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Implementation and Evaluation of Experiential Learning to Reinforce Research & Development Skills in a Biopharmaceutical Process Development Course

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Introduction

Biomedical engineering undergraduate programs must prepare students to enter research & development (R&D) focused post-graduate work, whether in industry or academia. However, traditional biomedical engineering coursework may not always adequately cover R&D skills. This work focuses on implementing and evaluating experiential learning activities in a biopharmaceutical process development course at the University of Maryland, College Park. In the field of biopharmaceuticals, "research" refers to determining the structure of the new drug based on the desired biological function, while "development" refers to creating the manufacturing process which can produce the drug at sufficient quantity and quality to use as a pharmaceutical product. Both research and development rely heavily on using laboratory experiments to optimize the drug design and the manufacturing process. Therefore, the course activities were designed to build students' R&D skills including designing experiments, developing laboratory protocols, analyzing data, optimizing a process, and making decisions based on data.

Incorporation of experiential learning-focused activities into engineering courses is well-documented in the literature. McKenna et al. developed industry relevant classroom activities at Northwestern including both hands-on experiments and team experiences [1]. Ripoll et al. focused on developing engineering skills in biotechnology students through laboratory-focused activities that enabled students to engage with engineering calculations and practice drawing conclusions from experimental results [2]. Figueiriedo et al. implemented experiential learning activities where students worked on industry-based projects; they found that students perceived that their teamwork and collaboration skills were the most improved [3]. Several studies have also focused on the development of engineering professional skills including Alkan et al. who explored using experiential learning to improve scientific process skills in a chemistry class [4], and Wallen et al. who focused on improving research skills through a project-based tissue-engineering modules [5]. Faculty at the University of Michigan have gone a step further to design and implement seven "biomedical engineering in practice" modules in their undergraduate curriculum [6]. These modules are designed to be student-centered, with most of the experiential learning activities occurring in the classroom. The modules led to significant learning gains, particularly in female students. These studies show the value of incorporating experiential learning in the classroom with the goal of not only reinforcing course content but also building professional engineering skills.

There is a significant need for workforce development for the biopharmaceutical industry with courses going beyond the science and emphasizing R&D skills used in process development and manufacturing [7]. Bioprocess engineering courses can be found in chemical engineering, biomedical engineering, and biotechnology curricula, but often focus purely on scientific modeling with less emphasis on the technical skills required for process development. Courses which focus on industry-relevant skills can be even more valuable in preparing students for careers in the biopharmaceutical industry. This work builds on a previous paper which focused on evaluating how traditional course elements like homework and projects improved R&D-focused professional skills in a biopharmaceutical process development course [8]. This work describes the implementation and evaluation of experiential learning activities with an expanded assessment of student perception of the activities and student skill development.

Research Questions

The purpose of this study is to evaluate the impact of including simulated industry experiences and hands-on laboratory activities in an engineering elective course on students' knowledge of and confidence in key research and development skills. In addition, the author wanted to understand if there is additional benefit in including the hands-on laboratory activities compared to simulated industry experiences alone.

Methods

Course Structure

The course, Biopharmaceutical Process Development & Manufacturing, is an elective course cross-listed between chemical engineering and bioengineering with the majority undergraduate students and up to 5 graduate students per offering. The course covers the fundamental steps involved in process development and manufacturing of biopharmaceuticals including cell culture, purification, and formulation as well as drug product manufacturing and analytical characterization, with a focus on production of monoclonal antibody therapeutics. The course is divided into five main modules: Development & Characterization of Protein Therapeutics, Upstream Process Development, Downstream Process Development, Formulation & Drug Product Development and Biopharmaceutical Process Development in Practice. In 2022, the author obtained a $20,000 grant from the University of Maryland to add experiential learning elements to the course. Experiential learning was implemented in two ways: 1) Students engaged in "simulated industry experiences" (SIEs) where they were challenged to solve open-ended industry-relevant problems in teams in class. 2) Students completed hands-on laboratory exercises with common instrumentation found in the biopharmaceutical industry. Students who were enrolled in the course in Fall 2022 participated in the simulated industry experiences only, while students in Spring 2023 completed the same simulated industry experiences plus a brief hands-on laboratory experience.

The grant funding was used to revise the course to include simulated industry experiences, to pay students to develop hands-on laboratory activities, and to purchase the laboratory supplies and instrumentation to conduct the laboratory activities. Additional funding in the future will be needed to cover the cost of the laboratory consumables only. The experiential learning elements were implemented in Fall 2022 and Spring 2023. The enrollment and study participation are shown in the table below:

Table 1. Students Enrolled in Study

Semester	# Students Enrolled	# Students in Study
Fall 2022	32	29
Spring 2023	31	29

Experiential Learning Activities

<u>Simulated Industry Experiences</u>

Simulated Industry Experiences (SIEs) were conducted at the end of each of the first four content modules and included 1) protocol development for protein concentration measurement, 2) development of an efficient bioreactor seed train, 3) scale-up and fit to plant assessment for protein A chromatography and 4) solution preparation for a formulation screening experiment. Details of each simulated experience are given in the table below. Students worked in teams of 5 during the entire 75-minute class period to solve these open-ended industry relevant challenges. In each case, students were given multiple criteria to consider when determining their final output, which encouraged them to weigh a range of factors including efficiency and economics.

Table 2. Experiential Learning Activities

<table>
<tr><th>SIE Topic</th><th>Brief description</th><th>R&D Skills Targeted</th></tr>
<tr><td><u>Module 1</u>: Protocol development for protein concentration measurement</td><td>Determine a gravimetric serial dilution protocol to prepare a highly viscous protein solution for protein concentration measurement via A280 given restrictions on the linear absorbance range of the instrument and accuracy of the microbalance and cuvette volume, while minimizing protein used. Perform a mock calculation based on absorbance results.</td><td>• Developing laboratory protocols
• Optimizing a process
• Analyzing data</td></tr>
<tr><td><u>Module 2</u>: Development of an efficient bioreactor seed train</td><td>Determine a seed train to produce enough cells to seed a 500L production bioreactor given a single working cell bank vial, a set number of shake flasks, wave bags, and bioreactors of set volumes, and growth information about the cells, all while trying to minimize the seed train duration and plan for the risk of contamination.</td><td>• Developing laboratory protocols
• Optimizing a process
• Making decisions</td></tr>
<tr><td><u>Module 3</u>: Scale-up and fit to plant assessment for protein A chromatography</td><td>Given the protocol, column dimensions, and dynamic binding capacity for a lab-scale protein A process, assess fit to plant for a 12,000 L bioreactor with expected titer and harvest ranges and select the best protein A manufacturing column size to balance cost, time, and productivity. Students were provided with a google sheets template to facilitate calculations.</td><td>• Optimizing a process
• Making decisions</td></tr>
</table>

<u>Module 4</u>: Solution preparation for a formulation screening experiment	Given a set of experiments that must be run at different protein concentrations and different volume requirements, develop recipes to produce a given formulation from a set of provided stock solutions. Note: Fall 2022 students completed this SIE for a theoretical laboratory experiment while Spring 2023 students completed this SIE to prepare for the laboratory exercises.	• Designing experiments • Developing laboratory protocols

<u>Hands-on Laboratory Exercises</u>

In the hands-on laboratory exercises, students measured the impact of formulation parameters (pH and presence of sodium chloride, an ionic strength modifier) on protein-protein interactions and viscosity of bovine serum albumin (BSA). BSA was selected as a model protein since it is commercially available and much more reasonably priced compared to monoclonal antibodies. Six teams of 5-6 students analyzed one of six different solution conditions (pH 5, 6 and 7 with and without NaCl) and then students analyzed the shared class data set. Solutions were studied for their viscosity up to 200 mg/ml using Cannon-Fenske viscometers. In addition, students measured the diffusion coefficient using dynamic light scattering at concentrations between 2 and 10 mg/ml to calculate the diffusion interaction parameter (kD) which is a measure of protein-protein interactions. Finally, students confirmed protein concentrations using the NanoDrop spectrophotometer. Prior to the laboratory, students developed recipes to produce the solutions they needed to prepare given stock solutions of concentrated buffer, BSA, and NaCl. Students prepared the solutions in the lab prior to conducting the viscosity, DLS, and protein concentration measurements. Students watched videos about each experimental technique along with pipetting and lab safety prior to the in-class lab period. The lab activities took four 75-minute class periods total with one period devoted to solution prep and a three-class period rotation with two groups conducting the lab activities supervised by the teaching assistant and the remaining groups working on the final group project with the professor.

Evaluation and Data Analysis

Quantitative Data Analysis

This work was approved by The University of Maryland IRB under protocol # 1947140-1. Pre- and post- semester surveys were used to determine how students' self-perceived confidence in R&D skills changed from the beginning to the end of the course. Students were asked to rate their confidence in skills including experimental design, developing experimental protocols, analyzing data, optimizing a process, and making decisions based on data, along with their confidence in their preparedness to complete hands on laboratory research and to work in the industry as a process development engineer on a 5-point scale from strongly agree (4) to strongly disagree (0). Grades on simulated industry experiences and the final laboratory report were used to assess student mastery of the relevant skills in each assignment. Finally, student experimental design skills were assessed before and after the semester using an experimental design assessment [9]. In this assessment, students were asked to design an experiment to answer a theoretical question. An example of the question is shown below. A similar scenario with a different application was provided in the post-semester survey.

Figure 1. Experiential Design Assessment from Pre-Survey

Q1 (Pre): Advertisements for an herbal product, ginseng, claim that it promotes physical endurance. What type of evidence would you like to see to evaluate this claim? Provide details of an investigative design. Be as specific as possible and include how you would decide if you should recommend using ginseng to promote endurance. Upload your response as a pdf document. You may hand write or type your response.

Q2 (Pre): Additional studies claim that more nighttime sleep also promotes endurance. Describe a study which could determine the optimum sleep hours and ginseng dose to maximize physical endurance. Upload your response as a pdf document. You may hand write or type your response.

Student experimental designs were scored using the rubric below, which was adapted from Sirum, 2011 [9].

Table 3. Experimental Design Scoring Rubric

Category	**Points**	**Rubric Items**
Protocol Development	Out of 4	□ Understanding that the data must be collected with multiple replicates (subjects) □ Discussion of how dependent variable is could be measured (e.g., how far subjects run will be measure of endurance). □ Recognition that groups should have similar starting levels of endurance, or a paired experimental design should be used □ Understanding that a control should be used (placebo)
Data analysis	Out of 1	□ Recognition that data should be analyzed using statistical tests to understand if there is a true difference between the groups.
Optimization	Out of 1	□ Recognition that a factorial experiment should be completed in the case of two independent variables
TOTAL	**Out of 6**	

In addition, students were surveyed after each experiential learning activity to understand which skills were reinforced and what they learned from the experience. Students rated how the exercise reinforced skills including experimental design, developing experimental protocols, analyzing data, optimizing a process, and making decisions based on data on a 5-point scale from strongly agree (4) to strongly disagree (0).

Qualitative Data Analysis

To better understand the impact of the experiential learning activities, several free response questions were included in the surveys. In the survey after each simulated industry experience, students were asked to briefly reflect on the activity by sharing things like what they learned from the activity, how this activity challenged them to think like an engineer in industry, or what could be improved about the activity. In addition, students were asked to identify the main challenges in the biopharmaceutical industry in pre- and post-semester surveys. All qualitative responses were analyzed using coding with representative quotations were selected to represent themes.

Results

SIE and Lab Activity Analysis

<u>Simulated Industry Experiences and Hands-On Laboratory Exercises Reinforced R&D Skills</u>

Students completed surveys after each simulated industry experience (Fall 2022 and Spring 2023) and after the hands-on laboratory activities (Spring 2023 only) in which they rated which research and development skills were reinforced by the activity. Since the simulated industry experiences were the same or very similar in both semesters, data across all 57 students was combined. Figure 2 below shows the percentage of students who responded "somewhat agree" or "strongly agree" that the activity reinforced each of the 5 R&D skills.

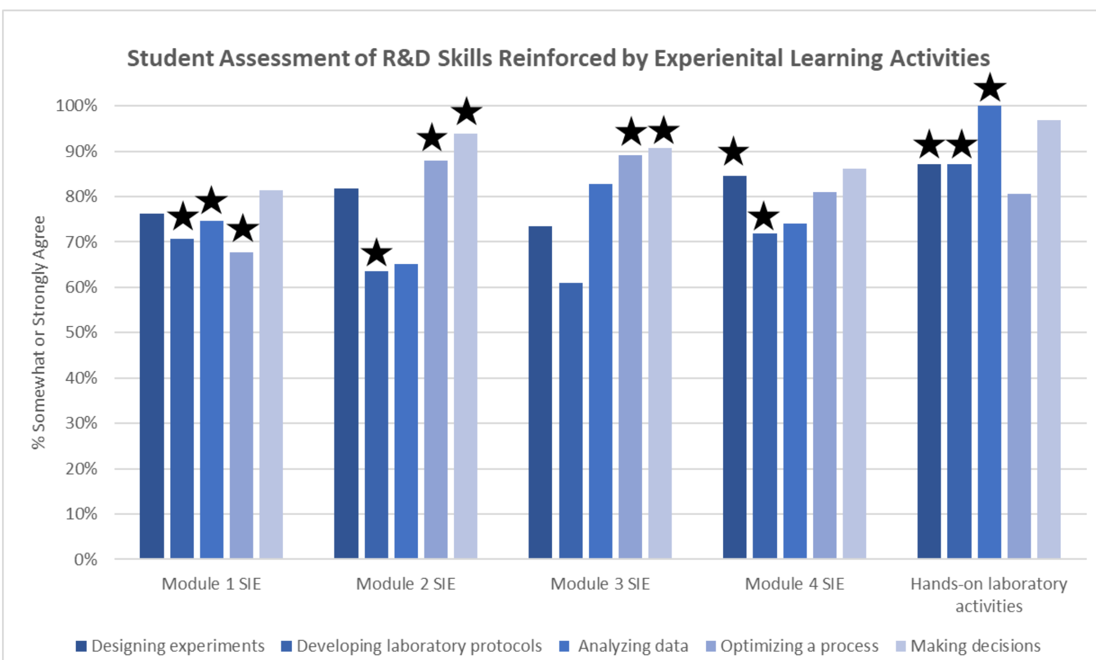


Figure 2. Student assessment of R&D Skills Reinforced by Experiential Learning Activities. Skills targeted by each activity are marked by a star.

This data illustrates the students perceived that the simulated industry experiences and hands-on laboratory activities strongly reinforced R&D skills, albeit to different degrees. Module 1 SIE which focused on protocol development for protein concentration measurement was the weakest SIE with a mismatch between the targeted skills and those ranked the highest by students. Developing laboratory protocols was consistently low throughout the surveys compared to designing experiments, which suggests that students did not perceive that the activities improved their protocol development skills, or perhaps students may not understand the difference between designing an experiment (determining which variables will be varied and which outputs will be measured), and laboratory protocols (determining what steps must be taken in lab to execute the experiment). It may be beneficial in future offerings to discuss skills needed in research and development and the distinct parts of the experimental design and execution process more intentionally. Module 2 and 3 SIEs, which focused on seed train design and protein A chromatography fit-to-plant assessment, respectively, rated the strongest for process optimization and decision-making, which was consistent with the goals of the activities. Students perceived that the module 4 SIE strengthened experimental design, which was consistent with the goals, and making decisions was also rated highly. Students may have a broader view of making decisions (i.e., deciding what volumes to use for the experiment) rather than the intended definition of the skill (making decisions for a process based on data). The hands-on laboratory experiences were perceived by students to provide the highest reinforcement of R&D skills, with a strong focus on data analysis which was included in the laboratory report. Overall, these results showed that students found value in the activities, and that the hands-on laboratory activities reinforced the R&D skills studied more strongly than any of the individual simulated industry experiences.

Table 4 shows average grades for each SIE in Fall 2022 and Spring 2023, along with the laboratory report grades for Spring 2023. The high grades indicate that students were able to master the skills reinforced in each activity, consistent with their perception that these skills were improved.

Table 4. Student Grades on Experiential Learning Activities

Activity	Average Grade ± Standard Deviation		Skills Targeted
	Fall 2022	Spring 2023	
SIE 1	83% ± 11.8%	97% ± 6.7%	Dev. protocol, opt. process, analyze data
SIE 2	96% ± 4.2%	93% ± 4.5%	Dev. protocol, opt. process, make decisions
SIE 3	90% ± 6.9%	98% ± 3.8%	Opt. process, make decisions
SIE 4	91% ± 7.6%	94% ± 6.1%	Design expt., dev. protocol
Laboratory Activity	N/A	93% ± 7.5%	Dev. protocol, opt. process, analyze data, make decisions

SIEs Provided Industrially Relevant Experiences that Reinforced Course Content and Improved Teamwork

After each SIE and the hands-on laboratory activities, students responded to the prompt "Briefly reflect on the activity. You can include things like: What did you learn from this activity? How did this activity challenge you to think like an engineer in industry? What could be improved about the activity?" Responses were analyzed by coding with the 2-3 most common themes and representative quotations for each SIE shown in the table below.

Table 5. Thematic Analysis of SIE responses

SIE	Theme (# of students mentioning theme)	Representative Quotation
1	Teamwork (15)	"I liked the group aspect of the SIE. This helped us bounce ideas off one another. We all had our own solution methods at first, but working together helped us to optimize the process and get a better understanding of the topic."
	Industry-relevant (14)	"I think the activity was a good way to combine all of the concepts we have been discussing and putting them into real-world situations. It was challenging to collaborate with all different skill sets that the team had, which is definitely something we will encounter in the real-world."
	Multiple constraints (10)	"I learned how to better understand the minimum/maximum of bounds and the limitations from pieces of equipment in the lab. This challenged me because there was not a necessarily a "right" answer or approach to solving the problem and there is not a concrete response. This challenged me to think about equipment and process limitations. I think maybe emphasizing that there is not a singular approach."
2	Optimization (22)	"One of the main aspects that I thought was rewarding about this activity was being able to see an actual problem that could occur in industry and trying to determine the best course of action. We used math and the science that we learned to make informed decisions about how to design a process. There were multiple possible ways theoretically but we used the knowledge we had had to do what we thought was best and most efficient."
	Difficult/ challenging (18)	"This was much harder than I thought. I 100% see why this is something that would be done in the industry, and even with some assumptions and simplifications, the problem was still very difficult. I did like how it challenged us to think."
	Reinforced course content (14)	"I learned about the direct applications of learned concepts and how they can be further optimized to fit a realistic setting. This optimization process, I believe, is uniquely engineering, especially in industry. I believe having a little more guidance or a little more time in class for this assignment in particular would have led to

		less confusion (though the problem-solving aspect helped me understand the material better)."
3	Spreadsheet software skills (19)	"I think using a spreadsheet was a good way to simulate real-world experience since that is most likely how computation would be done in our careers."
	Reinforced course content (14)	"I learned how to do chromatography calculations and how the conditions were for each step. It was hard to visualize every step in the purification process for me, but now I think I can visualize easily. Visualizing column volumes was challenging for me, it took some time to understand perfectly. It was a good activity, probably my favorite SIE so far!"
	Decision making (13)	"I feel like often times in engineering we are told that we will need to use our knowledge of science and mathematics in order to make process related decisions. This was one of few experiences so far in my undergraduate classes where I feel like we actually did this and applied what we were learning. Throughout the process, I was challenged to think critically about what we had learned and then use data given to us to decide what column would be most efficient."
4	Reinforced course content (12)	"It was a great exercise to demonstrate how you can optimize a process to use only the minimal amount of material you need, and it was especially helpful for learning how to accurately calculate the volumes needed to make formulations that have many components in them."
	Industry-relevant (9)	"This was very useful in terms of lab prep. It helped see the entire process beforehand and ensure we wouldn't waste much of the protein we are using, which is really important in the industry when the monoclonal antibodies are hard to come by, especially when they are first being produced."
	Connection to lab activities (6) (Spring offering only)	"I really enjoyed how this activity was preparatory work for the actual laboratories. I feel as though this SIE paired with the lab activities will really give an indication as to how this process occurs in industry. I am very excited for it!"
Hands-on lab activities	Lab techniques/ equipment (18)	"I mostly learned how to use the nanodrop, DLS, and the viscometer. It's important to learn about how we can use these tools to measure key parameters, however it is equally important to get hands-on experience. It's irreplaceable. I also liked how this had multiple steps (the SIE, the solution prep, and then the lab). It really made the whole experience more comprehensive."
	Industry-relevant (5)	"I really liked the hands-on aspect and how we were involved in the experience from start to finish - preparing the solution calculations during the fourth SIE, making the solutions, and then running the tests. It challenged me to think like an engineer because like in industry there are goals to be met and obstacles that must be planned for ahead of time."

Based on these responses, in addition to the five key R&D skills targeted, students perceived that the simulated industry experiences were industry-relevant and reinforced the course content itself along with improving teamwork skills and spreadsheet software skills. In general, students commented that it was often challenging to complete the activity during a single course period and that it was difficult to coordinate their groups outside of class on a short deadline, so the timing of simulated industry experiences should be further considered. During certain semesters, students requested to complete the SIE in class in teams, but submit their own solution individually, which could be a potential solution. The theme of the SIEs feeling "challenging" or students not knowing where to start also emerged in the free response in Fall 2022. In future offerings, the activities were prefaced with messaging that due to the open-ended nature of the activity and multiple constraints on the problem, that students might feel overwhelmed at first and that was to be expected. This messaging seemed to ease the frustration. Overall, the SIE feedback was very positive, with students feeling like the experiences were valuable, reinforced course content, and gave them a sneak peek at some of the challenges that engineers face in the biopharmaceutical industry.

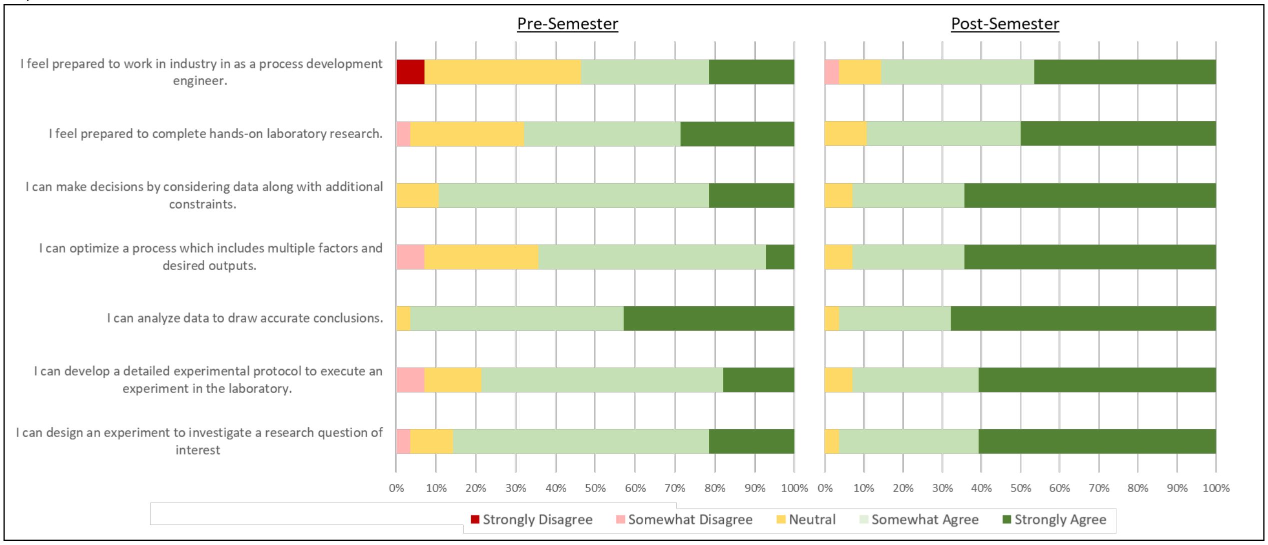
Pre- to Post-Semester Analysis

<u>R&D Skill Confidence Improves from Pre-Semester to Post-Semester</u>

Students were surveyed before and after the semester to understand their confidence in the R&D skills studied as well as their perceived preparedness to complete hands-on laboratory research or to work in the industry as a process development engineer. In each case, students responded to the question on a 5-point scale from strongly agree (4) to strongly disagree (0). Pre-semester means were compared using a two-sided t-test (α= 0.05) and no significant differences were found in student confidence prior to the semester between Fall 2022 and Spring 2023. The figures below present the data in two ways. Figure 3 shows the percentage of students who responded to the statements in strongly agree through strongly disagree before and after the semester for SIE only (Fall 2022) and SIE + Hands on Laboratory Experience (Spring 2023). In both semesters, there was a marked shift from neutral (yellow) and somewhat agree (light green) responses to strongly agree responses (dark green), with a more pronounced shift in Spring 2023 when students were also exposed to hands-on laboratory exercises.

Figure 3. Confidence in preparedness to work in industry and R&D skills pre and post semester for A) SIE only (Fall 2022) and B) SIE + Hands-on laboratory Experiences (Spring 2023)

A)



B)

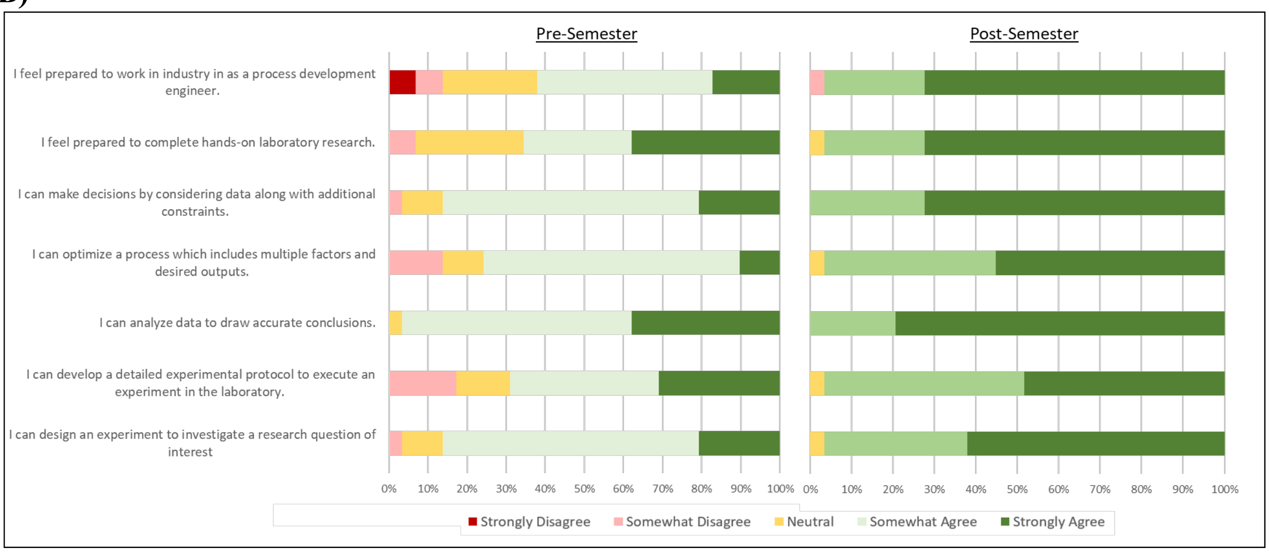


Figure 4 shows the data from a different angle, with each bar representing the average score gain on the survey from pre-semester to post-semester on a 4-point scale. This data shows that across both semesters and all R&D skills, confidence increased from the beginning of the semester to the end of the semester. A paired t-test confirmed that gains were significant for both semesters across all survey items with $p<0.01$ in each case. The largest gains were seen in process optimization and feeling prepared to work in industry. Although it is not possible for students to accurately self-rate their readiness to work in industry, the fact that course activities bolstered their confidence in their readiness is still an important metric. While there appears to be a difference in the mean gain between the two semesters, none of these differences were found to be statistically significant using a two-sided t-test with a significance level of 0.05.

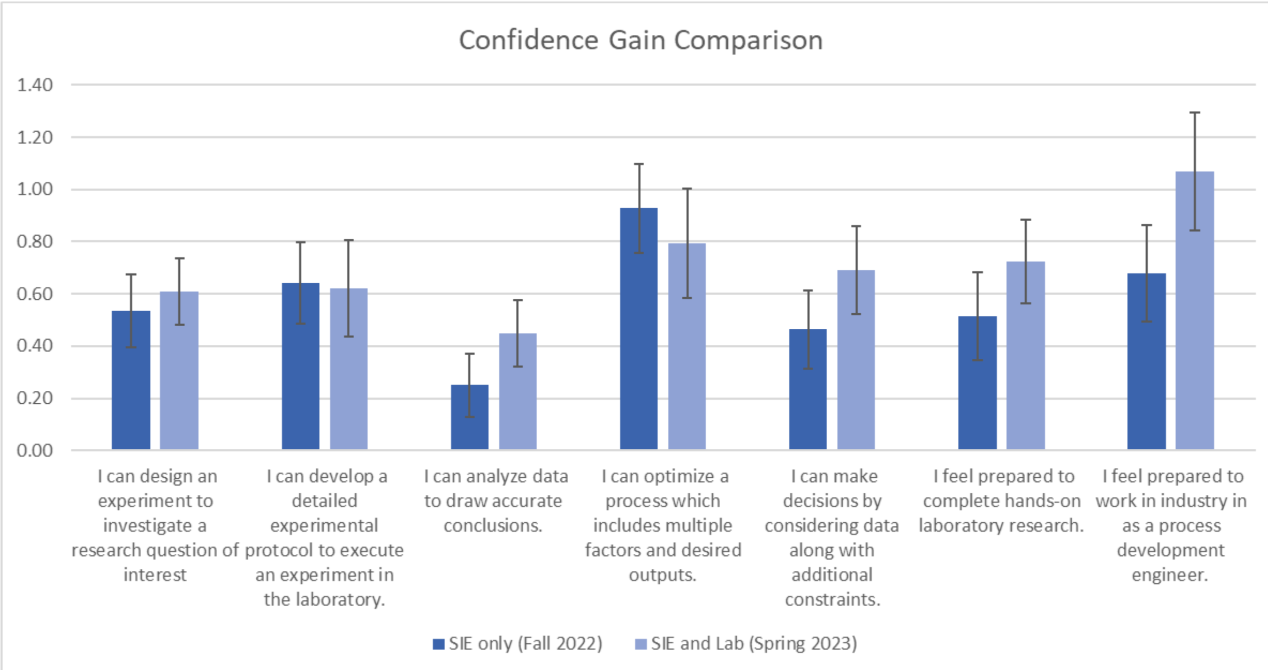


Figure 4. Confidence Gain Comparison. Gain is calculated as post semester average- pre-semester average out of a 4-point scale. Error bars indicate standard error of the mean.

<u>Student Experimental Design Scores Pre- and Post-semester were Similar</u>

Student understanding of experimental design and analysis was assessed using a modified version of the experimental design assessment tool (EDAT) developed by Sirum et al [9]. The goal of this quantitative metric was to determine how student experimental design ability changed from the beginning to the end of the semester with exposure to activities were designed to improve aspects of the research process including experimental design, protocol development, data analysis, and decision making. There was no significant change in the average score between the pre- and post-tests for spring Fall 2022 or Spring 2023 (Figure 5)

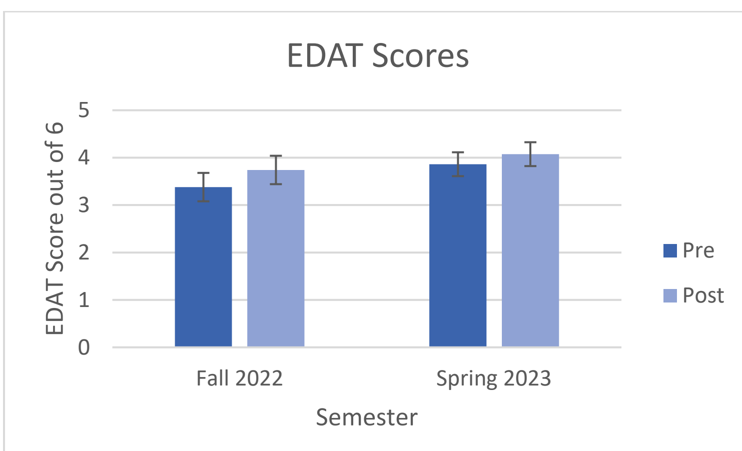


Figure 5. Experimental Design Ability Test score pre- and post-semester comparison for Fall 2022 and Spring 2023. Error bars represent the standard error of the mean.

Looking at scoring on individual items on the EDAT in Table 6, there is no significant difference between the proportions of students who identified each element of experimental design or analysis before and after the semester (2-sample normal method proportion test with significance level of 0.05).

Table 6. Percentage of students identifying each criterion on the Experimental Design Ability Test comparing Fall 2022 and Spring 2023 pre and post semester surveys

	Fall 2022		Spring 2023	
	Pre	Post	Pre	Post
	N=29	N=27	N=29	N=27
□ Understanding that the data must be collected with multiple replicates (subjects)	69%	79%	72%	66%
□ Discussion of how dependent variable could be measured (e.g., how far subjects run will be measure of endurance).	79%	72%	72%	63%
□ Recognition that groups should have similar starting levels of endurance, or a paired experimental design should be used	52%	45%	45%	38%
□ Understanding that a control should be used (placebo)	52%	59%	48%	47%
□ Recognition that data should be analyzed using statistical tests to understand if there is a true difference between the groups.	38%	28%	41%	19%
□ Recognition that a factorial experiment should be completed in the case of two independent variables	48%	66%	48%	56%

Since the experimental design prompts were human subject based, it is possible that students were not able to apply their knowledge of laboratory experimental design directly to a human study. In addition, because of the open-ended nature of the prompt, it is possible that students were not aware of how detailed the experimental design needed to be or were simply not putting in their best effort since the survey was not graded for accuracy. Therefore, the experimental design ability test may not be the best measure of the effectiveness of the experiential learning elements in improving experimental design skills in this context.

<u>Students identified additional challenges in the biopharmaceutical industry post-semester</u>

Students were asked to identify the main challenges faced in biopharmaceutical process development on pre- and post- semester surveys. Before and after the semester, students cited general business/ manufacturing challenges as well as challenges that were more specific to biopharmaceuticals (Table 6). After the semester, additional challenges were listed, including process development/ optimization, collaboration between different groups, and control of process and product related impurities, which indicated added appreciation for process development challenges. Students also identified the industry challenges of time, sterility, patient safety, and product stability more frequently in post-semester surveys. The new challenges identified after the semester were consistent with the course content, although the themes that emerged were not necessarily specific to the experiential learning components. Fall 2022 and Spring 2023 data was combined for this analysis. Table 7 summarizes the challenges identified by students before and after the semester.

Table 7. Thematic Analysis of Biopharmaceutical Industry Challenges identified Pre- and Post-semester

Challenge Type	Challenge	Count Pre-Semester	Count Post-Semester
General	Cost of development/ manufacturing	24	19
	Time of development/ manufacturing	6	13
	Market demand/ competition	7	5
Manufacturing	Scale up	12	12
	Product quality	10	12
	Consistency of product	11	2
	Appropriate manufacturing conditions/ GMP	9	5
	Supply chain	5	4
	Working with cells	3	3
	Sterility/ preventing contamination	8	13
	Equipment	1	5
	Process development/ optimization	-	11
	Collaboration between different groups (i.e., upstream and downstream)	-	5
Biopharmaceutical Specific	Regulatory requirements	14	11
	Patient safety	10	18
	Product efficacy	7	9
	Product stability	2	8
	Clinical trials	9	6
	Control of product and process related impurities	-	11

Discussion & Conclusion

This work describes the implementation and evaluation of experiential learning activities including simulated industry experiences and hands-on laboratory activities in a biopharmaceutical process development elective course. The goal of these activities was to strengthen research and development skills, specifically designing experiments, developing laboratory protocols, analyzing data, optimizing a process, and making decisions based on data.

Surveys after each activity indicated that students perceived that the experiential learning activities strengthened their R&D skills and reinforced teamwork and technical course content. In general, simulated industry experiences were perceived by students to strengthen 2-3 skills each while the hands-on laboratory experiments were able to build all 5 skills. Students in the offering with the SIEs only (Fall 2022) and the offering with the SIEs and hands-on laboratory experiences (Spring 2023) both showed significant gains over the semester in confidence in the R&D skills and their self-rated preparedness to complete hands-on laboratory research and work in the industry as a process development engineer. Although the average gains in the semester with the hands-on laboratory activities were higher, this difference was not statistically significant. Overall, students perceived the SIEs and laboratory activities as challenging, relevant to industry, and a positive learning experience. Therefore, faculty considering implementing experiential learning into their courses should consider a series of simulated industry experiences focusing on different R&D skills as a viable alternative to hands-on experiences if equipment, space, or budget is not available for laboratory activities.

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