

National Center for Therapeutics Manufacturing



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A Case Study: North Carolina



1950: NC ranks 47 out of 48 states in per capita income.

1984: NC Biotech Center established. State-funded non-profit to promote the life sciences industry.

2001-2007: Industry requests 2,000-3,000 new employees annually. Golden LEAF invests \$69M in workforce training initiatives to create BTEC and BioNetwork.

1980s: Research Triangle Park “tech hub” built around tech companies like IBM, SAS.

1990s: 70 companies in life sciences, employing 17,500 in the state

2024: Current landscape includes 810 life sciences companies, employing 75,000 individuals, with average annual wages of \$112,000 and generating \$2.4B annually in state and local government revenues. Estimated 8,000 new workers needed by end of 2026.

- Current landscape:
 - 108 biopharma manufacturing companies
 - >32,000 employed at biopharma companies
 - Average annual wages \$92,652
- Between January 2020 to December 2022, 31 public announcements from biopharmaceutical companies
 - Corresponding to 6,200 new jobs and \$7.6B investment
 - FUJIFILM: \$2B facility
 - Amgen, Eli Lilly, Fisher Scientific, Biogen, and more
- In recent years, several case studies have emerged in Texas reporting losses of biotechnology bids to other states, including North Carolina

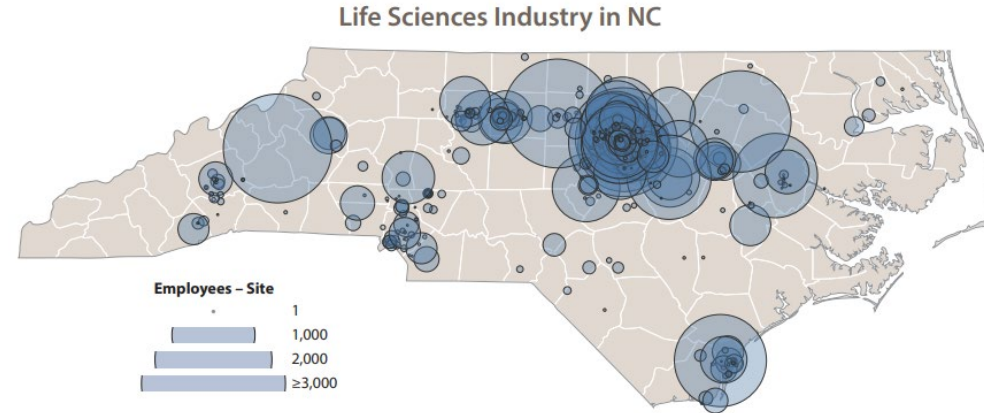


Figure 2: Life sciences industry in NC. Circle size indicates employment at site.

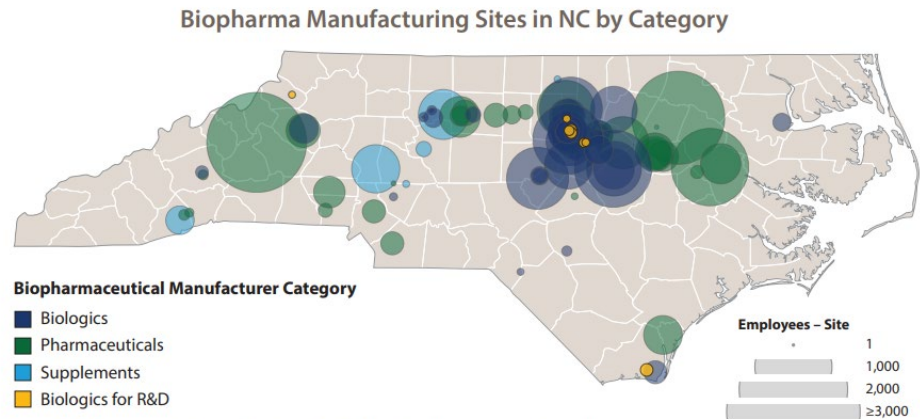


Figure 3: Biopharmaceutical manufacturing sites. Circle color indicates category by product type.

- BioNetwork: Works through the NC Community College System to offer the BioWork certificate for process technicians
 - Industry-recognized curriculum to train entry-level technicians

- Biomanufacturing Training and Education Center (BTEC): A 77,700 square foot simulated, pilot-scale cGMP training facility on the campus of NCSU. Supported by \$5.5M annual state appropriations.
 - Supports hands-on cGMP trainings on process-scale equipment
 - Offers more advanced courses, undergraduate certificates, and a Master's in Biomanufacturing degree



- TRIBEC: Texas Regional Industrial Biomanufacturing Education Certification
- Consortium of 10 colleges and universities across Texas
- Aiming to create a harmonized biomanufacturing training program, offered concurrently at several locations across the state
 - Same curriculum, same price, same certification
- Potential for hands-on capstone experience at the National Center for Therapeutics Manufacturing (NCTM)
 - Potential for state funding?

Current Organizations

Alvin Community College

Austin Community College

Blinn College

Collin College

Dallas College

Del Mar College

Lone Star College

San Jacinto College

Texas A&M University

University of Texas Arlington

TRIBEC Hands-on Capstone



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- 12,000 square foot simulated cGMP facility
 - Gowning areas with air locks, pressure cascades, and unidirectional flow
 - Mock production facility
 - Aseptic passthroughs
- Cleanroom processing suites include:
 - Central services
 - Fermentation and recovery
 - Purification
 - Formulation and filling suite
 - Additional suites for cell culture and QC
- Pilot and manufacturing-scale skids
 - Both single-use and stainless equipment



Topics			
Documentation	Pressurized vessels	Process control	Aseptic processing
Facilities and process equipment	Hazards	Upstream processing	P&IDs and process flow diagrams
Warehousing, distribution, material controls	Measuring volume, length, mass, flow, level, temperature, pressure	Process and performance parameters	Recombinant proteins, vaccines, gene therapy, cell therapy, mRNA products
Regulatory affairs, QA, QC	Facility flows and layouts	Downstream processing	Solution prep
Safety	Unit conversions	Pipetting	Technical writing
Cleanroom classifications	pH and conductivity	Facility monitoring and maintenance	Contamination control
cGMP operations	PPE and gowning	Material handling	Electrophoresis

- Completed:

- Partner organizations identified (new ones continue to be added)
- Industry survey to identify curriculum topics
- Curriculum content sourced/created by partners
 - All lectures and labs complete

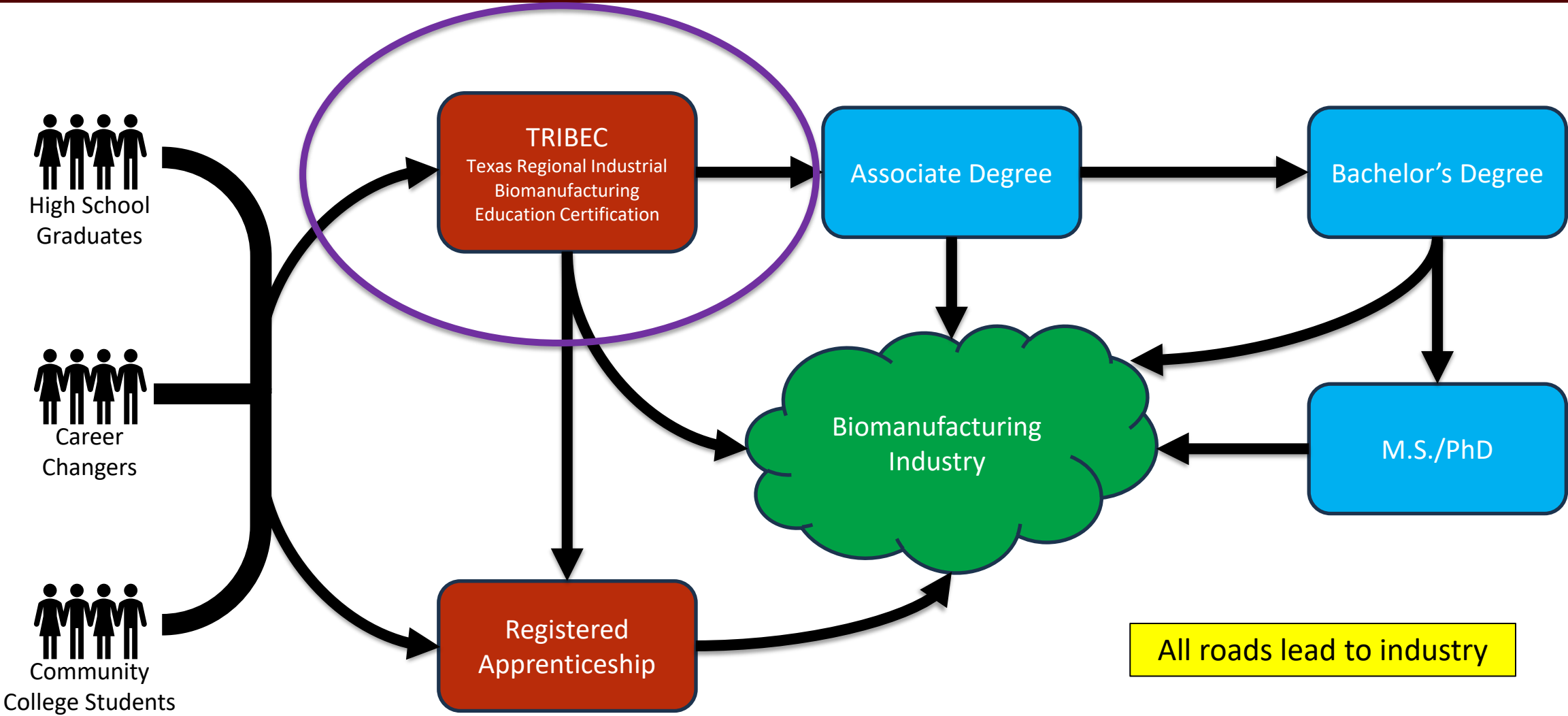
- To come:

- Contracts signed by all partner institutions
 - Allow sharing of IP and logo usage
- Initial cohort: TBD (pending contracts)
- State funding: Exceptional item? Annual appropriation? TWC Skills Development Fund?
 - \$2.5M annually to fund hands-on capstone for 500-800 students annually

TRIBEC: Integration with other Pathways



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Questions?