FINAL ASSIGNMENT

Choose one of the following case studies to develop a comprehensive presentation about the development of medical devices applied for tissue regeneration and diagnostics.

Case Study 1: Design of a medical device to replace pathological liver

You are employed by a company who has recently discovered a novel peptide system that seems to have cell adhesive properties. Your company is currently in the process of patenting this invention as they see significant potential for using it in tissue engineering applications. One of the scientists has suggested that the patent be targeted to a specific application and after lengthy discussions, it has been decided that the liver will be the target tissue. You have been placed on a team to research the issues surrounding the development of artificial liver substitutes for treatment and monitoring applications. There are several issues that will need to addressed. Your team will need to make a presentation to the company's board of directors to discuss your findings and make a recommendation for the purposes of patenting and future development.

- Discuss the design process required for the fabrication of the innovative medical device.
- What are the issues that will need to be addressed in moving this system forward?
- Discuss one risk management procedure to be implemented as well as preventive action.

Case Study 2: Design of a medical device to replace scar with skin.

You are working under a very tight budget due to your company’s efforts to survive the recession. You are asked to develop a device for regenerating skin in patients who have scars in their skin. Each scar will be removed surgically and your new device will be grafted on the freshly generated skin wound for treatment and monitoring purposes. If your device works, skin will be regenerated at the site of the former scar.

- Discuss the design process required for the fabrication of the medical device.
- What are the issues that will need to be addressed in moving this system forward?
- Discuss one risk management procedure to be implemented as well as preventive action.

Case Study 3: Design of a medical device to replace tendon rupture.

You are hired by a medical device company which is interested in tendon regeneration using collagen-Glycosaminoglycan (GAG) scaffold. You are asked to develop a biomimetic device for regenerating tendon in patients who suffered from tendon ruptures. To enhance tissue regeneration and monitor its progression, it has been hypothesized to functionalize the developed scaffold with TGFβ1 that binds extensively on the large surface of the highly porous collagen-GAG scaffold. It will be assumed that bound TGFβ1 is unavailable for regulation of cell function and that only unbound, or "free", TGFβ1 is involved in cell regulation. You are a researcher exploring the consequences of this new finding with the objective of using this fact in the design of new biomaterials-based approaches to regeneration.

- Discuss the design process required for the fabrication of the medical device.
- What are the issues that will need to be addressed in moving this system forward?
- Discuss one risk management procedure to be implemented as well as preventive action.

Case Study 4: Design of Nanoparticle system for the therapy of tumor brain metastases.

You have won a position in an institute whose main research activity is related to the development of new strategies for cancer therapy. You have been asked to design nanoparticles-based drug delivery systems to be used for this purpose in mice preclinical models who suffer of tumor brain metastasis. Your supervisor proposes to functionalize the nanoparticles system with siRNA that act against one of the genes that promote tumor cell proliferation. Moreover, the brain target marker where the nanoparticle system should be delivered has to be defined. Of note, the whole designed system must be tracked.

- Discuss the design process required for the fabrication of the nanoparticle system.
- What are the issues that will need to be addressed in moving this system forward?
- Discuss one risk management procedure to be implemented as well as preventive action.

Case Study 5: Design a Multi Organ-on-a-chip system for diabetes treatment.

The limitations of animal and conventional in vitro models have prompted researchers to develop alternative approaches including Organ-on-a-chip (OoC). You work in a company which planned to develop a new multiorgan microfluidic system to assess the efficiency and the side effects of a new patented anti-diabetic drug (ADD156478). Diabetes is a multiorgan syndrome whose chronicity might affect the cardiovascular system and the kidney functions. Your team is asked to develop a functional multiorgan chip which can provide information regarding the pharmacodynamics (PD) and pharmacokinetics (PK) of this new Green fluorescent protein-(GFP)-labelled drug (ADD156478). Of note, ADD156478 has been projected to be orally administered.

- Discuss the design process required for the fabrication of the OoC system.
- What are the issues that will need to be addressed in moving this system forward?
- Discuss one risk management procedure to be implemented as well as preventive action.

Case Study 6: Design of implantable prosthesis to replace bone defect.

You have been hired by a firm to assist in the development of biomedical device designed to regenerate femoral fracture. Bone is to form within the pores of the device and thereby form an interlocking bond with the prosthesis (bone ingrowth for biological fixation). Since the goal is to accelerate the bone ingrowth process, your boss has suggested that certain regulators be incorporated into the device in some way to be released after implantation. It has also been suggested that the bone ingrowth process will proceed more rapidly if new blood vessels are encouraged to also invade the pores of the material.

- Discuss the design process required for the fabrication of the medical device.
- What are the issues that will need to be addressed in moving this system forward?
- Discuss one risk management procedure to be implemented as well as preventive action.

Case Study 7: Design of Nanoparticle for regenerative medicine application.

You are at your second year of postdoc at the University of Pennsylvania and you are working on a project based on the use of mesenchymal stem cells (MSCs) for the regeneration of lung fibrosis. Your boss has recently won an important grant and wants that you start to develop an innovative nanoparticles (NPs) system to implement the uptake, the delivery and the regeneration of the target tissue. Your task is to find the best way to improve the NPs uptake in MSCs by maximizing the immune/phenotypic compatibility, thus avoiding any immune rejection. Similarly, NP should possess active immunomodulatory and anti-inflammatory actions and be released from MSCs only on the target site (lung). Of note, MSCs already have the ability to home in fibrotic lung. Develop this task keeping in mind that future aim is using this system in human pre-clinical study (tracking system).

- Discuss the design process required for the fabrication of the nanoparticle system.
- What are the issues that will need to be addressed in moving this system forward?
- Discuss one risk management procedure to be implemented as well as preventive action.