Bridging the Gap: Identification of Critical Knowledge, Skills, and Abilities (KSAs) to Fill Entry-level Bioprocess Technician Positions Using the BILT Model

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Abstract: Bioprocess manufacturing has grown tremendously, creating a shortage of skilled technicians to fill entry-level positions. The Business & Industry Leadership Team (BILT) model was used to bridge the gap between what students learn in college and what employers need from newly hired technicians. The active involvement of industry partners as co-leads provided insight to identify knowledge, skills, and abilities (KSAs) that have the highest priority for these jobs. Faculty used this information to analyze courses and align the curriculum to meet the industrial trends for future jobs. This report outlines how identifying critical KSAs has allowed us to bridge instructional gaps by implementing changes to the curriculum. Exchanging feedback and networking with the industry increased faculty and students' exposure to thoroughly enrich the Bioprocess Manufacturing program at Central Carolina Community College. The BILT model is also used to align curriculum in other departments to facilitate improvements across the college for different industries. This work can guide other institutions in developing programs and building a more diverse and inclusive workforce of highly skilled technicians.

Keywords: Bioprocess technician, Biomanufacturing, BILT Model, skilled technical workforce development, knowledge, skills, abilities, curriculum alignment, North Carolina

Introduction

Need for a Skilled Workforce in Biomanufacturing

The journey towards establishing national standards for roles within bioprocess manufacturing has been a collaborative effort spanning several decades. It began in Washington state in the early 1990s and gained momentum with initiatives by leaders such as Dr. Sonia Wallman at Great Bay Community College in the late 1990s. Bio-Link, now known as InnovateBIO, continued this work in Indianapolis in 2009. Additionally, the Northeast Biomanufacturing Center and Collaborative (NBC^2) played a significant role in the 2000s, culminating in the efforts of the Department of Labor's Trade Adjustment Assistance Community College and Career Training (TAACCCT) grant-funded Community College Consortium for

Bioscience Credentials. The consortium was led by the National Center for the Biotechnology Workforce, led by Russ Read, and an affiliate of NC BioNetwork based at Forsyth Technical Community College in Winston-Salem, NC.[1-3].

The increased growth of creating products by biomanufacturing has created a need for a workforce with a specific skill set for the jobs. In North Carolina, the industry has grown by close to 40% over the past decade, with the production of vaccines, biologics, new gene therapy products, traditional pharmaceuticals, other drug substances, food products, supplements, and bioplastics, according to the Economic Development Partnership of North Carolina (EDPNC) quarterly report [4-6]. Between January 2020 and December 2022, biopharmaceutical manufacturing companies have invested nearly $7.6 billion and nearly 6,200 new jobs in North Carolina [5]. Since 2022, North Carolina has invested over $2.1 billion and created over 2,700 new jobs to support the industry [7].

In 2022, a statewide coalition led by the North Carolina Biotechnology Center was awarded $25 million as part of the Build Back Better Regional Challenge. These funds promote training and career opportunities in the biomanufacturing industry and give greater access to more North Carolinians [5]. The infusion of funding from industry investments and federal grants has created a golden opportunity to bridge the gaps in employment by helping historically excluded groups access programs through community colleges. There are many community colleges across North Carolina that teach the BioWork Biopharma manufacturing training program, and the number is growing [5-6, 8].

The BioWork training program represents a culmination of efforts at both state and national levels to provide training for highly skilled, in-demand technicians in bioprocess manufacturing. It has a history of collaborative endeavors with community colleges, the North Carolina Biotechnology Center, and industry. BioWork training involves a variety of topics such as safety, quality, current good manufacturing techniques (cGMP), aseptic techniques, and other topics aimed at establishing robust standards and training protocols, ensuring that the workforce remains competitive in the evolving landscape of the life sciences industry [9]. The entry requirements allow for a vast range of students of all educational backgrounds. Funding for the program comes from the non-profit North Carolina Gold Leaf Foundation, which was created in 1999 to disperse tobacco settlement funds in financially distressed counties that had depended on tobacco for financial stability [6]. Currently 13 of the 58 North Carolina Community Colleges now offer the course to the general public in the form of continuing education and to newly hired biomanufacturing employees in the form of customized training. The BioNetwork is a life science training initiative of the North Carolina Community College System that connects and supports colleges, companies, and students to provide professional growth and network opportunities to facilitate successful career paths [6, 9].

In 2020, under the leadership of Dr. Lisa Smelser, CCCC restarted the Bioprocess Technology program in Lee and Harnett counties. The program encompasses stackable credentials starting with the BioWork Certificate, building to the Bioprocess Technology Certificate, and culminating with the Bioprocess Technology Associate in Applied Science Degree (AAS) [10]. In 2021, Dr. Brenda Grubb joined the department, taking the BioWork program to Chatham County. The program went from zero students at the start of 2020 to serving over 370 BioWork students through 2023, and currently, 50 Bioprocess technology students are enrolled in the AAS degree program. Developing a more robust training program improves the employability of students. Strengthening relationships with industry increases the capacity to reach underserved populations by increasing awareness of biomanufacturing careers and providing opportunities for students to be seen by employers who might not otherwise have connected with this untapped source of talent.

This paper focuses on the KSAs needed for entry-level bioprocess technician positions. These jobs would include process technicians in manufacturing preparation, formulation, or fill and finish, with a minimum education requirement of a high school diploma or GED plus relevant work experience and training. Other entry-level positions, such as quality control and lab technicians, would require a minimum of an Associate's degree. While a bachelor's degree is traditionally required for process engineer positions, those in research and development may require an MS with industry experience or a Ph.D.[6] and are not the focus of this paper.

Improving Industry Workforce Training using the BILT Model

The Business & Industry Leadership Team (BILT) model created by Dr. Ann Beheler from the National Science Foundation (NSF) Center of Excellence in Convergence Technology at Collin College was first used for Information Technology (IT) programs [11]. This model can be applied to any technical program using this process. The BILT model was established through work with business leaders from across the nation to determine the knowledge, skills, and abilities (KSAs) that "workforce ready" graduates would need to be competent in to meet the needs of the industry one to three years into the future. The model has been implemented at over 60 colleges in multiple disciplines [11-12].

The Biotechnology Department at CCCC also strives to reduce instructional gaps between what students learn in the classroom and the KSAs required to fill in-demand technical positions. CCCC has followed the BILT model and enlisted local industry partners to prioritize KSAs. This has allowed the development of a practice of aligning the curriculum at CCCC with the requirement for an entry-level bioprocess manufacturing technician. This iterative process can also be used to develop curricula for technicians in other industries. The BILT model is composed of local industry partners with a vested interest in actively playing a role in developing and training a workforce in collaboration with the educational institution. This is an innovative approach because, unlike an advisory board, the BILT meets more often and feels ownership of the training improvements by their commitment to contribute applied advice. The focus of this publication is to cover the use of the BILT model by CCCC and local biopharmaceutical industry partners to develop a skilled technical workforce. This model puts employers in a co-leadership role, significantly increasing their engagement with the program [11-12].

Methods

Essential Roles in the BILT Model

The BILT program quarterly meetings are conducted with the co-leadership of faculty and industry leaders.
Using a structured, repeatable voting process, KSAs are prioritized annually according to employers' predicted needs 12-36 months into the future [13].
This way, the training can produce the expected performance in graduates to meet the predicted labor market demand identified by industry trends [14]. The role of the faculty is to cross-reference KSAs to the existing curriculum and update the curriculum to address KSAs prioritized by industry members of the BILT. Stakeholders are provided with feedback from faculty regarding the implementation.

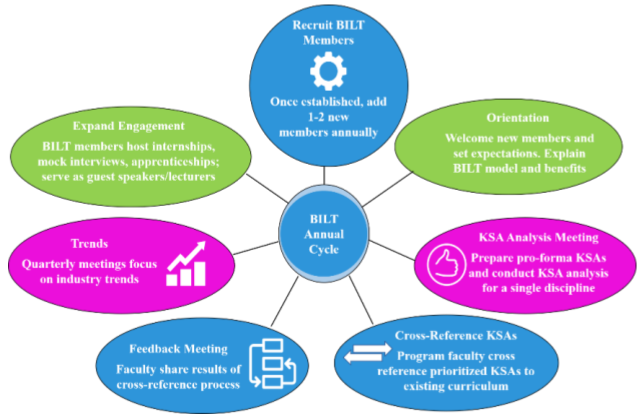

Fig 1. Annual Cycle of the BILT process [12]

Timeline and Process

First Quarter: The BILT model has a 12-month meeting cycle process [Fig 1, 12]. The first assembly of the BILT was an Orientation meeting to explain the process in January 2022. Once the KSAs needed for an entry-level bioprocess manufacturing technician were determined, a spreadsheet was created to use as a ballot [Table 1], and the first quarterly in-person meeting was scheduled for the voting process.

National standards were used to create the foundation for KSAs based on the Biopharmaceutical Manufacturing Industry Skill Standards, the Bioscience Skill Standards [1-2] and "Window on the Workplace 2023, Workforce Training Needs for North Carolina's Biopharma Manufacturing Industry," 2023, North Carolina Biotechnology Center [5]. The KSAs were validated in the context of local industries, allowing the curriculum to be aligned with continuous improvements based on future trends.

Second Quarter: The KSA Analysis meeting in May 2022 allowed industry partners to vote on KSAs. The meeting was in person and recorded by Zoom. All ratings were captured, and comments were added to the spreadsheet based on the discussion. The discussion was just as important as voting. Employer input at this stage is helpful when faculty later determine how the KSA will be addressed in the curriculum. Meeting participants included seven industry Subject Matter Experts participating in ratings and discussion, 1 Faculty Subject Matter Expert as an active listener, and 2 facilitating processed experts responsible for the efficiency and effectiveness of the meeting, including the creator of the BILT model, who attended via Zoom to facilitate the initial KSA vote ensuring that everything went smoothly.

Third Quarter: In the Fall quarterly, virtual meeting held in September 2022, the faculty shared results after the crosswalk of KSAs to the existing curriculum and the updates to address KSAs prioritized by businesses. Further feedback was requested from employers regarding implementation. Emphasis was also on growing a pipeline of right-skilled job candidates. Building and maintaining a thriving BILT is a high-touch activity with two-way communication. BILT members were encouraged to invite other colleagues in the industry to become a part of the team.

Fourth Quarter: The Trends meeting in November 2022 was a one-hour virtual meeting discussing future directions and innovations reported by Industry Partners. Implementation of the recommended changes to the curriculum began in the Fall 2022 semester was reported.

End of First Quarter Year Two: The established BILT team meeting in March 2023 introduced new members added to the team and gave an overview of the model and updates on the direction of the program and the industry. A mid-year meeting was held in July 2023. There was an in-person discussion of the training facility design and input from the industry on the flow pattern of the new building. Further information was shared about equipment for training necessary for a state-of-the-art curriculum to meet the coming needs.
Fourth Quarter Year Two: The virtual trends meeting was held in November 2023 to discuss KSAs for Quality Control (QC) positions.

Vote to prioritize Knowledge, Skills, and Abilities (KSAs)
The KSA priority vote is ranked from 1-4. One is the lowest, and four is the highest. Ranking criteria consider the following parameters together: Importance, level of proficiency, time spent doing the skill, difficulty, and how complicated the skill is to learn [12-13].
4= The KSA **must be included** in the curriculum
3= The KSA really **should be included** in the curriculum
2= It would be **nice to have** the KSA included in the curriculum
1= The KSA **can be left out** of the curriculum entirely

Table 1. Ballot Design with KSAs and Priority Levels

KSA#	Bioprocess Technology KSA	Priority Level (1-lowest, 4-highest)				
	Knowledge	4	3	2	1	Avg
K-1	Good documentation practices (GDP)					
K-2	Current good manufacturing practices (cGMP)					
	Skill					
S-1	Gowning, PPE, and hygiene at appropriate level/grade.					
S-2	Consistently following written and verbal instructions.					
	Ability					
A-1	Monitor process or indicators of system performance.					
A-1	Operate electronic communication systems and methods					

Cross-reference KSAs to existing curriculum
After reviewing the vote results, faculty compiled data to recommend changes in the course content. The course objectives and the syllabus content were cross-referenced and reviewed for each course to determine if each KSA was covered. Biotechnology faculty ranked coverage levels as Exposure (E) or Thorough (T) to indicate the level of coverage for each of the courses they teach. This was followed by highlighting the area of focus in the KSAs based on the voting of industry stakeholders and coverage by the instructors. Table 3 provides examples of the updates in the curriculum to address the prioritized KSAs. This subset of the faculty KSA cross-reference data focuses on the areas slated for change.

Results and Discussion

It was determined that changes would be focused on KSAs with an average score above 2.60. Votes from seven industry BILT team members were averaged to determine the priority of each KSA. A detailed description of each KSA can be found for the BILT KSA Voting Results in the Appendix [Table 2], with the average of priority rankings for each KSA. Results shown in Table 2A report knowledge (K) defined as subjects, topics, and items of information that employees should know. Table 2B reports (S) Skills defined as technical or manual proficiencies demonstrated by competency and skills checks. Table 2C reports (A) Abilities, described as the capacity to simultaneously apply several skills and knowledge to perform an observable task or behavior. Table 2D reports Certificates such as the BioWork Certificate and cGMP Quality Systems Certification.

Faculty determined that line items with an average priority above 2.60 were reviewed to ensure thorough coverage or multiple places of exposure in the curriculum. The goal is to elevate KSAs with no exposure to “E” (Exposure) and those that are providing exposure only to “T” (Thorough). Any line item with an average priority that falls below 2.00 was considered an area where the focus may remain the same or be reduced to allow for expansion in coverage of other materials. KSA areas slated for improvements are highlighted in green [Table 3].

Table 2. KSA Voting Results

Table 2A. KSA Vote for Knowledge:

KSA'S	KSA Task Name and Description	Number of Votes (4 = most important)				
K1-37	**Knowledge: subjects, topics, and items of information that employees should know**	**4**	**3**	**2**	**1**	**Avg**
K-1	Good documentation practices (GDP)	6	1	0	0	3.86
K-2	Current good manufacturing practices (cGMP)	6	1	0	0	3.86
K-3	Standard operating procedure (SOP) use and revision process	0	7	0	0	3.00
K-4	Aseptic technique to avoid contamination	4	2	1	0	3.43
K-5	Environmental monitoring	2	2	3	0	2.86
K-6	Mathematical principles, including the metric system and conversations	1	2	4	0	2.57
K-7	Identifying, selecting, and operating tools, equipment, or technological solutions with established operating procedures and safety standards	2	2	2	1	2.71
K-8	Potential hazards related to the use of tools, equipment, and materials	1	5	0	1	2.86
K-9	Data integrity and computer applications for gathering, storage, manipulation, and transfer of information	4	2	1	0	3.43
K-10	Methods to check, examine, and record by entering information, transcribing, storing, and maintaining in written or electronic/magnetic format like batch records	5	2	0	0	3.71
K-11	Foundational science principles like microbiology, genetics, and chemistry	0	5	2	0	2.71
K-12	Major technologies and historical development of biotechnology	0	3	4	0	2.43
K-13	Legal and ethical issues affecting the application of biotechnology	0	1	5	1	2.00
K-14	Emerging and future applications of biotechnology, like cell and gene therapy and regenerative medicine	0	3	3	1	2.29
K-15	Method to clean, sterilize, troubleshoot, calibrate, operate, and maintain instruments and equipment	4	2	1	0	3.43
K-16	Upstream and downstream process implementation and monitoring	4	2	1	0	3.43
K-17	Monitoring gauges and recording instruments to ensure that specified conditions are maintained using control systems	2	3	2	0	3.00
K-18	Obtaining, weighing, measuring, and checking raw materials	3	1	3	0	3.00
K-19	Cleaning methods for manual, Clean in Place (CIP), autoclave sterilization, and Sterilize in Place (SIP)	2	1	4	0	2.71
K-20	Preparing buffers and solutions	0	5	2	0	2.71
K-21	Inspecting materials at all stages of process to determine quality or condition	3	0	4	0	2.86
K-22	Operating reactors and recovering products	0	5	2	0	2.71
K-23	Purification techniques	3	2	2	0	3.14
K-24	Formulating, filling, and inspecting product	2	2	3	0	2.86
K-25	Controlling and maintaining documentation about qualification and validation	2	2	2	1	2.71
K-26	Calibrate and validate equipment systems and assess equipment performance using control systems	1	3	3	0	2.71
K-27	Documenting and taking corrective and preventive action according to Standard Operating Procedures	1	6	0	0	3.14
K-28	Safety mindset to anticipate and prevent work-related injuries and illnesses	3	3	1	0	3.29
K-29	How to properly handle, store, and dispose of hazardous materials	2	2	3	0	2.86
K-30	Safety symbols and signs	2	2	2	1	2.71
K-31	Best practices for maintaining a safe, clean, contamination-free, clutter-free environment	3	3	1	0	3.29
K-32	Standards for selecting appropriate PPE based on biological, chemical, and physical hazards	3	3	1	0	3.29

K-33	Calibration standards and traceability	0	0	4	3	1.57
K-34	Clean room classifications	0	5	0	2	2.43
K-35	Importance of task consistency	3	2	2	0	3.14
K-36	The importance of inventory control and material traceability	0	3	3	1	2.29
K-37	Single-use technologies and the importance of closed systems	4	1	2	0	3.29

Table 2B. KSA Vote for Skills

KSA'S	**KSA Task Name and Description**	**Number of Votes (4 = most important)**				
S1-29	**Skills: technical or manual proficiencies- demonstrated by competency and skills checks**	**4**	**3**	**2**	**1**	**Avg**
S-1	Gowning, PPE, and hygiene at appropriate level/grade	4	2	1	0	3.43
S-2	Consistently following written and verbal instructions	6	1	0	0	3.86
S-3	Aseptic technique and environmental monitoring	2	3	1	1	2.86
S-4	Documenting process measurements like time, temperature, volume, pressure, pH, conductivity	3	3	1	0	3.29
S-5	Process variable monitoring and corrective actions	0	4	2	1	2.43
S-6	Identifying potential hazards related to the use of tools, equipment, and materials	2	4	0	1	3.00
S-7	Checking, examining, and recording by entering information, transcribing, storing, and maintaining in written or electronic/magnetic format like batch records	4	2	1	0	3.43
S-8	Clean, sterilize, troubleshoot, calibrate, operate, and maintain instruments and equipment	2	5	0	0	3.29
S-9	Upstream and downstream process implementation and monitoring	1	5	1	0	3.00
S-10	Using SOPs to maintain cGMPs, including good documentation practices like batch records	5	2	0	0	3.71
S-11	Monitoring gauges and recording instruments to ensure that specified conditions are maintained using control systems	1	5	1	0	3.00
S-12	Obtaining, weighing, measuring, and checking raw materials	1	4	2	0	2.86
S-13	Cleaning (manual and Clean in Place (CIP)) and sterilization (autoclave and Sterilize in Place (SIP))	1	4	2	0	2.86
S-14	Preparing buffers and solutions.	0	5	2	0	2.71
S-15	Inspecting materials at all stages of process to determine quality or condition	2	1	4	0	2.71
S-16*	Operating reactors and recovering products (Moved to Knowledge K-22, Skill not required for entry-level)	0	4	3	0	2.57
S-17	Purification techniques	2	3	2	0	3.00
S-18	Formulating, filling, and inspecting product	2	4	1	0	3.14
S-19	Labeling, packaging, and distributing final product	3	1	3	0	3.00
S-20	Recognizing common hazards and unsafe conditions that occur at work, their risks, and appropriate controls to address them	3	3	0	1	3.14
S-21	Documenting and acting upon corrective and preventive action according to Standard Operating Procedures or as directed	2	5	0	0	3.29
S-22	Maintaining compliance with current federal, state, local, and industry regulations	3	2	2	0	3.14
S-23	Properly handling, storing, and disposing of hazardous materials	1	3	2	1	2.57
S-24	Properly handling, storing, and disposing of hazardous materials	1	3	2	1	2.57
S-25	Maintaining a safe, clean, contamination-free, clutter-free environment	3	3	1	0	3.29
S-26	Demonstrate task consistency	4	2	1	0	3.43
S-27	Selecting appropriate PPE based on biological, chemical, and physical hazards	2	3	1	1	2.86

S-28	Documenting and acting upon corrective and preventive action according to Standard Operating Procedures or as directed	2	5	0	0	3.29
S-29	Performing complex QC lab techniques required in the GT industry (e.g., HPLC, ddPCR, etc.)	4	0	2	1	3.00

Table 2C. KSA Vote for Abilities

KSA'S	KSA Task Name and Description	Number of Votes (4 = most important)				
A1-15	**Abilities: the capacity to simultaneously apply several skills and knowledge to perform an observable task or behavior.**	**4**	**3**	**2**	**1**	**Avg**
A-1	Monitor measures or indicators of system performance	1	2	4	0	2.57
A-2	Operate electronic communication systems and methods (e.g., e-mail, PLCs, DCS, LIMS, DeltaV, SAP)	1	3	3	0	2.71
A-3	Communicate with team members, give and receive feedback constructively, and collaborate with others	3	4	0	0	3.43
A-4	Ask questions, report problems/concerns to supervisors when information or procedures are unclear or need improvement, or when feeling unsafe or threatened in the workplace	4	3	0	0	3.57
A-5	Interpret and clarify incidents, problems, and events.	4	3	0	0	3.57
A-6	Collaborate effectively with others, especially to solve problems	3	4	0	0	3.43
A-7	Reduce variability in tasks	3	2	2	0	3.14
A-8	Read, interpret, and use technical documents, diagrams, and SOPs	4	2	1	0	3.43
A-9	Open to considering new ways of doing things and the merits of new approaches to work	3	3	1	0	3.29
A-10	Demonstrate self-control by maintaining composure and dealing calmly with stressful situations	2	4	1	0	3.14
A-11	Anticipate, recognize, and report the existence of a problem https://portal.cccc.edu/sso/default.aspx	3	3	1	0	3.29
A-12	Work in a regulated environment	4	2	0	0	3.67
A-13	Take actions to ensure the safety of self and others in accordance with established personal and job site safety practices	2	3	2	0	3.00
A-14	Report injuries, incidents, and workplace hazards to a supervisor as soon as safely possible	3	2	2	0	3.14
A-15	Engage in safety, security, and compliance training and emergency drills	2	3	2	0	3.00

Table 2D. Certificates

KSA'S	KSA Task Name and Description	Number of Votes (4 = most important)				
C1-8	**Certificate Name**	**4**	**3**	**2**	**1**	**Avg**
C-1	BioWork	4	3	0	0	3.57
C-2	Validation Fundamentals	2	0	4	1	2.43
C-3	cGMP Quality Systems	1	5	1	0	3.00
C-4	QA Fundamentals	1	4	2	0	2.86
C-5	OSHA	2	2	2	1	2.71
C-6	ASQ	1	3	2	1	2.57
C-7	Lean Six Sigma	0	1	4	2	1.86
C-8	Cell and Gene Therapy	0	5	2	0	2.71

Table 3. Updates in curriculum to address Prioritized KSAs

KSA#	Priority Average	Course Number and Name					
		BioWork Bioprocess Practices & Industrial Env	**BPM 111** Bioprocess Measurements	**BPM 112** Upstream Bioprocessing	**BPM 113** Downstream Bioprocessing	**PTE 116** Pathway to Employment	**PTC 228** Pharmaceutical Issues
K4	3.43			E to T			
K5	2.86			E to T			
K9	3.43			NC to E			NC to E
K16	3.43			E to T	E to T		
K22	2.71			E to T			
K24	2.86		NC to E	NC to E	E to T		
K37	3.29			E to T			
S4	3.29			E to T			
S5*	2.43						
S8	3.29			E to T			
S9	3			E to T			
S16*	2.57			E*			
S18	3.14	E to T			E to T		
S19	3				*		
S29	3		*				

*A subset of the Biotech Faculty KSA Cross Reference data focused on the areas slated for change and further discussion. Green indicates KSAs to be improved with an average priority score greater than 2.60. NC = No Coverage, E = Exposure only, T = Thorough coverage. Red indicates warrants discussion for future consideration of improvements, Blank = No coverage. Abbreviations: BPM-Bioprocess Manufacturing Technology, PTC-Pharmaceutical Technology, PTE-Pathway to Employment (*indicates skill competencies for future improvements, currently prioritized at knowledge level)*

Changes implemented in course content

A list of course numbers and titles are shown in [Table 4]. Specific areas of knowledge were increased in several courses. K24: knowledge of formulating, filling, and inspecting product coverage was slated for increased exposure. The Bioprocess Practices / Industrial Environment (BioWork) Course added an article and video to Unit 8, saline solution, and I V bags. For the Bioprocess Measurements Course, manual inspection was improved in the Unit 1 lab, where vials are measured with digital Vernier calipers. Recommendations were suggested for the Downstream Bioprocessing course, to require coverage of formulating, filling, and inspecting products in the course project.

With further discussion, additional changes to increase coverage and achieve improvements in knowledge were made in multiple courses. K4: knowledge of aseptic technique to avoid contamination, and K5: knowledge of environmental monitoring exposure were elevated from "E" to "T" in the Upstream course. Thorough coverage "T" will be implemented by student articulation of various plates used, responses to Environmental Monitoring (EM) failure, knowledge of particle counts, and identification of types of microorganisms that are potential contaminants.

Implementing the shake flask cell growth quantifier (CGQ) technology [15] for real-time monitoring in the Upstream Course and data analysis in the Bioprocess Measurements Course elevated K9: knowledge of data integrity and computer applications as they support the gathering, storage, manipulation, and transfer of data and information. Guest speaker lectures in the Pharmaceutical Issues Course produce further exposure to this knowledge. Hands-on activities in the Upstream Course using the shake flask system promote thorough coverage “T” of S4: skills needed for documenting process measurements like time, temperature, volume, pressure, pH, and conductivity.

Improvements in K37: knowledge of single-use technologies and the importance of closed systems by including industry tours and demonstrations, as well as related training in the Capstone Center at the Biomanufacturing Training and Education Center (BTEC) [8], in the Upstream Bioprocessing and Downstream Bioprocessing courses. Field trips also increase K16: student knowledge of upstream and downstream process implementation and monitoring.

Coverage increased from “E” to “T” for several skills with hands-on training in the Upstream Bioprocessing course using the shake flask system. Students perform bacterial cultures and monitor growth curves using the integrated computer software for the Cell Growth Quantifier (CGQ) system [15]. The addition of this equipment to the Upstream Course curriculum elevated several skills, including S4: documenting process measurements like time, temperature, volume, pressure, pH, and conductivity; S6: identifying potential hazards related to the use of tools, equipment, and materials; S7: checking, examining, recording, entering, transcribing, storing, or maintaining information in written or electronic formats; S8: clean, sterilize, troubleshoot, calibrate, operate, and maintain instruments and equipment. Instruction for these skills was increased from “E” to “T”.

Recommendations from Discussions

K10, gathering, recording, and maintaining records, was voted a high priority but was not slated for improvements because there is ample exposure coverage in 7 classes. Likewise, K11, foundational knowledge of science principles in microbiology, genetics, and chemistry, was voted a high priority but not slated for improvements because there is sufficient coverage in 6 classes.

Further discussion of KSAs determined that S5 (skill to process variable monitoring and corrective actions) was not a high priority for this entry-level position. Instead, having K 27, knowledge of Corrective and Preventive Actions (CAPA) and the impact of deviations was given priority. Likewise, S16 (skill in operating bioreactors and recovering products) was not a high priority for an entry-level position and was considered a Knowledge K-22 priority.

S19: Labeling, packaging, and distributing the final product was considered a high priority. Plans for the new training facility will have a fill suite and other equipment to allow students to address this skill. Future processes could include expansion that would permit the production of a protein product, like GFP, and adding a component to label, package, and distribute final products for educational purposes.

S29: Skill performing complex QC lab techniques required in the Cell and Gene Therapy industry was determined to be significant to an entry-level QC technician. Suggestions for implementation include High-performance liquid chromatography (HPLC), droplet digital PCR (ddPCR), and other techniques to be considered with future equipment setup and configurations.

Table 4. Major Courses for Bioprocess Technology Program [10]

Course Number	Course Title	BioWork Certificate	Bioprocess Certificate	Bioprocess AAS
BioWork/ BPM 110	Bioprocess Practices	X	X	X
BioWork/ PTC 110	Industrial Environment	X	X	X
BIO 110	Principles of Biology		X	X
BPM 111	Bioprocess Measurements		X	X
BPM 112	Upstream Bioprocessing			X
BPM 113	Downstream Bioprocessing			X
CHM 131	Introduction to Chemistry			X
CHM 131/A	Introduction to Chemistry Lab			
BIO 175	General Microbiology			X
ISC 121	Environmental Health & Safety			X
ISC 175	Quality Assurance Fundamentals			X
ISC 278	cGMP Quality Systems			X
ISC 280	Validation Fundamentals			X
PTE 116	Pathway to Employ-Bio/Chem			X
PTC 228	Pharmaceutical Issues			X
Gen Ed	Math/English/Econ/Hum			15 hrs

The Bioprocess Technology program encompasses stackable credentials starting with the BioWork Certificate, building to the Bioprocess Technology Certificate, and culminating with the Bioprocess Technology Associate in Applied Science Degree. The course numbers have three-letter prefixes from the following programs: BPM-Bioprocess Manufacturing Technology, PTC-Pharmaceutical Technology, BIO-Biology, CHM-Chemistry, ISC-Industrial Science, PTE-Pathway to Employment with a focus on Biology and Chemistry careers, Gen Ed-General Education. Current Good Manufacturing Practices abbreviated cGMP.

Industry Experience for Community College Faculty

The Biomedical Emerging Technology Applications (BETA) Fellows NSF project [16] sponsored an 8-week experience in the Biopharmaceutical Manufacturing industry at Pfizer, a major employer of the program's students. The BETA skills fellowship aims to get community college instructors into the industry, allowing them to gain experience and increase their leadership traits by experiencing the industry's environment first-hand. Many community college faculty do not have industry experience.

BETA Fellow Dr. Brenda Judge Grubb joined the Technical Operations Team at Pfizer in Sanford, NC, for an 8-week experience. This was a valuable opportunity to interact with process technicians, tour all parts of the facility, meet with managers, sit in on meetings, and have conversations with the engineers and members of the BILT, who arranged for guided tours of all major areas of the facility.

There were many key takeaways from the experience—first, the importance of good documentation and regular communication from the process technicians to the top managers. There was a constant intentional pursuit to make improvements. Secondly, a better understanding of the Industrial environment was gained by being immersed in the environment and learning about the facility and equipment for laboratory procedures for cell culture, fermentation, environmental monitoring, media preparation, lyophilization, qualitative analysis, and other processes. A third important aspect was interacting with industry personnel and getting input for the curriculum and new training facility. The direct exposure of Community College faculty to industry strengthens relationships and increases the participation of industry partners as part of the BILT team members, encouraging the commitment to CCCC. This has been demonstrated by visiting students in class, giving seminars, and participating in networking events. Instructors having industry experience also allow for better instruction to students, enabling them to provide clear examples and scenarios for class instruction that further allow for more thorough coverage of materials across the curriculum.

Value for Employers and Community Colleges

Using the BILT model to define critical KSA requirements for entry-level bioprocess manufacturing technician positions can be an excellent way to bridge the gap and align training with industry demands. This model will allow workforce partnerships to reach their full potential by using a model with industry as co-leaders in curriculum development to ensure a "right-skilled" workforce. Human Relations (HR) and hiring managers writing job descriptions and setting up the requirements for positions need to be aware that many entry-level positions in biomanufacturing can be done by individuals trained in focused technology programs such as this, that provide hands-on training and confer certificates in that area. Furthermore, instruction that leads to an associate degree produces a workforce pool that is highly capable of completing process technician tasks from day one. This is a win-win for the company and the employees. Recruiting, hiring, and training new employees is both time-consuming and expensive. Hiring employees with certificates and associate degrees designed using industry-identified KSAs creates a greater return on this investment. These individuals will be dedicated to the work and more likely to stay with the company for an extended period. Research has shown that employees hired for entry-level jobs who join the workforce with bachelor's degrees may require additional hands-on training and tend to move on to other positions or seek higher degrees [17]. Therefore, more is invested; however, there is not the same return on investment. Future use of the BILT model for aligning workforce development across the college and other industrial systems with the local workforce demands in emerging sectors like electric vehicles, semiconductors, and other industries coming to the area.

Some employers have not invested in collaborations with community colleges because they do not realize the potential value [18-19]. To influence the curriculum and potentially harness customized training for the company's specific workforce, it must be invested in by industry employers and readily accepted by community college faculty and administrators [14].

To make degrees more transparent to industry outside of the immediate area and more portable for the students, two efforts that are emerging and gaining national attention are the Bioscience Core Skills Institute (BCSI) and the Biotechnician Assistant Credentialing Exam (BACE) [20-21]. CCCC, is working towards adding micro-credentials and providing exams for workforce skills assessment that are valid, reliable, and trusted by the bioscience industry. Working with educational and industry partners through the BCSI will provide assessment opportunities and documentation of skills.

The CCCC Biotechnology program has experienced significant expansion since it was relaunched in 2020. The success and growth of the program can be attributed to outreach efforts throughout the high schools, Veteran groups, minority and ESL-focused groups, participation in Career fairs, open houses for friends and family to come to learn about the programs, and the creation of networking events both at CCCC and at the NC Biotechnology Center are all strategies that achieved this result. Another useful tool has been online videos and statewide recruiting tools with forms that direct those interested in the program to information to sign up for BioWork at the Community College in their region. Word of mouth is very common, so not only do we have ambassadors in alumni of the programs, but we often have relatives and coworkers of alumni come to take BioWork as a continuing education course. Continuing education students are encouraged to seek more credentials by enrolling in the curriculum program.

The addition of more full-time faculty included the first position of its kind, a Career navigator, who was tasked with expanding resume writing, interview preparation, and outreach to the local audience, giving visibility to the program to all potential sectors of the communities in our service area that could benefit from the program. The other full-time faculty members and Adjunct faculty actively working in the industry have made it possible to serve more students as the program continues to grow and expand to three counties offering classes in the morning, afternoon, and night. The support of our college administration has drawn statewide and national attention, and grant funding to support new hires and provided funding for the creation of the future home of the program in the Eugene Moore Manufacturing and Biotech Solutions Center. The Biotechnology Solutions Center (BSC) will be a hub of technician training in central North Carolina, housing the BioWork continuing education training, customized industry training, and the Associate in Applied Science degree program, as well as training and certification for future credentialing and certifications for skilled technicians in North Carolina.

The next iteration of this process will focus on the KSAs needed for quality control (QC) technicians and seek the necessary credentials to fill laboratory positions to support cell and gene therapy, environmental monitoring, and other biotechnology technician roles in industry and academia. In addition, more focus on soft skills and career development will be included to help prepare students and match them with employers.

Conclusion

This report can guide other community colleges in developing curricula for technicians in various roles, as programs are tailored to match the needs of potential employers in the regions they serve. Focusing on the skills needed to do entry-level jobs opens the pool of potential employees to a population that has not been tapped. Prioritizing diversity and inclusion in the Biomanufacturing program can attract a more diverse pool of students, including individuals from underrepresented groups. This can help bridge the skilled labor gap by ensuring that a wider range of individuals have access to training and employment opportunities in the biopharma manufacturing industry. Diversity and inclusion efforts can also help identify and address systemic barriers that may prevent certain groups from entering or advancing in the biomanufacturing field. By actively promoting equity, the program can work towards eliminating these barriers and creating a more inclusive and accessible environment for all individuals. A diverse workforce brings together individuals with different backgrounds, perspectives, and experiences. This diversity can lead to enhanced innovation and problem-solving within the biomanufacturing industry. By fostering an inclusive environment that values diverse perspectives, the program can tap into the full potential of its workforce and drive advancements in the field. The biopharma manufacturing industry is evolving rapidly, and companies are increasingly recognizing the importance of diversity and inclusion in their workforce. By incorporating diversity, equity, and inclusion elements in the program, graduates will be better prepared to meet the industry's demands and contribute to a more inclusive and diverse workforce.

Students educated in programs enhanced by the BILT model have the advantage of training better aligned to industry needs. Exposure to professionals in desired positions gives students the benefit of networking, access to work-based learning, internships, and apprenticeship opportunities that lead to employment for a higher percentage of students by participating in the program. Identifying critical KSAs with the BILT model will help bridge the gap between the education provided by institutions and the industry's needs. When students and educators are aware of the upcoming trends and have access to a curriculum tailored to match technician positions of the future, it will result in a better-prepared, more diverse, and inclusive workforce. The important implications include increased representation, addressing systemic barriers, enhanced innovation and problem-solving, and meeting industry demands.

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