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WIP: Biomanufacturing in Appalachia - Experimental Design of a Bioengineering Training Program

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Abstract

Building on our initial efforts to establish a regional center for biotechnology in the Appalachian Highlands, we present updates on our ongoing project to foster workforce development in bioengineering and biomanufacturing. In this update, we will discuss the research and evaluation strategy to assess the effectiveness of our training regime. This phase focuses on a hybrid training approach which allows students to establish knowledge competency asynchronously while developing practical industry-aligned skills in a series of short lab modules. We present a strategy of pre- and post-testing and industry assessment of participant competency. Additionally, we present this Work In Progress (WIP) to solicit critique of the proposed plan of strategy. We see this development as addressing the critical need for a more distributed and resilient bioeconomy.

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Introduction

Biomanufacturing has been described as a potential solution to a sustainable and circular economy and as a replacement for fossil chemicals. Recent efforts by government, industry, and academia have sought to accelerate the rate of commercialization of biologically engineered products, highlighting the increasing demand for a well-trained workforce (Garcia et al., 2021). Despite this, there remains a gap in educational programs designed to train students in biomanufacturing processes, particularly in rural regions such as Southern Appalachia. To address this gap, we have embarked on a multi-scale project to develop a pipeline to enhance training in synthetic biology, bioengineering, and bioengineering (Prince et al., 2024). While the wider project encompasses many initiatives at East Tennessee State University, here we present a WIP update on our major goal of developing a biomanufacturing training program focused on job-readiness and downstream processing skills suitable to develop a nascent workforce in rural Southern Appalachia.

In brief, we seek to catalyze workforce development concurrent to the growth of our industry partners and expansion of biomanufacturing in our region. We are developing a training program to effectively and quickly bring students with little relevant background up to speed in the requisite techniques of biomanufacturing. We identified a lack of available training for downstream processing techniques, namely separation, filtration, polishing, and packaging, and are offering laboratory training for each of these leading to a relevant microcredential and matriculation into an industry-sponsored internship for students. Concurrently, feedback from our industry partners identified a lack of general preparedness in the so-called soft skills of entry-level employees and we have incorporated preparation and assessment of those skills into our credentialing pathway. However, we recognize it is not sufficient to offer this training and make the claim that students who complete our program are truly workforce ready. In this WIP update, we outline a plan of study to evaluate the effectiveness of our training across four categories of metrics: student knowledge and technical ability change, soft-skill change, student self-efficacy, and industry partner perception of student readiness.

Literature Review on Educational Studies in Biomanufacturing

Educational research in biomanufacturing training has focused on the need for experiential learning and industry-aligned competencies (Brassard et al., 2019; Burnett et al., 2022). Studies have highlighted that traditional life sciences curricula often lack dedicated instruction in bioprocessing and downstream manufacturing techniques, resulting in graduates who are underprepared for industry roles (National Academies of Sciences, Engineering, and Medicine, 2020). Efforts such as the BioMADE initiative and NSF-funded workforce development programs have underscored the importance of integrating hands-on training with core biological and engineering principles (Garcia et al., 2021).

Research also emphasizes the effectiveness of competency-based education (CBE) models in training biomanufacturing students. CBE programs focus on assessing students based on demonstrated skills rather than seat time, making them particularly effective for bridging knowledge gaps among nontraditional learners (Jones & Black, 2021). The integration of work-based learning, such as internships and apprenticeships, has also been shown to enhance student readiness by providing real-world experience and exposure to industry expectations (Brassard et al., 2019).

Purpose

The purpose of this study is to examine the effectiveness of the biomanufacturing program's professional development modules on students' content knowledge, technical ability, and soft skills over time, including industry partners' perception of work readiness. The following research questions guided this inquiry:

1. To what extent, does student content knowledge of biomanufacturing & technical proficiency change after participation in the biomanufacturing pipeline program's training modules.
2. To what extent does a student's soft skills (i.e., time management, personal reliability, teamwork, and leadership) change after participation in the biomanufacturing pipeline program's training modules?
3. To what extent do students' sense of self efficacy change across the completion of the module sequence?
4. What is industry partners' perception of student interns that have completed the module sequence?

Methodology

The following study intends to use multiple methods to assess the effectiveness of the professional development modules. Specifically, we use a cross-sectional quasi-experimental pre-posttest design to assess content knowledge and soft skills before and after implementation of curriculum modules in downstream processing and workforce readiness.

Participants to compare will include a select cohort of high school students, veterans, as well as junior and senior undergraduate students within engineering and biology concentrations. Participants will complete content knowledge questions at the end of each module. Students will also take the Career Connect Student Survey (i.e., soft skills) and the self-efficacy measures (i.e., generalized self-efficacy, bioengineering self-efficacy, short form occupational self-efficacy), before taking any curriculum modules and then again after they complete the training program.

Measures

Soft Skills

To assess soft skill development, we utilize components of an existing validated survey, the Career Connect Student Survey. This survey measures student self-perceptions in areas such as time management, reliability, teamwork, and leadership. The Career Connect instrument builds upon a validated employability skills measure developed by Ciarocco and Strohmetz (2018). The Career Connect program, originally designed to support career readiness in rural settings, has undergone extensive evaluation through the Institute of Educational Sciences Regional Educational Laboratory (REL) Appalachia initiative. It aligns with college and career readiness frameworks and has been implemented across multiple school districts. Psychometric analyses of the survey have demonstrated strong reliability (Cronbach's alpha ranging from .66 to .87) and test-retest reliability (.76 to .89), making it a robust tool for assessing employability skills (Ciarocco & Strohmetz, 2018). This measure includes questions to assess soft skills (i.e., time management, personal reliability, teamwork, and leadership) before and after participation in the professional development modules. The quantitative questions use a Likert style format options ranging from: "1 = Strongly Disagree" to "5 = Strongly Agree". In our study, we will administer the Career Connect Student Survey at pre- and post-training intervals to evaluate soft skill development among participants.

Content Knowledge & Technical Ability

Students will also complete multiple-choice responses to indicate specific content knowledge of biomanufacturing (e.g., drying techniques, centrifugation, chromatography, distillation, filtration, cell lysis, safety, & sterile techniques). Questions will assess content knowledge, knowledge of techniques, and common pitfalls in process operation.

Students will be evaluated by trained evaluators through observation during the laboratory training procedures to assess their ability to successfully and autonomously carry out tasks relevant to each bioprocess technique, as well as umbrella tasks such as sterile technique, solution preparation, and documentation. To ensure comprehensive assessment, we have developed formal skills demonstration checklists in collaboration with the Bioscience Core Skills Institute, BCSI. These checklists provide a structured framework for evaluating technique proficiency and include key performance indicators for each bioprocessing task.

Each skills checklist requires students to demonstrate mastery of core competencies such as aseptic handling, equipment operation, process troubleshooting, and compliance with industry-standard safety protocols. The evaluators, who are experienced biomanufacturing professionals or instructors, will use these checklists to provide both quantitative scores and qualitative feedback on student performance. This approach ensures that students not only understand theoretical concepts but also gain hands-on expertise essential for success in biomanufacturing roles.

By integrating a structured, competency-based evaluation system, we enhance the reliability and validity of our training program assessments, reinforcing industry alignment and workforce preparedness.

Self-Efficacy Measures

At the beginning of the course, we will also ask students to complete both the generalized self-efficacy 10-item measure (GSE; Schwarzer & Jersusalum, 1995), the short form of the occupational self-efficacy scale (Rigotti et al., 2008), and our newly developed bioengineering self-efficacy measure.

Internship Placement within the Curriculum

A critical component of our biomanufacturing training program is the required industry internship. This internship is structured to take place upon completion of all curriculum modules, ensuring that students enter the workforce with foundational knowledge and technical skills. The internship will serve as a capstone experience where students apply their training in real-world biomanufacturing settings, further reinforcing both technical competencies and professional skills.

By integrating industry feedback and aligning our curriculum with employer needs, we aim to create a workforce that is not only technically proficient but also adept in workplace communication, teamwork, and problem-solving. The final assessment of student preparedness will include industry partner evaluations, providing external validation of student competency.

Data Analysis

All quantitative analyses will be conducted using R Studio (R Core Team, 2024). We will assess missingness of data. Using the pwr package (Champely et al., 2022), we ran an *a priori* power analyses ($1-\beta = .80$, $\alpha = .05$) and found that if we compared two groups and have a large effect (.4) we will at minimum need at least 25 participants. However, to detect smaller effects (.11 to .3), we will need in the range of 44 to 325 participants.

Using the lavaan package (Rosseel, 2012), exploratory factor analyses will be used among the Career Connect Student Survey 17 Likert-style items for the for the post-test responses. We will assess eigenvalues, Scree Plots, and factor loadings to evaluate potential factor solutions (e.g., two, three). We will also use exploratory factor analyses with the newly developed bioengineering self-efficacy measure and use confirmatory factor analysis for the generalized self-efficacy measure and the occupational self-efficacy measure.

At the completion of the module sequence, industry partners will also be provided a survey with open-ended responses regarding their perception of student interns performance and will be analyzed with thematic analysis (Braun & Clarke, 2006). After initial familiarization with responses, two coders will descriptively code and then group similar codes to form broader themes.

For the pre-and-posttest quantitative analyses, we will assess item-level data of soft skills from the Career Connect Student Survey and content knowledge (e.g., drying techniques, centrifugation, chromatography, etc.).

Dependent on the number of students in our sample, we plan to use statistical analyses appropriate to analyze changes in soft skills, content knowledge, and self-efficacy before/after participation in the curriculum modules (e.g., analysis of variance [ANOVA], multiple regression). Since we will not have a control group, we plan to include covariates (e.g., demographic information) to act as statistical controls and account for potential confounding variables. Descriptive statistics will be used to summarize frequencies among demographics, measures of central tendency, and variability of demographics on the items before/after participation in the training program. We also will report mean difference, percentage difference, and Cohen's *d* as a measure of effect size (Cohen, 1988).

Conclusion

The demand for a skilled biomanufacturing workforce continues to grow, yet traditional academic pathways may not keep up with the workforce demand in preparing students for industry roles. Our program seeks to bridge this gap by implementing a competency-based, industry-aligned training model. By leveraging validated assessment tools and requiring an internship for all students, we aim to provide a comprehensive training framework that equips graduates with both technical expertise and essential soft skills.

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Table 1

Career Connect Student Survey

Part 1. (Questions for all students at baseline and follow-up)

		1	**2**	**3**	**4**	**5**	**6**
		Strongly Disagree	**Disagree**	**Somewhat Disagree**	**Somewhat Agree**	**Agree**	**Strongly Agree**
1.	I prefer to work alone on projects.						
2.	People easily understand what I mean when I am talking to them.						
3.	It is difficult for me to remember information I only hear.						

4.	I can persuasively present my ideas in talking with others.						
5.	I often have difficulty verbally expressing my thoughts to others.						
		1	**2**	**3**	**4**	**5**	**6**
		Strongly Disagree	**Disagree**	**Somewhat Disagree**	**Somewhat Agree**	**Agree**	**Strongly Agree**
6.	I can easily fit into any group work setting.						
7.	I am eager to learn new information.						
8.	My mind tends to wander when someone is						

	verbally telling me what needs to be done.						
9.	I think I do some of my best work in group settings.						
10.	I struggle to manage my time						
11.	I typically comprehend information that someone tells me verbally.						
12.	I have trouble working in groups successfully.						
13.	When I have multiple projects, I can easily set priorities						

14.	My mind seems to go blank when I have to speak in front of a group of people.						
15.	It is easy for me to follow verbal directions.						
16.	I rarely procrastinate when working on projects.						
17.	I feel comfortable working in group settings.						

Note. Instructions provided to participants: Please indicate your level of agreement with the following statements using these options: 1 = strongly disagree, 2 = disagree, 3 = somewhat disagree, 4 = somewhat agree, 5 = agree, and 6 = strongly agree. Your answers to the survey are completely confidential and private. Your survey answers or name will never be reported to others. You can stop the survey at any time, and completing the survey is NOT a requirement.

There are no right or wrong answers to the survey questions. It is not a test. These questions help us to learn about you, and how we can make the Career Connect program better for students.