Transforming Biomaterials into Novel Therapies… from Science to Entrepreneurial Startups

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Introduction

The field of biomaterials encompasses a broad array of materials and technologies used to improve patient's lives. Over the last 20 years, the field has expanded well beyond its traditional scope of materials adapted or created for structural or surgical repair, such as artificial joints, cardiac stents, and wound sutures, to include cutting edge technologies such as nanoparticles, bioerodible polymers, wireless implants, and even viruses.

One particularly exciting area of growth is the application of biomaterials science to therapy delivery. Therapy delivery is a broad concept comprising technologies that address numerous aspects of patient care. For example, therapy delivery can include materials designed to control the release of a pharmaceutical drug, segment of DNA, or other substances to a patient, but it may also include sensor technologies that help determine the timing or type of optimal drug therapy.

Discussion

A common goal of therapy delivery is to get the right amount of a pharmaceutical drug to the right place at the right time for the right duration. As new drugs become more potent, targeted, and complex, the importance of technologies designed to maintain drug stability and precisely control the delivery of those drugs to the body increases. Therefore, an unmet need exists for novel biomaterials and devices that can: (1) store one or more drugs, (2) protect them from the body until they are needed, and (3) controllably release the right dose of each drug at the desired time. Advances in microfabrication and hermetic sealing technologies have enabled the creation of multi-reservoir drug delivery systems that address these needs. Precise control over the release of drug from each reservoir is enabled by novel formulation techniques, the application of outside energy sources such as lasers, and/or the use of pre-programmed microprocessors or wireless telemetry. The direct or indirect integration of biosensors can help optimize therapy by providing guidance on the timing or amount of drug required. The development of such a wireless, multi-reservoir drug delivery implant (Figure 1.) provides a good context for the subsequent discussion of both the excitement and challenge of moving cutting edge science from academia to industry.

Figure 1.

Biomaterials discoveries must be turned into products before they can begin to benefit patients, and startup companies have proven to be an effective way to quickly translate scientific and technological discoveries into new medical products. This talk will address some of the challenges faced by entrepreneurs and academic researchers involved in creating and managing innovative startups and will include examples of companies developing novel technologies to address various aspects of therapy delivery. Perspectives on defining the product's value proposition, dealing with difficult technical or personnel issues, raising capital, predicting timelines, conducting clinical trials, and navigating the regulatory process will be discussed in the context of one therapy delivery startup company.

Future Directions

The next 5-10 years will bring significant advances to the field of therapy delivery. New drug molecules designed to specifically target key disease pathways or that are selectively activated in response to the cellular or tissue microenvironment will require drug delivery systems capable of protecting and delivering such drugs. In addition, new noninvasive sensor technologies will greatly expand the health monitoring capabilities of mobile devices, enabling the transition of the nascent field of mobile health ("mHealth") into an integral part of our future healthcare system.