AC 2011-1634: A NEW INTERDISCIPLINARY COURSE FOR ENGINEERING AND BUSINESS STUDENTS: THE GLOBAL PHARMACEUTICAL INDUSTRY

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A new interdisciplinary course for engineering and business students: the Global Pharmaceutical Industry

Abstract

The workplace today is changing. Technological breakthroughs often cross disciplines countries and continents. In highly regulated industries such as the pharmaceutical business, it is essential for engineers designing the products and processes to be aware of the different regulatory legal guidelines worldwide and the technical and cultural challenges associated with relocating manufacturing and research facilities from the United States to countries such as Singapore, India and Ireland. A new interdisciplinary course was developed and taught for the first time this past 2009/10 academic year at Villanova University called "the Global Pharmaceutical Industry". The goal of this course was to provide an opportunity for engineering (primarily chemical engineering), science and business students to interact while gaining exposure to some of the key technical and non-technical issues driving the evolution and operation of the global pharmaceutical industry. The course included lectures and presentations by Villanova Engineering and Business faculty, as well as industry experts. The technical (molecules, process and equipment) and business (pharmaceutical economics, marketing and management basics were covered by Villanova engineering and business faculty respectively. Experts from the industry discussed current and complex issues facing the industry such as; drug manufacturing and marketing regulations in China, ethics and logistics of clinical trials in India and drug anti-counterfeiting efforts. The pedagogical approach included lecture, discussion, case analysis, and industry focused projects.

The purpose of this paper is to describe the benefits and challenges associated with this new course at Villanova. Two noteworthy and somewhat unexpected benefits of the course were the engineering students gaining an appreciation for how they can apply their problem solving abilities to some of the less technical problem but quite complex questions facing the industry (i.e. where to conduct clinical trials for a new drug) and the two faculty who co-taught the course getting an energizing experience as a result of exposure to new material and teaching styles. Some of the challenges included: achieving an interesting and fair mixture of technical and non-technical material in the lectures, exams and group projects; achieving connectivity between the wide range of topics in the course and achieving a fair mixture of exam, homework and group project questions that allowed for the business students to utilize their abilities to make convincing written and verbal arguments and the engineers to utilize their abilities to be quantitative and problem solve. The course was received very favorably by the students as indicated by surveys and deemed quite unique and valuable by the many industry experts that voluntarily participated in the course. In summary, this course was successful in a difficult and uncommon task of delivering material from technical (science and engineering) and non-technical (business) disciplines to a diverse group of students from three different colleges at Villanova via instruction from faculty and outside speakers.

Introduction

The workplace today is changing. Technological breakthroughs often cross technical disciplines countries and continents. For example, the new Boeing 787 reportedly has 132,500 engineered parts that are produced in 545 global locations. Companies no longer just look within themselves for innovation, nor do they just purchase it by acquiring smaller companies. Today they obtain innovation wherever it is found[1]. In highly regulated industries such as the pharmaceutical business, it is essential for engineers designing the products and processes to be aware of the different regulatory legal guidelines worldwide[2] and the technical and cultural challenges associated with relocating manufacturing and research facilities from the United States to countries such as Singapore, India and Ireland[3].

Today's innovations often cross technical disciplines such as biology and engineering. Academic and industrial research is becoming increasingly interdisciplinary, and universities such as Purdue are trying to develop within their engineering students knowledge within and outside of engineering to prepare them for modern workplace[4]. A search of American Society of Engineering Education (ASEE) conference proceedings from 2003 to 2006 returned 624 citations on "multidisciplinary" and 834 on "interdisciplinary" by authors from around the world[5]. Ollis[6] described the multidisciplinary design course that had been established at six of the institutions in the SUCCEED coalition. Dickinson reported that an appreciation of interdisciplinary approaches is perhaps the skill most deficient in our engineering graduates[7]. True entrepreneurism with regards to technology also ofcourse embodies identification of a societal or business need for novel new products as well as the discovery and development and side that is driven by technical creativity and persistence in research[8]. A global awareness is required of entrepreneurs in order to assess potential worldwide impact of, or market for, their innovations[9]. Engineering and business faculty collaborated on the development and teaching a course in socially conscious innovation at Grand Valley State University. The instructors observed that the students quickly understood the importance of symbiotic relationships. Engineers typically considered what was technically possible and business persons reviewed what was financially viable. When considering the idea of a locally produced food certification, an engineer tried to estimate potential for reducing pollution, whereas a business person confronting the same situation considered how much people would be willing to pay for locally grown produce. Consequently, combining the two disciplines enriched the conversation and content of the course[10].

Some of the goals of the college of Villanova's college of engineering (COE) is to produce engineers that have sufficient global awareness, an ability to be able to contribute to and eventually lead interdisciplinary teams and think in an entrepreneurial manner. These goals are in line with those put forth in a recent publication of the National Academy Press called "Educating the Engineer of 2020"[11]. To accomplish this, undergraduate students are encouraged to pursue a diverse portfolio of courses that broadly educates them in a fashion consistent with their individual interests and abilities. The COE has also developed a set of "strategic initiatives" in 2008, that includes a flexible undergraduate curriculum promoting interdisciplinary experiences and real-world applications. Consistent with one of these objectives is any new course allowing for inter-college collaboration of students and faculty that will enhance the students 'ability to work in multidisciplinary settings.

The objective of this paper is to describe a new inter-college (Villanova College of Engineering and Villanova School of Business) course at Villanova University : The Global Pharmaceutical Industry. In this course, technical and business issues from the industry will be examined in a unique interdisciplinary environment, with students and faculty from both colleges involved. The intended audience is multidisciplinary, reflecting the fabric and organization of the industry as it operates today. The opportunity created by this course is unique in that engineering, science and business students work together to understand and attempt to solve some of the complex issues regarding an industry whose life-saving products create significant ethical, technical, political and business challenges. By integrating more than just technical considerations into real world problem solving, the engineers in this class are beginning to develop a skill that is often obtained through experiences and a commitment to the lifelong learning philosophy that ABET endorses. The course will supplement nicely the other technical bioprocessing CHE courses and provides a unique undergraduate experience that other universities might be interested in adopting.

Motivation for development of the course

Villanova University is located amidst industrial pharmaceutical research and manufacturing; being within 20 miles of Merck, GSK, Centocor and Wyeth etc.. sites. These companies regularly hire our graduates, and participate in collaborative research that has resulted in several undergraduate researchers contributing to publications in journals. This new interdisciplinary course, The Global Pharmaceutical Industry, was developed to be an important addition to the existing three technical courses in biochemical engineering at Villanova. The courses together will interest engineering students that are motivated to learn biotechnology and pursue careers in the pharmaceutical industry. The engineering students taking these courses will receive a well-rounded and thorough foundation for entering the pharmaceutical industry. These students are positioned then to make positive impacts on the industry in their entry-level jobs and beyond. For the business students, this new inter-disciplinary course is the only undergraduate course in the VSOB that deals specifically with the pharmaceutical industry and represents an opportunity for these students to become familiar with this important industry.

Description of the new course: The Global Pharmaceutical Industry (CHE2900)

The learning outcomes

Upon completion of this course, we would expect the students to be able to:

- Describe and detail the size, scale, scope and critical features of the global pharmaceutical industry
- Graphically depict the basic composition, process and nature of pharmaceutical products (chemical and biological)
- Apply and evaluate the key elements of pharmaceutical business models, such as the role of R&D, pricing, distribution, etc
- Document and appreciate with some specificity the role of regulation, public policy, and ethics in pharmaceuticals and the different approaches to these issues internationally

- Discuss, reflect, and project alternate future directions and trends in the global pharmaceutical industry

The 5 modules of the course

The course was broken up into five teaching modules, shown in proper sequence and described briefly below, where module B was primarily technical and module D was primarily business:

A.) **Introduction to the Pharm. Industry:** The first week or two of the semester history was devoted to the course instructors providing some background information that included: the history of medicine, description of clinical trials, a summary of current drug products and financial information such as costs for research and profit figures.

B.) **Innovation and Operations**: The next few weeks were spent covering some basics of the science of bioprocesses and the engineering of manufacturing equipment and facilities, as well as defining quality management of manufacturing and product distribution. New technologies were highlighted such as novel product identification.

C.) **Corporate Responsibility:** The next few weeks focused on describing the US healthcare system, the current global regulatory structure, as well as discussing some humanitarian efforts led by pharmaceutical companies to provided access medicines.

D.) **Global Business Strategies:** The class was then provided with an introduction to the basic factors effecting the global pharmaceutical market and some models used to describe market behavior. Case studies of specific drugs then allowed assessing the impact of public versus government customers and the use of DTC marketing.

E.) **Future of the Pharm. Industry:** The final weeks focused on emerging medical advances such as gene therapy and personalized medicine, current quality approaches such six-sigma and the benefits and risks of moving manufacturing "off-shore".

The Approach to Instruction

Approximately half of the total class periods involve lectures from the two primary instructors: Dr. Jonathan Doh from the school of Business and Dr. William J. Kelly from the college of Engineering. Drs Doh and Kelly give the introductory lectures for each of the five modules of the course, to ensure that the students sense continuity between modules and have been adequately informed of the basics of the module before encountering more advanced topics. Ten speakers from the Pharmaceutical Industry (engineers, scientists and businessmen) brought more of a real world element to the classroom, as issues such as multi-disciplinary teaming across continents and drug regulation are explored through case studies involving real and modern drug products, processes and producers and the current global situations and challenges that the pharmaceutical industry is experiencing. Such exposure certainly helps the students entering this industry upon graduation to more effectively "hit-the-ground" running in their respective disciplines and especially as part of interdisciplinary teams that might be dealing with more "big picture" issues. Cases studies were employed that effectively engaged the students by providing current and thought-provoking information to be analyzed during or outside of class.

The two course instructors were in attendance at most/all of the classroom sessions, to promote and maximize interdisciplinary information exchange and discussion.

Evaluation of student performance

The grading for the course is shown in the following Table 1

		% of total Grade
Class participation		15
Quiz (Exam) #1		20
Quiz (Exam) #2		20
Mid-semester Project	- oral presentation	15
Final Project	- oral presentation	10
	- Report	20
		100%

The Results: Meeting the Challenges

Attracting students from both schools

For engineering students this course does not count at Villanova currently as a "technical" elective, but rather as a free elective, for which there is much competition. For business students, there was concern about potentially difficult technical (science and engineering) material being covered. There were no course prerequisites for either the engineering or business students, just a requirement that the student be sophomore status or above so that they have some skills that they can bring from their major to this interdisciplinary class. When the course was offered for the first and only time in the Spring of 2010, 25 students representing a mix of both engineering (5 students), business (19 students) and science (1 students) students had enrolled; with the majority of students being from the business school and all of the engineers being from the chemical engineering department. These results were attributed to better advertising for the course that was done (via email distribution and flyers) by the business school faculty and staff, and the number of chemical engineering students at Villanova with intentions of pursuing careers in the pharmaceutical industry. It is expected the next time the course is offered (Spring 2012) that a more even balance of engineering and business students will be achieved, since the chemical engineering curriculum has been recently revised to allow for more flexibility.

Integrating different (Engineering and Business) topics

The course instructors gave the first lecture of each of the 5 core modules. These lectures lecture included the fundamentals or "basics" for the material to follow. For example, Dr. Kelly covered "Science and Engineering Basics" to ensure that the business students in particular are prepared for subsequent lectures in module B by outside speakers covering technological advances and innovation in the pharmaceutical industry. Conversely, Dr. Doh provided an

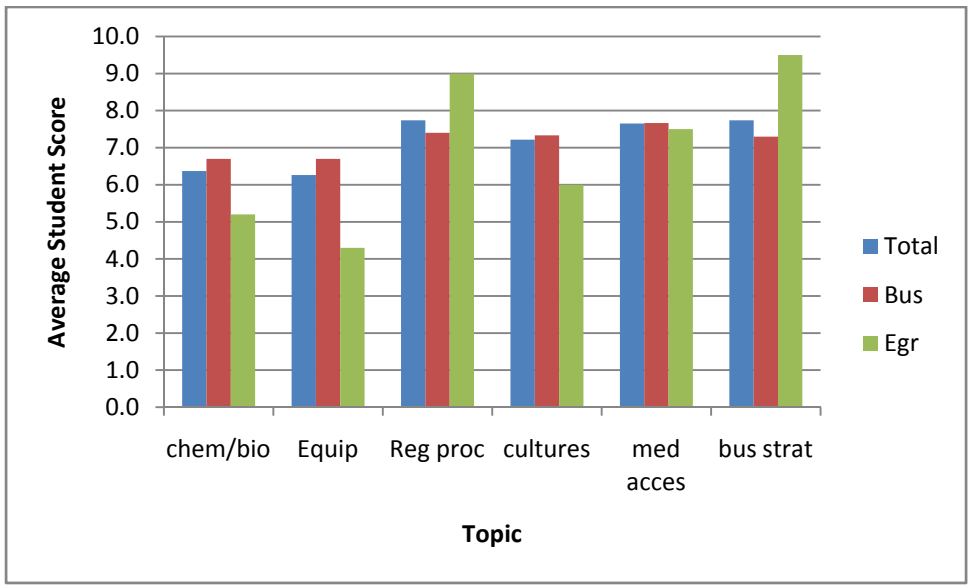
introductory lecture for module. Module B was entirely science and engineering material, and module D was entirely business material – the remaining three modules were mixtures of both.

Surveys: A post-course student survey included the following questions dealing with the balance of engineering and business material that they were exposed to in the class:

> Please rate each statement from 1-10, where 10 is "a great deal" and 5 is "an adequate amount" and 1 is "little". How much valuable new and/or interesting information did you learn about/from the following:
>
> 1. The chemical structure and biological activity of medicines/drugs? _____
> 2. Equipment and processes used in drug manufacturing? _____
> 3. Drug regulatory processes and agencies? _____
> 4. The culture, geography, and social/political climate of other countries? _____
> 5. Issues involving and examples of "access to medicines"? _____
> 6. Pharmaceutical business strategy(s)? _____

Figure 1 on the following page shows some of the survey results, namely the average scores from the engineering and business students on these questions 1 through 6 above. All average scores indicated that the students learned at least "an adequate amount" of new material in each of the six topical areas. The only border line case was with the engineers and the degree to which they learned more technical (chemistry/biology and equipment/processes). Surprisingly, from their response to questions 1 and 2, the business and engineering students in fact would have preferred exposure to more technical material. The response variability was +/- 23% on average for all of these six questions for all of the students.

Figure 1



Group Projects: : For the group projects, the students, as teams of multi-disciplinary consultants (business and engineering), made recommendations for an actual company's response to potentially market a new drug in an important emerging global market. The analysis from the groups was to be grounded in accepted theory and methodology, and integrate the readings and cases for the course in the context of the actions of a specific firm. The analyses was to include rigorous recommendations that included a thorough assessment of technical, business challenges, regulatory hurdles and competition from other similar products. The first or "mid-semester" group project that was handed out focused on manufacturing abroad (i.e. science and engineering issues), and the second or "final" group project (below) focused on global marketing strategies (i.e. business issues). The final project description is shown below:

> You are an internal consulting group for a major pharmaceutical company (could be large, company that produces a range of products, a generic firm, or smaller specialty company). You have been asked by your CEO to develop a comprehensive entry strategy for a pharmaceutical product that is currently sold primarily in the home market. She wants you to explore the potential for the product's introduction into a foreign market, and to develop a specific entry strategy for that market. For this assignment, you choose the product/company. Consider the following in your analysis:

- The overall political, economic and geographic climate of that country as it pertains to the product
- The potential demand, including market and customer segments (eg public v. private markets, demographic issues, distribution of population, insurance, government payment schedules, etc)
- The competitive environment (eg. what other competitor companies and products are present, how successful are these products, what challenges have emerged in their sale and distribution
- Ethical and regulatory concerns, such as clinical trials requirements etc..
- Recommended entry modes (eg Greenfield investment, joint venture, licensing)
- Marketing strategies (eg. direct-to-consumer, physician-targeted, government, etc)

For the final project, the student groups chose a wide range of products, company types/sizes and markets for product launch as indicated in Table 1:

Table 1

Drug	**Diseases**	**Company**	**Proposed Market**
Cayston	CF patients with pnemonia	Gilead Sciences	India
Xeloda	Colon/Breast Cancer	Roche	Ireland
Menveo	Meningitis	Novartis	South Africa
Ixiaro	Japanese Encephalitis	Intercell AG	Japan

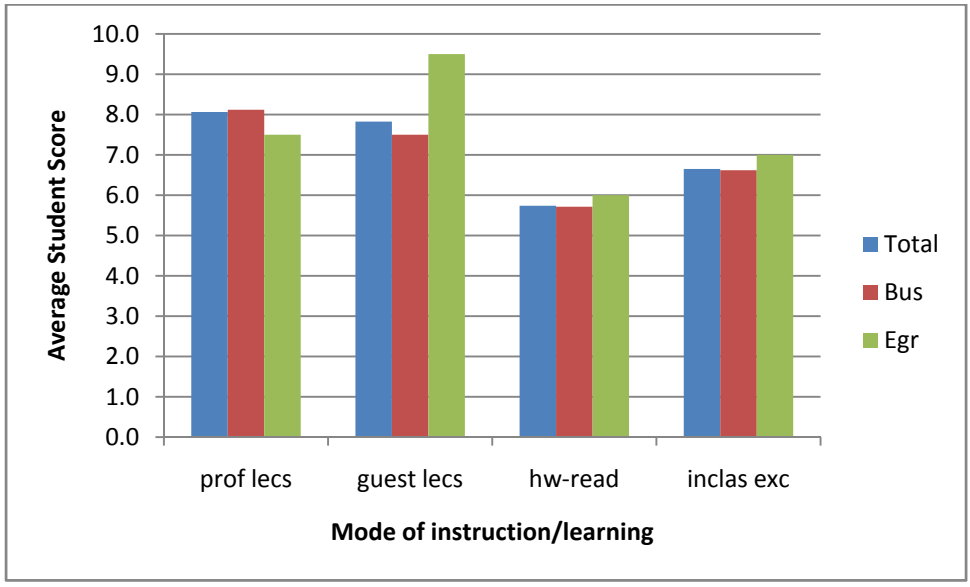
In general, the student reports used high quality references and identified an markets that were suitable for a successful drug launch from a business and societal perspective. The Xeloda market choice was particular wise, given the leveraging power that Roche has with Irish Oncologists as a result of Roche's very successful Herceptin product. Most of the reports considered important business issues such as: tax incentives, adequate infrastructure for transportation, regulatory requirements, intellectual property rights, product competition, and the potential for DTC marketing. The Menveo proposal included a clever two-phase launch scheme for the more risky and less established African market, whereby Novartis initially contracts a company such as Cipla-Medpro-Africa that has past successes obtaining Africa governmental subsidies and resolving drug supply chain issues.

Integrating different (Engineering and Business) teaching/evaluation styles

Teaching

Engineering instructors typically deliver content during class lecture, where lecturers for many business courses expect that the students read posted material before class, allowing for discussion/exercises during class. These approaches are not consistent, and give rise to confusion for a course such as the new course on the Global Pharmaceutical industry which is team taught. The solution to this inconsistent format was constant communication with co-faculty and students via email and verbally in class so as to preempt frustration with ever-changing approaches. This effort did result in the students, for the most part, remembering to print out the engineering slides or read the business material (articles/chapters) before class. Figure 2 indicates that the students learned comparably from the lectures by the two Villanova instructors as compared to the lectures/presentations by the outside speakers. Interestingly the students learned less from the more student- driven learning activities (outside reading and in-class exercises) as compared to the lectures, causing the two course instructors to think that the instructors should provide perhaps more background information or time during the in-class exercises and less material that is more focused on only key/core class topics for outside reading.

Figure 2



Evaluation

Classroom participation: Because classroom participation was counted as part of the student's grade, and the business students were much more accustomed to this, efforts were made to ensure that many of the case studies and questions posed involved issues with technical and non-technical components. This attempt at "evening the playing field" during the discussions was reasonably successful, in that the engineers at times could lean on their problem solving/analytical skills in making a unique and valuable contributions to the discussion. One such case study is presented below, in which the students were separated into groups (each of which had at least one engineering student) and were asked to answer the following question related to the drug Vioxx:

Vioxx (Merck and Company)

- Very effective against rheumatoid arthritis and pain

- Use information from the pre-class reading (i.e. article on Vioxx) to explain how the clinical trial process, potential mislabeling and other factors contributed to the problems (product withdrawal, lawsuits etc…)

The class participation portion of the grade came from student attendance as well as the student's ability to convey and critically evaluate, verbally and in writing, an understanding of the issues raised during these in-class assignments/exercises. The two instructors had frequent discussions regarding the in-class participation.

Exam questions/testing: questions on science and engineering exams typically test knowledge of facts and mathematical derivation of a single correct solution. Business exam questions test verbal and written communication that effectively conveys ideas and makes convincing arguments based on facts. There was a challenge to develop exams for this course that did not give Engineering or business students unfair advantage or disadvantage and required an understanding of the issues from class in sufficient detail. The solution included a combination of multiple choice science and engineering questions and essay (short and long) on business topics. An example of both type of questions is shown below:

> Multiple choice: Infectious diseases can be caused by a pathogenic virus or bacteria invading your body (T,F), and include (Hepatitis A, diabetes, asthma, high blood pressure); while (polio, smallpox, Cancer, measles) is an example of a chronic disease."
>
> Essay questions: Describe in a paragraph or two, at least two significant pros and two significant cons of conducting drug trials in India today. Include the terms: vulnerable subjects and informed consent"

Group Projects: The oral presentations and written reports were evaluated by both of the instructors for the course, and an average grade was arrived at. Individual grades for group members largely reflected group performance, but also reflected individual contributions especially with regards to the answering of instructor-posed questions following presentations.

Finding and working with appropriate outside speakers

Ten outside speakers were identified to discuss topics that included: Quality by Design and Global supply and distribution (Module B), Ethics with respect to Clinical Trials in India and the Impact on Regulation on Drug Approvals in China (Module C), Cross cultural marketing and Gardasil marketing in South Korea (Module D) and combating drug counterfitting (Module E). These speakers held mid to high level positions at either Merck, Glaxo SmithKline or Pfizer Inc. A considerable amount of time was spent last in the semester preceeding the course, preparing the potential speakers by ensuring that the material being presented was a logical extension of what would be presented previously in class. The original (draft) presentation from the speakers were typically modified by the course instructors so as to minimize use of organizations acronyms, provide some historical context and make time for interaction with the students. For the outside lecture on Quality by Design for example, the instructors suggested using a simple process for a familiar/fun product (i.e. recipe for making chocolate chip cookies) as a way to teach CQA and CPPS (mid and final process variables). The outside speaker adopted this idea and discussed how variation in mix time or cook time or type of chips effects the "quality" (taste) and "yield" (number of cookies). The students rated on average all but one of the outside speakers as at least 8 out of 10 on a post class survey.

Ensuring connectivity between lectures.

Given the broad scope of the class, that included technical and non-technical material, one of the biggest concerns that the instructors had was that continuity be achieved between the lectures and modules. To achieve this continuity, the instructors conceived a detailed course outline from which a course “story” could flow. The “story” began in module A with a historical perspective on medicine, regulation and the industry which brought us to the current situation. Module B covered some details of the more recent technological advances, including novel drugs and manufacturing technologies. Modules C and D covered regulation and business strategies. The instructors also provided introductory lectures for each module, that allowed the basics or fundamentals of that module to be covered. This was particularly important for example in module 2, as the business students in the class were in some cases for the first time since high school exposed to chemical structures and algebraic equations. The most important step in ensuring connectivity between lectures was for the instructors to have communicated with the outside speakers and given feedback with regard to their presentation at least once well before their actual visit. These outside speakers were able to bring into the classroom current and more complex topics. It was essential that the students had an adequate background to absorb these concepts and see how they related to the other material taught in that module and in the course.

A post-course student survey included the following questions dealing with the degree to which “connectivity” between material and lectures in the course was achieved:

> Please rate each statement from 1-10, where 10 is “a great deal” and 5 is “an adequate amount” and 1 is “little”.

- *The degree of good/logical connectivity between topics within modules/lectures?* _____

- *You were adequately prepared (by previous lectures etc…) to understand material presented by the outside speakers?* _____

The average scores for these two questions were 7.5 and 8.0 respectively, with no difference in response between the engineers and the business students and an average response variability of approximately 20%. These average values were as good or better than anticipated by the instructors, given that the topics in the course were so varied and the outside speakers focused on current and fairly complex issues.

Conclusions and Recommendations

The course was received very favorably by the 25 students who took it in the Spring of 2010, as evidenced by the high scores from every category of Villanova's standard course evaluation form. This form has the students rating things such as: value of the course, how much the student learned in the course and is the course intellectually stimulating. Perhaps just as importantly, the two instructors left the course energized as a result of the collaboration and the feedback from the students.

There were several areas of improvement that were identified either from the post-class student surveys or from observations by the instructors. All of the students, especially the business students were interested in getting more exposure to biotechnology science and engineering topics. For the next course offering, the following changes are planned for the course:

- Adding a few emerging technical topics such as genetic engineering, personalized medicine and cell-based therapies as at least one additional technical lecture

- Posting pre-class notes/reading material earlier (i.e. several days before class, as opposed to the night before), and posting less and more focused reading material.

- Impose a requirement for the group spokesperson for in-class exercises to change from class to class, to get the less "verbal" (i.e. engineering) students more involved in class discussions and activities

- Make the assignments more quantitative, allowing more opportunities for engineers to shine, and for business students to experience this problem solving approach. This might be accomplished by adding some lecturing and a corresponding assignment on Equipment sizing as well as quantitative cost/benefit analyses (i.e. on off-shore manufacturing, or different marketing approaches…).

- Create more opportunities for engineering and business majors to both wear the others "hat", as well as demonstrate and utilize their own (disciplinary) strengths and knowledge. For example, the data in Figure 1 indicates that the engineering students

did not learn as much as the business students in some of the technical sessions. These engineering students might then be more engaged during these sessions if allowed to take more a leadership role in delivering the technical material to and/or interpreting the technical material for the class.

- As a course assessment tool, hand out both pre-class and post class surveys to help in determine the degree to which the course improved students awareness of broad issues including roles and skill sets of engineers versus business specialists

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