



Golden LEAF Biomanufacturing Training & Education Center



What is BTEC?

- Simulated cGMP facility
- Education and training
- Bioprocess and analytical services
- First and largest in the world



Focus on biological products for treatment or prevention of human disease



- **BTEC** – NC State University
- **BioNetwork** – NC Community College System
- **BRITE** – NC Central University
- **NCBC** – North Carolina Biotechnology Center
- **NCBIO** – NC Biosciences Organization
- **Golden LEAF Foundation** – Building costs
- **State of North Carolina** – Operating support



Key Features

- 63,000 gsf labs
- 9,000 gsf classrooms
- \$39 MM infrastructure
- \$15 MM equipment
- \$5.5 MM/year state funding



Shared with the NCCCS BioNetwork
Capstone Center – Wake Tech CC

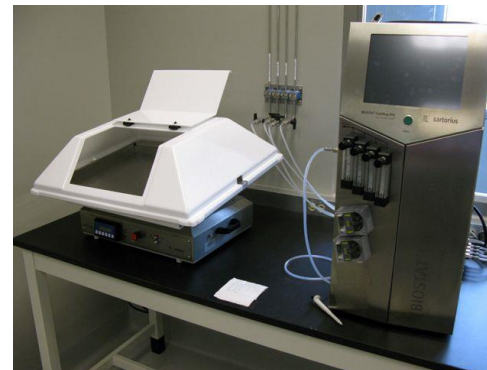
30-L and 300-L Stainless Steel Bioreactors





Single-Use Disposable Technology

- Storage
- Mixers
- 20-L rockers
- 2 x 50-L stirred tank
- 250-L stirred tank





BTEC Annex at Keystone Science Center

- Labs (4,000 gsf total)
 - BL2-LS for live virus in cell culture
 - Purification (inactivated virus)
- Process Equipment
 - Disposables (< 20-L scale)



CURRICULUM





Academic Programs

- **Undergraduate Minor**
- **Certificates**
- **MS Biomanufacturing**





Academic Programs

Chemical & Biomolecular
Engineering
(Biomanufacturing Concentration)

Food, Bioprocessing & Nutrition
Sciences
Bioprocessing Science (BBS)

BTEC Programs

Minors (Undergraduate & Graduate)
Certificates (Undergraduate & Graduate)
Post-Baccalaureate Studies Certificate
Masters

Biotechnology (BIT)

Other COE, CALS, COS Students



Graduate Programs

- Professional Science Master's (PSM) in Biomanufacturing – Thesis (MS) and Non-thesis (MR)
 - 28 students enrolled for Spring 2014
 - Upstream or downstream focus
- Graduate minor
- Graduate certificates





Professional Development Courses

Tracks

Biomanufacturing

Bioprocess Development

Bioprocess Engineering

Analytical Technologies

Customized courses also available





Contract Training

- FDA (since 2007)
 - Courses: Upstream Bioprocessing, Downstream Bioprocessing, QC/Analytical, Aseptic Processing

Trained 88 FDA Investigators to date

- BARDA (since 2011)
 - Courses: Influenza Vaccine Manufacturing (Fundamentals, Advanced, Regulators)

Trained 138 vaccine specialists from 13 different countries



AIChE Online Courses

BIOLOGICAL ENGINEERING An AIChE Technological Community

Topics ▾ Events & Resources ▾ People & Community ▾

SBE Events & Resources Education **Biomanufacturing for Chemical Engineers**

Biomanufacturing for Chemical Engineers



Photo courtesy of BTEC. Copyright 2012 North Carolina State University.

Course ID:	Course Type:	Course Length:
ELA103	eLearning (online) Course	7 Hours

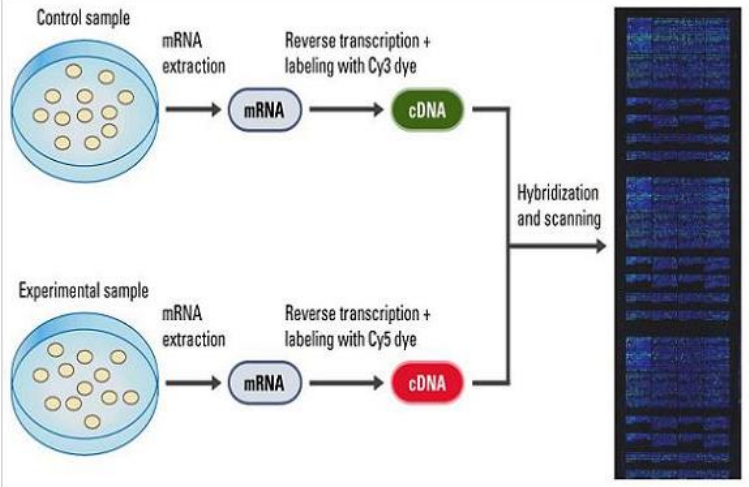
SOCIETY for BIOLOGICAL ENGINEERING An AIChE Technological Community

Topics ▾ Events & Resources ▾ People & Community ▾

SBE Events & Resources Education **Biotechnology for Chemical Engineers**

Biotechnology for Chemical Engineers

Share [in](#) share 0 [f](#) Like 0 [g](#) +1 0 [t](#) Tweet 0



Course ID:	Course Type:	Course Length:
ELA102	eLearning (online) Course	7 Hours

BIOPROCESS AND ANALYTICAL SERVICES



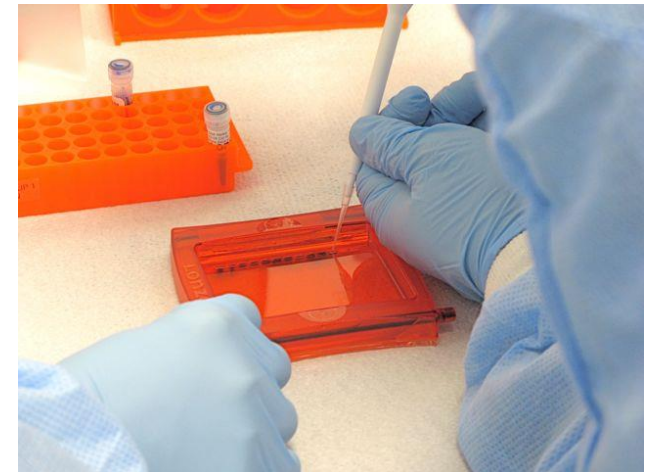


Capabilities

BTEC offers:

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

49 projects, 25 companies since 2009





Bioprocess and Analytical Services

- Process and Method Development
- Scale-up
- Equipment Testing
- Analytical Testing





Project Agreements

- Testing Services Agreement
 - Clients write protocols and analyze data
 - No intellectual property
 - Charge time and materials (no overhead)
- Sponsored Project Agreement
 - Research oriented
 - University owns its own intellectual property and maintains right to publish
 - Companies can negotiate exclusive license
 - Projects have larger scope than testing services
 - Longer time to put agreement in place



Analytical Lab

- HPLC
- Capillary Electrophoresis
- MALDI-TOF
- Circular Dichroism
- TOC
- LC-MS
- UPLC
- MALLS
- Lab-on-a-Chip
- Bioburden
- Microbial ID
- Real Time PCR
- Multimode Plate Reader

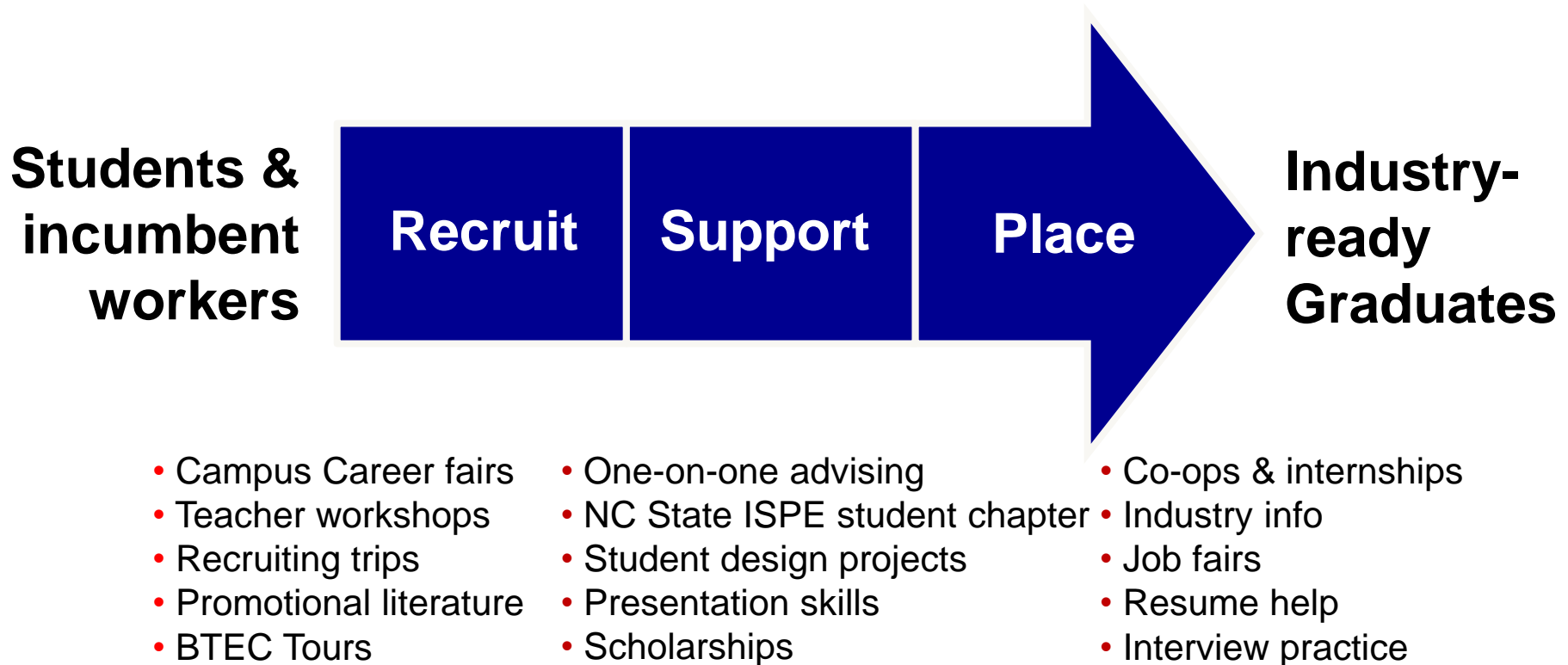




OUTREACH



Student Coordination



177 students have graduated with an undergraduate minor or a master's degree in biomanufacturing

K-12 outreach

- Collaborate with NC Science Teachers Association, NCABR, other outreach providers
- Coordinate workshops with career counselors
- High school tours
- High school advising





International Activities



- Centre of Excellence for Biosensors, Instrumentation and Process Control (COBIK), Slovenia
- BARDA – Vaccine manufacturing (13 countries)
- Haimen Biotech & Medical Center, China
- Instituto Químico de Sarriá (IQS), Barcelona, Spain
- NIBRT, Ireland
- Novartis/U. of Pernambuco, Brazil
- Shanghai Pharmaceutical School
- Singapore Economic Development Board
- University of Minho, Portugal
- University of PR, Mayagüez
- University of Strasbourg, France



Founding Members:

- NC State - BTEC
- University of Strasbourg - EASE



•• *The Life Force of Tomorrow's Industry*