Golden LEAF Biomanufacturing Training & Education Center
Presented by: Gary Gilleskie, Acting Director
BTEC Mission

Contribute to the social and economic well-being of the state of North Carolina by providing a wide variety of high quality educational and training opportunities to develop skilled professionals for the biomanufacturing industry and by providing services to industry, government and academia.
What is BTEC?

- Training/education for NC State students
- Training/education for professionals
- Contract services

Economic development

Focus on biological products for treatment or prevention of human disease, produced using cells
BTEC Organization

- Report to the Dean, College of Engineering, NC State University
- Organized into 3 main areas: operations, strategic programs, and academic programs reporting into the director
  - 46 full-time staff (> 50% from industry)
- Part of NCBioImpact
- Have an Industrial Advisory Board to provide an interface between industry, NCSU and other stakeholders

BTEC Industrial Advisory Board
Key Features

- **Main facility**
  - 63,000 gsf labs, including a simulated cGMP mfg area
  - 9,000 gsf classrooms
  - $39 MM infrastructure
  - $15 MM equipment

- **BTEC Annex** – 4,000 gsf labs

- **$5 MM/year state funding**

**NCCCS BioNetwork Capstone Center operates labs within BTEC**
BTEC’s Unique Educational Programs

Minimize training done by industry

- Industry-focused curriculum, with significant investment in lecture / laboratory content and model process
- Hands-on experiences
- Instructors with industry experience

Involve wide-ranging audiences and topics

- Multi-disciplinary
- Undergraduate, graduate, industry
- Upstream, downstream, analytical, regulatory
- Bench, intermediate, large scales
Academic Programs

Chemical & Biomolecular Engineering (Biomanufacturing Concentration)

Food, Bioprocessing & Nutrition Sciences
Bioprocessing Science (BBS)

Biotechnology (BIT)

Other COE, CALS, COS Students

BTEC Programs

Minor (Undergraduate & Graduate)
Certificate (Undergraduate & Graduate)
Post-Baccalaureate Studies Certificate
Professional Science Masters (BIOM)
Enrollment by Academic Year

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BTEC’s NC State Students

NC State undergraduates

- 2016-2017
  - Enrollment = 505
  - 54 minors + 13 certificates
- 376 minors or certificates since 2008
- >95% employment within 6 months

NC State graduate students

- 2016–17
  - Enrollment = 326
  - 9 masters + 3 certificates
- 64 masters or certificates since 2012
- >98% employed within 6 months
Impact of Academic Programs on NC

- Master’s students who work in state after graduation: 91%
- Undergraduate minors who work in state after graduation: 86%

“...the number of people I recognize here [Biogen] from BTEC is just overwhelming! It is a great feeling running into someone you have seen before in class, even if I never spoke or interacted with them before. It has really helped me meet a lot of different people here and I love it!”

— 2017 masters graduate
Short Courses for Industry

Open-enrollment tracks
- Analytical Technologies
- Biomanufacturing
- Bioprocess Development
- Bioprocess Engineering

Customized courses

“Some of the best aspects of this course: there were a lot of hands-on activities, not only having us look at single-use equipment but also being able to process actual media through the equipment…”

— Short course participant, 2016
Enrollment: Professional Development Courses

- Open
- Custom

Trained > 2,200
Impact of Professional Development Program on NC

- 1125 participants from NC
- 87 companies represented with NC participants
  - includes numerous vendor reps residing in state
- Has attracted students from various regions throughout NC
  - Research Triangle, Piedmont Triad, Charlotte, Southeast
Other Notable Training Programs

- **FDA (since 2007)**
  - Courses: Upstream Bioprocessing, Downstream Bioprocessing, QC/Analytical, Aseptic Processing
  
  Trained 155 FDA Investigators to date

- **BARDA (2011–2015)**
  - Courses: Influenza Vaccine Manufacturing (Fundamentals, Advanced, Regulators)
  
  Trained 150 vaccine specialists from 14 different countries

- **BioNetwork Capstone Bootcamps (since 2010)**

  Numerous educators and community college students involved

All programs involve collaboration with the BioNetwork Capstone Center
Bioprocess and Analytical Services

BTEC offers:

- **Faculty with expertise** in biomanufacturing topics
- Staff with **hands-on biomanufacturing experience**
- **Facilities and equipment ideal** for this type of work
- Multiple **contract** options
- **Flexibility** in the types of projects
  - “Risk-free environment”
  - Smaller projects that CMOs not likely to take on

137 projects, 57 companies since 2009
Examples of Projects

Bioprocess Services

- Development of bacteriophage process
- Fermentation optimization
- Production of cell culture broth
- Testing production conditions for human fusion proteins
- Ultracentrifugation of VLPs
- Low-endotoxin purification
- Optimization of thyroglobulin purification
- Videos for training video

Analytical Services

- Water analysis – TOC, LAL, bioburden, Micro ID, conductivity
- AA analysis – Spent media
- AA analysis – Tobacco leaf
- Polyamine detection
- Quantitative PCR
- Autoclave – Material structural integrity
- H$_2$O$_2$ analysis
- LAL analysis
Economic Development Activities

- Partner with university and state economic development professionals (NC Dept. of Commerce)
- Sponsor NC Pavilion at BIO International
- Present at national and international meetings
- Host local, national, international visitors
- Conduct tours for companies considering NC
- Help university researchers and local companies
- Provide facilities for workshops, demos, meetings
BTEC’s Strategic Plan

- Continue to provide state-of-the-art, hands-on educational and professional development opportunities

- Incorporate content related to manufacturing next-generation biopharmaceuticals (e.g., gene therapy, cell therapy) into academic and training programs

- Enhance our process technologies in areas such as single use and advanced process control/analytics

- Grow capacity of Bioprocess and Analytical Services to assist small, mid-size and large companies

- Implement GMP production for Phase I clinical trials

- Integrate BTEC more directly with the research mission of NC State by playing a major role in National Institute for Manufacturing of Biopharmaceuticals (NIIMBL)
Additional Nonrecurring Funds 2017–2018

To keep undergraduate, graduate enrollment high and labs functioning, BTEC will use additional nonrecurring funds for the following:

- **Enhanced marketing of BTEC’s academic programs**
  - Because we are not a department with a bachelor’s degree, getting word out to students is important to maintain/expand enrollment

- **New equipment capabilities**
  - Fills a need to expose students to the new technologies that are rapidly being adopted by industry

- **Maintenance and upgrades on frequently used equipment**
  - Maintenance/upgrades on equipment to ensure reliable performance leading to positive student experiences
The Life Force of Tomorrow’s Industry