A Model for a Biomedical Engineering Senior Design Capstone Course, with Assessment Tools to Satisfy ABET "Soft Skills"

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This model provided exercises and deliverables in accordance with industry practices that enabled students to develop basic product development and project management skills. Students participated in team and project selection, then were guided through exercises to assess clinical and market needs, and technical feasibility. They delivered oral and written reports in various formats that resembled typical corporate forums. Commercial project management practices were introduced and applied in building a working "proof of concept" prototype. Student teams were required to collaborate with an outside physician throughout the project. They honed their oral and written communication skills and learned to capitalize on collaborative expertise by developing their teamwork and leadership. Students learned to identify and solve and unmet clinical need, and in the process, built essential professional and multidisciplinary skills. The course has been delivered to approximately 170 students over a 6 year period. These students have consistently achieved significant results. They have implemented eight patent applications and one successful start-up company has been established. They have repeatedly been awarded top entrepreneurship prizes, won "Elevator Pitch" competitions, and have received statewide and international recognition. Participating alumni and their employers report that they have exceeded expectations with regard to their resourcefulness and their capability to integrate tasks well. The Stevens BME program was evaluated by ABET and recommended for accreditation in October 2009.

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Background

The Biomedical Engineering Senior Design Course at Stevens Institute of Technology (Hoboken, NJ) has been designed to teach and train students in industry practices of product development and project management in biomedical design.

The following is a summary of the model which has involved approximately 170 students over a 6 year period. In this model, students operated in small teams—groups of 3 or 4—to solve a clinical unmet need. They collaborated with a clinician to understand and address "real life" product development and project management challenges. They were guided to address those challenges while abiding by common industry and clinical practices in an entrepreneurial fashion[1].

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 physician in addition to their faculty advisor. Furthermore, teams adhered to all appropriate regulatory guidelines during the project.

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, and were measured as grade point milestones. The deliverables were devised in a sequence such that students were guided through learning and training processes in product development and project management. The deliverables were structured in formats similar to those practiced in industry.

Methods

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.

The students traveled with the Instructor to the advising doctor's office where the doctor performed a demonstration, and a "kick-off" meeting was held.

The student teams were given approximately five 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 sixth week in the form of a non-graded "practice proposal presentation". Faculty advisors listened and critiqued their projects.

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.

Certain deliverables were required on a routine basis throughout the entire course. 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[2].

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. Advisors checked lab books weekly.

Student teams were required to submit a weekly action plan by close of business every Monday. Team meeting were held with the faculty advisor at least once per week, where project issues and plans were reviewed and discussed. 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".

In addition, students met with the doctor two or three times per semester, but maintained e-mail communication regarding design decisions. Their regular "Clinical Advisory" communication enabled them to maintain the "voice of customer" VOC in their design. The student practices in routine communication served to provide for appropriate opportunities to assess and maintain priorities, and to verify critical project requirements.

Project Review Meetings (PRM) were held approximately once per month. In these meetings, the teams presented their progress to the class. The formats for these presentations varied. Some required power point, some required model demonstrations, and some even prohibited visual aids. Typical corporate scenarios were simulated, both formal—from weekly project meetings to Board meetings—and informal, e.g., "imagine you are driving to see a client and your boss calls you for an update" or "imagine you just met the CEO of your company in the hallway and he asks you how your project is going."

Each team maintained a "team leader". At the project onset, students selected their leader. At approximately 2-3 unannounced intervals throughout the course, the instructor re-assigned the leadership, attributing the change to a "corporate take-over", or a result of "down-sizing and restructuring". During the PRM, the instructor may choose to balance team performance by restricting the team leader. A realistic scenario was portrayed for implementation, such as "your team leader's plane was grounded in a snowstorm and cannot attend the presentation; he may be able to 'dial-in' but the connection is 'spotty'." This permitted for all students to have leadership experiences.

Adherence to this process resulted in timely and effective management of priorities which enabled teams to complete a working proof of concept in the second semester.

Several specific milestone deliverables were defined for each semester (Tables I-II). The deliverables were reviewed and graded by the Instructor. The grade and comments further served to steer the students toward a successful path in their project execution.

By achieving the milestones outlined in Table I during the first semester, the students were guided through the discovery and concept development process. Several opportunities for formal and informal written and oral communications were included.

TABLE I
COURSE DELIVERABLES DURING SEMESTER 1

Item No.	Milestone	Week/ mode	
1	Problem definition	3	W
2	Market assessment	4	W
3	Preliminary intellectual property review	5	W
4	"Mission Statement"	5	W&O
5	"Practice" proposal presentation	6	O
6	Mid semester "Formal Proposal"	8	W&O
7	Confidential Team Assessments	10	W
8	Project Review Meeting presentation	11	O
9	Draft "Invention Disclosure"	13	W
10	Formal "Execution Plan"	14	W&O

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 (or improve lives) and reduces costs or define an entrepreneurial opportunity".

A formal written and oral proposal was required. This followed two weeks after the practice, ungraded oral proposal presentation. Content evaluation elements included:

- Mission Statement/ Statement of Purpose: Unmet Need, Demographics, Value Summary
- Background and Precedent: Pathology, Clinical practice "gold standards", Alternates or Competition, Prior work
- Concept Description: Concept Design, Use of Engineering Disciplines, Budget, Schedule and Deliverables, Expected Outcomes
- Strategy Overview: Technical, Regulatory, IP and Legal, Market, Resource utilization, Challenges or obstacles

Performance evaluation elements included: team dynamic, resource utilization, ability to define direction, presentation materials, and individual contributions.

Later in the semester, the students prepared a "Draft Invention Disclosure" based upon their research and concept. In the next semester, students used the Invention Disclosure as a basis for their publications and presentations.

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 was most useful to them—and Gantt chart scheduling was optional.

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 II
COURSE DELIVERABLES DURING SEMESTER 2

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

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. Teams greatly enhanced their presentation by presenting their device and a video demonstration of it in use on a patient. Stevens Institute of Technology invited several local media, potential investors, and financiers to attend the exhibit. Teams 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

Since implementation of this model in AY 2004-2005, student teams from this course have consistently achieved significant results. Based upon senior design projects from this program, eight patent applications have been implemented. One successful start-up company has been established. Students remained engaged in these efforts.

Student teams from this program have repeatedly been awarded the top entrepreneurship prizes of all senior design teams in the Institute. Student teams have won "Elevator Pitch" competitions. Four student teams have received statewide recognition by the International Society of Pharmaceutical Engineers (ISPE) and two student teams went on to win first prize in an international competition sponsored by the ISPE one 2007 and the other in 2009.

Several alumni have provided exceptionally positive feedback regarding their personal confidence and feeling of preparedness for their employment. They attribute their confidence to their entrepreneurial "senior design" experience. Recent alum also felt as though they were better prepared for their job than many peer hires from other programs. They have consistently relayed that they exceeded their employer expectations with regard to their resourcefulness and their capability to integrate tasks well. They have been commended for their ability to prepare strategic reports and summaries, manage projects, and apply their technical skills and knowledge in a clinical situation. Several employers, after having a first hire from this program, have returned to us, requesting, "Do you have another graduate just like the one we recently hired."

This model readily allowed for straightforward quantitative assessment (grades on oral and written reports) of some of the harder to assess course and program outcomes required in the ABET accreditation process, in particular outcomes in criterion 3a-k, such as: communication (3-e), teamwork (3-d), professionalism (3-f) and societal and social issues (3-h,i,j)[3]. The following assessment questions were used in connection with the deliverables listed in tables I and II. The ABET criterion 3 a – k outcome(s) is/are in parentheses.

Assessment questions Semester 1

1. (3 –d,h,i,j) For a given clinical problem, I can identify the unmet medical need in terms of technical, clinical and market needs.
2. (3 –h,j) I can present my project effectively, including a concise mission statement that explains how my project will save/improve lives and provide entrepreneurial opportunities (or save costs).
3. (3 -c). I can develop a project strategy that takes these aspects into consideration: Intellectual Property, FDA/ Regulatory, Resource availability
4. (3 -c). I can schedule a project in accordance with the industry accepted methods, including the Critical Path Method or a Gantt chart.
5. (3 -g) I can apply engineering and physiology training, as well as use standard resources to design a solution to a clinical problem (i.e. write a project proposal).
6. (3 –d) In a collaborative manner with medical and/or industry professionals, I can design a simple and effective "proof of concept" model to address an unmet clinical need.

Assessment questions Semester 2

1. (3 –d) I can function as a productive member of a team to execute my project.
2. (3 –f,g) I am comfortable explaining my project in various oral formats such as Project Review Meetings, Student Forums and Research
3. (3 – h,i,j) I understand how my project may be applied to solve a medical need in society.
4. (3 – g) I understand how to write an Invention Disclosure.

Leadership was assessed using an anonymous team participation questionnaire. The Stevens BME program was evaluated by ABET and recommended for accreditation in October 2009.

Discussion

To collaborate successfully, students learned to communicate effectively. This included the need for effective teamwork and leadership. They had to convey and exchange ideas with teammates, professors, and advisors. They had to communicate with members within their discipline and outside their field of study, to reach beyond engineering, e.g. financial, clinical, industry, faculty and administration. They learned to write purchase orders, e-mails to vendors and doctors, as well as write project plans and reports with their team. They built formal and extemporaneous oral presentation skills.

Teamwork and leadership skills were necessary to conceive of ideas and plans for a successful project. Tasks and roles had to be established and linked in an appropriate sequence in order to effectively design, build and test that product in the allotted time frame. Leadership was needed to focus upon tangible goals which define "success" and to provide guidelines for project planning and defining milestones, deliverables and creating stages for evaluation along the commercialization track.

To optimize and streamline solutions, students had to capitalize on collaborative expertise among the team and outside. Routine communications enabled 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. Adherence to industry practices and regulatory guidelines further enhanced their professionalism.

Conclusion

This model provided effective exercises and deliverables in accordance with industry practices. It enabled students to develop basic product development and project management skills. Students learned to identify and solve and unmet clinical need. In the process, they developed their professionalism and honed essential teamwork, leadership and communication skills.

References

1. Hazelwood, V., Wisniewski, H., Ritter, A.B., **Entrepreneurship in Biomedical Senior Design, from Classroom to Corporation,** International Conference on Engineering Education, Annual Symposia, Coimbra Portugal, September 2007
2. Hazelwood, V., **The Value in Linking Entrepreneurship and Undergraduate Engineering Education,** 2nd International Multi-Conference on Engineering and Technological Innovation: IMETI 2009, Orlando FL, July 2009.
3. http://abet.org