



# North Carolina

Programs & Initiatives Advancing the Biopharmaceutical Industry



## Key Programs & Initiatives

The opportunities generated by the biopharmaceutical sector as a leader in innovation and high quality job creation are not limited to just a few states, but have a substantial national footprint across states. States proactively pursue the development of the biopharmaceutical sector because it represents: a large-scale, geographically dispersed supply chain spanning R&D through to production and distribution; a key driver of the economy including the recent economic recovery; and a sector paying high wage rates in quality jobs. States are deploying a range of programs and initiatives to support and grow the biopharmaceutical industry, including: comprehensive state development strategies; investments in R&D and related infrastructure; programs to boost venture capital, entrepreneurship, and innovation development; advanced manufacturing; economic incentive initiatives; and programs working to advance STEM education and training. North Carolina has become one of our nation's top bioscience industry states as a result of a strategic, focused and sustained effort in North Carolina by industry, government, university and other key stakeholders to catalyze the emergence of biotechnology-related industry development.

### Quick Guide: North Carolina's Programs & Initiatives Advancing the Biopharmaceutical Industry



#### Comprehensive State Strategies to Support Biopharmaceutical Development:

- North Carolina Biotechnology Center (NCBiotech)



#### R&D Investment:

- Institutional Development Grant
- Collaborative Funding Grant
- Centers of Innovation



#### Biosciences Infrastructure Development:

- Numerous University-Affiliated Research Parks



#### Venture Capital, Entrepreneurship, and Other Innovation Related Programs and Initiatives:

- Biotechnology Innovation Grants
- Technology Enhancement Grant
- Phase I Matching Funds Program
- BATON Referral Network
- Small Business Research Loan
- Strategic Growth Loan
- Company Inception Loan
- Economic Development Award
- Carolina Research Ventures



#### Advanced Manufacturing:

- Golden Leaf Biomanufacturing Training and Education Center
- NCBioNetwork Capstone Center
- Biomanufacturing Research Institute and Technology Enterprise



#### STEM Workforce & Education:

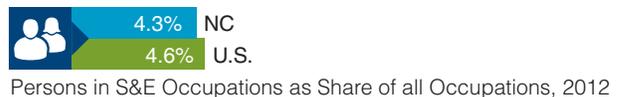
- NCBioImpact

## Impacts

Recent study of the impact of the bioscience venture financing made by NCBiotech found:

- Since 1989, 272 business loans made to 188 companies, 102 are currently active.
- These 102 companies directly employed 2,914 workers in 2016, with estimated revenues of \$2.8 billion. The full multiplier impacts on the NC economy generate \$4.3B in economic activity in the state, and create or support 12,666 jobs earning \$887 million in labor income.
- Annual revenues resulting from the total economic activity of these companies generate more than 5 times the tax revenue (an estimated \$73.6 million in state revenues in 2016) than the state's appropriation for NCBiotech.

## North Carolina by the Numbers



Source: National Science Foundation, Science & Engineering Indicators 2014.

## Comprehensive State Strategies to Support Biopharmaceutical Development

Over the past two decades North Carolina has become one of our nation's top bioscience industry states as a result of a strategic, focused, and sustained effort in North Carolina by industry, government, academia, and other key stakeholders to catalyze the emergence of biotechnology-related industry development.

The rise of the bioscience industry in North Carolina is a reflection of the state's long-term commitment to growing this industry. In 1984, when just a few companies were applying the new advances in a fledgling field known as biotechnology, the State of North Carolina recognized the transformative power of bioscience advancements and became the first state in the nation to target the biotechnology sector for economic development. North Carolina created the unique model of the **North Carolina Biotechnology Center (NCBiotech)** to be a catalyst and resource for sustaining economic development in this emerging field.

NCBiotech was formed as a private, non-profit organization charged with promoting biotechnology research, education, and business. Since its formation in 1984, NCBiotech has developed a comprehensive set of programs to fulfill the Center's mission to provide long-term economic and societal benefits to North Carolina through support of biotechnology research, business, education, and strategic policy statewide.

The Center administers a number of grant-related and other programs that:

- Provide direct support for bioscience R&D at universities
- Provide technology commercialization support
- Make loans to support bioscience entrepreneurs and start-up and emerging bioscience companies
- Provide job services
- Address business recruitment, retention and expansion.

The sustained effort of the biosciences development in North Carolina has resulted in a comprehensive set of programs supporting biotechnology research, business, and education involving active partnerships across the NCBiotech Center, the state's colleges and universities, industry associations, and economic development organizations.

North Carolina's approach to bioscience development continues to evolve. Advancing new strategic directions are embedded in the focus of the NCBiotech Center, which has been examining new areas of bioscience development for the state, such as nanobiotechnology, biodefense, and advanced medical technology.

## R&D Investment Programs and Initiatives

**NCBiotech's Institutional Development Grant** provides funding of up to \$200,000 for core equipment that will be used by multiple faculty members to enhance and grow the infrastructure for biotechnology research at North Carolina research institutions.

**NCBiotech's Collaborative Funding Grant**, which is jointly sponsored with the Kenan Institute for Engineering, Technology and Science at North Carolina State University, supports university-company research partnerships that will advance a company's technology toward commercialization by providing funding for a post-doctoral fellow or technician in a university laboratory to conduct a specific research project. The grant award is \$50,000 per year for up to 2 years with a company match of \$20,000 per year and a university in-kind contribution of \$20,000 per year.

**NCBiotech's Centers of Innovation** is designed to advance strategic public-private partnership and alliances across the state in targeted areas of biosciences development, bringing together North Carolina universities, industry partners, and other stakeholders. The goal is to develop alliances between academic and industry partners that will build off of regional research strengths and capacity statewide in a specific, targeted bioscience opportunity area to advance technology commercialization and new bioscience job creation. The program provides two phases of funding, with the first phase offering a planning grant to develop a business plan and the second phase to help implement the business plan. Only potential applicants who can demonstrate that they have a cohesive academic-industry consortium receive an invitation to submit an application for a Center of Innovation. One example of such a center of innovation is in the area of nanobiotechnology. The North Carolina Center of Innovation Network (NC COIN) is an independent, membership driven non-profit with a mission to foster innovation and economic development in the nanobiotechnology industry in North Carolina through networking, seminars and educational programs.

## Programs and Initiatives to Build Bioscience Infrastructure

North Carolina is the home of one of the nation's earliest and most successful research parks, Research Triangle Park. The state, in partnership with its colleges and universities along with private sector leaders, continues to advance research parks, and is now home to a broad network of parks offering wet lab space and other specialized facilities and services for bioscience-related companies including:

- Centennial Campus at North Carolina State University, Raleigh
- Wake Forest Innovation Quarter at Wake Forest University, Winston-Salem
- NC Research Campus of NC University System, Kannapolis
- CREST Research Park at UNC Wilmington, Wilmington
- WCU Millennial Initiative at Western Carolina University, Cullowhee

Other university-affiliated research park developments are being planned in North Carolina and should come on-line in the years ahead.

## Venture Capital, Entrepreneurship, and Innovation Development Programs and Initiatives

### Innovation Development

**NCBiotech's Biotechnology Innovation Grants (BIG)** support studies at North Carolina research institutions exploring the potential commercial applications of early-stage university life science inventions. Funding supports studies that yield a "go/no-go decision" regarding the pursuit of intellectual property protection and/or commercialization of the invention. Awards under the BIG program are for a maximum of \$100,000.

**NCBiotech's Technology Enhancement Grant** provides grants up to \$75,000 for North Carolina universities or other North Carolina research institutions to fund commercially-focused research studies to enhance the university's licensing position for a commercially promising technology. The proposed project will ideally incorporate study endpoints designed to meet key milestones defined by potential licensees or industry-experienced technology development advisors.

**Phase I Matching Funds Program** of North Carolina's Department of Commerce is designed to award matching funds to North Carolina businesses who have been awarded an SBIR or STTR Phase I award of 50% of the Phase I award, not to exceed \$50,000. Companies are limited to five such awards in total.

### Entrepreneurial Development

**NCBiotech's BATON Referral Network** fosters emerging North Carolina bioscience companies access to prequalified business service providers and CEO candidates representing a vast array of business and technical expertise through a searchable database. Service providers pledge to contribute services or provide preferential pricing for referrals coming through the BATON network for registered bioscience companies.

### Venture Financing

**NCBiotech's Small Business Research Loan** program provides loan financing of up to \$250,000 to advance the development of commercially viable technologies/products. This program supports companies in reaching specific and meaningful research milestones that could position them to obtain additional funding from private and public sources.

**NCBiotech's Strategic Growth Loan (SGL)** program is designed to help North Carolina life science product companies reach specific and meaningful milestones that will enable them to obtain further funding from investors and/or to commercialize their products. For most applicants, SGL awards of up to \$250,000 will be matched by an equal or greater investment from one or more organized angel groups or venture capital firms. For certain exceptionally well-qualified applicants that have a larger matching investment from a top-tier life science investment group, an SGL award of up to \$500,000 will be possible.

Both of these NCBiotech business loan programs are unlike traditional bank financing since they are made at earlier stages of a company's development when few others will invest in these companies, and reflects the expertise of NCBiotech in assessing specialized life science company development.

**NCBiotech's Company Inception Loan** program provides loans of up to \$75,000 for life science start-ups in North Carolina. The loans are intended to support activities at business inception to help companies position themselves for start-up and early-stage funding or partnering.

**Outcomes.** A recent study of the impact of the bioscience venture financing made by NCBiotech demonstrates the long-term return from these investments in supporting bioscience industry development.

- Since 1989, 272 business loans have been made by NCBiotech to 188 companies. Of the 188 companies that have received loans, 102 are currently active.
- These 102 companies directly employed 2,914 workers in 2016, with estimated revenues of \$2.8 billion. The full multiplier impacts of these 102 companies on the North Carolina economy generate \$4.3 billion in economic activity in the state, and create or support 12,666 jobs earning \$887 million in labor income.
- The annual revenues resulting from the total economic activity generated by these 102 companies funded by NCBiotech generate more than 5 times the tax revenue (an estimated \$73.6 million in state revenues in 2016) than the state's appropriation for NCBiotech of \$13.6 million.

**NCBiotech's Economic Development Award (EDA)** program works in collaboration with local community efforts to support life science company projects. The EDA program provides grants to local governments linked to job creation and retention milestones. The local government administers the grant and allocates the funding to the company for use in project-related investments. EDA grants awards are made in amounts of up to \$100,000 per project based on project job-creation estimates.

**Carolina Research Ventures (CRV)** was launched by UNC-Chapel Hill to focus on investing in University-sourced startups and other seed to early-stage companies seeking to develop or commercialize technology and inventions developed at UNC. The industries of focus for CRV investments includes the life sciences and specifically notes biopharmaceuticals. Initial investments are typically between \$100,000 and \$250,000 with follow-on investments as appropriate, throughout the company's development.

## Advanced Manufacturing Programs and Initiatives

North Carolina's colleges and universities offer several advanced manufacturing facilities for contract services and workforce training.

**Golden Leaf Biomanufacturing Training and Education Center (BTEC)** at North Carolina State's Centennial Campus houses 63,000 square feet of fermentation, cell culture, recovery, purification, and analytical lab space for training North Carolina State students and industry professionals in bioprocessing. BTEC also offers its space and expertise for protein production and purification, process/technology development,

and analytical testing/development, serving both industry and other academic labs. It operates under the auspices of the university's College of Engineering (COE). It features more than \$12.5 million of industry-standard equipment and a simulated cGMP (current Good Manufacturing Practice) pilot plant facility capable of producing biopharmaceutical products using cell growth and expression, recovery, and purification processes in a sterile environment. Undergraduates, graduate students, and working professionals come to BTEC for hands-on learning with the latest biomanufacturing technologies.

**NCBioNetwork Capstone Center**, offered by the North Carolina Community College System, is co-located at the BTEC in Centennial Campus. It offers a simulated industry cGMP environment for hands-on instruction. Four community college certificates are offered by the Capstone Center. Courses can be taken individually and focus on a variety of critical skill sets within areas importance to biomanufacturing: good manufacturing practices (GMP), aseptic manufacturing, operations in biotechnology processes, industrial microbiology, good laboratory practices (GLP), HPLC, and validation.

**Biomanufacturing Research Institute and Technology Enterprise (BRITE)** at North Carolina Central University (NCCU), provides 31,000 square feet of laboratory space for applied research in areas related to biomanufacturing and biotechnology, with a number of core facilities including:

- **Protein Expression, Purification and Formulation Core Facility** – Capable of expressing and purifying large quantities of recombinant proteins for biopharmaceutical research and investigating protein stability/aggregation using advanced techniques such as differential scanning calorimetry, self-interaction chromatography, dynamic light scattering, circular dichroism, etc.
- **Monoclonal Antibody Production Core Facility** – For production of monoclonal antibodies to be used in research and formulation studies. This Core generates and purifies monoclonal antibodies. Equipment includes a Fluorescence Activated Cell Sorting (FACS) system for the selection of high-affinity clones.
- **Drug Discovery Core Facility** – Assay development and high throughput screening (HTS) for drug discovery. The drug discovery core is a state-of-the-art HTS facility with over 450,000 compound small molecule chemical libraries.

# STEM Workforce & Education Programs and Initiatives

**NCBioImpact** is a joint undertaking of NCBiotech, the North Carolina Biosciences Organization, the North Carolina Community College System, and the University of North Carolina System. Its objective is to work to ensure that North Carolina can meet the talent needs of the biopharmaceutical sector. NCBioImpact was created in 2003 with a grant from the Golden Leaf Foundation, which invests North Carolina's tobacco settlement funds in economic development initiatives.

NCBioImpact includes three components:

- **BioNetwork** is a statewide initiative that connects more than 20 community colleges and includes specialized centers with training for specific aspects of biotechnology. It offers incumbent worker training, transitional worker training, and pre-employment classes on specific topics and skill sets, as well as supports the future biotechnology and life science workforce through teacher training and outreach.
- **Biomanufacturing Training and Education Center (BTEC)** is a specialized biomanufacturing training and education facility at North Carolina State University. The pilot-scale production plant provides advanced, hands-on training and education for students and current workers.
- **Biomanufacturing Research Institute and Technology Enterprise (BRITE)**, located at North Carolina Central University, provides degree programs and laboratories for scholars conducting research in several areas critical to biotechnology and biomanufacturing.