

This column addresses aspects of lifelong learning for current students, alumni, and faculty. Examples of student and faculty activities that involve industrial practice and engagement as well as continuing education are welcome. These topics may not always lend themselves to the traditional scholarly format with formal assessment and extensive literature review but may be more editorial in nature. Please submit manuscripts to Professor Lisa Bullard at lisa_bullard@ncsu.edu

A “LIFE CYCLE” APPROACH TO EDUCATION AND TRAINING FOR THE BIOPHARMACEUTICAL INDUSTRY

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Chemical engineering fundamentals are frequently used to design, understand, model, and execute processes for the biopharmaceutical industry. Oxygen transfer in bioreactors, transport across ultrafiltration membranes, and diffusion of proteins into porous chromatography media are just a few of the many examples in which basic chemical engineering principles are central to bioprocess operations. As a result, many biopharmaceutical companies hire candidates with chemical engineering backgrounds, as these candidates possess a unique understanding of both the chemistry and engineering principles involved in the complex unit operations that comprise a biopharmaceutical process. Highly skilled professionals are needed by the industry as expectations for the quality of these injectable drugs is high. Chemical engineers are well positioned to fill a variety of roles, in areas including manufacturing, process development, process engineering, manufacturing sciences, technology transfer, and validation.

Despite a solid theoretical knowledge of engineering principles, the chemical engineer entering the biopharmaceutical industry faces a long, complex learning curve. Recent graduates often do not have a detailed understanding of how the basic engineering principles they acquire through their formal university education specifically apply to operations such as cell culture, chromatography, or ultrafiltration. It is also unlikely that they have hands-on knowledge of these operations and almost certain that they are not aware of the regulatory expectations with which they will be confronted. Students transitioning from a university environment to a position in

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industry may be shocked by the stringent documentation rules, operating procedures, validation requirements, and litany of additional expectations required under current Good Manufacturing Practice (cGMP) regulations that govern a biopharmaceutical manufacturing facility. Students who are aware of these realities in advance will surely find their transition from the university to industry faster and smoother.^[1]

Even once in the industry, both novice and experienced professionals—regardless of educational background—have learning needs. A college degree does not guarantee that you will remain “competitive” during your entire career and that you will be able to best serve the organization that employs you. Professionals must continue to grow and evolve. They may be

- *in need of expanding their understanding of emerging technologies that their organization is implementing, such as high-throughput process development tools, single-use equipment, or continuous manufacturing;*
- *tasked with a new job function or entering a new job assignment that requires a different skill set;*
- *preparing themselves for transfer or promotion to a job that requires additional knowledge;*
- *in need of acquiring basic knowledge on operations/concepts that they have never been exposed to but are expected to know for performance of their current position.*

Consequently, relevant education and training opportunities throughout the “life cycle” of a biopharmaceutical professional—from students at the university level to professionals already involved in the industry—are needed. Availability of these opportunities benefits the career of the professional (or soon-to-be professional) and the industry that he/she is part of.

This article describes the approach that the Biomanufacturing Training and Educational Center (BTEC) at North Carolina State University has taken to meet educational needs throughout the life cycle of the biopharmaceutical professional, including the design of our programs and their impact.



Figure 1. The BTEC facility on NC State's Centennial Campus.

ABOUT BTEC

BTEC is an instructional center that opened in 2007. Our mission is to contribute to the social and economic well-being of the state of North Carolina by providing a wide variety of high-quality educational and training opportunities to develop skilled professionals for the biomanufacturing industry and by providing process services to industry, government, and academia. There has been a close link between BTEC and the biopharmaceutical industry from the beginning: local industry made the case for establishment of the center, the facility was designed by industry, and multiple workforce needs assessments were conducted by the North Carolina Biotechnology Center to gain a baseline understanding of industry's needs.

BTEC is part of NC State's College of Engineering and provides hands-on educational opportunities for undergraduate and graduate students as well as professionals in the areas of biopharmaceutical process development and manufacturing. In addition, BTEC has an active bioprocess and analytical services program that offers a range of process development, technology development, and analytical testing/development services to clients from academia, government, and industry.

BTEC's main facility, shown in Figure 1, includes 82,500 square feet of laboratory, classroom, and office space. Laboratories range from bench scale to the largest simulated-cGMP pilot plant dedicated to education and training in the United States, and are equipped with more than \$15 million worth of industry-standard equipment. The center is capable of developing processes for and producing biological products



Figure 2. Students working in BTEC's large-scale simulated-cGMP fermentation suite.

These two goals direct BTEC in designing programs that are appropriate throughout the professional life cycle. Programs that BTEC has in place to implement these goals are described in what follows.

Undergraduate programs

BTEC offers a number of undergraduate courses, ranging from bench-scale, lab-based courses focused on molecular biology to courses covering upstream and downstream manufacturing operations in our simulated cGMP facility. Although students cannot obtain a bachelor's degree at BTEC, undergraduates can choose between the biomanufacturing minor and the undergraduate certificate in biomanufacturing, as shown in Table 1, which summarizes all degree program options.

The biomanufacturing minor requires a minimum of 15 credit hours of coursework. Course requirements include classes on microbiology and molecular biology techniques, basic principles of bioseparations, and an introductory course on fermentation. Students then have the option to specialize in either upstream or downstream biomanufacturing, and are required to complete both a process development-focused course and a cGMP manufacturing operations course in their chosen track. Lastly, students must complete a minimum

(biopharmaceuticals) using cell growth, recovery, and purification processes. Figure 2 shows a photo of students working in BTEC's large-scale fermentation area.

WHAT BTEC DOES

To carry out BTEC's mission, a number of key goals have been established to guide our activities. Two of the most relevant to this paper are:

1. *Educating NC State undergraduate and graduate students in all aspects of biomanufacturing;*
2. *Enhancing the knowledge and skills of professionals involved in the biomanufacturing industry.*

of 5 credit hours of electives, which could include courses in novel expression systems, bionanotechnology, tissue engineering, regulatory affairs, or cell culture engineering, among others. Students pursuing the undergraduate certificate take fewer credit hours than those pursuing the minor—12 versus 15—and choose from a pared down list of introductory biomanufacturing courses, as well as 9 credit hours of biomanufacturing electives.

For the 2014-2015 academic year, the undergraduate enrollment in BTEC courses was 606 (corresponding to 390 individual students). Students represented 20-plus departments, with 44% of them majoring in chemical engineering. Other majors represented include biology, bioprocessing science,

Program	Credit Hours Required	Specializations
Minor in Biomanufacturing	15	Upstream or downstream processing
Undergraduate Certificate in Biomanufacturing	12	none
Master of Biomanufacturing (M.R.)	36	Upstream and/or downstream processing
Master of Science in Biomanufacturing (M.S.)	36	Upstream and/or downstream processing
Graduate Minor in Biomanufacturing	10	none
Graduate Certificate in Biomanufacturing	12	Upstream or downstream processing
Post-baccalaureate Certificate in Biomanufacturing	13	Upstream or downstream processing

microbiology, biochemistry, and biological and agricultural engineering, to name a few. Forty-nine students completed the biomanufacturing minor, while an additional 16 students were awarded the undergraduate certificate in biomanufacturing. Since December 2008, more than 200 students have earned the biomanufacturing minor.

Various BTEC courses have been cross-listed with other departments, including Chemical and Biomolecular Engineering, Biomedical Engineering, and Food, Bioprocess, and Nutrition Sciences. These departments have incorporated BTEC courses into their curricula, either as required courses or electives. Notably, the Department of Chemical and Biomolecular Engineering offers a concentration in biomanufacturing sciences that requires students to complete seven BTEC courses as part of their chemical engineering degree. That program is designed to allow students to develop traditional chemical engineering skills, while at the same time applying those skills to biomanufacturing operations. The program is also designed to be completed in four years. Students who are not majoring in chemical engineering, however, typically take BTEC courses in addition to their standard degree program requirements and, consequently, may require an extra semester to graduate with the biomanufacturing minor.

A recent article in *Chemical Engineering Education* looks more closely at the design of two of BTEC's downstream courses and offers some insight as to how chemical engineering principles are developed and used in the context of biomanufacturing.^[2]

Professional science master's in biomanufacturing and other graduate programs

BTEC currently offers two graduate degree options: the master of biomanufacturing (M.R.) and the master of science (M.S.) in biomanufacturing. The M.S. requires completion of a research-based thesis; the M.R. does not. In addition, graduate students from departments throughout the university can work toward a BTEC Graduate Certificate. The M.R. and M.S. are both professional science master's (PSM) degrees, which provide advanced education and training in a specific discipline while simultaneously developing business skills highly valued by employers. Both degrees offer students the choice of upstream or downstream concentrations along with courses in global regulatory affairs, biopharmaceutical characterization techniques, and industry case studies. A unique feature of the BTEC PSM degree is that an industry internship is one of the graduation requirements of the program. BTEC's graduate program coordinator maintains close relationships with many biopharmaceutical companies, including a large number within a 30-mile radius of NC State as well as a number of others throughout the country. With the assistance of the graduate program coordinator, the vast majority of students are able to find internships, and the requirement does not slow student progress through the graduate program.

Students pursuing the M.S. degree are advised primarily by BTEC instructional staff who are part of the university's graduate faculty and, to a lesser extent, faculty in academic departments (outside of BTEC) who have graduate faculty status at BTEC. The makeup of BTEC's instructional staff is discussed shortly.

For the 2014-2015 academic year, total enrollment in BTEC's graduate courses was 325, which includes students from our own master's programs as well as other graduate programs throughout the university. Currently, there are 30 students enrolled in the two BTEC master's programs (M.R. or M.S. degrees), and eight students in the graduate certificate program.

Professional development (short course) program

BTEC's short course program consists of both open-enrollment courses, which are open to the public, and customized courses, in which content is tailored to meet an organization's needs. From July 1, 2014, to June 30, 2015, BTEC offered 16 open-enrollment professional development classes (14 courses) and seven courses customized for individual companies. More than 340 students from across the globe attended these courses. Table 2 shows a list of offerings for 2015-2016.

Open-enrollment courses are typically offered by BTEC on an annual basis. These courses cover topics in the general

TABLE 2	
List of BTEC's open-enrollment professional development courses for 2015-2016	
Open-Enrollment Course Title	
Applied Principles and Techniques of Depth Flow Filtration (DFF) and Tangential Flow Filtration for Biopharm Downstream Purification (offered twice)	
Assay Development and Validation for Biomolecules	
Biopharmaceutical Analysis	
Biopharmaceutical Particle Characterization	
Cell Culture Engineering	
Commercialization of New Biological Drugs	
Development of LC-MS Methods for Biomolecules	
Downstream Biopharmaceutical Processes: Fundamentals and Design (offered twice)	
Fermentation Engineering (offered twice)	
Fundamentals of Mammalian Cell Line Development	
GE Chromatography Column Packing	
Hands-on cGMP Biomanufacturing Operations	
Hands-on Single-use Processing for Biopharmaceuticals	
Hands-on Viral Vaccine Manufacture	
Introduction to Design of Experiments (DoE) for Bioprocess Analysis and Optimization	
Microbial Contamination Control in Bioprocessing Operations	
Molecular Perspectives in Downstream Processing and Biopharmaceutical Formulation	

areas of analytical technologies, biomanufacturing, bioprocess development, and bioprocess engineering. Courses last 1-5 days. Some are condensed versions of our academic courses, while others take on a different flavor. For example, one of our more popular open-enrollment short courses—cGMP Biomanufacturing Operations—provides a hands-on overview of all the upstream and downstream operations that comprise a biopharmaceutical process. It resembles a condensed version of two academic courses: cGMP Fermentation Operations and cGMP Downstream Operations. In contrast, courses on more specialized topics are also held, such as Hands-on Single-use Processing for Biopharmaceuticals, Microbial Contamination Control in Bioprocessing Operations, and Introduction to Design of Experiments (DoE) for Bioprocess Analysis and Optimization. In most courses, there is an emphasis on hands-on experiences, with a significant portion of time being devoted to lab activities and other exercises that allow students to apply the fundamentals they learned in the classroom.

Participants in our short course programs are typically scientists and engineers who serve a variety of roles. For participants attending our short courses between 2010 and 2015, the breakdown of professional roles is as follows: manufacturing (29%), sales/marketing (21%), scientist/research lab (19%), engineering (15%), QC/QA/regulatory/validation (8%), teaching/academia (3%), planning (3%), and maintenance/instrumentation (2%). Participants are also eligible to receive continuing education units (CEUs) for completing a course. It is worth mentioning that BTEC has worked closely with fellow educators—a number of whom have attended our courses—seeking to build biotechnology programs at their home institutions. We have provided input on course content, program design, and even the design of BTEC-like facilities. BTEC has also partnered with organizations who have similar missions by providing access to our equipment and space for delivery of courses. And we have established BTEC International in an effort to partner with other academic institutions in providing standardized, high-quality biomanufacturing education. Registration fees for the majority of open-enrollment course participants are paid for by the companies with whom they are employed. Some of these companies not only pay for the courses, but also actively promote them within their organizations. In addition, BTEC provides significant discounts to participants from a number of professional organizations with whom we have partnered.

In addition to open-enrollment courses, BTEC also works with companies to create custom short courses, specifically tailored to their individual needs. Short course content is collaboratively designed by both company representatives and BTEC staff, and once a course outline has been established, BTEC instructors develop specific lectures and lab modules per the agreed upon outline. Attendance in these courses is limited to staff from the client organization.

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and experienced professionals—
regardless of educational back-
ground—have learning needs.*

Contract courses

In addition to our open-enrollment and customized courses, BTEC has been involved in leading various training programs for governmental agencies. Since 2008, BTEC has delivered a training program to the U.S. Food and Drug Administration (FDA), which instructs investigators in the area of biologics manufacturing. Since its inception, 118 FDA staff members have participated in the program, which includes courses such as Upstream Bioprocessing, Downstream Bioprocessing, Quality Control/Analytical, and Aseptic Processing. The program uses a blended design, combining online instruction with on-site lab activities.

In addition to the FDA training program, BTEC was awarded a training grant from the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services, to provide hands-on training for global vaccine manufacturing organizations and national regulatory authorities on influenza vaccine manufacturing. Since its inception in 2010, this program has trained 130 individuals who have completed one or more of three different courses: the Fundamentals of cGMP Influenza Vaccine Manufacturing, Advanced Upstream Processing, and Advanced Downstream Processing. These trainees are from Brazil, Egypt, India, Indonesia, Kazakhstan, Mexico, Romania, Russia, Serbia, South Africa, South Korea, Thailand, and Vietnam.

Bioprocess and analytical services

The same facilities and staff used to support our education and training programs are also used to collaborate with partners from industry, academia, and government agencies to address process development, technology evaluation/development, analytical testing, and analytical method development needs. Projects executed under BTEC's bioprocess and analytical services program inform course content by supplementing the knowledge of BTEC instructional staff on the latest technologies, methods, and general thinking in the field.

HOW BTEC DOES IT

By all measures, BTEC's attempt to provide educational and training opportunities at both ends of the student-to-employee pipeline has been successful. Enrollment in our NC State courses has grown from 184 students in 2007-2008 (our first year of operation) to 931 in 2014-2015. Enrollment in our short course program was more than 340 in 2014-2015, only six years after the program began. Numbers are only part of the story, however. Feedback on course offerings has been extremely positive and will be discussed shortly.

There are a number of design attributes that factor into this success. Some of these are described below.

Hands-on experience in a “real-world” environment

Students in most of our academic and short courses spend more time in the lab, performing hands-on activities, than in lecture. For example, many academic courses consist of two hours of lecture and five hours of lab activity per week. Most short courses consist of an even split between time spent in lecture and in lab. Figure 3 shows students and instructors working in one of our bench-scale downstream laboratories.

The emphasis on hands-on learning is good pedagogy. Hands-on laboratory activities are an excellent active-learning tool, and for many years, the importance of active learning in education has been recognized.^[3] Further, the emphasis on hands-on learning at BTEC seeks to connect real-life experience with fundamental principles—something that neither an industrial internship nor traditional academic courses relying on lecture alone are able to provide.

In addition to being good pedagogy, hands-on learning is important because many roles within the industry require employees—regardless of educational level—to be hands-on. For example, chemical engineers working in the area of process development will likely execute numerous studies using bench-scale equipment because biopharmaceutical process development is largely an experimental endeavor. Chemical engineers working in the area of validation will execute studies using process equipment as part of installation qualification and operational qualification protocols.

Where appropriate, BTEC's courses provide a real-world environment by using equipment that is industrially relevant and real process “streams.” For example, in both the cGMP Biomanufacturing Operations short course and the cGMP Downstream Operations academic course, students purify



Figure 3. Students and instructors working in one of BTEC's bench-scale labs.

a target protein from clarified *E. coli* lysate, which contains numerous impurities, using a 30-cm anion exchange chromatography column—commonly used for pilot-scale or small production-scale runs in industry—connected to an AKTApurify (GE Healthcare) system.

As discussed previously, BTEC's academic enrollment is made up of students from a variety of majors throughout the university. This is one of the advantages of offering minors and certificates rather than a bachelor's degree, and results in multidisciplinary teams that reflect the biopharmaceutical industry work force. Our short courses are likewise “multidisciplinary” in the sense that they attract participants with a range of educational backgrounds, industry experience, and roles within their organizations.

Informed curriculum and course design

One of the most important steps that BTEC has taken to ensure that course offerings are relevant to both those about to enter industry and those already in industry is to hire staff with wide-ranging industrial experience in cGMP manufacturing, process development, and analytical testing and development. Many of these staff members have Ph.D.s, teach BTEC courses, and are subject-matter experts in areas such as cell line development, cell culture engineering, protein purification by chromatography, and analytical testing, to name a few. They have titles of scientist, senior scientist, teaching professor, or director (for those who also manage one of BTEC's programs), with responsibilities that include design and delivery of academic and professional development courses. Many of these staff members also work closely

with the organizations we collaborate with as part of our bioprocess services program. This keeps them up to date on the latest processing technologies and methodologies. It is this staff—armed with significant biopharmaceutical industry experience—who have been largely responsible for developing curriculum and designing individual courses for BTEC’s academic and short course programs.

It is worth noting that our professional development program also takes advantage of outside expertise—from both industry and academia—to design and deliver short courses on topics in which BTEC may not have sufficient internal expertise.

There are a number of other features that ensure the BTEC curriculum and course content are relevant to the industry we serve. These include:

- *An advisory board, comprised primarily of industry representatives, who meet regularly and advise BTEC on a number of issues, including curriculum development.*
- *Close association with the vendor community, who keep us up to date on the latest bioprocess and analytical technologies.*
- *Our bioprocess and analytical services program, which helps to inform our course content, as mentioned previously.*
- *A collaborative approach with our clients on the design of customized short courses to ensure that the course meets the needs of participants.*

To offer a specific example of the curriculum offered to our NC State students, Table 3 shows the courses that an undergraduate minor specializing in upstream processing might take.

From this table, you can see that students are exposed to many of the steps involved in bringing a biopharma-

ceutical to market—from discovery to cell line development to process development to commercialization in a cGMP environment. The courses listed in Table 3 also represent most of the courses that a student working on a concentration in biomanufacturing sciences as part of a chemical engineering degree would take.

The course Global Regulatory Affairs for Medical Products (BEC 475), listed in Table 3, is one of two academic courses that is offered online. The other is BEC 577, Advanced Biomanufacturing and Biocatalysis. Because neither course has a laboratory component, each lends itself to online delivery.

Focus on student placement

To ensure that our university students successfully make it out of the student-to-employee pipeline and into a job that will lead to a career, BTEC offers significant support to students seeking employment. Every year, BTEC holds a career fair that serves to place students into industry. In 2015, 108 students participated. As a result of the career fair, ongoing placement support by BTEC staff, and our students’ broad knowledge of biopharmaceutical processing and regulations, BTEC boasts a 98% placement rate (employment or acceptance into a graduate program) within six months of graduation among undergraduate students who receive a minor. For our graduate programs, BTEC has 100% placement within six months of graduation.

TABLE 3
Course schedule for an undergraduate student working toward the biomanufacturing minor and specializing in upstream processing

Course	Course title	Credits	Brief Description
BEC 220	Introduction to Drug Development and Careers in Biomanufacturing	1	Introductory course covering the steps involved in developing biopharmaceuticals
BEC 363	Foundations of Recombinant Microorganisms for Biomanufacturing	2	Basic microbiology and molecular biology techniques, particularly as they apply to biomanufacturing
BEC 463	Fermentation of Recombinant Microorganisms	2	Introduction to fermentation concepts, fermentor operation, control parameters, and testing, at 2-L scale
BEC 330	Principles and Applications of Bioseparations	2	Introduction to the fundamental scientific principles underlying recovery, purification, and formulation of biomolecules
BEC 426	Industrial Microbiology and Biomanufacturing Laboratory	2	Fermentation process development and equipment design, at 30-L scale
BEC 480	cGMP Fermentation Operations	2	Execution of all steps required for a fermentation process for production of a biopharmaceutical, at 300-L scale in a simulated cGMP environment
BEC 440	Expression Systems in Biomanufacturing	3	Development of bacterial and yeast expression systems
BEC 475	Global Regulatory Affairs for Medical Products	3	Introduction to the quality systems used to meet the regulatory requirements for developing, testing, manufacturing, and selling medical products in the global marketplace

Courses accessible to adult learners

In addition to participating in BTEC's short course program, professionals have another option for engagement in lifelong learning at BTEC. BTEC has designed its graduate course offerings to allow most courses required for our M.S. and M.R. degrees to be taken in the evenings to minimize conflicts with a student's work schedule. Of the 38 students who have completed BTEC's master of biomanufacturing program since the first degrees were granted in May 2012, five are working professionals that continued working while completing their graduate degree. The percentage of working professionals has increased in the past two years to include 11 of the current 30 master's students. It is worth noting that professionals not in BTEC's master of biomanufacturing program can take these same academic courses by enrolling as a post-baccalaureate student.

IMPACT

In all of BTEC's academic and professional development (short) courses, feedback is obtained through end-of-course surveys aimed at assessing the overall effectiveness of the courses offered. The feedback from these surveys is extremely positive. For example, short course participants are asked to respond to the statement "the course provided information and skills needed to effectively carry out the responsibilities of my job." Among participants taking open-enrollment short courses between July 2014 and June 2015, more than 85% agreed or strongly agreed with that statement. Additional information on feedback from these end-of-course assessments has been reported in other articles.^[2,4-5]

In addition, for a number of courses, BTEC has administered follow-up surveys to students, months after a course was held, to assess the relevance and impact that the material taught had to their job duties and responsibilities. Results from these follow-up surveys also indicate that the BTEC courses described in this article have a significant positive impact on the students' ability to carry out their jobs. Details on feedback from these survey has also been reported in previously published articles.^[2,4-5]

Supervisors of former students who have taken BTEC's academic courses have also had positive feedback regarding the role of BTEC as a source of qualified engineers. One company representative offered that "BTEC-trained engineers tend to assume independent responsibility about two months faster than others straight out of college, resulting in reduced training costs of approximately \$12,000 per year."^[1, p. 45]

For a more personal account of the impact of BTEC's educational programs, we asked Veronica Adams, who earned a B.S. in chemical engineering from NC State in 2010 and was part of BTEC's first class graduating from our master of biomanufacturing program in 2012, to share her thoughts on the influence of BTEC's program on her career thus far.

1. **What company do you currently work for?**

Biogen. We develop and manufacture therapies—mostly large molecule therapies, such as proteins—for neurological, autoimmune, and rare diseases. For example, we have the world's most extensive portfolio of multiple sclerosis therapies.



2. **What is your current job title and what are your primary responsibilities?**

Engineer I. I work in the Pilot-scale Bioseparations Development and Tech Transfer group, within the Process Biochemistry department. Our main focus is downstream process development, which includes harvest operations such as centrifugation and depth filtration, ultrafiltration, and all other filtration steps that are part of the process. My main responsibility is leading downstream pilot-scale activities to produce larger quantities of process intermediates that are used for additional development studies at smaller scale or are passed off to another downstream group for chromatography development studies. I am also involved in transferring processes from small scale into clinical or commercial manufacturing.

Veronica Adams, part of BTEC's first master of biomanufacturing program graduating class in 2012.

3. **How has your chemical engineering background helped you in the biopharmaceutical industry?**

Companies are looking to hire people with chemical engineering degrees. I think the main reason is the critical thinking and problem-solving skills that the chemical engineering curriculum teaches. Chemical engineers are good at determining root causes to problems. General mass balance concepts taught in early chemical engineering courses are also important, particularly for calculating process and step yields. Being able to perform scale up and scale down calculations for unit operations like ultrafiltration is particularly important to the process transfer work I am involved in. The transport courses I took in the chemical engineering program at NC State really helped with the theory behind my current work in ultrafiltration.

4. **Did BTEC adequately prepare you for your current position? If so, how?**

Yes. Chemical engineering helped, but without BTEC, the learning curve in industry would have been much "steeper." BTEC taught me the basic concepts behind all of the work that I do now at Biogen. For example, I learned the theoretical and operational concepts underlying ultrafiltration and chromatography at BTEC. I learned about the equipment for those unit operations and how to use it. BTEC also taught me about

the analytical testing required to support various processing steps. And even though I don't work in the analytical area, knowing about the tests performed on the samples that we submit to the analytical lab as part of our process work is advantageous, particularly when process troubleshooting is needed.

5. Did your master's degree from BTEC give you an advantage entering industry?

Yes. As I mentioned before, the learning curve in industry would have been much steeper without it. I took an introductory course in downstream processing at BTEC before entering the master's program. That course alone was good preparation for industry. But after completing the master's program, I feel that I was "super" prepared. At BTEC, hands-on use of the type of equipment actually used in industry was beneficial.

When I started in my first position after finishing the BTEC master's degree, I quickly became the "go-to" person for chromatography column packing because that was a skill that I learned in one of my BTEC courses. Also, the industry internship that was part of my master's degree not only helped me to understand what industry is like, but helped me establish the connections that led me to my current position at Biogen. The soft skills I learned in the BTEC master's program were equally important to the technical skills—interviewing, resume writing, networking, presenting. I gave many presentations as part of the BTEC master's program, and that helped me to get over any fear I had in presenting to a group.

6. Do you plan on taking courses from BTEC in the future (i.e., do you plan on engaging in lifelong learning opportunities at BTEC)?

Yes, I do plan on taking BTEC short courses. It can be a challenge to fit courses into my schedule, but we are encouraged—and even have it written into our yearly goals—to participate in training. For the position I am currently in, training is particularly necessary on new technologies being implemented in biomanufacturing—like single-use equipment. It's important to be current on what's going on in the industry, because it's easy to get stuck in the "bubble" of what you are used to. There is definitely a need to expose yourself to new ideas.

7. When you become a supervisor, will you encourage your employees to seek out learning opportunities?

Definitely. Again, it is important to keep up to date on new technologies and new industry practices. The people that excel and move up in an organization, taking on more responsibility, are the ones that take additional courses and go to conferences to learn about new things. It's a good way to advance yourself. I am encouraged by my managers to attend conferences and short courses, and I would encourage my staff to do the same if I find myself in a supervisory role in the future.

CONCLUSIONS AND BTEC'S FUTURE

BTEC at NC State University has designed programs that offer needed educational opportunities throughout the "life cycle" of a professional. These include a biomanufacturing minor for undergraduate and graduate students, a master of biomanufacturing, and a professional development program offering both open-enrollment and customized short courses. Topics covered include drug discovery, cell line development, process development, biopharmaceutical commercialization, commercial production in a cGMP environment, and analytical testing/development.

Demand for these programs has grown significantly since BTEC opened its doors in 2007. Enrollment in our academic courses has increased from 187 in 2007–2008 to 931 in 2014–2015. Similar growth has been seen in our professional development program. Placement rates for our NC State students are good, with more than 98% of our students finding jobs or entering graduate school within six months of graduation. Further, based on numerous end-of-course and follow-up surveys, we believe that our programs are having a significant positive impact on the ability of both novice and experienced staff to perform their jobs and on the companies they work for.

BTEC will continue down the current path of offering courses to university students and professionals. We will keep a close eye on industry's evolving needs and revise curriculum and course content as appropriate. For example, we recently introduced short courses on the topics of single-use technologies and the development of mass spectrometry methods for biomolecules, and are developing new short courses on stem cell production and continuous biomanufacturing. We are also evaluating the need for an executive leadership program in the biomanufacturing industry. We will increase our use of delivery methods that allow for greater access to our courses. We expect that our online offerings will become more numerous in the next several years as will blended courses that include both online and on-site instruction. We have also begun offering a professional certificate in biomanufacturing science as part of our professional development program and are evaluating the need for professional certification within the industry.

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