

Sponsored Industrial Research Experiences for Undergraduate Students: Student Perspectives on Collaborative Projects with Pharmaceutical Industry

L. Kuczynski, C. McGuinness, S. Farrell, B. G. Lefebvre, and C. S. Slater

**Rowan University
Chemical Engineering
201 Mullica Hill Rd.
Glassboro, NJ 08028-1701 USA**

Abstract

Rowan University's Engineering program uses innovative methods of teaching and learning to prepare students better for a rapidly changing and highly competitive marketplace, as recommended by ABET¹. Rowan has developed a program that fosters synergistic interaction between industry and academia and prepares undergraduate students for careers in regionally and globally important industries. Through the Engineering Clinic program industrially sponsored research or design projects are performed in an academic environment.

The abundance of pharmaceutical companies in New Jersey demands a steady pipeline of well-prepared engineering graduates. Undergraduate Rowan Engineering students have worked on a variety of research projects sponsored by pharmaceutical companies such as Bristol-Myers Squibb, Johnson Matthey Pharmaceuticals, and Novartis. This paper presents case studies which examine successful synergistic interaction between pharmaceutical industry and academia through the Rowan Engineering Clinic Program. The case studies are presented from the student perspective, focusing on the educational and professional benefits to students who have worked on these projects.

Keywords: Industrial Projects, Undergraduate Research, Pharmaceutical Industry

1. Introduction

Undergraduate engineering and technology students benefit from "real-world" experiences which are usually obtained through internship and co-op experiences. Through these work experiences, students have the opportunity to apply their technical skills to industrially-relevant problems, gain exposure to company culture, and build a foundation which helps provide motivation for future learning in an academic environment. While these "real-world" experiences are highly valuable to students, they are still separate from the engineering curriculum and academic experience. It would be desirable to integrate more "real-world" experiences into the undergraduate curriculum at universities; however, industry-academic relations have not, in general, been developed to their full potential. Rowan University has developed an Engineering Clinic Program which fosters collaboration between academia and industry and provides "real-world" project experiences to undergraduate students.

At Rowan University, all engineering students participate in an eight-semester course sequence known as the Engineering Clinics. In the Junior and Senior years, these clinic courses involve multidisciplinary student teams working on semester-long or year-long research and design projects sponsored by a company in our region. Every engineering student participates in these projects and benefits from project-based learning, exposure to emerging technologies, industrial contact, teamwork experience and technical communications.

The majority of the leading pharmaceutical companies have headquarters, research & development centers and manufacturing facilities in New Jersey, New York and/or Puerto Rico. The abundance of pharmaceutical companies in the region demands a steady pipeline of well-prepared engineering graduates. This paper focuses on student experiences related to Junior and Senior Clinic projects sponsored by pharmaceutical companies in the region.

1.1 Engineering Clinics

The Engineering Clinics are taken each semester by every engineering student at Rowan University. In the Engineering Clinic, students and faculty from all four engineering departments work side-by-side on laboratory experiments, real world design projects and research. The solutions of these problems require not only proficiency in the technical principles, but, as importantly, require a mastery of written and oral communication skills and the ability to work as part of a multidisciplinary team which are essential skills for professional success^{2,3,4}. Rowan's Clinic Program integrates these diverse challenges of "real-world" projects with pedagogically valuable hands-on learning experiences^{5,6} and technical communications^{7,8,9}.

1.2 The Junior/Senior Engineering Clinic Project

The development of industrial Junior-Senior Clinic projects has been described previously¹⁰ and is included here for clarity.

The typical engineering clinic project starts well before the first day of the semester, when the preliminary work of defining a project must be complete. This work usually begins when an industrial engineer is invited to Rowan for an informational meeting which includes a tour of the facilities. At this meeting, the Engineering Clinic Program is introduced and a brief overview of expertise and interests of college faculty members is provided.

The next stage is to match faculty interest with the operations of the company. Then further meetings are set up to brainstorm and sketch out project ideas. Professors research these ideas to develop and scope the difficulty level of the project to upper level engineering students. Outcomes must be achievable within one semester or, more typically, one academic year. Finally a budget is prepared for the project and negotiations are undertaken with the company to finalize the agreement. A confidentiality agreement is established between the company and the university. Normally, the time between first contact and obtaining a defined and funded clinic project averages about one year.

Prior to the start of the semester, background work is done so that undergraduate students will be able to "hit the ground running". A graduate or advanced undergraduate student is assigned to the project during the summer, and this student initiates a literature search and becomes familiar with the technical aspects of the project before the semester begins.

When the semester begins, undergraduate students are matched to projects based on their ranked project choices and on the needs of the project. The professor provides a brief introduction to the project, and the students are required to read introductory material for familiarization. Early in the semester, typically in the second week, the team meets with industry representatives who provide an overview of their industry as well as a description of the technical problem that is to be addressed. At this meeting, students begin to develop a rapport with the industry representatives. They begin to see what aspects of a project are important to industry, that industry has very short deadlines, and that they expect results. They also see that these projects have a goal that will directly impact the operations of the plant and the engineers and scientists in the meeting room. Close interaction with industrial representatives is critical to success of the project, and regular meetings continue throughout the semester, typically on a bi-weekly basis.

Students begin immediately to review the technical literature, and then to develop a project plan. Students then establish a budget and begin to purchase equipment and supplies necessary for their experiments. Students learn that it is necessary to work diligently and aggressively through this phase of the project due to the inevitable lag time between choosing the equipment and receiving it.

The student team has weekly meetings with the faculty members involved in the project, as well as regular (biweekly or monthly) informal meetings with the industry representatives. The frequency of the meetings with the industry representatives depends on their availability and their desired level of involvement in the project. Our experience has been that frequent meetings are highly beneficial because accountability, progress and results are required. Formal presentations to the industry are given mid-semester and at the end of the semester.

These projects also help the program address many of the "softer" skills required by ABET (2000). Students function in multidisciplinary teams, design and conduct experiments, learn about safety and environmental issues, analyze and interpret data, communicate through oral and written reports, and use modern engineering tools.

Case studies are presented below for projects that have been conducted in collaboration with two pharmaceutical companies in our region – Novartis and Bristol-Myers Squibb. The case studies are written to emphasize the unique features and individual nature of the projects. Beyond having clearly expressed project objectives, expectations, timeline, and budget, we believe that there is no "formula" for the framework of a successful project and that flexibility is the key to success.

2. Project Descriptions and Outcomes

2.1 Novartis

Novartis is a new sponsor of the Clinic program, having supported its first project in the spring semester of 2006. The project has been renewed for the fall, 2006 semester. This project investigated palladium removal from a reaction mixture in a step for producing a pharmaceutical intermediate. The US FDA requires palladium concentrations in drugs to be less than 5 parts per million. During one of the steps in the production of a pharmaceutical intermediate, palladium from a homogeneous organometallic catalyst contaminates the product. Currently a time-consuming process is used to remove the palladium from the reaction mixture. This procedure involves a batch adsorption with activated carbon to remove the palladium, followed

by extensive rinsing to remove all the activated carbon from the reaction vessel. The Rowan-Novartis project focuses on the development of an external fixed-bed adsorption column to remove palladium in a process that is greener and less time-intensive than the current method.

This project has several objectives: (1) Experimental determination of equilibrium isotherms, (2) design and construction of a laboratory column (3) experimental investigation of factors affecting column operation, (4) development of an analytic technique for the quantification of palladium, (5) mathematical modeling of column operation, (6) developing a design for pilot-plant scale-up, and (7) comparison of the performance of different resins. The clinic program gives students the opportunity to work on real industrial problems. For instance in this project they perform an actual reaction run in the pilot plant at Novartis. This project has offered students the unique experience of working with a consultant from Novartis Pharmaceuticals on weekly basis. This project became an employment opportunity when two students on the team were hired to continue research during a summer internship at Novartis Research and Development. Students were given the experience in working with many industry representatives with various areas of expertise and specialty analytic areas. There are many opportunities to develop both verbal and written communication skills as well. Students have written many formal documents regarding the project and formally presented work both at Rowan University and Novartis Pharmaceuticals. Students also had the opportunity to present their work at the AIChE regional conference at Penn State in April and the national conference in San Francisco in November.

2.2 Bristol-Myers Squibb Initiative

For the United States pharmaceutical industry to grow and develop in a sustainable way (while at the same time meeting current and future EPA regulations), adoption of green engineering principles is necessary from R&D through manufacturing. Through this project, a student-faculty team is working with Bristol-Myers Squibb scientists and engineers to develop green engineering protocols that can be adopted by the pharmaceutical industry. This project is sponsored by the Pollution Prevention Grants Program and the Conservation Challenge Grants Program of EPA Region 2 which includes New Jersey, New York, Puerto Rico, the U.S. Virgin Islands and the Tribal Nations in those states. Greater detail on this project is provided in Slater et al.¹¹.

The majority of drug products made through organic synthesis routes require many sequential reaction steps, large quantities of organic solvents (with varying degrees of toxicity), and are made in batch processes. All of the above are not optimal from a green engineering manufacturing standpoint. A significant reduction in the use of solvents, in terms of quantities and toxicity, can be made if investigations into the early stages (Phase I or II) of drug development are performed. It is important to work with drugs in Phase I or II of development, since these changes can be incorporated into the final manufacturing steps that are approved by the FDA. By Phase III, “synthesis lock” and “process lock” prevent innovations from being easily implemented. The team is working on developing a heuristic that pharmaceutical companies can follow in the development of new drugs.

The specific objectives of this project are to identify reductions in the use of hazardous chemicals in a drug synthesis. The Rowan team first met with the Bristol-Myers Squibb staff and discussed several possible drugs at various stages of development that we could examine. A confidentiality agreement was signed which limits the amount of information we can reveal

about the drug and the manufacturing process. A cancer drug in the early stages of development was selected. The team then met to set and review project goals/objectives.

The initial part of the project involved a review of process development documentation and a pilot plant visit to understand equipment issues. The basic data on raw materials, products, byproducts of the process were analyzed. Green engineering metrics for lab-scale (discovery), intermediate and pilot-scale processes were compared. Life cycle assessment was made using overall material and energy balances along with environmental performance tools. Tier 1 tools such as economic criteria, environmental criteria, exposure limits, toxicity weighting in analyzing various drug production pathways.

Since organic solvents typically account for 80% of all chemicals in a pharmaceutical process, a significant part of the work focuses on process modifications to reduce solvents used. Several process opportunities for greener processes were explored. A life cycle assessment is conducted to compare these alternatives and show broader impacts on the ecosystem (greenhouse gas production, etc). These alternative production routes include new solvents and processing methods. Throughout this process, we are in constant contact with Bristol-Myers Squibb R&D staff and get feedback for continuous improvement of our approach. The analyses of these alternative approaches are presented to the company in bimonthly progress meetings.

The process improvements made by the Bristol-Myers Squibb scientists have been quantified by the student and faculty team using several approaches. The student team investigated and applied metrics for process, safety and environmental impacts.

Solvent selection and use was also measured by a unique solvent selection spreadsheet that quantifies all of the various process streams into one value that can represent the greenness of the process. This facilitates the comparison of process improvements for the different drug synthesis routes using one unifying index that combines various environmental and safety metrics such as TLV (threshold limit value), ingestion toxicity, biodegradation, aquatic toxicity, carcinogenicity, ozone depletion, global warming potential, half-life, smog formation, acidification, soil adsorption and bioconcentration factor.

Students working on this project gained familiarity with the issues and concerns of pharmaceutical R&D. Valuable insight was gained into the factors determining the cost of pharmaceutical end products: not only the cost of drug development, but the cost of manufacturing according to good manufacturing practices (GMPs). The importance of greener manufacturing processes, and particular the need for reduction of solvent use were realized.

This project required intensive application of concepts learned in the classroom, with emphasis on separation techniques and membrane separations in particular. Working on a project with frequent deadlines for EPA and industrial deliverables provided students with experience in meeting "real-world" deadlines. Frequent meetings provided experience in preparation for different types of interactions with faculty, engineers, and industrial executives. Professors are concerned with the technical details of work, whereas the executives are interested in the impact of the project on the company. One undergraduate student working on this project noted that most pharmaceutical researchers have advanced degrees, and has decided to attend graduate school to prepare for a career in pharmaceutical R&D.

3. Assessment

The impact of the industrial Engineering Clinic projects on industrial constituencies and the benefits to faculty have already been addressed. In this section we will examine the benefit of the industrial Engineering Clinic projects to the engineering students. In their 2005 senior exit interviews, 100% of the graduating students indicated that Junior Senior Clinic was very a very valuable component of their chemical engineering education. Industrial internships often require the same skills (beyond basic technical knowledge) that are critical to the success of an industrial Clinic project, and interns are often hired for their industrial Clinic experience. The development of these skills is a Clinic educational objective, and therefore employers' evaluations of summer interns are useful instruments in determining whether Clinic objectives are met. Employers' evaluation of summer interns is consistently very positive, as shown in Table 1. Summer intern ratings were outstanding in areas that are essential to the success of an industrial Clinic project: the ability to design and conduct experiments, the ability to analyze and interpret data, mastery of written and oral communication skills, ability to function with minimal guidance, the understanding of professional responsibilities and the ability to work as part of a multidisciplinary team. It is difficult to isolate the contribution of the Junior/Senior Clinics to the development of these skills; however, these skills are essential in Clinic projects and are used more extensively than they are in traditional classes. Therefore, we believe that the Junior/Senior Clinic contributes significantly to the development of these skills.

Table 1: Mean ratings of chemical engineering students working as summer interns in 2004.
1=poor to 5=excellent.

	Summer 2004
Ability to design/conduct experiments and analyze/interpret data:	4.33
Understanding of professional responsibilities:	4.23
Ability to function independently with minimum guidance:	4
Ability to work in teams	4.60
Multidisciplinary teams:	4.57
Ability to communicate effectively - Verbal:	4.15
Ability to communicate effectively - Written:	4.08

4. Summary

Rowan University has developed a program that fosters synergistic interaction between industry and academia which provides a mechanism for performing industrially sponsored research or design projects in an academic environment. Undergraduate junior and senior engineering students work in multidisciplinary teams on semester-long or year-long projects that are supported by external industrial sponsors. In addition to providing a mechanism to introduce emerging technologies relevant to regional industries, the Clinics provide the students with exposure to industrial projects with real deadlines and deliverables, and an opportunity to develop their project management, teamwork and oral and written communication skills.

This program offers the industrial sponsor a cost-effective approach to problem solving with potential for a high return on investment through technical assistance from advanced undergraduate engineering students supervised by faculty. Successful projects have led to the several new process modifications and process units that have resulted in greener processes, increased capacity, higher product purity, decreased labor cost, and less process down time. In addition, the company has the opportunity to watch for potential interns and employees for future hire. Faculty members have developed valuable relationships with industrial partners, secured funding for research projects, learned about new technologies, and occasionally have published results externally.

The Clinic model provides a framework for academic-industrial interaction involving undergraduate students. Students have learned new technology through industrial projects, have gained exposure to industrial culture, gain experience with deadlines, progress meetings, presentations and written deliverables, and in many cases have secured summer or full-time employment with the sponsoring company. Students have won external awards for their work and have presented their work at national conferences.

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