

North Carolina: A Biopharma Manufacturing Powerhouse



North Carolina has earned a distinguished reputation as a leading global biopharma manufacturing hub. As new products emerge to help patients with debilitating diseases, North Carolina is an excellent place to bring these important therapies to market quickly.

North Carolina's biopharma manufacturing sector, which includes biologics and pharmaceuticals, emerged in the mid-1990s as research and development programs from years prior began to yield commercial products. Educating citizens on the opportunities in biomanufacturing helped fill the talent pipeline. In the early 2000s, biopharma training organizations, including **North Carolina State University's Biomanufacturing Training and Education Center (BTEC)**, **North Carolina Central University's Biomanufacturing Research Institute and Technology Enterprise (BRITE)**, and the **North Carolina Community College System's NC BioNetwork** program were established. From 2004–2008, leading companies, including Merck, Novartis, and KBI Biopharma, expanded their biomanufacturing operations in the Research Triangle region.

More recent growth of this sector has been fueled by expanding product lines and new FDA approvals of innovative technologies. Today, the state's biopharma expertise spans vaccines, cell- and gene-based therapeutics, monoclonal antibodies, RNA/DNA products, recombinant proteins, regenerative therapies, and industrial enzymes.

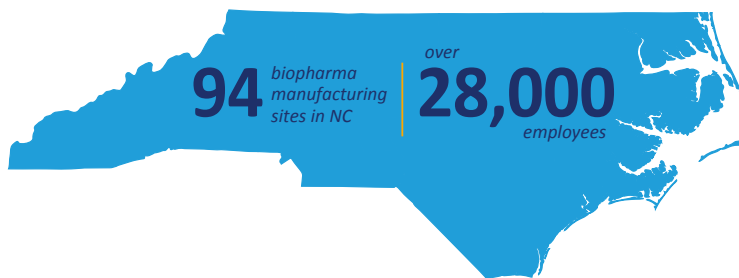


North Carolina's rich history in biopharma manufacturing began in the mid-1990s. This cluster continues to grow and flourish with more company expansions announced each quarter.

A Diverse, Established Cluster

From university spinouts to large pharmaceutical companies, North Carolina's biopharma manufacturing cluster is broad and diverse. These companies are leaning on North Carolina's deep expertise to transform research into commercially viable products that can be manufactured at scale. Below is a sample of biopharma companies with manufacturing operations in North Carolina. This list continues to grow.

- **Baxter Healthcare Corp.** has a large manufacturing facility in the Western North Carolina town of Marion, with more than 2,000 employees producing intravenous and peritoneal dialysis solutions, as well as empty containers and component parts for other Baxter facilities.
- **Biogen** has invested more than \$125 million in its RTP campuses, which support production of biologics, oral solid dose, and oligonucleotides, and will soon expand to include gene therapies.
- The **Fresenius Kabi** Center of Excellence for pre-filled syringes, located in Wilson, produces complex and critical drugs in ready-to-administer delivery systems.
- **Glenmark** chose North Carolina for its first U.S. biopharma manufacturing site to produce a variety of fixed-dose pharmaceutical formulations.
- **Grifols** is investing \$351.6 million in a new plasma fractionation facility and logistics center to help meet the growing demand for its plasma-derived medicines.
- **Merck** has invested nearly \$1.6 billion in its Maurice R. Hilleman Center for Vaccine Manufacturing in Durham, which produces vaccines for pediatric, adolescent, and adult patients.



Many biopharma manufacturing companies are located in and around Research Triangle Park, a central region named for three world-renowned universities—the University of North Carolina at Chapel Hill, Duke University and North Carolina State University—at its vertices. However, biopharma manufacturing expertise spans throughout the state.



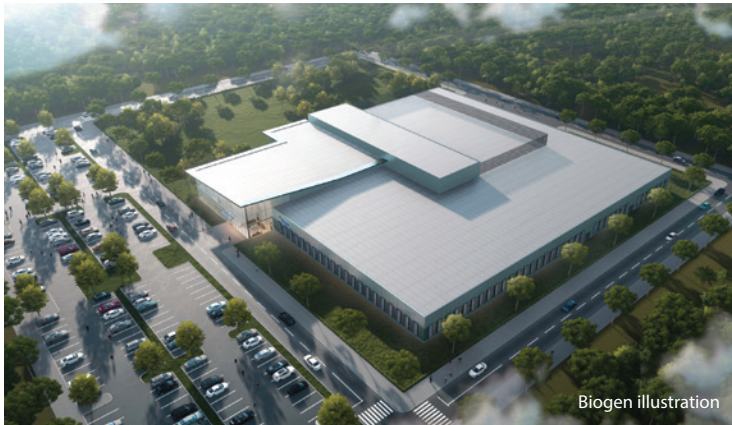
North Carolina has a growing number of contract development and manufacturing organizations (CDMOs) that are powering pharmaceutical discovery worldwide. Their services help pharmaceutical companies develop and produce lifesaving products, from formulation to testing to scale-up to regulatory compliance.

Here is a sample of CDMOs with major operations in North Carolina:

- Research Triangle Park-based **Catalent** has a Center of Excellence for Analytical Services for product development and manufacturing services of inhalation products.
- **FUJIFILM Diosynth Biotechnologies** is investing \$2 billion in a new biomanufacturing site in Holly Springs. The site will employ 725 people and will be the largest end-to-end facility for mammalian cell culture manufacturing in North America. This will be the company's second location in North Carolina.
- **KBI Biopharma**, headquartered in North Carolina, is investing \$150 million in a new commercial biologics manufacturing facility in Durham to support production for existing and future clients.
- **Lonza** focuses on producing hepatocytes for use in drug research at its Research Triangle Park site.
- In Greenville, **Thermo Fisher Scientific** is investing more than \$650 million to support development, production, and manufacturing of therapies for a range of diseases including cancer, heart disease, and blood clots.

A Diverse, Established Cluster *(continued)*

- **Novo Nordisk** operates three manufacturing facilities, including an active pharmaceutical ingredient site, in the Research Triangle region to meet the growing demand for injectable and oral diabetes products and obesity medicines.
- **Novozymes** chose North Carolina for its North American headquarters in 1979. It's one of the world's largest enzyme manufacturing sites.
- **Pfizer** leans heavily on its North Carolina facilities to produce critical products. It has one of the world's largest sterile injectable facilities in Rocky Mount and a new state-of-the-art manufacturing facility in Sanford to advance vaccines and gene therapies.
- **Seqirus**, the largest cell-based influenza vaccine producer in the world, employs more than 600 individuals in Holly Springs.



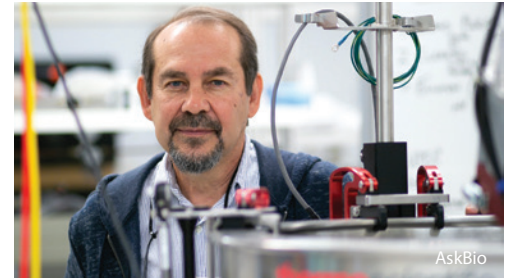
Biogen illustration

Rendering of Biogen's new RTP facility that will support gene therapy production for its clinical pipeline.



NCBiotech/Robin Deacle

Collectis team announcing plans for the company's first North American manufacturing facility in Raleigh.



Jude Samulski, Ph.D.

The state's gene- and cell-therapy sector is built upon world-class academic and corporate research and the largest concentration of clinical research organizations in the world. Pilot- and commercial-scale manufacturing capabilities bring therapies to market. Our talent pool rounds out North Carolina's strengths that fully support the growth of gene- and cell-therapy companies.

North Carolina's gene- and cell-therapy cluster was born in 1993, when adeno-associated virus pioneer Jude Samulski, Ph.D., helped to create the **Gene Therapy Center at the University of North Carolina at Chapel Hill**. The technology was brought to life in a North Carolina university, and to commercial reality by **Asklepios BioPharmaceutical (AskBio)**, a Research Triangle Park company co-founded by Samulski, life sciences attorney Sheila Mikhail, CEO, and Xiao Xiao, Ph.D., also a world-leading scientist and gene therapy pioneer. Today, the Gene Therapy Center continues to contribute to cutting-edge therapies through two core facilities—the **UNC Vector Core** and **Human Applications Laboratories**—which facilitate the progression and translation of gene therapy research from the laboratory bench to Phase 1 clinical trials to treat human disease.¹

North Carolina's gene- and cell-therapy cluster continues to grow with leading companies such as **Astellas Gene Therapies, Beam Therapeutics, Biogen, CARsgen Therapeutics, Cellectis, Jaguar Gene Therapy, Novartis Gene Therapies, Pfizer, Precision BioSciences, StrideBio** and **Taysa Gene Therapies**.

¹UNC Medical School, Gene Therapy Center, 2021. <https://www.med.unc.edu/genetherapy/about-us/>

A Thriving Ecosystem for Biopharma Manufacturing

Biopharma manufacturing companies succeed in part because of North Carolina's life sciences ecosystem. Emerging and established companies alike can benefit from the connectivity among North Carolina's specialized organizations, top-tier universities, and statewide medical experts.

Unlike any other state, North Carolina has a resource dedicated to the growth of its life sciences sector. Since 1984, the **North Carolina Biotechnology Center (NCBiotech)** has taken a unique approach to statewide life sciences economic development and has the capabilities to guide companies through the challenges they encounter at all stages of company growth. Headquartered in the Research Triangle Park, NCBiotech has funding and mentoring programs, workforce development initiatives, and an in-house team of analysts, among other relevant life sciences experts.

NCBiotech organizes more than 25 exchange groups that bring together academic, government, and life sciences professionals. The **Biomanufacturing and Process Development (BPD)** exchange group meets six to eight times per year providing a forum for process development and manufacturing professionals to discuss bioprocessing issues.

North Carolina Biosciences Organization (NCBIO) is the trade association for North Carolina's life sciences. Members include companies and research institutions working in the pharmaceutical, medical device, diagnostic, clinical research, and agricultural biotechnology sectors, as well as firms and nonprofits that provide support services to life sciences companies. NCBIO organizes regular meetings of the **Biotech Manufacturers Forum** to help late-stage clinical and commercial-stage biopharma manufacturing companies and related firms share information and address common concerns.

The **National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)** is a national public-private consortium dedicated to advancing biopharmaceutical manufacturing innovation. North Carolina universities and community college system are leveraging NIIMBL membership to further amplify their strengths via technical and workforce development efforts, access to shared facilities, and facilitated teaming to better enable engagement among academic, industry, and federal groups.



NCBiotech/Susan P. Murray

NCBiotech brings together professionals for collaboration and engagement.



NCBiotech/Susan P. Murray

BPD members tackle industry's most challenging bioprocessing issues.



NCBiotech hosts a variety of events for both emerging and established companies.

A Thriving Ecosystem for Biopharma Manufacturing (continued)

North Carolina's life sciences ecosystem is the foundation for the state's strong biological and pharmaceutical manufacturing cluster. Pharma giants such as Biogen, Eli Lilly, Grifols, GSK, Novo Nordisk, Novartis, Merck, Pfizer, and Seqirus established operations in North Carolina because they were confident in the availability of specialized resources to support their growth. From industry-driven training programs to funding opportunities and abundant physical infrastructure, North Carolina is well-positioned to support growing companies in this highly specialized field.

Currently in North Carolina, biopharma production happens in a cluster of 790+ life sciences companies, including 140 sites dedicated to production and manufacturing. Of the 70,000+ total life sciences employees statewide, more than 28,000 skilled professionals support the manufacture of pharmaceuticals, vaccines, monoclonal antibodies, and more at 94 sites. More than a third of the state's life sciences jobs are dedicated to our thriving manufacturing sector, ranking North Carolina among the top states in biological product manufacturing employees in the U.S.

In addition to the myriad manufacturing capabilities, North Carolina has expertise in clinical trial design, patient recruitment, data management, and regulatory requirements. Contract research and testing industry founders IQVIA, Labcorp, and PPD call North Carolina home as do innovative leaders Rho and Syneos Health.

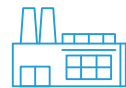


Burlington, North Carolina-based Labcorp Drug Development assists pharma and biotech companies with nonclinical, preclinical, clinical and commercialization services.

N.C.'s Life Sciences Ecosystem

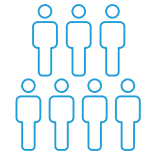
790+

life sciences companies



70K

employees



including

94



biopharma production and manufacturing sites



28,000

employees working at these sites



one of the
top states

in biological product manufacturing employees

Sources (above): NCBiotech Life Science Intelligence; U.S. Bureau of Labor Statistics, Quarterly Census of Employment and Wages for NAICS code 325414

Talent to Drive Creativity and Commercialization

Perhaps our state's biggest advantage is our ever-evolving, customizable, and industry-driven **talent infrastructure**. Companies choose North Carolina time and again for our robust workforce. A workforce of more than 70,000 grows each year, fueled by more than 4,900 bachelors, masters and doctoral degree graduates in biological and biomedical sciences from local universities and colleges. The extensive North Carolina Community College System, working closely with industry, offers certificate and associate degree programs as well as customized training to meet companies' specific needs.

NCBioImpact combines the resources of North Carolina's university and community college systems to meet the growing demands of the biotechnology and pharmaceutical industries. The training programs partner closely with NCBiotech, NCBIO, the North Carolina Department of Commerce, and industry to form a unique academic, industry and government collaborative.

Key partners include BTEC at North Carolina State University; BRITE at North Carolina Central University, and BioNetwork, the North Carolina Community College System's statewide initiative providing life sciences support to all colleges.

North Carolina is home to a robust network of local community colleges and public and private colleges and universities.

University-level training is available at programs throughout the state including **BTEC**. Undergraduates, graduate students, and working professionals, including FDA inspectors, train at BTEC for hands-on learning with the latest biopharma manufacturing technologies. This facility includes a cGMP pilot plant and industry-standard equipment that helps prepare students for on-the-job, real-world application of the technologies.

In Durham, **BRITE** offers undergraduate and graduate degree training with a strong focus on research and drug discovery. Students move through curricula designed with industry input to ensure that graduates learn up-to-date techniques.

In addition to North Carolina's globally recognized universities, there are **58 community colleges** located across the state. The life sciences training initiative of the N.C. Community College System, **NC BioNetwork**, provides support for students looking to advance their career. A key asset in the community college system, NC BioNetwork developed the **BioWork certificate program** to prepare participants for technician and operator roles at biotechnology, pharmaceutical, and chemical manufacturing companies (see sidebar). NC BioNetwork collaborates

NC BioNetwork's flagship course BioWork teaches foundational skills needed to enter the biomanufacturing workforce in a process technician role.

Ten community colleges across the state offer the BioWork certificate program, a 136-hour course that teaches the science and bioprocessing techniques required for entry-level positions. Designed for people with a wide range of educational backgrounds, the course provides a comprehensive understanding of current Good Manufacturing Practices, current chemistry for process manufacturing, process flows, fermentation, cell growth and more. Visit ncbionetwork.org/biowork for details.



NC BioNetwork prepares students for entry-level positions in biopharma manufacturing.

58 community colleges



10 community colleges offering BioWork



Talent to Drive Creativity and Commercialization (continued)

with local community colleges to develop **customized training programs** with companies that are looking to grow their talent pipeline or train their future leaders. Companies such as Grifols, KBI Biopharma, Thermo Fisher, Pfizer, and Merck lean on N.C.'s community colleges for customized training solutions.

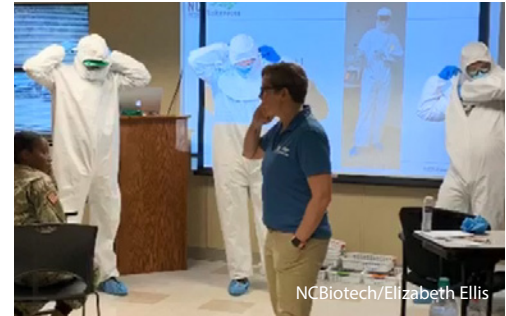
NCBiotech champions workforce development initiatives to continue to expand the state's talent pipeline. Its programs engage individuals at various points in their careers including members of the military community and graduating high school seniors. Other programs work in underserved communities to increase diversity in the workforce pipeline and attract nontraditional workers to these jobs.

The **NCBiotech Military Outreach and Veterans Engagement Program** offers a pathway for those transitioning from the military to springboard to new careers in biopharma manufacturing. The program connects service members in transition, veterans, and military spouses to learning pathways and careers in the life sciences. With many shared values – discipline, leadership, adaptability, attention to detail, innovative thinking, teamwork, and communication – engaging our military attracts a well-trained population to support biopharma's growing talent needs.

The **NCBiotech Pharma K12 Workforce Development Training Initiative** engages high school graduates in eastern North Carolina, giving them a pathway to rewarding and well-paying life sciences jobs. High school seniors who meet specific math and science requirements are provided with a 2.5-day training program in a pilot-scale manufacturing environment with laboratory equipment to learn oral solid dosage theory and manufacturing techniques. This industry-led initiative creates a unique pipeline to fill jobs at local pharmaceutical companies.

The **North Carolina Pharmaceutical Services Network** was created as companies in eastern North Carolina expanded. The partnership between Pitt Community College and East Carolina University provides GMP/GLP courses, analytical services training, and a pilot-type manufacturing environment to develop company-specific skills.

The **Bio Jobs Hub** is a resource for individuals looking to enter the industry, make a career transition, or simply learn more about opportunities and training in North Carolina's growing biopharma manufacturing industry. Visit biojobshub.com for details.



NCBiotech's Military Outreach and Veterans Engagement Program has created pathways for those transitioning from the military to springboard to a new career in biopharma manufacturing.



High school student learn valuable skills in the Pharma K12 Workforce Development Training program.



The Bio Jobs Hub educates both scientists and non-scientists on job opportunities and training in North Carolina's growing biopharma manufacturing industry.

Exceptional Business Climate and Quality of Life

North Carolina has an advantageous business climate and offers an **exceptional quality of life** to its residents.

Compared to other life sciences hubs, North Carolina's **cost of doing business is lower**. N.C. boasts the lowest corporate income tax rate at 2.5%, which will be reduced to zero in 2030. Utility costs are below the national average, and infrastructure and water are abundant here. For biopharma manufacturing specifically, labor and operating costs in North Carolina's Research Triangle region are the lowest of all major U.S. hubs. In fact, it is 24% less expensive to operate in North Carolina than the Boston and San Francisco areas.²

Targeted, performance-based **incentives** are provided through the North Carolina Department of Commerce for companies expanding in the state. Commerce works closely with the Economic Development Partnership of North Carolina to support business growth in the state.

North Carolina's **prime mid-Atlantic location** provides easy access to millions of people. The state's infrastructure includes four international airports, the largest consolidated railroad system in the country, and the second-largest highway system with more than 90,000 miles of road.

As a **culturally rich state**, North Carolina has something for everyone. The iconic Blue Ridge Mountains. Hundreds of miles of coastline dotted with lighthouses. Bustling cities. The moderate climate includes mild winters, warm summers, and enjoyable spring and autumn seasons. Arts and culture, professional and nationally ranked sports teams and a welcoming cost of living round out a first-rate business climate, making North Carolina the optimal destination for businesses.

**Top State
for Business Climate**
Site Selection Magazine, 2020, 2021

Prosperity Cup Winner
Site Selection Magazine, 2021, 2022

Best State for Business
CNBC, 2021

**North Carolina:
State of the Year**
Business Facilities, 2020

²The Boyd Company Inc. "Comparative Biomanufacturing Industry Operating Costs." 2019

[Learn more at **ncbiotech.org/biopharmamanufacturing**](https://ncbiotech.org/biopharmamanufacturing)

North Carolina Biotechnology Center®

15 T.W. Alexander Drive | Research Triangle Park, NC 27709-3547
Asheville · Charlotte · Greenville · Wilmington · Winston-Salem