

**North Carolina Biomanufacturing and Pharmaceutical
Worker Training Program
Business Plan**

August 1, 2003

Table of Contents

General Project Description.....	1
Mission Statement.....	1
Goals and Objectives	1
Nature and Scope of Economic Opportunity.....	1
Projected Economic Impacts	3
Biomanufacturing & Pharmaceutical Training Consortium.....	4
BioNetwork.....	4
Biomanufacturing Research Institute and Training Enterprise	7
Biomanufacturing Training Center	7
Description of Participating Entities & Qualifications to Operate Consortium.....	8
North Carolina Community College System	8
University of North Carolina System.....	9
North Carolina Biosciences Organization	11
Marketing.....	11
Governance.....	11
BPTC Council	11
Institutional Advisory Committees.....	11
Consortium Services	12
NCCCS BioNetwork System.....	12
BioNetwork Architecture and Programs.....	14
Special Funds	15
Biomanufacturing Research Institute and Training Enterprise	15
Education and Training Component	16
Research Component.....	16
Support Component.....	17
Biomanufacturing Training & Education Center	17
Other Program Services.....	18
Student Housing	18
Student Financial Assistance.....	18
Curriculum and Student Throughput	18
NCCCS BioNetwork	18
Biomanufacturing Research Institute & Training Enterprise	19
Biomanufacturing Training & Education Center	19
Distance Learning.....	20
Other UNC System Schools.....	23
Inter-Institutional Articulation.....	23
Consortium Facilities	23
Biomanufacturing Research Institute and Training Enterprise	23
Biomanufacturing Training & Education Center / BioNetwork Learning Center	25
Large Scale Bioprocessing Training and Education.....	25
Aseptic Operations Training and Education	26
Laboratories	26
Classrooms	27
Administration	27
Conclusion	27
Start-Up and Operation	28
BioNetwork	29
BRITE.....	29
BTEC.....	30
Interim Initiatives	31
Budget	32
Table of Appendices.....	33
Glossary of Acronyms	34

North Carolina Biomanufacturing and Pharmaceutical Worker Training Program Business Plan

General Project Description

Mission Statement

The North Carolina Biomanufacturing and Pharmaceutical Training Consortium (“Consortium” or “BPTC”) is created by the North Carolina Community College System (“NCCCS”), the University of North Carolina, with North Carolina State University and North Carolina Central University as the lead institutions, and the North Carolina Biosciences Organization (“NCBIO”) on behalf of the State’s biotechnology and pharmaceutical industries (collectively, the “Sponsoring Entities”) to prepare North Carolina’s workforce for employment in biomanufacturing and related industries and to establish North Carolina as a world-class center for excellence in these areas.

Goals and Objectives

The Consortium’s objectives are to assure the availability of the following training and educational opportunities:

- Basic and advanced biomanufacturing skills training – including “hands-on” experience with commercial scale biomanufacturing equipment and technologies – for North Carolinians seeking employment in the biomanufacturing industry or biotechnology cluster;
- State-of-the-art undergraduate and graduate education and applied research for North Carolinians in engineering and life science disciplines with application in the biomanufacturing industry or biotechnology cluster; and
- Continuing education and training in state-of-the-art technologies for North Carolinians seeking continuing education or advancement and professional development opportunities in biomanufacturing, pharmaceutical manufacturing, or related employment.

In pursuing these objectives, the Sponsoring Entities have the following goals, which they believe are critical outcomes of the Consortium:

- To assure that the training and education opportunities identified above are available to all North Carolinians regardless of their ethnic or racial background or geographic location;
- To make North Carolina the most attractive location in the nation for biomanufacturing, pharmaceutical manufacturing and biotechnology-related business activity by providing state-of-the-art training facilities for expansion and recruitment of life science companies.

Nature and Scope of Economic Opportunity

Biotechnology has become one of the nation’s fastest growing and most highly sought industries. The industry has experienced substantial growth over the past decade, tripling in revenues from \$8 billion in 1992 to \$27.6 billion in 2002. The Biotechnology Industry Organization reports that as of 2002 there were currently roughly 179,000 people employed by 1,457 biotechnology companies in the United States. Some 340 of these companies are held publicly and have a total value of \$224 billion.

Biomanufacturing is the use of biological systems for large-scale production of pharmaceutical and other commercially useful products. According to most industry analyses, biomanufacturing is

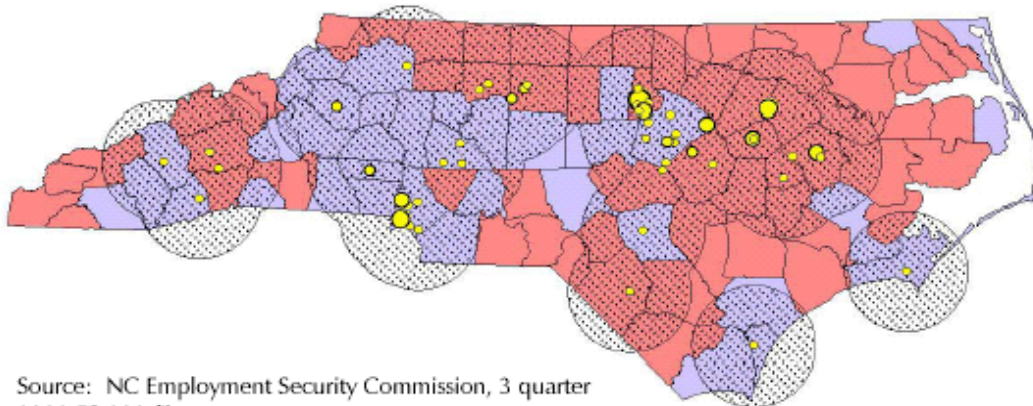
poised for tremendous growth in the next decade with a sharp increase in the number of new biotechnology products on the market. Further supporting this growth, the Food and Drug Administration is implementing new procedures that will speed the time-to-market for new products and drugs. As an industry, biomanufacturing offers enormous potential for job and wealth creation in our State. Biomanufacturing requires the construction of facilities to produce large quantities of biopharmaceuticals, specialty enzymes, vaccines, and other products.

Although North Carolina's biotechnology sector historically has been centered in urban areas, the industry's shift from research and development to manufacturing presents an important opportunity for creating new jobs and investment in non-urban counties. Like all manufacturing industries, biomanufacturing site location decisions are influenced by a number of factors. Among the most important of these are cost of land and cost of labor. These factors naturally drive manufacturing facilities away from urban areas where land and labor costs are high.

Among emerging technology industries, the need for scientific and high-level professional oversight of manufacturing processes may initially limit the migration of manufacturing to rural areas. In North Carolina, decisions by biomanufacturing companies such as Biogen and Diosynth to locate in Research Triangle Park appear to reflect these concerns. As manufacturing technologies become more widely used and understood, however, the need for scientific and engineering oversight decreases and traditional land and labor cost drivers become increasingly important.

Figure 1

**30 mile radius approximate commuting sheds
Pharmaceutical establishment location scaled to employment size**



Source: NC Employment Security Commission, 3 quarter 2002 ES-202 file.

Establishments classified in NAICS codes: 325411 (medicinal and botanical manufacturing); 325412 (pharmaceutical preparation manufacturing); 325413 (in-vitro diagnostic substance manufacturing); 325414 (biological product (except diagnostic) manufacturing).

Clear examples of this reality can be seen in the migration of traditional pharmaceutical manufacturing facilities to North Carolina that culminated in the 1980s. During that growth cycle, North Carolina's rural areas enjoyed enormous manufacturing investment and job creation by these companies. Burroughs Wellcome located in Greenville. Baxter Health Care located in Marion. Abbott Laboratories located facilities in Rocky Mount and Laurinburg. Merck located in Wilson. Today, roughly 89% of the civilian labor force in tobacco-dependent counties live within 30 miles of a pharmaceutical manufacturing facility. Approximately 83% of workers live within 20

miles of such facilities. Figure 1 illustrates the geographic dispersion of existing pharmaceutical manufacturing facilities in North Carolina.¹

The potential for biomanufacturing companies to create similar employment opportunities is clear. Novozymes, a company that biomanufactures industrial enzymes, is already located in Franklinton. Bayer operates the world's largest blood products manufacturing facility in Clayton. Wyeth operates the largest vaccine plant in the world in Sanford. In Lenoir, Greer Laboratories conducts biomanufacturing for the Research Triangle-based drug development company Alphavax. Continued advances in biomanufacturing technology should accelerate this trend.

A second factor suggesting that biomanufacturing will have a favorable long term impact on rural North Carolina is the potential for the creation of plant-made pharmaceuticals and other plant-based biomanufactured products. Current biopharmaceutical manufacturing techniques are very expensive. Biopharmaceutical companies are under huge economic and social pressure to cut the costs of manufacturing. One promising strategy is to use genetically modified plants to make these drugs. Such crops would still need to be processed in traditional manufacturing facilities, but the costs could be much lower. Producing drugs with genetically modified livestock is also a possibility.

Biomanufacturing also offers the potential to produce a host of bulk chemicals, fuels and even biological polymers that can be used to replace plastics and other synthetic materials currently produced from petroleum. These new technologies will produce new demand for a variety of agricultural inputs.

North Carolina is well positioned to take advantage of these opportunities. Our state's natural resources and agricultural heritage have produced farms large and small with the expertise and infrastructure to grow a new generation of value-added crops. North Carolina is also home to some of the strongest agricultural research programs in the world – at universities like North Carolina State University and North Carolina A&T – and at industry giants like BASF, Syngenta and Bayer Crop Science. These factors suggest a significant opportunity to combine North Carolina's traditional agricultural resources with advanced biotechnology to produce new and affordable medicines as well as other plant-based biomanufacturing products.

Projected Economic Impacts

The North Carolina Department of Commerce recently conducted a preliminary analysis of the potential gross and net economic impacts of the biomanufacturing and pharmaceutical employment growth targeted by the Consortium. The analysis used job creation estimates projected by the North Carolina Biotechnology Center in an analysis of biomanufacturing and pharmaceutical job training needs. Although the Department cautions that the analysis is based on limited data, it concludes that the analysis provides a general indication of the overall magnitude of economic impact associated with projected biomanufacturing growth in North Carolina.

In its analysis, the Department reviewed two possible growth scenarios. In the first, the Department assumed the creation of 490 new biomanufacturing jobs and 500 new pharmaceutical jobs a year, for a total of 990 new jobs in North Carolina annually. In the second scenario, the Department assumed the creation of 490 new biomanufacturing jobs and 1,400 new pharmaceutical jobs, for total annual job creation of 1,890.

Based on the more conservative assumptions of the first scenario (990 jobs annually), the Department's analysis forecasts the following impacts attributable to the projected growth in biomanufacturing and pharmaceutical employment:

- Total new direct, indirect and induced employment of almost 5,270 workers in the first year and over 32,700 workers after ten years.

¹ Memorandum from Ed Feser, North Carolina Department of Commerce, to John Merritt, Office of the Governor of North Carolina, Impact of Biomanufacturing on Tobacco Dependent Counties of North Carolina (May 24, 2003), 1.

- Total new North Carolina income of \$926 million in the first year, growing to \$3.3 billion in the tenth year, for a cumulative gross income impact of \$24.2 billion in current dollars over the ten-year period.
- Net state revenue impacts of \$41.1 million in the first year, increasing to \$118 million in the tenth year, for a cumulative net state revenue impact by year ten of \$960 million current dollars.

Based on the more aggressive assumptions of the second scenario (1,890 jobs annually), the Department's analysis forecasts:

- Total new direct, indirect and induced employment of 8,660 jobs in the first year, with total job creation reaching almost 60,000 by year ten.
- Total new North Carolina income of \$1.5 billion in year one, growing to \$5.9 billion in year ten, for a cumulative income impact of \$42 billion in current dollars.
- Net state revenue impacts of \$68.2 million in the first year, increasing to \$205 million by year ten, for a cumulative ten-year net revenue impact of \$1.6 billion current dollars.

A copy of the Department's memorandum outlining its assumptions, methodology and findings is attached as Appendix A.

Biomanufacturing & Pharmaceutical Training Consortium

The growth of North Carolina's biomanufacturing and pharmaceutical industries is limited by the lack of an adequately trained workforce. Both the numbers of workers trained for the industry and the type of training they receive are insufficient to meet demand. An estimate of the necessary number of new employees for the biopharmaceutical and pharmaceutical manufacturing industry in North Carolina is roughly 2,500 per year. Currently, fewer than 200-300 workers are trained annually.

The Biomanufacturing and Pharmaceutical Training Consortium will help meet this critical shortage of trained workers. If successful, the Consortium will support both the expansion of existing biomanufacturing and pharmaceutical companies in North Carolina, as well as enhance the State's ability to attract new companies to locate here. Developing a comprehensive and integrated strategy for biomanufacturing training and education will enable North Carolina to lead the nation in future commercialization of biotechnology and the manufacturing of biotechnology-based products.

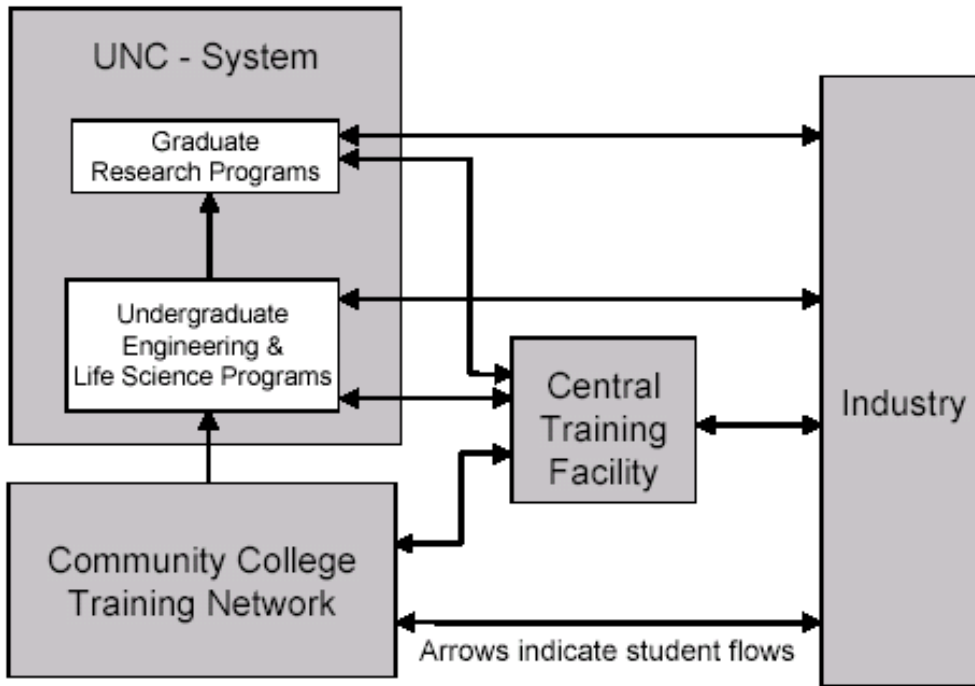
The Consortium will consist of three key elements: a statewide network of community colleges (BioNetwork) capable of delivering biomanufacturing and pharmaceutical skills training anywhere in North Carolina, a Biomanufacturing Research Institute and Training Enterprise ("BRITE"), providing university-level education in biomanufacturing and pharmaceutical-related life sciences, and a Biomanufacturing Training and Education Center ("BTEC"), designed to provide "hands-on" experience with large-scale biomanufacturing equipment and other work environments encountered in biomanufacturing and pharmaceutical manufacturing. Figure 2 illustrates relationship between the various elements of the BPTC and industry.

BioNetwork

The Consortium will be anchored by the statewide North Carolina Community College BioNetwork. The North Carolina Community College System is the state's primary provider of workforce education and training. The BioNetwork will substantially expand current NCCCS biomanufacturing education and training capacity. BioNetwork will include cutting-edge biomanufacturing and biotechnology/life sciences cluster curricula, equipment, and facility enhancements necessary to keep pace with industry needs and technologies. BioNetwork will provide a comprehensive and responsive education and training mechanism that expands the

economic and employment benefits to a broader segment of the population throughout North Carolina.

**Figure 2
BPTC Architecture**



The recently completed study conducted by the North Carolina Biotechnology Center indicated that 67% of biomanufacturing jobs require less than a baccalaureate degree. In the next three years, more than 6,000 employees in the state will be sought to work in North Carolina's biomanufacturing firms. These are high paying jobs -- well above the state's average pay for other manufacturing jobs. Biomanufacturing companies will need technical-level employees that function in the following positions: process technician, process operator, documentation specialist, quality control/quality assurance specialist, industrial manufacturing technician, assay analyst, process control technician, facilities technician, and shipper/receiver. A typical biomanufacturing company operates continuously and adheres to stringent protocols and exacting quality standards with precise measurements and documentation. Therefore, this industry has high expectations of its workers' skills, knowledge, and competencies.

Community colleges across the state will need to educate and train thousands of North Carolinians how to operate and maintain biomanufacturing production and packaging equipment. These technical level employees will require training for competencies beyond those required in traditional manufacturing. Workers will be trained for competencies in GMP (Good Manufacturing Practices), knowledge of SOPs (Standard Operating Procedures), teamwork, communication, critical thinking, biotechnology processes, computer skills, industrial and environmental safety, quality assurance and quality control, validation and documentation, calibration and instrumentation.

In addition to the front line production workforce, biomanufacturing also requires the support of other critical functions such as purchasing, quality control, engineering, maintenance, inventory/planning, and marketing and sales. Each of these units within the company includes

positions for which employers prefer workers with some post-secondary education or training but less than a baccalaureate degree.

NC community colleges have an excellent reputation for delivering customized incumbent worker continuing education for all levels of positions in biomanufacturing companies, including production directors, engineers, scientists, personnel, and production level employees. Many of these employees already have academic degrees but require industry specific training and ongoing continuing education.

Many of the skills for the technical-level positions overlap the skills with related industries. The “cluster” approach to economic development has become very important as our economy continues to demonstrate the danger of focusing specialized training too sharply on a narrowly defined industry. The estimate of more than 6,000 employees needed with less than a bachelor’s degree does not include job projections for companies in the biotechnology or life science cluster but not engaged in advanced biomanufacturing or pharmaceutical production. A more useful estimate for the demand for workers that need similar skill sets is considerably higher. Some examples of other companies that work with bioprocessing are wine, beer, cosmetics, medical devices, operations dealing with nutraceuticals, and related suppliers to this industry. The NCCCS BioNetwork will focus on the wider cluster approach.

Demand for industry expansion can sometimes be influenced. The availability of a qualified, skilled workforce is one of the most critical factors manufacturing companies consider in deciding where to locate or expand their production business. Manufacturers place more emphasis on an area’s entry and mid-level workforce, which is much less mobile than the more advanced positions that can be recruited from anywhere. North Carolina’s displaced workers from manufacturing and agriculture already have a proven work ethic and experience in the workforce. They are a unique resource for biotech/life science manufacturing. The BioNetwork will provide a mechanism capable of reacting swiftly to market demands by deploying expertise, curricula, and equipment and facility resources necessary for workforce education and training.

The North Carolina Community College BioNetwork has three major components. These components include system-based resources, enhanced deployment mechanisms, and the NCCCS “Central Learning Center” at the BTEC.

System Based Resources. A “Biotechnology Office” at the North Carolina Community College System will be established with dedicated staff to manage the programs and operations of the BioNetwork. All elements of the BioNetwork are coordinated through this office and provide leadership and continuity for the internal and external partnerships and in the modularization of training courses and the expansion of distance learning options.

Enhanced Deployment Mechanisms. A unique strength of the NCCCS is the ability to provide education and training locally for companies and workers. BioNetwork builds on that infrastructure by adding resources and new mechanisms to deploy opportunities across the state.

- Five community college based “Centers” will address work-based specializations required for training in this sector. Each of the centers will be charged with disseminating programs and expertise throughout the system.
- Two special-purpose funds established within the Network will provide needed resources for curricula, equipment, and facility enhancements.
- A mobile training laboratory, outfitted with faculty and equipment, will extend the outreach of every local college.
- Academic partnerships and articulation agreements will be expanded to prepare more students for transfer into related university programs.

Central Learning Center. The large-scale biomanufacturing facilities at the BTEC will include a dedicated NCCCS aseptic suite. The BTEC will provide additional “hands-on” short course training for community college sponsored students and incumbent workers.

Biomanufacturing Research Institute and Training Enterprise

The Consortium will also include the Biomanufacturing Research Institute and Training Enterprise at North Carolina Central University (“NCCU”). This Institute will provide unprecedented opportunities for student training, education, and inter-institutional collaborations between NCCU and other public and private colleges and universities, the community colleges, and members of the North Carolina biotechnology community. Educational programs at BRITE will provide a unique platform for students to obtain education and “hands-on” experiences (both basic and applied) and support the development of bachelor’s, master’s, and doctoral degree programs in Applied Process Research. Working in conjunction with NCCU’s Early High School program, BRITE will expose middle school students to career opportunities in the biotechnology industry. In addition, BRITE will support ongoing and developing research programs in the state and region by providing collaborative technical and logistical support in a way that will encourage faculty, staff, and students to participate in biomanufacturing training.

BRITE will permit NCCU to maximize the state’s current investment in the Julius L. Chambers Biomedical/Biotechnology Research Institute (“JLC-BBRI”). The JLC-BBRI’s core research programs in the areas of cardiovascular biology, neuroscience, and cancer have enabled NCCU to attract a critical mass of active research scientists in areas such as analytical chemistry, biochemistry, microbiology, mammalian cell biology, molecular genetics, genomics, and bioinformatics. These disciplines and sub-disciplines will complement the research and training activities of BRITE.

Biomanufacturing Training Center

Basic biomanufacturing coursework offered through BRITE and the BioNetwork will be augmented by short-course experiences at a new cost-effective, Biomanufacturing Training Center outfitted with commercial-scale equipment and facilities too expensive to replicate locally. The BTEC will be operated in conjunction with North Carolina State University’s nationally prominent Department of Chemical Engineering and Colleges of Engineering and Life Sciences.

The Biomanufacturing Training and Education Center will provide a “hands-on” biotechnology educational experience for all levels of post-secondary educational experience for all levels of post secondary education students using state-of-the-art equipment and systems as a supplement to academic studies. The purpose of the BTEC will be to provide biomanufacturing skills to meet the employment needs of North Carolina’s growing biotechnology-related industry base, including continuing education for existing industry employees.

The design of the BTEC will simulate a biomanufacturing facility capable of producing sterile bulk biopharmaceutical compounds and will include supporting training and education classrooms, laboratories, and building and process utilities. The facilities will be equipped to provide students with a large-scale bioprocessing experience, including bioreactors, downstream separation and purification processes, and aseptic processing operations. In addition, the facility will provide a training and education laboratory for a biotechnology support staff such as validation specialists, instrumentation technicians, equipment mechanics, microbiologists, sterile preparation technicians, biochemists, and various engineering disciplines.

The objectives of the BTEC are to provide (i) basic and advanced biomanufacturing skills training – especially “hands-on” experience with commercial-scale biomanufacturing equipment and technologies and Good Manufacturing Practices – for North Carolinians seeking employment in the biomanufacturing industry or biotechnology cluster; (ii) state-of-the-art undergraduate and graduate education for North Carolinians in engineering life science disciplines with application in the biomanufacturing industry or biotechnology cluster; and (iii) continuing education and training in state-of-the-art technologies for North Carolinians seeking continuing education or advancement opportunities in biomanufacturing or other biotechnology-related employment, and (iv) a catalyst for new rural biomanufacturing job creation and agribusiness development.

Description of Participating Entities & Qualifications to Operate Consortium

The Sponsoring Entities collectively possess the resources and capabilities to launch and operate the Consortium.

North Carolina Community College System

The North Carolina Community College System is the third largest community college system in the country with 59 institutions, multiple satellite locations, and specialized technology centers throughout the State. Last year the NCCCS served more than 800,000 individuals in North Carolina. Almost everyone in North Carolina is within 30 miles of a North Carolina community college facility and hundreds of courses are available through distance learning. The mission of the NCCCS as it relates to economic and workforce development is to:

- Provide high quality, accessible education and training and services that enable North Carolinians to acquire knowledge and skills to obtain and maintain prosperous career opportunities and enhance quality of life, and;
- Provide North Carolina businesses and industry with a world-class workforce and a competitive advantage as a result of their presence in North Carolina.

The NCCCS pioneered customized training over forty years ago and has received the highest annual ranking of any state in the nation over the past five years in Expansion Management Magazine's national survey of site selection consultants. One of the State's greatest incentives to attract companies to North Carolina is the NCCCS New and Expanding Industry Training Program.

The real strength of the NCCCS lies in the training support provided after the company locates in North Carolina. The NCCCS operates one of the largest continuing education programs in the world, with colleges providing almost 1,400 different types of courses that are customized to meet specific company needs. Most of the continuing education training occurs on-site at company workplaces.

North Carolina community colleges have extensive experience working with bioprocess and pharmaceutical companies in North Carolina including: Wyeth, Bayer Corporation, Novo Nordisk, Biogen, Eisai Pharmaceutical, DSM, and Novozymes. Community colleges have developed an extensive network of highly skilled and experienced instructors and training offerings for pharmaceutical and bioprocess companies. The following courses and programs have already been developed to meet the specific workforce development needs of growing pharmaceutical and biomanufacturing companies in North Carolina.

BioWork is a 128-hour, competency-based course for process technicians. It is recognized as one of the best technician training programs in the nation. BioWork brings together the basics of manufacturing and the fundamentals of science. BioWork was developed by the North Carolina Biotechnology Center and the North Carolina Community College System in response to the biotechnology industry's need to increase the pool of potential manufacturing employees for entry-level process technician jobs. BioWork is currently being offered at six community colleges.

BioQuality is a ten-part seminar series conducted by leading pharmaceutical and bioprocess experts. The program covers Good Manufacturing Practices, technical communication and critical thinking skills. The BioQuality Series has been developed with industry input.

BioBusiness is an experiential learning program, designed to teach financial and economic literacy to biomanufacturing workers in North Carolina. The program features a sophisticated business simulation in which workers learn not only how a business operates but also the impact of their roles and the consequences of their actions on business strategy and financial success.

In addition to industry training programs, the North Carolina community colleges also provide certificate, diploma, and Associate Degree Programs. Currently there are a number of curriculum

programs directly related to the biotechnology cluster and other life science, environmental, agricultural, and industrial maintenance technology programs. An increasing number of these programs have articulation agreements with universities.

University of North Carolina System

The University of North Carolina is a public, multi-campus university dedicated to the service of North Carolina and its people. It encompasses 16 diverse constituent institutions and other educational, research, and public service organizations. The mission of the University System is to discover, create, transmit, and apply knowledge to address the needs of individuals and society. Two of the University's constituent institutions – North Carolina State University and North Carolina Central University – will take leading roles in the Biomanufacturing and Pharmaceutical Training Consortium. North Carolina Central University will build on the strong drug-discovery and biotechnology research capability at the Julius L. Chambers Biomedical/Biotechnology Research Institute to support expanded undergraduate and graduate educational opportunities in biology, chemistry, and other life sciences related to biomanufacturing and biotechnology. North Carolina State University is contributing the resources of its existing engineering and life sciences programs with the goal of supporting training, research, and education in large-scale biomanufacturing technologies.

North Carolina Central University (NCCU) is well positioned to rapidly respond to the statewide demand to develop a highly trained workforce in support of the anticipated growth of the biotechnology industry. NCCU established an undergraduate biotechnology program nine years ago to grant baccalaureate degrees in biology and environmental sciences related to biotechnology. Over the past five years, and consistent with its strategic plan, NCCU has expanded its infrastructure in the science and technology areas, and is now conducting mechanism-driven research in its Julius L. Chambers Biomedical/Biotechnology Research Institute. This unique research institute is providing NCCU faculty and students with access to the most sophisticated tools of biotechnology, emphasizing creativity and productivity, and utilizing project teams for problem solving. Through its education and training programs supported by industry partnerships, the JLC-BBRI is exposing NCCU undergraduate and graduate students to the “Pharmaceutical Drug Discovery Process.” Using non-traditional instruction methods and workshops, students are gaining valuable insights into how the R&D process works, and the range of disciplines, expertise, and technologies required to move a synthetic organic chemical or a biopharmaceutical entity from discovery through the development, manufacturing, and marketing stages.

Currently, in its role as a focused growth institution, NCCU is gearing up to become a major player in providing students with greater access to a broader array of technology intensive education and training programs. Major initiatives already underway include (i) construction of a new, 120,000-square foot Science Complex; (ii) planning for the development of new degree programs in the biomedical sciences and bioinformatics; and (iii) collaborating with the Durham Public Schools to create a new high school program that will serve as a model for attracting students to careers in the biomedical sciences and biotechnology. NCCU's record of service to the Community College System is also widely recognized. It currently has in place over 40 community college affiliation agreements, of which several conduct significant distance learning activities.

North Carolina State University, as the premier engineering and technology institution within the sixteen-campus University of North Carolina System, is uniquely qualified to serve as a home for the Biomanufacturing Training and Education Center. In particular, location of the BTEC on NCSU's Centennial Campus, within close proximity to faculty and research facilities in the Colleges of Agriculture and Life Sciences and of Engineering, will create a natural synergy of resources and expertise that will enhance the BTEC, its programs, and its outreach throughout North Carolina.

NCSU is a nationally recognized leader in science and technology with historic strengths in agriculture, textiles and engineering. NCSU also has outstanding degree programs in the

humanities and social sciences, design, education, natural resources, business and veterinary medicine. NCSU has an annual budget of approximately \$820 million and an endowment valued at more than \$312 million. It is ranked 13th among national research universities in non-federal funded research, 8th among national research universities in industry-funded research, and 32nd nationally in total expenditures for research and development. NCSU is ranked 2nd in total research expenditures in the 16-campus University of North Carolina system, and 2nd in total state and local research funding among national research universities. NCSU's expenditures for research and sponsored programs exceed \$440 million. NCSU is ranked 17th in the nation for launching start-up companies, and has received more than 350 patents for beneficial technologies developed by our world-class faculty.

The strength of faculty resources within the College of Engineering is indicated by its national rankings of third among engineering schools in technology transfer and economic development, sixth in research support by industry, and eleventh in total research expenditures for 1999-2000 (last year data are available). In 2000-01, the Industrial Extension Service (IES) of the College of Engineering served 42,000 individuals and firms, and IES' North Carolina Manufacturing Extension Partnership (now the Engineering and Technology Group) produced \$209 million in economic impact. Within the Department of Chemical Engineering, faculty have established research programs in biochemical engineering, enzyme, cell and metabolic engineering, bioseparations, plant biology, and reaction design and engineering, biocatalysis at extremely high temperatures, biophysical phenomena, and biosensors. This strong foundation of intellectual talent will ensure that the BTEC's course offerings – much of which will be taught by NCSU faculty - and technical competencies will remain current as new technologies are developed by researchers and then implemented by industry.

Comparable strength of resources exists within NC State's College of Agriculture and Life Sciences (CAL S). Consistently ranked among the top five agriculture and life sciences colleges in the nation, CAL S is also home to the North Carolina Agricultural Research Service (NCARS), as well as the North Carolina Cooperative Extension Service (NCCES). NCARS is the principal state agency for research in agriculture, life sciences, and forestry. Its research projects involve NC State University's Colleges of Agriculture and Life Sciences, Natural Resources, Physical and Mathematical Sciences, Veterinary Medicine, and Engineering. Within CAL S, NCARS coordinates research in 18 departments and works in partnership with the NCCES and Academic Programs. NCARS personnel include 180 tenure track faculty, 370 non-tenure track scientists and over 600 support staff conducting over 600 projects to support more than 70 commodities, as well as many related agribusiness and life sciences industries.

The North Carolina Cooperative Extension Service provides knowledge and technology solutions resulting from university research to individuals, firms, and industries throughout North Carolina. Much of this work centers upon enhancing agricultural systems, developing new uses for traditional agricultural commodities and creation of value-added agricultural products. NCSU, through its Cooperative Extension programs, is uniquely positioned to serve the growing needs of the state's biotechnology and agribiotechnology sectors with new products and production technologies, including biomanufacturing. This immense extension and outreach capacity, able to reach and assist manufacturers and agricultural producers statewide, is an essential element of NCSU's contribution to the ultimate success of the BTEC and larger BPTC. Additionally, the existing collaborations and complementarity between CAL S and the College of Engineering at NC State ensure the critical multi-disciplinary synthesis that will be needed to leverage the impacts and benefits of the BTEC and to facilitate creation of rural manufacturing jobs and agribiotechnology production opportunities.

North Carolina State University has more than 6,000 employees, including approximately 1,600 faculty and extension field faculty providing Cooperative and Industrial Extension services in every county of North Carolina. NCSU offers bachelor's degrees in 92 fields of study, master's degrees in 101 fields and doctoral degrees in 58 fields, as well as a Doctor of Veterinary Medicine degree. Fifty-five research centers, institutes and laboratories support more than 400 faculty, 900 graduate students and 200 undergraduates. The NCSU Libraries ranks 32nd among national research libraries.

North Carolina Biosciences Organization

NCBIO is North Carolina's leading trade association for the North Carolina biotechnology industry. Established in 1994, NCBIO now has approximately 85 member companies, including biomanufacturers, pharmaceutical companies, biotechnology research and start-up businesses, and companies providing services to North Carolina's biotechnology business community. NCBIO has organized within itself a Biomanufacturers Membership Forum ("BMF") through which biomanufacturing members are collaborating to address issues of concern to Forum members. Six of North Carolina's eight largest biomanufacturing companies -- Bayer, Biogen, Diosynth, Novo Nordisk, Novozymes, and Wyeth -- are members of the BMF. All BMF members have participated actively in the development of this Biomanufacturing and Pharmaceutical Training Consortium Business Plan.

Marketing

Each Sponsoring Institution will prepare a marketing plan specific to its BPTC initiative and relevant constituencies. These marketing plans will be developed consistent with an overall branding strategy for the BPTC. Additionally, each Sponsoring Institution will provide information regarding its activities to assist regional economic developers and state agencies in the overall marketing of the State to the biomanufacturing, pharmaceutical, and other related industries.

Governance

BPTC Council

A Biomanufacturing and Pharmaceutical Training Coordinating Council ("Coordinating Council") will be established to provide oversight of the Consortium and coordination among the NCCCS BioNetwork, the Biomanufacturing Research Institute and Training Enterprise, the Biomanufacturing Training Center at North Carolina State University (the "Initiatives"), their sponsoring institutions (NCCCS, NCCU and NCSU, respectively), and the North Carolina biomanufacturing, pharmaceutical, and biotechnology-related industries.

The Council's members will include the president of the UNC System, the chancellors of NCSU and NCCU, the president of the NCCCS (or their respective designees), a representative appointed by the North Carolina Biotechnology Center, a representative appointed by the Golden Leaf Foundation, a representative appointed by the Governor's Office, and at least one representative from the following sectors of the biopharmaceutical industry in the State: biotechnology, pharmaceutical, fine chemical, and agricultural.

The BPTC Council will receive reports from the Sponsoring Institutions and their respective Initiatives, provide a forum for coordination of the activities of the separate Initiatives, and serve as an advocate for the Consortium.

Institutional Advisory Committees

Each Initiative will have an Institutional Advisory Committee to provide a forum for interface between industry and the Sponsoring Institution.

Each Institutional Advisory Committee will include the Initiative's Director, one or more faculty members from the Sponsoring Institution, such other members as the Sponsoring Institution may consider appropriate, and representatives from industry to comprise at least 50% of the total committee membership.

In order to meet the overriding objective of program offerings meeting industry needs, there will be an annual meeting of each Initiative's Institutional Advisory Committee to review the target skills and knowledge that should be provided by the program offerings of the Initiative. If the Sponsoring Institution does not choose to accept in substantial part the recommendations of the

Institutional Advisory Committee regarding target skills and knowledge, the Sponsoring Institution will advise the Committee of the basis for its conclusion.

The Institutional Advisory Committees also will meet quarterly or biannually, as each Committee believes appropriate, to undertake the following processes.

- *Target Content.* Provide industry input in identifying the scope of skills and knowledge to be imparted by the training and instruction provided by the Consortium and the various Initiatives.
- *Curriculum Development Assistance.* Coordinate assistance from industry to the various Sponsoring Institutions and Initiatives in the development of courses and related “hands-on” experiences necessary to impart the desired Target Content.
- *Instructional Assistance.* Coordinate assistance from industry, through instructors- and managers-on-loan to Sponsoring Institutions and Initiatives.
- *Certification Requirements.* Receive guidance from industry regarding knowledge and skills requirements it may establish as part of any industry-sponsored worker certification program.
- *Assessment.* Review of the value provided by the Initiative to the State and industry.
- *Marketing.* Receive industry input and assistance in the development and implementation of marketing programs designed to attract prospective students and new and expanding biomanufacturing facilities.
- *Facilities and Equipment Needs.* Coordinate assistance from industry in the procurement of facilities and equipment required for the optimal operation of Initiative or the BPTC.

At any time it is considered useful, a single Consortium committee for a given topic (e.g., Marketing) may be established with representatives from each Sponsoring Institution and industry.

Budgets for each Initiative will be proposed by the Director of the Initiative for the approval of the Sponsoring Institution (in accordance with its customary practices) and after a presentation to, and opportunity to comment by, the Institutional Advisory Committee.

The Director of each Initiative will be hired by the Sponsoring Institution after a presentation to, and opportunity to comment by, the Industry Advisory Committee of the Initiative. The Executive Director will report to the Sponsoring Institution through its customary structures. Appropriate opportunity will be provided for the Industry Advisory Committee to provide feedback as a part of routine evaluation of each Director’s performance.

Consortium Services

The Biomanufacturing & Pharmaceutical Training Consortium will provide a variety of educational opportunities and services. Curriculum offered by the Consortium will encompass not only formal degree programs, but also continuing education, non-credit courses, certificates, and customized training and education for industry. Students interested in advanced degrees will have access to faculty and research programs spanning a broad spectrum of biotechnology-related disciplines. A conceptual diagram of the BPTC is shown in Figure 2. Educational products and services to be provided through the Consortium are set out in Table 1 of this Business Plan.

NCCCS BioNetwork System

The North Carolina Community College System currently offers biotechnology-related education and training programs. The System’s existing pipeline of graduates is too small to fill the needs of the fast-growing biotechnology industry.

NCCCS therefore proposes the establishment of a new BioNetwork System to provide an effective, cost-efficient, cluster-responsive training and education network that will share expertise and resources throughout the Community College System to provide an adequate supply of skilled works for biomanufacturing and pharmaceutical companies across North Carolina.

Table 1 BPTC Educational Products and Services		
Suppliers	Educational Products	Customers
UNC System (including NCCU and NCSU)	Existing Programs <ul style="list-style-type: none"> • Bachelor's Degrees • Master's Degrees • Doctoral Degrees • Continuing Education • Certificates (Post Baccalaureate) • Non-credit Courses • Instructor Training 	<ul style="list-style-type: none"> • Students enrolled full-time in degree programs • Part-time Students • Industry Employees • General Public (e.g., career changers; military) • Secondary School Students • K-12 Teachers • Industry Employees (workshop attendees) • Industry Researchers
Community Colleges	Existing Programs <ul style="list-style-type: none"> • Associate Degrees (AS and AAS) • One-year diplomas • Certificates • Continuing Education • Instructor Training • Customized Industrial Training • Assessment and Credentialing 	<ul style="list-style-type: none"> • Students enrolled in full-time degree programs • Part-time Students • Industry Employees (new hires and incumbents) • General Public (e.g., career changers; military) • Traditional Industry Dislocated Workers • K-12 Teachers (preparation and certificate renewals) • Industry Certifications, Re-Certifications
BTEC	Proposed Programs <ul style="list-style-type: none"> • Industry-Defined Modules (Lecture and Hands-On) • Continuing Education • Certificates • Instructor Training • Service Courses (UNC campuses) 	<ul style="list-style-type: none"> • Students enrolled full-time in degree programs • Part-time Students • Industry Employees (new hires and incumbents) • General Public (e.g., career changers; military) • School and Civic Groups • College Faculty • K-12 Teachers

The BioNetwork will provide full equity of access across North Carolina to under-represented populations and rural areas. The BioNetwork System will have the following goals:

- *Worker Pipeline.* To provide a continuous pipeline of new workers for North Carolina biomanufacturing, pharmaceutical, and biotechnology-related companies.
- *Dislocated Worker Assistance.* To complement the existing skills of dislocated workers, career changers, and other North Carolinians seeking employment in the biotechnology sector.

- *Continuing Education.* To upgrade the skills of incumbent biotechnology sector workers.
- *Supplementary Services.* To provide supplementary services and resources to enhance the curricula and facilities of North Carolina community colleges so as to maintain a competitive advantage for North Carolina in the expansion and recruitment of companies within the biotechnology sector.
- *Professional Development.* To provide ongoing professional development opportunities for community college faculty and staff professionals.
- *Evaluation.* Continuously monitor and evaluate the economic and workforce development impact of the BioNetwork program.
- *Student Pipeline.* To increase the numbers of students prepared academically to transfer to universities.

BioNetwork Architecture and Programs

Through the BioNetwork System, NCCCS will assign key responsibilities to particular institutions. These lead colleges will serve as hubs of specialized expertise for the entire State. By providing resources and support to the “cluster centers” and networking all of the colleges that offer education and training for this industry, the System will enable all campuses to have access to the highest quality resources. Lead colleges will also be tasked with collaboration and articulation with the universities in order to offer students and workers a seamless higher education opportunity. The BioNetwork System will be composed of a Biotechnology System Office, five Functional/Skill Centers operated by colleges within the NCCCS System, and a BioNetwork Learning Center located at the proposed Biomanufacturing Training and Education Center at North Carolina State University.

Biotechnology System Office. This unit, located at the North Carolina Community College System Office in Raleigh, will be responsible for coordinating the work of lead campuses and other system colleges that offer biomanufacturing, pharmaceutical, and other biotechnology-related training programs. The Biotechnology System Office will also operate a bench-scale mobile biotechnology laboratory, a distance learning system, and web-based education and training.

Functional/Skills Centers. These five centers will be lead institutions responsible for initiating projects, developing curricula, and accruing expertise that will be shared with all colleges within the State that express interest. Active partnerships with other educational institutions, including universities, local school systems, and other community colleges, will be looked upon favorably. These centers will be selected in a competitive process utilizing selection criteria, including market/demand, anticipated impact, center design, access for under-represented populations and locations, outcomes assessment, partnering dissemination systems, sustainability, and qualifications of personnel. A review board will consider all proposals. The State Board of Community Colleges will give final approval.

Each Functional/Skill Centers will have a different focus. Three Centers will focus on the development of skills programs for the following industry subgroups:

- *Bioprocessing.* Biomanufacturing technologies utilizing fermentation cell culture and other associated processes.
- *General Pharmaceutical Manufacturing.* Clean room skills and sterile techniques, fill and finish operations, general biotechnology bench techniques and pharmaceutical skills including introductory quality assurance/quality control, validation, and GMP standard operating procedures.
- *Agricultural Biotechnology.* A diverse array of processes that have in common the application of biotechnology techniques in agricultural settings. This may include avian transgenics,

molecular farming, biomass processing, transgenic seeds, crop protection, general plant biotechnology, and environmental science applications.

In addition, two Centers will concentrate on the following functional activities required to build critical capacities with the community colleges to support all aspects of biotechnology:

- Continuing Education. Creating and updating employer-driven and continuing education and training products including BioWork.
- Biotech Enterprise Catalyst. Assisting small biotechnology enterprises through incubation and support services and by developing entrepreneurial skills.

BioNetwork Learning Center. Finally, the BioNetwork will utilize a centrally located biomanufacturing learning center, located at the Biomanufacturing Training and Education Center at North Carolina State University, to provide a sophisticated and realistic learning environment for students, incumbent workers, and faculty from across the state. The BioNetwork Learning Center will be operated and staffed under the supervision of the North Carolina Community College System Office. The Learning Center will include dedicated space necessary to provide a capstone experience for hundreds of students and workers employed in existing industries or completing training and associate degree programs across the state.

The Learning Center will include a Clean Room/Aseptic Operations Suite that will focus on providing students, technicians and critical technical support personnel an enriched “hands-on” learning experience in clean room, aseptic operations. The following three types of training and education activities are envisioned:

- *Introductory* course for clean room/aseptic processing.
- *Intermediate* level training for clean room/aseptic processing techniques providing performance-based feedback based on qualitative observations, quantitative monitoring data, and academic testing.
- *Advanced* studies and short courses designed for support staff functions around aseptic/sterile processing operations.

Special Funds

NCCCS also proposes the creation to two special purpose funds, to equip and support community colleges providing training and education programs for biomanufacturing, pharmaceutical, and biotechnology-related companies.

A Biotechnology Innovation Fund will provide local community colleges with resources to expand access and services, improve quality, and maintain standards to strengthen the State’s leading position in biotechnology and biomanufacturing.

A Biotechnology Equipment and Facilities Expansion Fund will provide community colleges with resources to enhance and expand laboratories, equipment and facilities to meet the changing demands of the biotechnology industry.

Biomanufacturing Research Institute and Training Enterprise

North Carolina Central University will establish a new Biomanufacturing Research Institute and Training Enterprise designed to provide unprecedented opportunities for student training, education, and inter-institutional collaboration between NCCU and other members of the North Carolina biotechnology community. Educational programs at BRITE will provide a unique platform for students to obtain education and “hands on” experiences (both basic and applied) and support the development of bachelor’s, master’s and doctoral degree programs in Applied Process Research. In addition, the Institute will support ongoing and developing research programs and interface with existing and developing programs in the state and region to provide

collaborative technical and logistical support in a way that will motivate faculty, staff, and students to participate in biomanufacturing training and education.

The BRITE will allow NCCU to maximize the return on its recent investment in the JLC-BBRI. The JLC-BBRI's core research programs in the areas of cardiovascular biology, neuroscience, and cancer have enabled NCCU to attract a critical mass of research active scientists in areas such as analytical chemistry, biochemistry, microbiology, mammalian cell biology, molecular genetics, genomics, and bioinformatics. These disciplines and sub-disciplines will complement the research, education and training activities of BRITE.

Education and Training Component

North Carolina Central University has a unique opportunity in working with the Bill and Melinda Gates Foundation and the Southeast Consortium of Minority Engineers (SECME) to plan and develop a Early High School program. BRITE will collaborate with the Durham Public Schools to create a new high school program that will serve as a model for attracting students to careers in the biomedical sciences and biotechnology. Beginning in the fall of 2003, this program will identify and work with seventh graders, preparing them to matriculate to NCCU. The focus of their intensive instruction in mathematics and science will include course work that will prepare the students for collegiate study in the areas of biotechnology

The education component of BRITE will include formal degree programs, expanding the current bachelor's degree offering in biology and environmental sciences and progressing to seek the approval of the UNC Board of Governors for masters and doctoral degrees as the program matures. Opportunities will also be provided for students to receive education and training in any or all of the modules as desired. The undergraduate degree program will utilize traditional (formal classroom lectures and laboratories) as well as non-traditional (conducting research in basic or applied areas with a faculty mentor during the academic year and summer, and participating in a range of biomanufacturing-related activities such as fieldtrips, workshops, seminars, etc) teaching techniques. It is envisioned that students enrolled in biology, chemistry, and environmental science degree programs will be the initial participants. NCCU rising juniors will also be recruited to pursue a concentration in biomanufacturing sciences.

In collaboration with the biomanufacturing industry, BRITE will identify niche area(s) for basic/applied research, develop relevant biomanufacturing curricula and degree programs, recruit faculty with the relevant skills and experience, and provide undergraduate and graduate students with skills that will increase their competitiveness for employment. BRITE will serve as a major resource for promoting alliances with the biomanufacturing industry, other academic institutions engaged in biomanufacturing training, state agencies, foundations, and non-profit public interest organizations such as NCBIO and the North Carolina Biotechnology Center. Establishing this Institute that supports ongoing and developing research programs will create unprecedented opportunities for student training and professional development.

Building upon NCCU's School of Business and the School of Law, the Institute will work with emerging, small and medium sized biotechnology or pharmaceutical companies to offer workshops on patent and other regulations applicable to the scientific and biomanufacturing industries. Input from industry will guide the workshop offerings, which could be offered via distance education to rural locations. Moreover, the recruitment of new scientists with active research programs in industry and the collaborations generated from such efforts will provide exciting training opportunities for BRITE trainees. Further, NCCU will build upon its growing partnerships with a network of community colleges to expand advancement and professional development opportunities.

Research Component

BRITE will emphasize support for eight research areas – microbiology, quality control/quality assurance, analytical chemistry, cell culture, microbial physiology, purification, virology, and bench-scale process development and recovery. The Institute will recruit faculty/research

scientists with expertise relevant to the emphasis areas. Two mechanisms will be used for faculty recruitment -- tenure track faculty in the new academic program that will be created and non-tenure track faculty in the new Institute.

Support Component

The efforts of the Institute will be directly aligned with the vision of the statewide biomanufacturing and pharmaceutical education and training enterprise. NCCU is committed to developing the appropriate alliances with the community colleges, other academic institutions, state agencies, and industry with respect to program marketing, curriculum development, new degree offerings, concentrations, etc. Scientists in the Institute will interact with JLC-BBRI investigators as well as with colleagues in industry, especially scientists employed in the biotechnology industry. Support in the area of pilot plant operation and large-scale process training and education will be accessed through the Biomanufacturing Training and Education Center at North Carolina State University or provided through a strategic partnership with industry.

Biomanufacturing Training & Education Center

The proposed Biomanufacturing Training and Education Center, to be located at North Carolina State University, will provide a “hands-on” biotechnology educational experience for all levels of post-secondary education students using state-of-the-art equipment and systems as a supplement to academic studies. The purpose of the Center will be to provide “real world” biotechnology processing skills training to meet the employment needs of North Carolina’s growing biotechnology-related industry base, including continuing education for existing industry employees.

The design of the BTEC will simulate a small biotechnology facility capable of producing sterile bulk biopharmaceutical compounds, including supporting training and education classrooms, laboratories, building and process utilities, and other educational support needs. The facility will be equipped to provide students with a large-scale bioprocessing experience including work with bioreactors, downstream separation and purification processes, and aseptic processing operations. In addition, the facility will provide a training and education laboratory for a multitude of biotechnology support staff such as validation specialists, instrumentation technicians, equipment mechanics, microbiologists, sterile preparation technicians, biochemists, and various engineering disciplines.

The BTEC’s design is based on training and education scenarios for both large-scale bioprocessing and aseptic and clean room procedures prepared by working committees from North Carolina biomanufacturing companies. The company workgroups also defined processes and equipment needed to meet the BTEC’s educational objectives.

Overall demand and student throughput was determined by an analysis of biotechnology industry employment needs conducted by the North Carolina Biotechnology Center. The analysis demonstrates a need to train initially a minimum of 1,080 BTEC “hands-on” students per year. The estimate comprises college degree program students (400), industry incumbent experienced employees (420), and industry new hires (260). The figure does not include students who might enroll in lecture-only portions of courses delivered via distance education, nor does it include numbers for course enrollees not associated with industry in North Carolina; as a result, this should be considered to be a lowest-case estimate. Furthermore, the estimate does not include any growth in the industry or attraction of new biomanufacturing companies. The BTEC is designed and programmed to be adaptable to future requirements.

The BTEC facility will be engineered to support the delivery of distance learning modules to downlink sites located throughout North Carolina. This will include the design of distance education classrooms that support synchronous learning via Videoconferencing and Online Internet instruction. Curricula will also be designed to support asynchronous (web-based) instruction. This web-based instruction will allow individuals in the rural areas of North Carolina to

have online access to fundamental biomanufacturing lecture content from the BTEC. The hands-on laboratory sessions will need to take place onsite at the BTEC.

Other Program Services

Student Housing

The UNC and Community College Systems will work with North Carolina State University to identify low-cost, temporary housing for students attending the central facility on that campus.

Student Financial Assistance

Institutions participating in the BPTC are consulting with existing North Carolina educational assistance programs regarding the development and marketing of financial assistance mechanisms targeted to Consortium trainees.

Curriculum and Student Throughput

Curriculum for the Biomanufacturing & Pharmaceutical Training Consortium initiative will take place on three fronts -- the UNC System, the NCCCS, and the BTEC. Curriculum development will encompass not only formal degree programs but also continuing education, non-credit courses, certificates, and customized training and education for industry. Courses or modules available at the BTEC will be developed in collaboration with industry to take advantage of the unique facility and equipment and will meet the needs of diverse audiences. Curricula, courses, and modules at the educational institutions will build on existing curricula and interface with opportunities at the BTEC. Where possible, courses will be designed in modular fashion, and be formatted for distance learning delivery.

Table 1 outlines the different audiences that will be served by the BPTC initiative and the educational products that each component of the Consortium.

Curriculum development will proceed along different lines in each educational system and institution.

NCCCS BioNetwork

NCCCS will provide release time and/or stipends for current faculty and industry experts to review courses and curricula (both credit and non-credit) and to produce appropriate new courses/curricula and enhance current curricula. NCCCS will use its curriculum development system already in place. In this system, advisory committees from industry define competencies for target occupations, then courses and curricula are developed to match those competencies. The modular format already in place for development of courses for the Virtual Learning Community could be employed to build new courses and revise existing courses for greater flexibility of instruction.

Typically, non-credit courses will be approved monthly. Approval of credit courses will likely take two to six months. Development of distance education courses usually takes somewhat less than nine months. Colleges are expected to be approved to offer programs that have existing curriculum standards (meaning that industry has already identified the components of the program) within 90 days. Approval of programs new to the system (needing a more extensive research of programmatic needs) should be accomplished within 120 days.

Biomanufacturing Research Institute & Training Enterprise

All student trainees will be required to participate in biomanufacturing-related activities (traditional as well as non-traditional) throughout the four years of their undergraduate experience. There is little question that active participation in ongoing research is the best way to train students for entry-level positions in the biomanufacturing industry. The program will enable NCCU to respond to a critical need that addresses research, resource development, education and training, and workforce development on a statewide basis.

Based on modest estimates of 50 students (25-35 students recruited directly by NCCU and 10-15 students from the Community Colleges and industry) per classification level (i.e. freshman, sophomore, junior, and senior), BRITE projects that four years after launch, the Program will serve approximately 190-200 students in its 42 training modules.

A unique feature of this proposed model is that from their freshman year, all student trainees will be required to participate in biomanufacturing-related activities (traditional as well as non-traditional) throughout the four years of their undergraduate experience. There is little question that active participation in ongoing research is the best way to train students for entry-level positions in the biomanufacturing industry. The facility design simulates a small biotechnology company and is capable of replicating the environment that the education and training program is targeting. A summary of BRITE faculty and staffing requirements is attached as Appendix C-2

Biomanufacturing Training & Education Center

BTEC curriculum will focus on providing students an enriched “hands-on” learning experience to support employment in biomanufacturing, pharmaceutical, and biotechnology-related companies. BTEC courses will provide knowledge and skills to better qualify students at all educational levels for entry-level positions, to facilitate training for new employees and to broaden the knowledge of experienced employees. The Center will be able to support education in a wide range of areas essential to manufacturing operations, which may include those indicated below in Table 2.

Table 2 Industrial Knowledge and Skills	
Regulatory Compliance for the Pharmaceutical Industry	
GMP principles and procedures GLP principles and procedures QA principles and procedures SOP writing Validation methodology Validation study design	Industrial safety practices Laboratory safety practices Environmental regulations Environmental health and safety
Maintenance and Engineering	
Facility design Facility commissioning and qualification Electrical systems Mechanical systems HVAC for aseptic manufacturing	Power distribution Utility systems Process equipment maintenance
Instrumentation and Process Control	
Measurement of process variables Instrumentation calibration Process control system operation	Process control system tuning Process control system design/ programming Metrology

**Table 2, continued
Industrial Knowledge and Skills**

General Process Operation	
Equipment commissioning, qualification Common pumps, piping, valves, tanks Solids handling equipment CIP & SIP systems Clean-out-of-place and sterilize-out-of-place operations	Heat exchangers, evaporators, condensers Simple mixing and dosing operations General equipment inspection, monitoring
Biopharmaceutical Manufacturing Technology	
Growth media prep for mammalian cells Growth media prep for microbial cells Bioreactor operation for mammalian cell cultures Bioreactor operation for microbial cell cultures Cell disruption Centrifugation Depth filtration	Membrane filtration (micro/ultra/nano/RO) Diafiltration Chromatography — affinity Chromatography — ion-exchange Chromatography — hydrophobic- interaction Chromatography — size-exclusion Pasteurization/flow-through sterilization Aseptic operations—working in cleanrooms Working in laminar flow hoods
Analytical Methods for Quality Control and Process Monitoring	
Equipment calibration Colorimetric assays — manual Colorimetric assays — automated Microscopy Microbiological culture and identification methods Dry weight determinations Dissolution assays Flame tests Environmental monitoring methods Water quality monitoring Immunoassays	Mammalian cell culture methods Viral culture and assay methods Sampling technique Sample labeling/handling/storage Enzyme assays PCR Electrophoresis Capillary electrophoresis Chromatography/FPLC TLC
Analytical Instrumentation	
UV/visible spectrophotometry Fluorescence spectroscopy Infrared spectroscopy NMR spectrometry Mass spectrometry	Atomic absorption spectroscopy Gas chromatography HPLC Refractometry Polarimetry

Education and training will be provided in different formats as appropriate to various audiences. For example, new process technicians would require extensive “hands-on” training in the production areas. Students preparing for jobs in quality control would need less time in production areas and more in laboratories learning analytical methods. Experienced professionals seeking updates on new technology or implementation of FDA regulations might attend workshops or seminars with no “hands-on” component.

Distance Learning

The BTEC facility will be engineered to support the delivery of distance learning modules to downlink sites located throughout North Carolina. Services will include support for synchronous learning via videoconferencing and online Internet instruction. Curriculum will be also designed to

support asynchronous (web-based) instruction. This web-based instruction will allow individuals in the rural areas of North Carolina to have online access to fundamental biomanufacturing lecture content from the BTEC. All “hands-on” laboratory sessions will take place onsite at the BTEC.

Levels of Instruction

Three levels of instruction are envisioned to meet entry level and professional development needs. A summary of instructional levels appears in Table 3. Level I courses will typically be one to two weeks in duration and will involve a minimum of ten hours of gownned hands-on experiences in the sterile suite and six hours of experience in the sterile preparation area. Level II instruction will involve intermediate-level education for clean room/aseptic processing techniques and will providing performance-based feedback keyed to qualitative observations, quantitative monitoring data and academic testing. Some Level II courses may focus on sterile preparation and environmental monitoring technician positions. Minimum prerequisites would include high school or associate degree background with Level I training or some aseptic processing experience. Since Level I, II and III courses will all be taught at the BTEC, it is anticipated that some students with High School diploma or A. A. educational backgrounds may wish to enroll in courses where more advanced academic backgrounds are normally required. In such cases, students who have completed the course prerequisite and experience requirements will be considered for enrollment on the same basis as all other course applicants.

Table 3 Summary of BTEC Instructional Levels	
Level	Description
Level I	General introductory training with some “hands on” experience in the clean room environment.
Level II	Aseptic/sterile processing technician training with more extensive “hands on” experience in the clean room environment. A certification process will be offered to reflect minimum competency.
Level III	Modules with specialty focus such as environmental monitoring, validation of aseptic/sterile operations, aseptic/sterile processing facility design and/or operation, sterilization techniques etc.

Level III instruction will include advanced studies and short courses designed for support staff functions around aseptic/sterile processing operations. The aseptic/sterile processing facilities will provide a working laboratory experience with real time data. The program will enrich the learning process by showing students the link between theory and the actual equipment and working environments. Prerequisites will be largely dependent on the topic but will typically require a BS degree or experience in biomanufacturing. A list of probable Level III course topics follows:

- Large-scale Bacterial Cell Culture
- Large-scale Mammalian Cell Culture
- Large-Scale Downstream Processing (Chromatography, Ultra-, Microfiltration, Centrifugation, Cell Disruption, Evaporation)
- Aseptic Processing – Clean Room – Sterile Filling
- Bioreactor Control, Process Troubleshooting
- Regulatory Issues, Validation, SOPs
- Six Sigma Process Training
- GMP Training
- Laboratory Scale Cell Culture (bacterial, mammalian cell)
- Laboratory Scale Downstream Processing

- Instrument Calibration
- QA/QC
- Large-Scale Equipment Maintenance

Most courses will be designed as short modules to facilitate access by a wide variety of students in different degree programs, as well as industrial personnel. Apart from hands-on instruction, the content of many modules can be made available through distance learning. Techniques and standards for working in clean room environments are an essential element in the biomanufacturing of pharmaceutical products. The course content for this topic, Clean Room/Aseptic Operations Instruction, is summarized on Table 4 as an example of how training modules will be organized.

Table 4				
BTEC Type I Clean Room/Aseptic Operations Instruction				
Module	Course	Location	Time	Max. Students
Basic Cleanroom Operations (BCO)	Basic Industrial Microbiology	Classroom	1 hour	*
	Basic Cleanroom Control	Classroom	1 hour	*
	Basic Cleanroom Control Lab	Class 10,000 & 100,000 Rooms	2 hours	8
Basic Environmental Monitoring (BEM)	EM Equipment	Classroom	2 hours	*
	Environmental Monitoring Lab	Class 10,000 Room	2 hours	8
Glassware/Equipment Preparation (GP)	Glasswash /COP/CIP	Classroom	1 hour	*
	Sterilization	Classroom	1 hour	*
	Glasswash & Sterilization Lab	Class 100,000 Room	6 hours	8
Solution Processes (SP)	Chemical Handling	Classroom/Demo	1 hour	*
	Solution Making	Classroom/Demo	1 hour	*
	Filtration & Integrity Testing	Classroom/Demo	2 hours	*
	Solution Processing Lab	Downstream Processing Room	4 hours	8
Aseptic Processing (AP)	Aseptic Processing	Classroom	2 hours	*
	Aseptic Processing Lab	Class 100 Hood	2 hours	4
	Aseptic Process Simulation	Class 100 Hood	4 hours	4
* Indicates the number of students is not limited by the physical facility due to distance education capabilities.				

Other UNC System Schools

In addition to NCCU and NCSU, a number of other universities in the UNC system have expressed interest in participating in this initiative. All fifteen schools were represented in a meeting on this initiative at the Office of the President on July 16, 2003. Follow-up efforts to this beginning will help ensure that the initiative will reach all parts of the State at all educational and training levels.

Inter-Institutional Articulation

There is already a Comprehensive Articulation Agreement in place between the UNC System and the NCCCS. This covers general education and pre-major programs (AA and AS degrees). There is also already in place a Transfer Advisory Committee to work out specific articulation agreements as needed. This committee has members from both educational systems. Moreover, the NCCCS has a common course library that facilitates development of new degree programs as well as student transfers within the system. Included within this library are courses designated as college transfer, i.e., they are transferable to UNC System institutions.

Both community colleges and four-year institutions plan to engage in more curriculum development to be responsive to the biotechnology industry, but an initial framework of majors and tracks are in place. In addition to the Comprehensive Articulation Agreement, there are some bilateral agreements between individual institutions covering biomanufacturing-related programs. The BPTC Participating Institutions will build upon the existing arrangements and assess where new agreements or modifications of existing agreements are needed for new curricula or course work. The flow of students from one curriculum to another within the overall Consortium will determine what new agreements are needed.

The BPTC Coordinating Council should early on work with the Transfer Advisory Committee to establish a subcommittee to work on matters of articulation in biotechnology-related programs and make recommendations to the Transfer Advisory Committee in resolving specific issues. Issues to be considered include the following:

- Articulation agreements may need to include private four-year institutions. For example, Central Carolina Community College's Bioprocessing Technology Program has an agreement with Campbell University. Wake Forest University is providing laboratory space to Forsyth Technical Community College's new Biotechnology AAS program. This program can be expected to generate graduates who will want to continue to a BS degree at Wake Forest or other area universities.
- There is a distinction between articulation of *programs* (i.e., students can transfer seamlessly from a degree program at one institution to a degree program at another institution) and articulation of *courses* (i.e. students can take a course at one institution and have it accepted as part of a degree program at another institution). Articulation of programs on a system-wide basis through the existing process is slow and unwieldy, at least in part because of the different structures of degree programs at UNC-System institutions. Articulation agreements for individual courses or bilateral agreements between individual institutions are easier to obtain in a timely way and these procedures will likely be the most efficient starting point for cooperation among institutions in the initiative.