – multi skilled Salaried – not linked to hours or output – work under pressure to get result Non union Jaguar Land Rover large corporate large numbers of semi skilled workers strongly unionised