Experiential Learning in Tissue Engineering

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Student-centered and active learning instruction has been shown to be an effective pedagogy. Although there is currently not a consensus of the skill set necessary for BME graduates, particularly in tissue engineering, there is some agreement. There have been workshops and sessions at SFB on this topic as well as research groups (e.g. VaNTH) trying to determine core competencies for BME graduates. The goal of the instruction strategy described here is to use student centered experiential learning to teach some of the key competencies claimed to be necessary for BME students to work in biomaterial/tissue engineering such as working in teams, communication skills, and understanding the regulatory and business sides of the medical device industry.

Methods: At UAB students get exposure to tissue engineering in a biomaterials course as juniors, labs in the senior Living Systems Analysis course, a senior tissue engineering elective course, and two courses with experiential learning where students can choose tissue engineering projects. The goals of this experiential learning is for students to understand the key steps in taking a medical device from idea to the product launch phase. This is broken down into two parts: the business side and the regulatory side of medical devices.

The business side is covered in a class that is a mixture of graduate students and seniors. This class has evolved into the first semester of senior design and is therefore a required class for undergraduate BME students. This 16-week semester course aims to have students understand the process of developing a medical device into a profit center with student teams acting either as a start up company or a project team within an established company. Although the course leads up to a business plan and presentation to solicit funds from investors or their company, additional emphasis is placed on the product design than would normally be required for a business plan. The course meets 2 times per week with one class period to explain and provide guidelines on the next assignment and the other period for the student groups to turn in and present the assignment.

The semester begins with an overview of the design process and each student selects a device and briefly describes it to the whole group with emphasis on the marketability and profitability of the concept, in the 2nd week of class. By the end of the 3rd week the students have selected or are placed in groups (3-4 members) based on interests and have narrowed down the ideas to one device. They are then given examples and guidelines on how to do a product specifications; presenting and turning one in the 4th week. This pattern is followed in subsequent weeks through the first half of the class with patent claims, market research, and a commercialization plan with time-line. At this point, a few weeks are spent on the economics of a business plan. During this time, the students are also given information and guidelines to complete a design specification (due the 10th week) as well as the economic analysis for a business plan (due the 11th week). Each assignment is graded and turned back at the next class and student teams have the opportunity to revise the assignment based on feedback and turn it back in (multiple times, if desired) to improve their grade. The student teams now take the previous assignments and put them together for a business plan (due and presented the 12th week). The students are then instructed on strategies to present their business plans to potential investors or company executives. The goal being to raise funds for their start-up or convince their company to continue to fund their project. The student teams present in class during the 14th week and with feedback present at the weekly BME seminar during the 15th week of class; getting feedback from the entire department on device design and presentation skills. For the 16th week each student team puts together an ethics paper on the compromises they made in determining the company strategies and how they are related to the professional engineering code of ethics.

The other class is a graduate course/senior elective on tissue interactions. It is divided into 3 parts: histology and pathology; biocompatibility responses, and the medical device regulatory process. The 3rd part is the experiential learning, although it actually covers about half the semester. It works similar to the other class in that each student selects a device and presents it to the whole group the 6h week. They break into groups of 3-4 and pick one device by 7th week. They are then given examples and guidelines on how to do a product specifications; presenting and turning one in the 8th week. This pattern is followed in subsequent weeks with animal testing approval, IRB approval, hazard analysis, an IDE, and a quality assurance plan. Similarly, each assignment is turned back at the next class and student teams have the opportunity to revise the assignment based on feedback and turn it back in (multiple times, if desired) to improve their grade. The student teams then take the previous assignments and put them together for a 510K document with a summary of what would be different, if they would have to submit a PMA instead.

Results: In the second class all students select a biomaterial/tissue engineering product. In the other class they have that option, with at least one team in each class having done so. In both classes, students see what is required to complete each task, whether or not they have the time to get to the final finished form. They also see that the more they put into it the more they get out of it. Although no one has started a company yet, many of the ideas have been patentable and a few groups have gone that route. In addition, a few student groups have taken their idea and made workable prototypes for the second semester senior design class.