#### AC 2012-3722: PROFESSIONAL DEVELOPMENT-STYLED SHORT COURSES FOR A HIGHLY EFFECTIVE BIOPROCESS ENGINEERING LABORA-TORY EXPERIENCE

#### Dr. Rick Williams, East Carolina University Dr. Loren Limberis, East Carolina University

Loren Limberis joined the engineering faculty at ECU in Aug. 2006. He earned his B.S. in electrical engineering and Ph.D. in bioengineering from the University of Utah. Limberis taught for several years as an Assistant Professor at the College of New Jersey and was a research analyst with Southwest Research Institute prior to his academic career. His research interests focus on designing techniques to utilize nature's highly complex and sophisticated biological systems to develop biohybrid devices for use in biotechnology applications.

#### Mr. Rebel Umphlett, BioNetwork Capstone Center

Rebel Umphlett is Director, Aseptic Facilities and Operations.

#### Mr. David Hobson Yarley, BioNetwork Capstone Center

David Yarley is the Director of BTEC Training and the Validation Academy at the BioNetwork Capstone Center. Yarley has 23 years of industrial experience in the biopharmaceutical industry including production management, business development, and project engineering. He received his B.S. degree in chemical engineering at North Carolina State University and his M.S. degree in chemical engineering at the University of Virginia.

# Professional Development-Styled Short Courses for a Highly Effective Bioprocess Engineering Laboratory Experience

#### Abstract

Professional development-styled short courses often provide working engineers an intensive hands-on learning experience that is difficult to achieve within the confines of the daily workplace. Can this model be extended into engineering education and provide engineering students hands-on laboratory experiences that are difficult to achieve within the confines of campus? This collaborative project between the Engineering Department at East Carolina University (ECU) and the BioNetwork Capstone Center, an industrial-scale training facility located at the Biomanufacturing Training and Education Center (BTEC), answers this question while accomplishing the following objectives:

- Develop and integrate two 2-day BTEC short course laboratory experiences into the ECU's bioprocess engineering curriculum. These short courses are a required and graded component of two bioprocess engineering courses.
- Develop companion web-based materials to provide students with prerequisite material, maximizing the time spent on hands-on laboratory activities on-site at BTEC, as well as providing an opportunity for students at other institutions to enroll.
- Enhance ECU engineering students' competiveness in the workplace by providing handson experiences in critical areas that are deemed important by the bioprocess industry.
- Provide the ECU engineering students a foundation for life-long learning through exposure to professional development type courses.
- Provide a model for other institutions to develop custom short courses for integration into their curricula.

The effectiveness of each short course was measured using pre- and post-tests of material and concepts taught and reinforced through each course and a student survey of each course's learning objectives. In addition, a survey of the students' attitudes toward professional development and attending such a course as a mandatory and graded component of their engineering course was conducted both prior to and after attending the short courses. All assessment metrics show that both short courses were highly effective laboratory experiences that provided the students with unique experiences that are not easily attainable through an on-campus laboratory. In this paper we present our rationale for developing the short courses, each short course's objectives, an overview of the laboratory experiences and prerequisite material of each course, and details of the assessment instruments and results of the assessment.

#### Introduction

Laboratories have been an essential part of engineering education since the inception of formal engineering programs. In the early days of engineering education much of the instruction took place in the laboratory as the focus was primarily on practice. However, after World War II, the American Society of Engineering Education recognized that many of the inventions resulting from the war were from the work of scientist and not engineers and thus chartered a committee that determine that the engineers being produced were too practically oriented and not adequately trained to seek solutions through the application of first principles. This committee's report, known as the Grinter Report<sup>1</sup>, recommended strengthening engineering education in the basic sciences including mathematics, chemistry and physics. Following the issue of the Grinter Report, the Engineer's Council for Professional Development (ECPD and today's ABET) quickly implemented changes that resulted in a shift from the practical aspects of engineering that were taught in the laboratory to an increased emphasis on theory and basic science.<sup>2</sup>

In the 1970's with the completion of the moon mission and the cancellation of major engineering projects such as the supersonic transport, engineering education saw a significant decline in funding and as a result, many schools reduced laboratory requirements to save money. At the same time, industry demanded more practical skills and in response, many education institutions developed technology programs. The boundaries between engineers and technologist became blurred and so ECPD began to accredit two and four year programs. Then in the 1980's when ECPD became the Accreditation Board for Engineering and Technology, new criteria were developed that required adequate laboratory practice with plans for instrumentation maintenance and replacement required for every engineering program.<sup>2</sup> In 1999, ABET introduced a new set of assessment criteria known as EC2000<sup>3</sup> providing an impetus for engineering programs to increase the amount of laboratory instruction and activities. While EC2000 does not explicitly require laboratory instruction on multi-disciplinary teams, communicate effectively, use modern engineering tools all indicate an increased emphasis on laboratories within engineering education.

One of the challenges facing many institutions in providing a quality laboratory experience is the increasing complexity and costs of laboratory equipment and well as the space to house laboratories. In order to overcome these challenges (and in some cases to provide laboratory access for distance education), two predominate approaches have emerged; computer simulations and remote laboratory access.

Computers have become invaluable in engineering education for data collection, data analysis and reporting, and simulation. Advancements in simulation technology have made simulations

more realistic and they are now a useful alternative to laboratory exercises that previously were too expensive, too dangerous, or just too time consuming. One such simulation tool, CyclePad<sup>4</sup> has been developed to allow for the study of the design and analysis of thermodynamic cycles. In this case, a set of real full-scale thermodynamic cycles is obviously too large and expensive to build, maintain and operate for most educational institutions, and the CyclePad simulation has been shown to be an effective method to bring a laboratory-style experience to thermodynamics. A second simulation tool, Virtual BioR Laboratory<sup>5</sup> was developed to simulate a biological process in a bioreactor. This tool helped to overcome the time constraints associated with running a parametric study of a process that can take a day or more to obtain just one set of data. Using the virtual bioreactor, 237 batches were processed in a three week period, demonstrating the value of using a simulation tool in place of a physical bioreactor.

Remote laboratory access, generally via the internet, has gained a foothold over the last decade with much of the motivation driven by the expansion of distance education. Prior to the development of remote laboratory access, distance education students would be required to travel to their home campus to complete labs or complete the lab at a local facility such as a community college. Now days, many labs are delivered synchronously over the internet in such a manner that the students can actually take control of the experimental apparatus. For example, the Remotely Accessible Laboratory (REAL)<sup>6</sup> allows students remote access to robots, not only allowing students to manipulate the robots, but allowing students to perform complex robotics experiments, such as controlling the robot with a user supplied algorithm. Systems like REAL have opened up the concept of resource sharing, where institutions located anywhere in the world can share laboratory facilities via the internet and thus have access to equipment that they otherwise cannot afford.

One concept of expanding laboratory access that is not well discussed in the literature, but addresses some of the same resource issues as virtual or remote access laboratories, is the concept of conducting a lab at an off-site facility such as another educational institution or an industrial facility. One advantage an industrial facility may offer over an educational institution is that the students are exposed full-scale systems in real-world environment. A report issued by the North Carolina Biotechnology Center (NCBC)<sup>7</sup> indicated engineering graduates "need knowledge and skill sets specific to biomanufacturing and pharmaceutical manufacturing that are not typically taught in the classroom as part of traditional academic programs." In the report several characteristics were specifically noted as being critical to the training of the biomanufacturing and pharmaceutical manufacturing workforce:

- Operation in a GMP-like manner (GMP is the FDA-mandated Good Manufacturing Practice)
- Provision of hands-on experience with production equipment, at least at pilot scale, as well as laboratory equipment
- Training in aseptic manufacturing processes and clean-room work

- Instruction by faculty with prior experience in the industry
- Close oversight of curricula and programs by industry

Based upon the recommendations of the NCBC, the State of North Carolina opened a production-scale biomanufacturing facility for the training of all levels of the biomanufacturing and pharmaceutical manufacturing workforce. The facility, named the Biomanufacturing Education and Training Center (BTEC)<sup>8</sup>, provides workforce training primarily via short-courses. Professional development-styled short courses often provide working engineers an intensive hands-on learning experience that is difficult to achieve within the confines of the daily workplace. The question that we answer in this paper is: Can the professional development-styled short course model be extended into engineering education and provide engineering students hands-on laboratory experiences that are difficult to achieve within the confines of campus?

### Background

The East Carolina University (ECU) engineering program features a common core that develops the fundamental engineering skills and five concentrations that build specialized knowledge, including industrial and systems engineering, mechanical engineering, electrical engineering, biomedical engineering, and bioprocess engineering. The engineering graduates that specialize in the bioprocess engineering concentration will work in one of the fastest growing segments of the eastern North Carolina's economy—bioprocessing and pharmaceutical manufacturing. These engineers will require the skills to support, operate, and improve these biomanufacturing processes. The current bioprocessing curriculum has six additional courses beyond the engineering core curriculum: Organic Chemistry, Engineering Applications in Microbial Systems (BIOE 3016), Bioprocess Engineering Systems (BIOE 3250), Bioprocess Validation and Quality (BIOE 4006), Bioprocess Separation Engineering (BIOE 4010), and Bioprocess Plant Design, and Simulation and Analysis (BIOE 4020).

The courses BIOE 3250 and BIOE 4010 each have a lab component that provides the students with hands-on experiences in cell growth, fermentation, distillation, extraction, chromatography, and characterization of protein concentration and purity. However, based upon the report issued by NCBC<sup>7</sup> stating:

There is a critical need for new training programs to provide a qualified workforce for company expansions and for new manufacturing enterprises locating in North Carolina... and they also need knowledge and skill sets specific to biomanufacturing and pharmaceutical manufacturing that are not typically taught in colleges as a part of traditional academic programs. Employers place a premium on prior experience in the pharmaceutical industry, and new graduates are at a distinct disadvantage in competing for jobs at any level with applicants with prior experience. Since the number of such experienced job applicants is limited in our market, it is essential to find ways to prepare graduates better.",

we felt we needed to provide our bioprocess engineering students additional, more industry specific hands-on experiences. To this end, we pursued the development and implementation of short courses in collaboration with the North Carolina's Community College System's BioNetwork's Capstone Center located at BTEC for the ECU engineering students. The Capstone Center is administered through Wake Technical Community College and has a mission to provide "affordable high-quality hands-on training in biotechnology, biomanufacturing, and biopharmaceutical/pharmaceutical operations in a simulated industrial environment."<sup>9</sup> The rationale for developing these short courses is that they dovetailed with the existing ECU engineering curriculum while providing the students with unique hands-on experiences that are not typically taught as part of a traditional academic program, thus addressing many of the education shortfalls highlighted in the NCBC report. Our ultimate goal was to educate high quality engineers who will be competitive in the high growth biotechnology industry.

Project planning activities began with a meeting between key ECU and Capstone Center personnel. The meeting was held at BTEC and had two important outcomes: 1) a general agreement that a collaboration between ECU and the Capstone Center in the area of bioprocessing and biomanufacturing would be beneficial 2) that it would be beneficial to further planning for ECU faculty to attend at least one of the Capstone Center courses in order to develop a better understanding of the format, content, and delivery of the current Capstone Center course offerings. Following up on the initial meeting, an ECU faculty member attended a 2-day course titled "High Performance Liquid Chromatography". Shortly after attending this course, a second meeting was held where it was collectively determined that the courses need to be limited to 2-days to ensure accessibility by the ECU engineering students (longer courses would result in the ECU students missing too much class time from their other ECU courses). The project team also discussed how to proceed and select course topics and determined that valuable input could be obtained from the ECU's Engineering Advisory Board (EAB), which was about to convene a meeting. During the EAB meeting, the Bioprocess Engineering concentration curriculum was thoroughly reviewed and the proposed project was presented and discussed. The EAB was very enthusiastic about the proposed project and recommended a list of possible topics that included topics such as GMP, aseptic manufacturing, facilities water, chromatography column packing and troubleshooting, and analytical chemistry. This list was then used as the basis for discussion and final selection of the topics during the project team's third planning meeting. During that meeting, Capstone Center personnel provided their assessment of the proposed course topics and recommended pedagogical approaches that emphasize hands-on learning. Using the information gathered from our third project meeting, the input from the Engineering Advisory Board, and a review of ECU's strengths, three topics for the 2-day short courses were selected to be Analytical Biochemistry, Chromatography, and

Aseptic Manufacturing and Facilities. As a result of limited resources and a subsequent curriculum change in ECU's bioprocess engineering program, the list of short courses was pared down to two courses; Chromatography and Aseptic Manufacturing and Facilities.

As the project moved forward, the following five project objectives were developed:

- 1. Develop and implement two 2-day BTEC short courses into the ECU bioprocess engineering curriculum,
- 2. Develop companion websites to provide students with prerequisite material and allow students from other institutions to enroll in the short courses,
- 3. Enhance ECU engineering students' competiveness in the workplace by providing handson experiences in critical areas as identified by the NCBC report,
- 4. Provide the ECU engineering students a foundation for life-long learning through exposure to professional development type courses, and
- 5. Provide a model for other institutions to develop custom short courses for integration into their curriculums.

## **Short Course Descriptions**

The first short course, titled *Industrial Chromatography*, was integrated as a graded component into ECU's course BIOE 4010, *Bioprocess Separation Engineering*. The second short course, titled *Bioprocess Facilities and Aseptic Manufacturing*, was integrated as a graded component into ECU's course BIOE 4020, *Bioprocess Plant Design, Simulation, and Analysis*.

Each course consisted of online prerequisite content in addition to the 2-day on-site experience, thus allowing for the maximum possible hands-on laboratory experience while on-site at BTEC. The prerequisite content was housed on-line using the course delivery software Moodle. The on-line material was designed to be self-paced and included quizzes to ensure that the students mastered the material.

Course objectives were developed for each short course and the objectives that could be met through the prerequisite material were identified so that the ECU faculty could develop the prerequisite course material while the BTEC faculty developed the lab-based course material. The objectives and the associated topics for each short course and the prerequisite material is listed in Appendix A.

#### **Course Level Assessment**

The short course, *Industrial Chromatography*, was held at BTEC during the fall semester of 2010. The course was attended by 9 students, which consisted of 5 BIOE 4010 students, 1 lab teaching assistant, 1 lab supervisor, and 2 ECU engineering professors. The short course *Bioprocess Facilities and Aseptic Manufacturing*, was held at BTEC during the spring semester of 2011. The course was attended by 7 students which consisted of 5 BIOE 4020 students, 1 lab supervisor, and 1 ECU engineering professor. It should be noted that the ECU bioprocess program is relatively small, and all students in the program attended the short courses.

### Industrial Chromatography Short Course Assessment

The primary evaluation tool for the *Industrial Chromatography* short course was a pre- and posttest. This test was also used for a previous curriculum development project<sup>10</sup>, thus providing a control for the short course project. The control group was taught the chromatography topic using a problem based learning approach while the study group was taught chromatography using the same problem based learning approach and attended the short courses. The specific test questions are listed in Appendix B.

Tables 1 and 2 show the individual scores by student for the control pre-test and the short course pre-test, respectively. The mean score of the control pre-test was 4.2, while the mean score of the short course pre-test was 2.4. A t-test comparing the means at a 95% confidence shows no statistical difference between the two populations, meaning both the control group and the short course group had the same level of base knowledge prior to their respective chromatography experiences.

Question	Student Scores							
(points)	Student 1	Student 2	Student 3	Student 4	Student 5			
1 (2)	0	2	0	2	1			
2 (5)	2	2	2	3	2			
3 (1)	0	1	0	1	0			
4 (2)	0	0	0	1	0			
5 (5)	0	0	0	2	0			
6 (3)	0	0	0	0	0			
Total (18)	2	5	2	9	3			

Table 1: Control Pre-test Scores

Question	Student Scores								
(points)	Student A	Student B	Student C	Student D	Student E				
1 (2)	2	2	1	0	0				
2 (5)	1	2	1	1	0				
3 (1)	0	0	1	0	0				
4 (2)	0	0	0	0	0				
5 (5)	0	0	1	0	0				
6 (3)	0	0	0	0	0				
Total (18)	3	4	4	1	0				

Table 2: Industrial Chromatography Pre-test Scores

Tables 3 and 4 show the individual scores by student for the control post-test and the short course post-test, respectively. The mean score of the control post-test was 8.0, while the mean score of the short course pre-test was 12.0 A t-test comparing the means at a 95% confidence shows a statistical difference between the two populations indicating that the short course made a significant improvement in the students' mastery of the chromatography material.

Question	Student Scores							
(points)	Student 1	Student 2	Student 3	Student 4	Student 5			
1 (2)	2	2	2	0	2			
2 (5)	3	3	3	1	3			
3 (1)	1	1	1	0	0			
4 (2)	1	2	1	0	0			
5 (5)	2	3	1	3	3			
6 (3)	0	0	0	0	0			
Total (18)	9	11	8	4	8			

Table 3: Control Post-test Scores

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Question	Student Scores								
(points)	Student A	Student B	Student C	Student D	Student E				
1 (2)	2	2	1	2	1				
2 (5)	2	4	4	3	3				
3 (1)	0	1	1	1	1				
4 (2)	1	1	1	0	1				
5 (5)	1	5	5	4	4				
6 (3)	2	3	0	2	2				
Total (18)	8	16	12	12	12				

Table 4: Industrial Chromatography Post-test Scores

A second indicator of the effectiveness of the *Industrial Chromatography* short course was based upon a student survey of the course learning objectives of BIOE 4010. At the conclusion of every ECU engineering course, the students are surveyed to obtain their opinion of how well

they mastered the course objectives. The students rate each objective on a 5-point Likert scale, with 1-5 being Strongly Disagree, Disagree, Neutral, Agree and Strongly Agree, respectively. The following two course objectives (in question form) pertained to chromatography:

#### 1) I am able to describe the mechanisms of chromatography and

2) I am able to analyze chromatography systems.

These two objectives were rated the highest of all 16 course objectives with an average rating of 4.8 each compared to the overall 16 course objectives average rating of 4.2. This indicates that the students felt they learned chromatography better than all other bioprocess separation processes taught in the course.

### Bioprocess Facilities and Aseptic Manufacturing Short Course Assessment

The primary evaluation tool for the *Bioprocess Facilities and Aseptic Manufacturing* short course was a pre- and post-test. Unlike the *Industrial Chromatography* course, there was no control set available this assessment. The specific test questions are listed in Appendix B.

Tables 5 and 6 show the individual scores by student for the short course pre-test and post-test, respectively. The mean score of the pre-test was 10.2, while the mean score of the short course pre-test was 20.6. A t-test comparing the means at a 95% confidence shows a statistical difference between the two populations indicating that the short course made a significant improvement in the students' mastery of the bioprocess facilities and aseptic manufacturing material. However, it is noted that the students did not perform well on question 9 (water treatment). The coverage of this topic (water treatment) will be reviewed prior to the second offering of the course.

Question	Student Scores								
(points)	Student A	Student B	Student C	Student D	Student E				
1 (4)	0	0	0	2	2				
2 (3)	0	2	0	0	0				
3 (4)	1	1	1	1	1				
4 (4)	0	1	0	2	1				
5 (4)	3	3	1	2	1				
6 (4)	2	4	0	4	4				
7 (3)	0	0	0	0	0				
8 (2)	0	1	0	0	1				
9 (9)	0	1	0	0	1				
10 (3)	2	2	0	2	2				
Total (40)	8	15	2	13	13				

Table 5: Bioprocess Facilities and Aseptic Manufacturing Pre-test Scores

Question	Student Scores							
(points)	Student A	Student B	Student B	Student D	Student E			
1 (4)	2	4	0	2	4			
2 (3)	2	3	1	2	2			
3 (4)	0	2	1	2	1			
4 (4)	1	4	2	2	4			
5 (4)	4	4	2	2	2			
6 (4)	4	1	3	4	4			
7 (3)	3	2	3	3	3			
8 (2)	1	1	1	2	1			
9 (9)	0	1	0	0	3			
10 (3)	2	2	0	2	2			
Total (40)	19	24	13	21	26			

Table 6: Bioprocess Facilities and Aseptic Manufacturing Post-test Scores

A secondary evaluation tool for the *Bioprocess Facilities and Aseptic Manufacturing* short course was a student survey of their opinion of mastering the learning objectives. The students rated each objective on a 5-point Likert scale, with 1-5 being Strongly Disagree, Disagree, Neutral, Agree and Strongly Agree, respectively. The 16 short course objectives are listed in Appendix A.

Table 7 shows the individual results of the survey of the short course objectives. Also shown are the mean ratings and the percentage of students that rated the achievement of the objective as satisfactory as indicated by a rating of 4 or 5. Within ECU's engineering program, an objective is considered satisfactorily achieved when 60% of the students rate the objective a 4 or 5. Only one objective was rated unsatisfactory by the students with only 40% of the students rating objective 15 either a 4 or 5. This objective is deals with water purification and the low rating is consistent to the students' performance on the post-test.

Objective		Student Ratings							
Number	Student A	Student B	Student C	Student D	Student E	Mean	% 4 or 5		
1	4	4	4	4	4	4	100		
2	4	5	5	5	4	4.6	100		
3	4	4	4	5	4	4.2	100		
4	4	4	4	4	4	4	100		
5	4	4	5	4	4	4.2	100		
6	5	5	5	4	4	4.6	100		
7	4	4	4	5	4	4.2	100		
8	4	3	4	4	4	3.8	80		
9	4	5	4	4	4	4.2	100		
10	4	4	5	4	4	4.2	100		
11	4	4	4	4	4	4	100		
12	3	5	5	5	4	4.4	80		
13	4	4	5	4	4	4.2	100		
14	4	3	5	5	4	4.2	80		
15	3	3	4	4	3	3.4	40		
16	4	4	4	5	3	4	80		

Table 7: Student ratings of mastery of the Bioprocess Facilities and Aseptic Manufacturing learning objectives.

#### **Project Level Assessment**

The evaluation of the achievement of the five project objectives previously listed was accomplished primarily through the use of student surveys; however, project objectives 1-3 were implicitly met by the development and running of the courses. Although no students from other institutions or programs participated in the courses, the online material is in place, and we fully expect students from ECU's Biotechnology program (offered through the Biology Department) to enroll in these courses in the next year.

Project objective 3 was further assessed through a post graduation survey asking the graduates to reply to the following opened ended statement: *Please comment about your experience with the courses at BTEC and if and how they have contributed to your career in terms of landing a job, helping you with your job, or any other positive experiences you wish to convey.* The three responses were received from the five graduates and the excerpts below all clearly show that the short courses helped these students land a job and excel in the workplace:

"The experiences I had at the BTEC facility helped me obtain a job after graduation as I had additional experiences from other recent graduates that helped me stand apart. Using the knowledge I gained from both the chromatography class and the clean room class, I was able to describe real-world experiences rather than just knowledge of the practices. During an interview, I was asked about what steps were needed to work in a clean room and I was able to describe an actual experience I had at the BTEC facility. I believe that the BTEC experience is extremely beneficial for all students in the Bioprocess Engineering program at East Carolina University."

"The experience that I had from BTEC chromatography helped me understand the chromatography process enough to explain it to others. The experience gained from the clean room design BTEC program aided me in landing a job; (My employer) liked that I knew how to gown and had clean room knowledge."

"Being able to see and operate some of the processing equipment talked about in our courses, provided me with a better understanding of the industry and only increased my desire to work in it. The hands-on approach to the courses kept me engaged the entire time. In my first job after graduating, some of the things I learned at BTEC have benefited my new position, such as the rigorousness of documentation. Now in my new position I am able to understand and competently perform the documentation required of me."

Objectives 4 and 5 were assessed using a student survey of their attitudes towards professional development. The purpose of the survey was to determine the students' attitudes toward 1) attending a short course as a mandatory and graded requirement of their engineering class, 2) attending a short course as an element of professional development, 3) paying for the short course as part of their engineering class, 4) paying for a short course as an element of professional development. The survey was administered prior to attending the first short course (and in fact, prior to the students having any knowledge of the short courses), after attending the *Industrial Chromatography* short course and again after attending the *Bioprocess Facilities and Aseptic Manufacturing* short course. The survey is shown in Appendix B.

*Tab*les 8 -10 show the results of the short course survey for the three time periods: prior to attending any short course, after attending the *Industrial Chromatography* short course, and after attending the *Bioprocess Facilities and Aseptic Manufacturing* short course. It should be noted that the surveys are anonymous and there is no known relationship between the students from survey date to survey date.

Question		Student Ratings							
Number	Student A	Student B	Student C	Student D	Student E	Mean	% 4 or 5		
1	5	5	5	3	5	4.6	80		
2	4	4	4	3	4	3.8	80		
3	3	4	2	2	3	2.8	20		
4	3	1	1	1	1	1.4	0		
5	4	3	2	3	2	2.8	20		
6	2	1	1	1	1	1.2	0		
7	5	4	4	4	4	4.2	100		
8	4	4	4	1	5	3.6	80		
9	2	4	4	1	2	2.6	40		

Table 8: Students' Attitudes Towards the Short Courses Prior to Attending any Short Course

Table 9: Students' Attitudes Towards the Short Courses After Attending the IndustrialChromatography Short Course

Question	Student Ratings							
Number	Student A	Student B	Student C	Student D	Student E	Mean	% 4 or 5	
1	4	5	5	5	5	4.8	100	
2	4	5	4	5	5	4.6	100	
3	4	5	5	2	5	4.2	80	
4	1	2	4	1	2	2.0	20	
5	3	5	5	2	3	3.6	40	
6	1	2	3	1	1	1.6	0	
7	4	5	5	5	5	4.8	100	
8	3	5	4	5	4	4.2	80	
9	3	5	4	5	2	3.8	60	

Table 10: Students' Attitude Towards the Short Courses After Attending the BioprocessFacilities and Aseptic Manufacturing Short Course

Question		Student Ratings							
Number	Student A	Student B	Student C	Student D	Student E	Mean	% 4 or 5		
1	5	5	5	5	5	5.0	100		
2	4	5	5	5	4	4.6	100		
3	3	4	5	5	3	4.0	60		
4	2	3	3	1	3	2.4	0		
5	3	4	4	2	4	3.4	60		
6	1	2	2	1	1	1.4	0		
7	4	5	5	5	5	4.8	100		
8	2	5	5	5	5	4.4	80		
9	2	5	5	5	5	4.4	80		

In general, the students' attitudes towards the short courses became more positive after taking each course. Note that there were several questions (4, 5, and 6) in which a positive response

was not necessarily expected. Question 6 became more positive throughout the duration of the study, indicating that the students feel that the courses are worth paying for at a nominal fee. The analysis of each objective of the survey follows.

Survey Objective 1: Attending a short course as a mandatory and graded requirement of their engineering class. This objective was addressed by questions 8 and 9. The responses to both these questions became increasingly positive as the students attended the course. In fact if it were not for one student (who in general had a very negative attitude toward ECU's engineering program), there would have been 100% agreement with the short courses being a mandatory and graded component of the engineering classes.

Survey Objective 2: *Attending a short course as an element of professional development*. This objective was primarily addressed by questions 1, 2, and 7. Based upon all of these questions, the students did initially understand the importance of professional development and the value of short courses for professional development. The courses further strengthened this attitude.

Survey Objective 3: *Paying for the short course as part of their engineering class*. This objective was primarily addressed by questions 5 and 6. Initially the students were very negative towards paying for the short courses, but after attending the short courses, this attitude toward paying a nominal fee for the courses improved, with 4 of the 5 students neutral or positive. The students' attitudes towards paying a large fee for the courses did not significantly change over the duration of the study.

Survey Objective 4: *Paying for a short course as an element of professional development*. This objective was primarily addressed by questions 3 and 4. Initially the students were very negative towards paying for the short courses, even for professional development, but after attending the short courses, the attitude improved toward paying a nominal fee for the courses with all of the students neutral or positive. The students' attitude towards paying a large fee for the courses did not significantly change. Although \$500 is a reasonable fee for a short course within the professional world, perhaps the students do not realize this or perhaps they answered the question assuming they were attending the short course while still college students.

#### Discussion

The two short courses were primarily developed to provide ECU's bioprocess engineering students a laboratory experience that was impossible to duplicate on campus. In this case there were two limiting issues; resources and expertise. The engineering graduate of today faces a very specialized job market and many academic institutions are not poised to provide their

graduates with the degree of specialized knowledge and experience expected by industry; this is especially true for biomanufacturing and pharmaceutical manufacturing. The use of computer simulation and remote laboratory access has become common place in an effort to continue to provide engineering students meaningful laboratory experiences in an environment of ever-decreasing resources. The model presented here expands the concept of remote laboratory access in that instead of remotely accessing a third-party site via a computer to conduct an experiment, the students physically go to a third-party site to complete the laboratory experience. While both concepts have their merit, there are certainly experiences such as gowning up and working under a class-100 clean room hood that cannot be effectively simulated or remotely accessed and controlled. Although we worked with an industrial training facility to provide the resources and expertise, we believe that the laboratory access model successfully demonstrated by this project can be extended to industry partners.

The course specific assessment indicated that the laboratory experiences provided by the two short courses were very successful at meeting the course level objectives. Project level assessment indicated that the courses met the five project objectives. More specifically, prior to the attendance of the short courses, student's attitudes towards attending the courses as a graded component of their engineering class and paying a nominal (\$60) fee to attend the courses was very negative; however their attitudes towards these two parameters became very positive after attending the courses. Perhaps as meaningful as the formal assessment was at indicating success was observed anecdotal evidence. Students were attentive, enthusiastic, focused, and professional over the two days of each course, even taking late lunches and working into the evenings to complete the activities. Many students indicated interest in returning on their own to attend additional courses offered by BTEC. But perhaps the most telling was a universal report by the students to the engineering department chair during senior exit interviews that the short courses were at the top of these students' list of the best experiences of their four years in the ECU engineering program.

One concern of both the investigators of this grant and of the funding agency was the long-term sustainability of running the short courses. The key issue is funding and the students' willingness to pay for the short courses. The BTEC facility is located 90 miles from ECU's campus, so in addition to the cost of the courses (now \$120/course) the students must incur the travel costs. The running of the short courses is now in the second year, and so far, the students have had friends or family to stay with overnight or had the opportunity to ride to BTEC with a faculty member. The course fees have been paid through the grant or by department funds; however, the professional development attitudes survey indicates that the students are more than willing to pay to attend the courses. This notwithstanding, an effort is being pursued to obtain long-term funding to provide student scholarship support for the courses. The positive results of the short courses were presented to ECU's Engineering Advisory Board (EAB) and they have enthusiastically supported the opening of a Bioprocess Engineering foundation account to which

funds can be donated in order to support these courses as well as other bioprocess related activities. Based upon the current level of support, we believe we will be able to offer these courses tuition free to our bioprocess engineering students for the foreseeable future.

#### Conclusion

Two professional development-styled short courses were developed and implemented as a graded component of two bioprocess engineering courses. These short courses provided the students with hands-on experiences that could not be duplicated on campus due to a lack of resources and expertise. Both formal assessment and anecdotal evidence indicate that the courses were very successful in meeting course level and project objectives. This project provides a model for educational institutions to collaborate with a third party such as an industry partner to provide engineering students a unique experience that cannot be duplicated on the confines of a college campus.

#### Acknowledgement

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Appendix A: Short Course Objectives and Topical Modules

### Industrial Chromatography Objectives

(Note: Italicized objectives represent prerequisite material)

Upon completion of this course, the students shall be able to:

- 1. Explain the principle of chromatographic separation.
- 2. Explain the four key chromatography mechanisms.
- 3. Demonstrate an understanding of how chromatography fits within a typical bioprocess separation scheme.
- 4. Demonstrate an understanding of the value and costs of chromatography and the importance of performance monitoring.
- 5. Demonstrate knowledge of resin types, properties and manufacturing techniques.
- 6. Explain the importance of buffer preparation.
- 7. Explain the modes of operation of chromatographic processes.
- 8. Explain the basic components and flow path of the AKTA prime plus chromatography instrument.
- 9. Perform a system washing and air removal operation using the AKTA prime plus.
- 10. Condition the chromatography column using the AKTA prime plus.
- 11. Calculate yield and purity using a chromatograph.
- 12. Monitor the performance of a chromatography process using HETP, Asymmetry, and SPEW.
- 13. Compare the separation performance of two or more different chromatography column chemistries using the same feedstock.
- 14. Utilize Batch Production Records (BPR) for controlling a chromatography process.
- 15. Demonstrate knowledge of column maintenance and troubleshooting.
- 16. Explain the basic procedure of packing a chromatography column.
- 17. Demonstrate an understanding of chromatography column design and scale-up.
- 18. Demonstrate an understanding of chromatography automation.

## Industrial Chromatography Prerequisite Topical Modules

Chromatography Introduction, The Chromatogram, Chromatography Resins, Columns, and Systems, Quiz1, Affinity Chromatography, Size Exclusion Chromatography, Ion Exchange Chromatography, Hydrophobic Interaction Chromatography, Quiz 2, Modes of Operation, Performance Monitoring, and Quiz 3.

## Industrial Chromatography On-site Topical Modules

## <u>Day 1</u>

- 1) Module 1
  - a) Questions to Answer Before Beginning Purification

Appendix A: Short Course Objectives and Topics

- b) Fundamentals of Chromatography
- 2) Module 2
  - a) Cost of Chromatography
  - b) Key Mechanisms
  - c) Operations
- 3) Lab 1 Aktaprime (chromatography system) Familiarization
- 4) Module 3
  - a) Performance Testing
- 5) Lab 2 Green Fluorescent Protein Purification using Anion Exchange Chromatography

### **Day 2**

- 1) Lab 3 Green Fluorescent Protein Purification using Hydrophobic Interaction Chromatography
- 2) Module 4
  - a) Chromatography Equipment and Scale-up
- 3) Module 5
  - a) Troubleshooting and Maintenance
- 4) Wrap-up

### **Bioprocess Facilities and Aseptic Manufacturing Objectives**

(Note: *Italicized* objectives represent prerequisite material)

Upon completion of this course, the students shall be able to:

- 1. Provide a detailed definition of aseptic manufacturing.
- 2. Describe the differences between aseptic processing and terminal sterilization.
- 3. Become familiar with aseptic manufacturing terms and definitions.
- 4. Describe the buildings and facilities air classifications.
- 5. Describe general clean room design and operation.
- 6. Understand and practice general personnel aseptic techniques.
- 7. Describe the contaminants that affect aseptic manufacturing.
- 8. Describe the different types of disinfectants and their use.
- 9. Describe sanitization issues in aseptic manufacturing.
- 10. Understand how to maintain a clean room.
- 11. Describe the general environmental control and monitoring programs.
- 12. Understand and practice aseptic process simulations (media fills).
- 13. Understand and practice batch record review and process control documentation.
- 14. Describe the basic operations of instrumentation and control systems in a bioprocess facility.

Appendix A: Short Course Objectives and Topics

- 15. Describe how pharmaceutical grade water is produced, maintained, and distributed.
- 16. Describe the utilities associated with a biotechnology production plant.

### Bioprocess Facilities and Aseptic Manufacturing Prerequisite Topical Modules

Aseptic Processing (AP) Introduction, AP Buildings and Facilities, AP Personnel Training Qualification and Monitoring, AP Contaminants, Disinfectants and Sanitation, Quiz 1, AP Control Procedures Maintaining the Clean Room, AP Control Procedures Environmental Monitoring, AP Process Simulations Media Fills, AP Elements of Batch Record Reviews - Process Control Documentation, Quiz 2, Facility Design (FD) Instrumentation and Control of Bioprocesses, FD Pharmaceutical Water Systems, FD Biotechnology Production Plant Utilities, and Quiz 3.

### Bioprocess Facilities and Aseptic Manufacturing On-site Topical Modules

## <u>Day 1</u>

- 1) Module 1
  - a) Why Aseptic Processing?
  - b) Batch Record Review
  - c) Review of Lab Exercises
- 2) Lab 1 Equipment Preparation
- 3) Equipment Demonstration
  - a) Particle Counter
  - b) Active Air Sampler
- 4) Lab 2 Disinfectant Experiment
- 5) Lab 3 Measuring Contamination
  - a) Finger Touch Plates
  - b) Environmental Monitoring
  - c) Rodac Plates
  - d) Swabs
- 6) Module 2
  - a) Clean Room Gowning
  - b) Aseptic Technique Review
- 7) Lab 4 Compounding/Filtration Lab Practice
- 8) Lab 5 Aseptic Processing
  - a) Compound Media
  - b) Filter Sterilized Media
  - c) Perform Growth Promotion
  - d) Perform Bubble Point Test on Filters

Appendix A: Short Course Objectives and Topics

## <u>Day 2</u>

- 1) Module 1
  - a) Review of Lab Exercises
- 2) Lab 1 Aseptic Processing, Media Fills
  - a) Hand Fills
  - b) C-L Filling Machine
- 3) Module 2
  - a) Barrier Isolators
- 4) Lab 2 Facilities Tour
  - a) Process Distributed Control System
  - b) Process Water
- 5) Lab 3 Aseptic Processing Future
  - a) Closed System Filtration/Isolators
- 6) Lab 4 Measuring Contamination and Disinfection
  - a) Review and Discussion of Day 1 Results

Appendix B: Assessment Tools

Industrial Chromatography Pre- and Post-test Questions

- 1. Define the terms adsorbent and adsorbate?
- 2. The physical binding of a molecule onto an adsorbent takes place due to interactions (or force systems) between the molecule and the surface. What are the 5 interactions?
- 3. The process of removing a target molecule from an adsorbent is commonly called:
  - a. washing
  - b. recovery
  - c. elution
  - d. de-binding
- 4. Describe the fundamental difference between adsorption and chromatography.
- 5. What are 5 separation mechanisms used in chromatography?
- 6. In a chromatography column, the retention time of a solute is 2 minutes and characteristic peak width is 1 minute. How many theoretical plates make up this column?

Bioprocess Facilities and Aseptic Manufacturing Pre- and Post-test Questions

- 1. Describe the differences between aseptic processing and terminal sterilization.
- 2. What is the primary difference between Class 10,000 conditions and Class 100 conditions?
- 3. An aseptic gown provides a barrier between the body and exposed sterilized materials. What are the four FDA recommendations for gowns?
- 4. What is an endotoxin and a patient's symptoms of being exposed to an endotoxincontaminated drug product?
- 5. List four general liquid disinfectants.
- 6. What is the difference between Alert Levels and Action Levels when conducting Environmental Monitoring?
- 7. Why are media fill process simulations conducted?
- 8. What is the definition of a Colony Forming Unit (CFU)?
- 9. Name and describe 3 water treatment systems.
- 10. What are three major uses for plant steam systems?

#### Student Attitudes Survey

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## Integration of Hands-on Short Courses into a Bioprocess Engineering Curriculum Short Course Survey

Please rate each statement on a scale from 1 to 5 as follows:

- 5 = I strongly agree with the statement
- 4 = I agree with the statement
- 3 = I neither agree nor disagree with the statement
- 2 = I disagree with the statement
- 1 = I strongly disagree with the statement
- 1. Professional development is important for advancing my career as an engineer.
- 2. A one- or two-day short course that provides focused training is an effective means of professional development.
- 3. A fee of \$60 is a reasonable amount to charge for a one- or two-day short course for professional development.
- 4. A fee of \$500 is a reasonable amount to charge for a one- or two-day short course for professional development.
- 5. As a student, I would be willing to pay \$60 to attend a one- or two-day short course for professional development.
- 6. As a student, I would be willing to pay \$500 to attend a one- or two-day short course for professional development.
- 7. I believe that attending one- or two-day short course for professional development as a student will improve my marketability as an engineer when I enter the workplace.
- 8. I believe that requiring attendance to a one- or two-day short course for professional development as a component of my bioprocess engineering classes is reasonable.
- 9. I believe that requiring attendance to a one- or two-day short course for professional development as a component of my bioprocess engineering class grade is reasonable.

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