

**GOLDEN LEAF
BIOMANUFACTURING TRAINING AND EDUCATION CENTER (BTEC)
NORTH CAROLINA STATE UNIVERSITY (NC SU)
CHARTER**

BACKGROUND

In 2003, North Carolina State University, in concert with North Carolina Central University and the North Carolina Community College System, requested and subsequently received funding from North Carolina's Golden LEAF (Long-term Economic Advancement Foundation) to establish the North Carolina Biomanufacturing & Pharmaceutical Training Consortium (BPTC). A public/private partnership between North Carolina's university and community college systems and industry, the BPTC was formed to meet the growing demands of the biotechnology and pharmaceutical industries through three novel education and training programs. These are the Golden LEAF Biomanufacturing Training and Education Center (BTEC) at NCSU, the North Carolina Community College System BioNetwork, and the North Carolina Central University Biomanufacturing Research Institute and Technology Enterprise (BRITE) Center for Excellence. In 2008, the BPTC changed its name to NC BIOIMPACT. The name change was made to improve the recognition and streamline the access to the collaboration of the multiple entities involved in the unique statewide training effort.

Funding from the Golden LEAF, along with substantial industry donations, has provided for the development of instructional programs at each of the NC BIOIMPACT partner institutions and facilities to house these programs. The North Carolina Community College System (NCCCS) has established BioNetwork centers across the state, while a new building was constructed on the campus of North Carolina Central University to house BRITE with a dedication ceremony held in June 2008.

At NCSU, ground was broken in 2005 for the 85,000-square-foot Golden LEAF Biomanufacturing Training and Education Center. A state-of-the-art, hands-on education and training center for future and current biomanufacturing employees, the Golden LEAF BTEC contains approximately 63,000 square feet of laboratory training space, which simulates a biomanufacturing pilot plant facility capable of producing biopharmaceutical products and packaging them in a sterile environment. Classroom space to support training and education occupies an additional 9,000 square feet, while the remaining 13,000 square feet is dedicated to administrative and building support space.

The facility opened for instruction in fall 2007 and offers a core curriculum of biomanufacturing courses at the undergraduate level. In addition, professional development courses for those currently employed within the biomanufacturing industry began in the spring of 2008. BTEC, which contains the BioNetwork Capstone Center, is outfitted so that both community college and university students will gain experience using the same large-scale equipment they will use on the job. Through its NC BIOIMPACT partnerships, BTEC will train as many as 2,000 students, prospective and current employees per year. In addition, BTEC engages in outreach efforts targeting K-12 students and teachers.

1. NAME OF THE CENTER

The center for which this document requests authorization is called the Golden LEAF Biomanufacturing Training and Education Center (BTEC).

2. MISSION, GOALS AND OBJECTIVES

The Golden LEAF Biomanufacturing Training and Education Center provides a unique pilot-scale, industry-informed, cGMP (current Good Manufacturing Practice) environment critical to developing a workforce proficient in the skills needed in the biomanufacturing industry. The mission of BTEC is to fuel prosperity by positioning North Carolina as a global leader in bioprocess education and biomanufacturing workforce development.

Specifically, BTEC will help attract new biomanufacturing companies to North Carolina; assist the development of new technologies for production of value-added biopharmaceuticals, protein-based products and chemicals from organisms, plants, cell cultures and other bio-based systems; and enhance the creation of rural biomanufacturing jobs and new agribusiness opportunities.

The objectives of the BTEC are to provide the following:

- A. State-of-the-art undergraduate and graduate education in engineering and life science disciplines with application in the biomanufacturing industry or biotechnology cluster;
- B. Basic and advanced biomanufacturing skills training – especially hands-on experience with commercial scale biomanufacturing equipment and technologies and current Good Manufacturing Practice – for North Carolinians seeking employment in the biomanufacturing industry or biotechnology cluster;
- C. Continuing education and training in state-of-the-art technologies for those seeking continuing education or advancement opportunities in biomanufacturing or other biotechnology-related employment, and
- D. A catalyst for new rural biomanufacturing jobs and new agribusiness opportunities.

In pursuing these objectives, NC State University and its partners in the NCBIOIMPACT have the following additional goals, which they believe are critical outcomes of the consortium's programs:

- A. To ensure that the training and educational opportunities identified above are available to all North Carolinians regardless of their ethnic or racial background or geographic location, and
- B. 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-based companies.

3. THE CENTER 'S RELATIONSHIP TO OR POTENTIAL IMPACT UPON THE EXISTING ACADEMIC DEPARTMENTS, COLLEGES AND/OR SCHOOLS, AND OTHER CENTERS AND INSTITUTES IN THE UNC SYSTEM

BTEC will be an NC State University Center under the administrative control of the College of Engineering at NC State University. The responsible administrator for BTEC will be Dean of the College of Engineering at NCSU. BTEC will work with the College of Engineering and other colleges at North Carolina State University to provide essential hands-on biomanufacturing experience for university students enrolled in curricula at NCSU and other institutions within the UNC System. In addition, through the North Carolina Community College System's BioNetwork Capstone Center at BTEC, essential hands-on training, cGMP training, and cleanroom and aseptic procedures training will be provided to entry-level workers at the high school and community college levels; to current industry employees; and to trainers and instructors throughout North Carolina. This training will augment the basic laboratory skills and training they receive in regional locations.

Interdisciplinary programs at NCSU

BTEC will enhance and support a number of interdisciplinary programs already in place at NCSU. These include the following:

Biotechnology Minor (BIT) — The BTEC will complement NC State University's Biotechnology Minor, which currently trains approximately 300 students per year. This minor combines NCSU's strengths in agriculture and engineering and offers a unique set of core and advanced course offerings that are highly relevant to medical, agricultural, engineering, and veterinary fields. The Minor in Biotechnology is available to all students who have met its prerequisites and helps to prepare its graduates to meet the challenges of rapidly changing technologies and explosions in information. By increasing the depth and sophistication of the training our students receive via BTEC, we will provide a competitive workforce for industry, as well as future industry leaders who will keep North Carolina at the leading edge of biotechnology.

The modules currently taught in the Biotechnology Minor include Protein Purification, Fermentation, Manipulation of Recombinant DNA, Animal Cell Culture, and Plant Tissue Culture. All BIT courses use bench-scale laboratory equipment. BIT students interested in large-scale or commercial biomanufacturing would benefit from BTEC courses.

Bioprocessing Engineering Concentration in Biological and Agricultural Engineering — The Department of Biological and Agricultural Engineering (BAE), jointly administered by the College of Agricultural and Life Sciences and the College of Engineering, offers a Concentration in Bioprocess Engineering. This concentration includes both food engineering courses and post-harvest handling and processing of crops before they reach the processing plant. The increasing emphasis on food quality and safety and the trend in our society to use more processed foods is generating many employment opportunities for graduates of this area. Students in this program can choose biological science and engineering electives from various departments throughout the university. In the student's last year of study, a Senior Design Project provides real-world experience. The BTEC facilities and courses would provide additional resources and hands-on experience for students completing the Concentration in Bioprocess Engineering.

College of Engineering

Within the Department of Chemical and Biomolecular Engineering, faculty have established research programs in biochemical engineering, enzyme, cell and metabolic engineering, bioseparations, plant biology, reactor design and engineering, biocatalysis at extremely high temperatures, biophysical phenomena, and biosensors. This strong foundation of intellectual talent will ensure that BTEC's course offerings and technical competencies will remain current as new technologies are developed by researchers and then implemented by industry.

It is anticipated that many of the students taking BTEC courses will be engineering majors, including Biomedical Engineering, Chemical and Biomolecular Engineering, Environmental Engineering, Industrial and Systems Engineering, Materials Science and Engineering and Operations Research. The Department of Chemical and Biomolecular Engineering has established a Biomanufacturing Sciences concentration within the chemical engineering B.S. degree program. Students who complete this concentration will simultaneously earn a Minor in Biomanufacturing. This combination is intended to enable interested chemical engineering graduates with the knowledge base and hands-on skills to quickly contribute to a cGMP Biomanufacturing operation.

College of Agriculture and Life Sciences

The existing collaborations and complementary relationship between the College of Agriculture and Life Sciences (CALS) 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 BTEC and to facilitate creation of rural manufacturing jobs and agribiotechnology production opportunities.

The new Bioprocessing Science program (BBS), within the CALS Department of Food Bioprocessing & Nutrition Sciences, is the first undergraduate program at NCSU created to utilize the BTEC facilities. Graduates from the BBS program will have the technical competence and hands-on experience to immediately contribute to the North Carolina biomanufacturing and pharmaceutical industries. In addition to a strong technical background, students earning a B.S. in Bioprocessing Science will understand other subject matter relevant to the bio-industries, including quality control and assurance, validation procedures, and ethical and regulatory issues. This unique collection of courses is designed to provide bioprocessing students with a special skill set specific to bioprocessing and pharmaceutical manufacturing needs, which to date have not been taught by U.S. universities. BTEC also offers students majoring in related sciences, e.g., microbiology, biology and biochemistry, the opportunity to take courses in large-scale commercial biomanufacturing.

Centers and Institutes

BTEC has established a mutually beneficial relationship with the Center for Integrated Fungal Research, with which it jointly sponsors the Summer College in Biotechnology and Life Sciences (SCIBLS) course for talented high school students. This selective four-week program recruits outstanding high school students interested in a career in science. SCIBLS participants take coursework for college credit, work in state-of-the-art laboratories on the

NCSU campus, practice techniques used in research laboratories and explore biotechnology careers.

In addition, BTEC works with the Kenan Fellows for Curriculum and Leadership Development to sponsor and mentor a Kenan Fellow. The Fellows program, an initiative of the Kenan Institute for Engineering, Technology & Science, is an innovative model to promote teacher leadership, address teacher retention and advance K-12 science, technology and mathematics education. Kenan Fellows are public school teachers selected through a competitive process to participate in a prestigious two-year fellowship while remaining active in the classroom. Kenan Fellows work in partnership with scientists, university faculty, and the NC Department of Public Instruction, developing curriculum and teaching resources that bring cutting-edge research into the hands of students. BTEC support for the Kenan Fellow began in 2008 and will continue for two years.

Additional collaborations are being established with the Industrial Extension Service in the College of Engineering at NC State University, with the office of the Vice Chancellor for Extension, Engagement and Economic Development, the Biotechnology Program, and several other units of NC State University. One of BTEC's major goals is to reach out to as many university units as possible in an effort to enhance its offerings and maximize its impact.

4. THE DIRECTOR AND ADVISORY COMMITTEE

Director: Dr. Ruben G. Carbonell serves as the Director of the Golden LEAF Biomanufacturing Training and Education Center. Dr. Carbonell has extensive administrative experience as Department Head of Chemical Engineering, Director of the Kenan Institute at N.C. State University, and Co-Director of the NSF Science and Technology Center for Environmentally Responsible Solvents and Processes. In addition, he has extensive research experience in the area of protein separation and purification.

The responsibilities of the Director of BTEC include the following:

- A. Provide leadership in short- and long-term planning for the center.
- B. Represent BTEC in University meetings and at events external to NCSU, as appropriate.
- C. Establish and maintain collaborative relationships between BTEC and other units across NCSU, the UNC system, other educational institutions in the area (including NC BIOIMPACT partners), and business enterprises and other organizations within the biomanufacturing and pharmaceutical industry.
- D. Develop training grants, program project grants and center grants as appropriate.
- E. Establish and convene meetings of the BTEC Advisory Board.
- F. Work with the relevant postdoctoral, graduate, and undergraduate programs to ensure that research and educational opportunities at the BTEC are maximized.
- G. Assist with recruiting of exceptional faculty.

BTEC Advisory Board: A BTEC Advisory Board was established to provide a forum for interface between industry, NCSU and other stakeholders and to assist with strategic development of the center. Highly qualified representatives from industry comprise at least 50% of the total board membership. Other members include the BTEC Director, BTEC partners, NCSU faculty members and others as deemed appropriate by NCSU. A roster of current Advisory Board members is provided in Appendix A. To meet the overriding objective of program offerings meeting industry needs, the BTEC Advisory Board meets at least three times per year 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.
- **Curriculum Development Assistance.** Coordinate assistance from industry 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.
- **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 BTEC 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 BTEC or NC BIOIMPACT.

1. BTEC BUDGETS AND FUNDING MECHANISM

Estimated 5-Year Budget for Biomanufacturing Training & Education Center (BTEC)

ITEM	(X \$1000)				
	Year 1	Year 2	Year 3	Year 4	Year 5
	2005-06	2006-07	2007-08	2008-09	2009-10
	Actual	Actual	Actual	Estimated	Estimated
Salaries					
Instruction	253	318	827	1646	1700
Operations	162	426	1155	1155	1200
Administration	400	837	1017	1017	1100
Total Salaries	815	1581	2999	3818	4000
Operating Expenses					
Equipment	2153	3363	2137	1560	1250
Educational Supplies	246	421	1165	800	800
Rent	87	165	130	0	0
Other Operating Expenses	109	134	522	314	660
Total Operating Expenses	2595	4083	3954	2674	2710
Building Operations	0	64	1300	1300	1300
TOTAL ESTIMATED EXPENDITURES	3410	5,664	8,253	7,792	8,010
FUNDING SOURCES					
	Year 1	Year 2	Year 3	Year 4	Year 5
	2005-06	2006-07	2007-08	2008-09	2009-10
	Actual	Actual	Actual	Estimated	Estimated
State Appropriation to BTEC	3,409	5,600	6193	5,600	5,600
Contracts/Grants	0	0	0	50	200
Fees from Short Courses	0	0	0	82	150
NCSU - Operating Reserve for Process Equipment	0	64	760	760	760
NCSU - Operating Reserve for Building Operations	0	0	1,300	1,300	1,300
TOTAL ESTIMATED FUNDING	3,409	5,664	8253	7,792	8,010

NOTE: Estimates Assume no inflation or state increases

Actual and estimated expenditures

Spending in BTEC's first year (05-06) was \$3,410,000. A small staff was hired to develop curricula and purchase equipment for the center. Due to the increase in staffing and the need to further equip the new building, the budget increased to \$5,664,000 for the 06-07 fiscal year. Based on plans for curriculum and short courses, BTEC's staff doubled in size by the 07-08 fiscal year. The overall budget for the 07-08 fiscal year increased to \$7,020,000 due to additional salaries, equipment, materials, and building operation after the building opens. Expenses for building operations, such as housekeeping, maintenance supplies, etc., are paid directly by NC State Facilities. These expenses and payments are reflected in the 5-year budget to illustrate the true costs of BTEC. NC State Facilities will allocate an additional \$715,812/year to BTEC to employ specialized personnel to maintain biomanufacturing process equipment and utilities.

For the 08-09 fiscal year, BTEC hopes to secure additional funding in the form of grants and/or contracts. This funding will be used for additional staff and supplies to adequately train the individuals taking these courses. If the funding is not received, the budget will be adjusted accordingly. BTEC also assumes development of additional short courses, which will also increase revenue for the department and the need for additional staff.

For the 09-10 fiscal year, BTEC hopes to receive additional grant and/or contract funding. BTEC will also continue development of short courses. These courses will all require additional staff to develop and deliver the courses. BTEC will purchase the last of its initial process equipment during the 09-10 fiscal year. Equipment spending will drop dramatically in the 10-11 fiscal year. The current BTEC Equipment Plan costs are shown in Appendix B.

Anticipated sources of funding

The Golden LEAF has contributed \$38 million toward construction of the BTEC facility. NCSU has responsibility for the operations and deliverables associated with the BTEC, not including those costs and deliverables resulting from NCCCS activities in the facility. In addition to construction and start-up costs provided by Golden LEAF, BTEC's ongoing operations will have to be supported through State legislative appropriation to NCSU for annual operating funds. Specifics relating to NCCCS operation within the BTEC are addressed through a lease and associated Facilities Use Agreement being established between NCCCS and NCSU. As indicated in the previous section, the BTEC will also pursue training or technology development grants to fund specific programs. Fees obtained from professional development offerings will be used to fund labor and materials required for those short courses.

It is understood that in the event of any future legislated budget cuts to the University, the BTEC operating budget will sustain similar levels of reduction as any other unit.

2. CURRENT SPACE AND CAPITAL EQUIPMENT SECURED FOR THE OPERATION OF THE CENTER AND PROJECTIONS OF FUTURE NEEDS

Space: The new Golden LEAF Biomanufacturing Training and Education Center facility was constructed and equipped specifically to meet the space needs of this initiative.

Capital Equipment: A wide array of equipment has been acquired for the large scale bioprocessing spaces, bioprocessing support spaces, laboratory spaces, classrooms, and administrative areas. Significant equipment donations and discounts, valued at more than \$4 million to date, have been provided by industry. Additional equipment will be purchased over the next two years; Appendix B lists planned expenditures.

3. A STATEMENT REGARDING THE EFFICACY OF PLANS IMPLEMENTED TO ASSURE PROPER RECOGNITION OF PARTICIPATING JUNIOR FACULTY WHERE RELEVANT

The majority of the faculty who teach within BTEC hold tenure-track appointments in their academic departments (e.g., Food Bioprocessing & Nutrition Sciences, Poultry Science, and Chemical and Biomolecular Engineering), and each academic department is expected to develop these faculty appropriately in areas of scholarship, teaching, service and other realms of faculty responsibility. BTEC will foster and support professional development through mentoring by the Center's Director, Associate Directors, and other senior BTEC personnel as appropriate. Examples of services that may be provided through this mentoring include the following:

- Providing guidance on institutional and national resources and related scholarly opportunities for professional development.
- Providing encouragement to promote excellence in teaching and suggesting ways for efficient use of time to make the maximum impact on students at every level.
- Assisting in linking the junior faculty member with others, both locally and nationally, who share common scholarly interests.
- Facilitating the development of professional collaborations and encouraging participation at professional meetings. This may include sponsoring faculty participation in workshops and seminars or attendance at professional meetings.

BTEC currently maintains one Teaching Associate Professor, one Teaching Assistant Professor and three Lecturer positions that are dedicated fully to the BTEC mission.

4. ANTICIPATED EFFECTS ON INSTRUCTIONAL PROGRAMS, AND PROVISIONS FOR ADVANCED OR GRADUATE TRAINING OR DEGREE PROGRAMS

The purpose of the BTEC and its partners in NC BIOIMPACT is to provide the wide range of North Carolina biomanufacturing and biotechnology firms with graduates who have the education and skills necessary for employment. North Carolina ranked third in the nation in number of biotechnology companies for the fourth consecutive year in the 2007 Ernst and Young industry survey. For the state to sustain the growth of this economic sector, approximately 3,000 students and current employees need to be trained each year, according to industry estimates. To meet this need, plans call for 2,000 students and employees to participate in coursework at BTEC each year, while the NCCCS BioNetwork and North Carolina Central University's BRITE Center for Excellence anticipate providing non-BTEC training to 1,000 learners per year.

Of the projected 2,000 students and current industry employees who will engage in coursework at BTEC annually, estimates call for approximately 25% (500 learners) to enroll in NCSU courses. The remaining 75% (1,500 learners) will enroll in the NCCCS courses that will take place at the BioNetwork Capstone Center, which is located within the BTEC facility.

Of the estimated 500 learners per year who will enroll in NCSU courses at BTEC, approximately 150 are expected to enroll in undergraduate-level courses. The remaining 350 learners are expected to be industry employees who participate in professional development offerings provided by BTEC. While the unique facilities at BTEC are a key part of the for-credit and professional development courses to be offered, distance education technologies will be leveraged whenever possible to provide learners with increased access and to increase the pool of potential students.

Those enrolled in the BTEC's undergraduate courses are most likely to be full-time students completing degree programs offered by the College of Engineering or the College of Agriculture and Life Sciences. (See section 3, *The Center's Relationship to or Potential Impact upon the Existing Academic Departments, Colleges and/or Schools, and Other Centers and Institutes in the UNC System.*) BTEC's course offerings will enable these undergraduates to develop industry-relevant skills and acquire substantial hands-on experience that will complement their majors.

Further, the new BTEC Minor in Biomanufacturing approved by the University Courses and Curricula Committee will provide for more in-depth learning on large-scale equipment and additional experience in a simulated cGMP (current Good Manufacturing Practice) work environment. The minor will consist of a minimum of 16 credit hours, to include a base biomanufacturing sequence, a two-course specialization focused on either upstream or downstream processing, and electives. In addition, courses will be developed for graduate students and professionals looking for advanced programs of study.

In sum, the intensive hands-on curriculum and unique pilot-scale facilities that the BTEC offers will enable learners along a continuum of educational levels to gain valuable educational experiences that are currently not available elsewhere in the country.

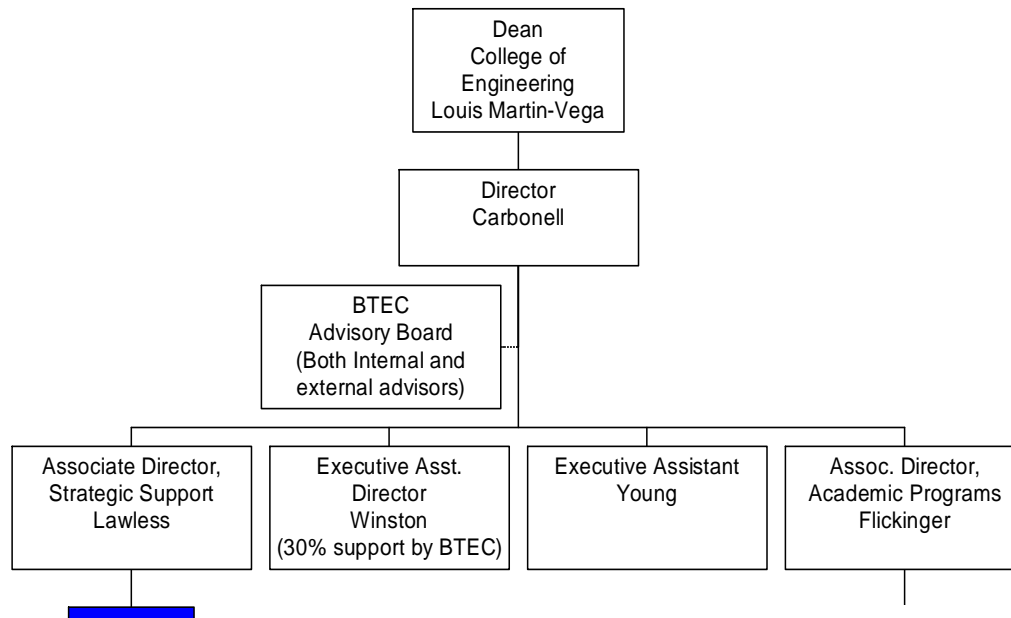
5. BTEC'S ADMINISTRATIVE STRUCTURE

The Dean for the College of Engineering will act as the responsible administrator (RA) of the Golden LEAF Biomanufacturing Training and Education Center.

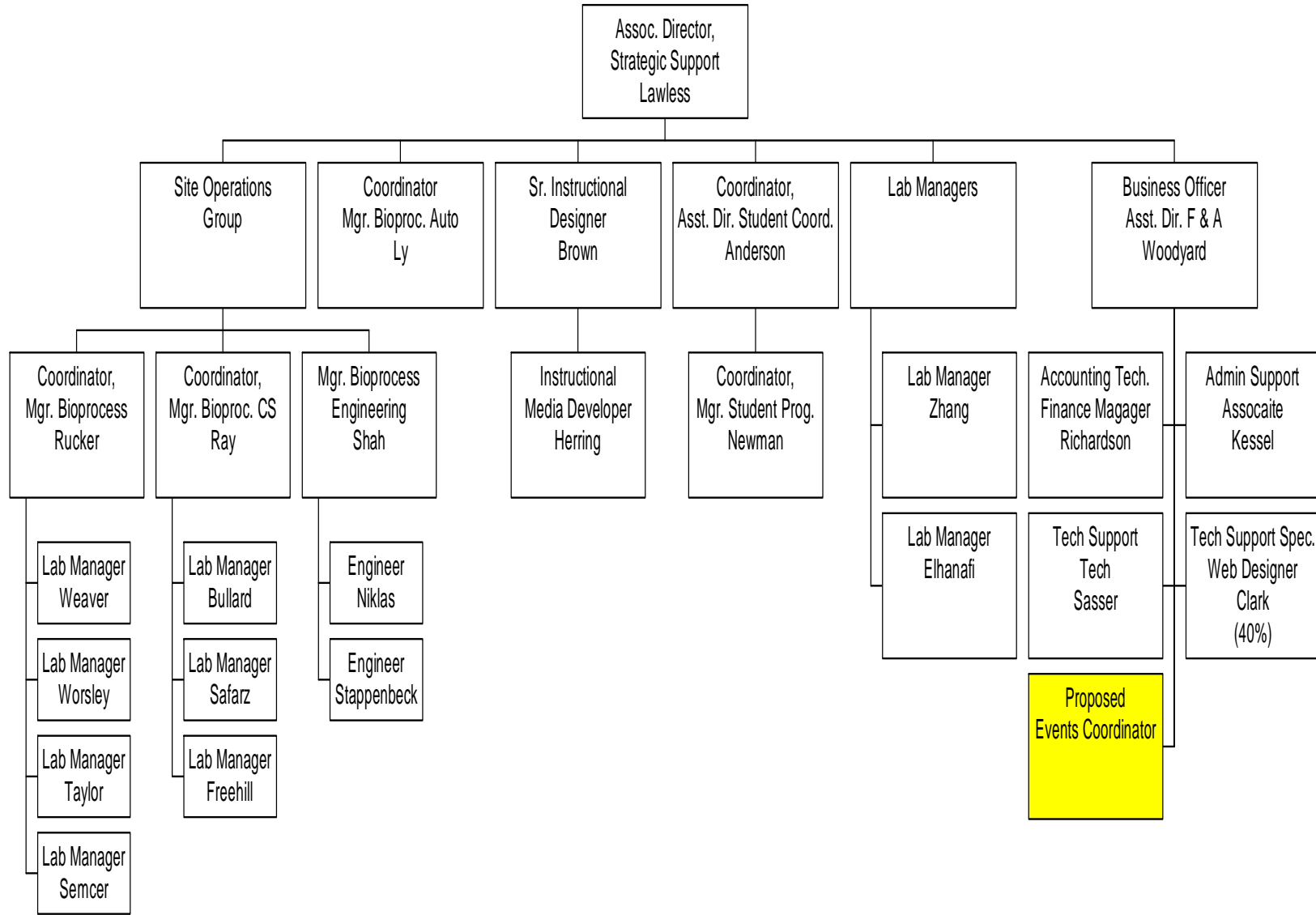
Dr. Ruben G. Carbonell serves as BTEC's director.

The chart on the next page reflects the relationship of BTEC to university organizations and shows the internal organization of the Center.

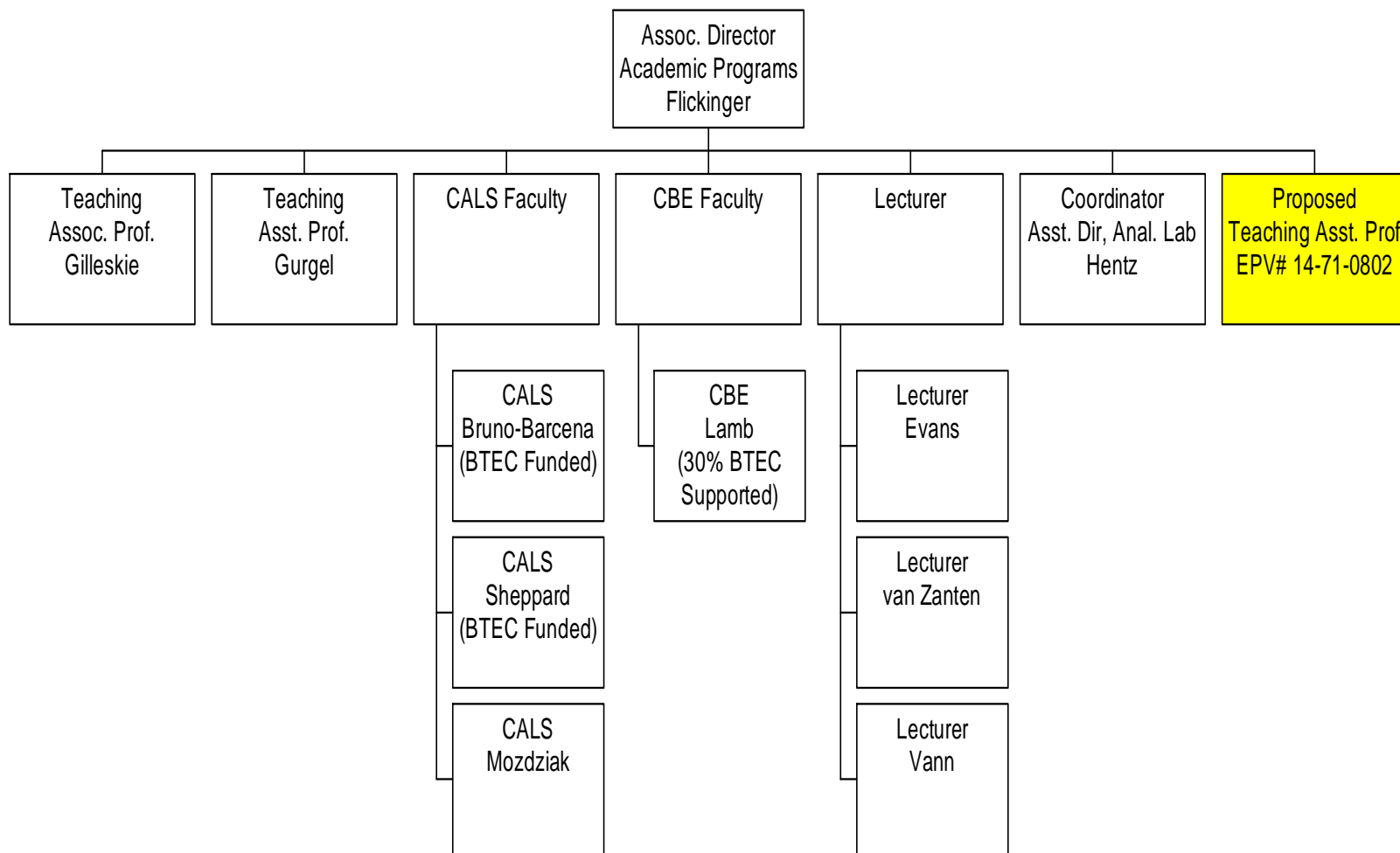
BTEC Organizational Chart



BTEC Organizational Chart
(Strategic Support)



BTEC Organizational Chart
(Academic Programs)



APPENDIX A – BTEC ADVISORY BOARD MEMBERS (As of January 2008)

Industry Members:

Name	Title	Organization
Lou Arp	Vice President, Operations	Eisai
Tom Brna	Operations Lead	Merck
John Cox	Vice President & General manager	Biogen-Idec
Lynn Dickey	Vice President, Research	Biolex
Gerry Farrell	Senior Director, Ups tream Development & Production	Diosynth-RTP
Shawn Gallagher	Vice President & General Manager	Cardinal Health
Tommy Hielscher	Director, Business Support	Novo Nordisk
Tim Kelly	Vice President, Biopharmaceutical Development	KBI BioPharma
James Kennamer	V. P., Manufacturing	Talecris Biotherapeutics
Dennis McKinley	Corporate Account Executive	ABB, Inc.
Mike McLean	Associate Director, Manufacturing Systems	Wyeth Biotech
Kumar Namdev	Director, Manufaturing Technology	Novartis Vaccines & Diagnostics
Mark Paige	Vice President, Technical Operations	Novozymes
Franco Pierpan	Site Director	Glaxo Smith Kline
Mahesh Prashad	Head of Product Management	Sartorius Biotechnology
Mark Sorrells	Senior Vice President	Golden LEAF

Governmental and Educational Members:

Ruben Carbonell	North Carolina State University	Director, BTEC
Stephanie Curtis	North Carolina State University	Department Head, Genetics
Willa Dickens	North Carolina Community College System	V. P., Economic & Workforce Development
Bob Kelly	North Carolina State University	Director, BIT
Louis Martin-Vega	North Carolina State University	Dean, College of Engineering
Matt Meyer	North Carolina Community College System	Director, BioNetwork
Ken Tindall	North Carolina Biotechnology Center	Senior Vice President for Science & Business Development
LiAn Yeh	North Carolina Central University	Director, BRITE

Appendix B – BTEC Equipment Plan

Fiscal Year	Planned (\$MM)	Actual (\$MM)
2005-2006	\$2.15	\$2.15
2006-2007	\$2.90	\$3.36
2007-2008	\$2.35	\$2.14
2008-2009	\$1.85	--
2009-2010	\$1.75	--
Total	\$11.0	\$7.65