Entrepreneurship in Biomedical Engineering, from Classroom to Corporation: A Model and Case Study

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***Abstract* – Background: A biomedical engineering project was executed by a team of 3 students during a two-semester Senior Design course. Students learned and honed skills in entrepreneurship to identify and solve and unmet clinical need in pain management. Purpose: To enhance the educational experience for biomedical engineers by bringing entrepreneurship into the classroom. Methods: The course provided lectures and exercises that enabled students to successfully execute the discovery and concept development processes, then build and test a working proof of concept. Students were guided through exercises to assess clinical and market needs, and technical feasibility. Industry practices in project management were introduced and applied in execution of the prototype build. The student team was required to collaborate with a physician; an initial meeting was facilitated by the instructor and subsequent meetings were managed independently by the student team. Results: The students wrote and filed a patent with assistance from the University Research and Enterprise Development Office (URED). A human clinical trial was performed. An extramural investment was obtained and a medical device corporation was established. Students remained involved; one student became chief engineer in the corporation. Conclusion: Students can learn and execute successful entrepreneurial projects from within the classroom.**

Index Terms – Biomedical Engineering, Entrepreneurship, Senior Design, Project Management, Start-up Company

BACKGROUND

The Biomedical Engineering Senior Design Course at Stevens Institute of Technology has been designed to teach and train students about entrepreneurship and project management in biomedical design.

The first semester of the two-semester course required that students conceive of a valid technology solution to an unmet medical need. In this period, students were introduced to and guided through a discovery process. The most critical aspect of this process was for students to obtain and manage the "voice of customer" (VOC). To ensure this, students were required to collaborate with a clinical advisor in addition to their faculty advisor.

During the second semester, students were required to build and test a working "proof of concept". In this phase, it was most critical that the biomedical engineering student teams remain focused upon execution of primary concept objectives. Students were taught how to implement professional project management practices to ensure that they remain "on track".

Specific deliverables were required by the students; these were measured as grade point milestones. The deliverables were devised as a sequence such that students were guided through a learning and training process in entrepreneurship and project management in biomedical engineering design.

METHODS

I. Project Scope and Definition

At the beginning of the course, the Instructor described all course requirements and objectives, and presented some example projects. The students were given the option of selecting a project supplied by the Instructor, or to develop one of their own, provided that an appropriate clinical advisor could be identified.

The students were then directed to form teams consisting of either 3 or 4 students. They were advised to join a team with classmates who had similar project interests. Once the team was formed, the teams selected their team leader and team name.

Students Jeckin Shah, Ryan Stellar, and Daniel Silva chose to work together because they had a similar interest in developing their own project involving an electrical device to assess physiologic function. They joined to form "Team MECCo".

The student teams were given approximately three weeks to research their ideas and prepare a preliminary concept, including some design options. They also prepared an assessment of technical and clinical feasibility and market position. The teams presented their projects in the fourth week in the form of a non-graded "practice proposal

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presentation". Faculty advisors listened and critiqued their projects.

As a result of this process, Team MECCo realized that while their concept was technically feasible, it would not be feasible to implement clinically, and had to abandon the idea. This is a very important experience of the discovery process. Though they had to "drown their puppy"[1], the students effectively applied Stage Gate[1,2] and Design Review[3] principles to halt further investment in the concept.

The Instructor and Team MECCo brainstormed for some new and technically related idea. At that time, the Instructor was introduced to Dr. Norman Marcus, a renowned pain physician from NYU Medical Center. Dr. Marcus expressed a need for a handheld electrical device to complement his muscle pain diagnostic method.

The Instructor determined that Dr. Marcus' requirements defined a reasonable scope for a senior design project for Team MECCo. The Instructor then facilitated the first meeting between Dr. Marcus and Team MECCo. The students traveled with the Instructor to Dr. Marcus' office, where Dr. Marcus performed a demonstration, and a "kick-off" meeting was held.

The meeting was structured in this manner to provide the students with very significant clinical and project management experience. This was crucial experience for effective concept development. By visiting the doctor's facility, they gained insights into the capabilities and limitations of a clinical practice. This gave the students an opportunity to observe, first hand, the needs of the primary stakeholders. The kick-off meeting provided the students with their first opportunity to communicate directly with a physician as biomedical project engineers. They practiced their skill of communicating with a physician by applying their academic training, and learned where bridges in expertise were required to facilitate a collaborative agreement upon the primary concept needs and objectives.

II. Execution: Routine Disciplines

Each student dedicated approximately 8 hours per week to their project. Class meetings were held twice per week for two, 2 hour periods. The remaining hours were divided into individual work and team work as needed.

While certain deliverables were required on a routine basis throughout the entire course period, (Table I) several specific deliverables were defined for each semester (Tables II-III). The deliverables were reviewed and graded by the Instructor. The grade and comments served to steer the students toward a successful path in their project execution.

TABLE I
ROUTINE COURSE DELIVERABLES

Item No.	Milestone	Period Due
1	Maintenance of a current lab book	Checked Weekly
2	Written "Action Plan"	Weekly
3	Team meetings with faculty advisor	Weekly
4	"Project Review Meeting" presentation	Monthly
5	"Clinical Advisory" meetings	2-3 times per semester

Practices in entrepreneurship--as well as in project management that are applied successfully in industry--were established and taught via the execution of these course deliverables.

Each student was required to maintain a lab book, and was shown how to record their notes, and properly sign and witness them. They learned that this discipline was tantamount in the protection of their intellectual property. While team MECCo was writing their patent, they learned just how critical this practice was. In the due diligence process, their notes successfully defended their contributions to the patent, as well as the patent content.

The weekly team meetings with faculty advisor served as an informal Stage Gate and Design Review process. Students were introduced to these formal processes during class lectures, and the weekly meetings reinforced these concepts, serving to develop the student's individual rationale or "intuition". Team MECCo continued to adhere to this process diligently as they developed their design concept, resulting in very effective management of priorities which enabled them to complete a good working proof of concept device to Dr. Marcus by February of the second semester.

Team MECCo continued communication with Dr. Marcus on a regular basis. Note that this did not demand a lot of time on the part of the physician. Students met with the doctor only two or three times per semester, but maintained e-mail communication regarding design decisions. Their regular "Clinical Advisory" communication enabled them to maintain the VOC in their design. Specifically, MECCo was able to address circuitry and ergonomic issues that would've rendered the first prototype concept too cumbersome for clinical practice.

The student practices in routine communication served to provide for appropriate opportunities to assess and maintain priorities, and to verify critical project requirements. Entrepreneurs are most successful when they remain focused upon their primary objective to execute tasks swiftly. The routine communications also enable the students to readily identify errors and perform corrective actions, thereby preventing delays or excessive resource demands that severely jeopardize the success of the project. Often times, critical errors are made due, simply, to incomplete and/or ineffective communication.

Team MECCo applied these practices to effectively review technical design parameters, clinical requirements, commercial development direction, while completing their project within the required period. This enabled them to deliver their device within a window of opportunity for Dr. Marcus to present it with his Grand Rounds and on national network news. (Grand Rounds is when an expert physician formally presents his clinical methods and results to his peer physicians).

III. Execution: Semester 1

By achieving the milestones outlined in Table II during the first semester, the students were guided through the discovery and concept development process.

TABLE II
COURSE DELIVERABLES DURING SEMESTER 1

Item No.	Milestone	Week Due
1	Problem definition	3
2	Market assessment	4
3	Preliminary intellectual property review	5
4	"Mission Statement"	5
5	Concept design	6
6	Mid semester "Formal Proposal"	7
7	Draft "Invention Disclosure"	13
8	Formal "Execution Plan"	14

Entrepreneurship in biomedical engineering requires that a technical solution be well matched to an unmet clinical need. While engineering students are well studied in technologies, they must apply their technical solution in a manner that is useful to the clinician. This requires that they recognize and understand the stakeholder's needs and expectations. (A stakeholder is anyone who influences the decision to use the product, e.g. doctors, patients, manufacturer's, financiers, etc.). During their concept development, students were guided through exercises and class lectures which include "lessons from industry" to help them learn to integrate entrepreneurial decisions with their technical evaluation.

The students were directed to focus upon defining and solving an unmet clinical need. Emphasis is placed upon assessing clinical needs compared with technical needs. Students determined market size and value, and performed a preliminary search of Intellectual Property (IP) to assess competitive solutions. They were then trained to prepare a "Mission Statement" by describing how they planned to "save lives and reduces costs and/or make money".

With guidance from their faculty advisor and Dr. Marcus Team MECCo prepared their Mission Statement aptly recognizing that many patients suffer pain even after treatment, perhaps due to the need for more accurate diagnosis. They further performed some basic research in readily available business and medical related publications to learn that "the pain market is 100 billion dollars annually in the US and that back pain affects 3 out of 4 people in their lifetime".

Later in the semester, the students prepared a "Draft Invention Disclosure" based upon their research and concept. At Stevens Institute of Technology, the policy was that students retain their rights to their intellectual property, but may elect to submit their Invention Disclosure to the University Research and Enterprise Development office (URED) in the Institute for assistance in furthering the development of their invention. A standard policy for exchange of rights and compensation to the inventor were in place for consideration by both the student team and the Institute. Later in the year, students used the Invention Disclosure as a basis for the presentation.

At the end of the first semester, students were required to submit a formal "Execution Plan", which outlined their proposed activity for the second semester. The Execution Plan included a detailed design, Bill of Materials (BOM), 14-week schedule, and a description of test methods. Note that students were guided by "critical path" scheduling—which were most useful to them—and Gantt chart scheduling was optional.

IV. Execution: Semester 2

During the second semester, exercises and milestones were provided to train the students in tactical aspects of entrepreneurship and project management. This semester was designed to represent the "product development" processes that are applied successfully in industry. In these processes, design details are implemented and reviewed for technical and commercial feasibility.

TABLE III
COURSE DELIVERABLES DURING SEMESTER 2

Item No.	Milestone	Week Due
1	Completed materials order	1
2	Scientific Abstract	3
3	Detailed test protocol	5
4	Working "proof of concept" prototype	8
5	Recorded "Invention Disclosure"	8
6	Poster presentation	9
7	Evaluation of test results	12
8	Participation in "Senior Day Exhibition"	13
9	Final report	14

To achieve growth and development into new areas, entrepreneurship often requires the creative use of resources which are not necessarily available within the company. Frequently, resources are "borrowed" e.g. via consultants and outsourcing, rather than acquired. Students learned to find help from other faculty outside the department, or from corporate or clinical mentors to execute their projects.

Upon completion of their project, the students exhibited their device at a "Senior Day Exhibition". In past years, this program had been structured as a scientific poster presentation. Team MECCo greatly enhanced their presentation by presenting their device and a video demonstration of it in use on a patient. Their video also included the news clip that was aired on a major network television station a month earlier. The URED office of Stevens Institute of Technology invited several local media, potential investors, and financiers to attend the exhibit. Team MECCo had the opportunity to deliver their "elevator pitch", and discuss commercial development opportunities with the invited guests.

The students prepared a final report summarizing their project and included recommendations for future work and direction. They were instructed to describe any suggested product improvements and include their rationale. This activity represented another step in the Design Review and Stage Gate processes.

All student projects were treated as if they might be fully commercialized, therefore, for those students who did not commercialize their design, the experience during the class was no different.

RESULTS

Upon completion of building and testing, Team MECCo delivered an original working "proof of concept" prototype to Dr. Marcus in February of semester 2. Dr. Marcus tested the device and provided positive feedback, and also suggested some improvements. Before the completion of semester 2, the students delivered a 2nd prototype, based upon Dr. Marcus' feedback. That prototype was used to perform a human clinical trial at NYU.

Team MECCo prepared and presented their Invention Disclosure. They subsequently wrote and filed a patent application on behalf of themselves and Dr. Marcus, with the assistance of the Institute's University Research and Enterprise Development office.

The student team received the University President's Technogenesis® award which recognized them as having the best entrepreneurial project out of approximately 60 senior design projects in the Institute.

A collaborative agreement was struck between the students and Dr. Marcus and the Institute. Stevens Institute of Technology, under the direction of the Vice President of URED provided guidance and financial support to establish a medical device company shortly after the students completed the course.

The students negotiated the exchange of their rights to the patent for an equity position in the company. Extramural funding in the form of a seed investment of $500,000 was obtained from a qausi-public authority responsible for technology investing and innovation development. Students remained involved in the process; one serves as chief engineer in the company.

This course model has been applied for three years; fourteen teams, consisting of a total of 54 students have completed the course to date.

Students provided feedback upon completion of the course and were positive in all cases. Most noteworthy is that student feedback grew even more strongly positive amongst the alumni, after they began working in industry or graduate school. Many unsolicited testimonials have been received, expressing appreciation for the experience.

CONCLUSION

This model successfully introduced entrepreneurship into the classroom, enhancing the educational design experience for biomedical engineers.

Though it is not required that all student projects achieve full potential for commercial success, several have done so. In addition to the case presented, one team has completed a patent for a capnograph guided intubation device that is expected to be licensed to a manufacturer. Another team has developed a novel device to more accurately image breast cancer. These teams also received the President's Technogenesis® award in the second and third years during which this course model was applied. Four teams have written and submitted formal patent applications.

Many of those students who have not elected to commercialize their product have instead published their work as a contribution to the public domain. Several of those project concepts are undergoing further development and are likely to be adopted as product improvements.

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