A Multidisciplinary Biomedical Product Development Course Incorporating Entrepreneurial Thinking

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Statement of Purpose: The goal of this presentation is to share one method of incorporating biomaterials and entrepreneurship concepts into a bioengineering course. Biomedical Product Development is a multidisciplinary course taught in the mechanical engineering department at the University of Kansas. The course is open to senior or graduate students from any discipline.

The goals are to learn: 1) critical research and development steps required to develop an invention into a marketable product; 2) regulatory issues; 3) quality system control documentation required in medical device development; 4) product feasibility and commercialization processes; and 5) the business aspects of starting and sustaining a company. In this project-driven course, biomedical product inventions by faculty and small businesses were brought into the classroom for examination by teams of students. The inventions were at various stages ranging from initial conceptualization to prototype.

Methods: In the first offering of the class, thirty-four students from various areas of engineering, industrial design, and business enrolled. Nine teams were formed to examine and explore initial development of six inventions from faculty and three inventions from small regional businesses. Lectures on subjects such as general product development processes, regulatory issues, and basic biomaterials and biomechanics were made in the first half of the semester. Limited homework was also assigned only in the first half of the semester; homework examples included exercises to force students to explore the FDA website to predict device classifications and find guidance documents, practice product development concepts using everyday items, and selection of biomaterials for various medical devices.

Team deliverables included (1) keeping a bound notebook detailing all steps in development process, (2) preparation of a preliminary Design History File including Design Input, Risk and Verification documentation including a Failure Modes and Effects Analysis, (3) development of a business plan for a small company started around the invention, (4) a mock NIH Fast-Track SBIR proposal, complete with a commercialization plan, and (5) a presentation of the concept to a panel of real Venture Capitalists.

An engineering faculty taught the course in collaboration with the university Director of Technology Transfer and a Business School graduate teaching assistant. Students in the course were required to attend the KU Entrepreneurship Thematic Learning Community (E'ship TLC, http://eship.engr. ku.edu/) to supplement business, intellectual property, legal and ethical topics. In addition, a Kauffman Foundation Venture Planning workbook was used to provide students with additional insights into the business planning aspects. Individual behavior assessments through DISC analysis were done for the students; though not required, all students shared these assessments with their team members.

In the second half of the semester, students did not meet for lecture. Teams met weekly with the instructor to go over their project progress, including inspection of documents and notebooks. Students were required to present oral progress reports to their classmates and submit drafts of the NIH SBIR proposal three weeks before the final due date.

Results / Discussion: Most teams worked effectively to produce moderate quality assessments of the product inventions, though some teams had difficulty addressing the deliverables even with substantial guidance. Two teams produced such high quality deliverables that part of their work could be used (with permission) by the faculty inventors in preparation of SBIR proposals. After receiving the deliverables regarding his invention, one faculty inventor started a company centered around the invention. By the end of the course, all students appeared to grasp fundamental concepts regarding the critical role of biomaterials selection on the engineering, financial and regulatory factors in medical product development. Student evaluations were very positive. It is hoped that this type of experience will positively influence students' outlook toward scientific research and their interactions with industry partners.