

Bio manufacturing in North Carolina

Biotechnology companies throughout North Carolina are using living cells to produce medicines, vaccines, diagnostics, enzymes, amino acids, veterinary medicines and related products that improve our lives, create jobs and boost our economy. The making of these biological products is called biomanufacturing or bioprocessing.

“North Carolina’s business climate, low tax burden and high-skill work force make this region an attractive place for industries like biotechnology and biomanufacturing.”

— NORTH CAROLINA GOVERNOR
MIKE EASLEY

North Carolina is a national leader in this growing industry. Sixteen companies have biomanufacturing operations in North Carolina, and at least 30 other companies are engaged in related manufacturing of pharmaceuticals, diagnostics and medical devices. These companies employ an estimated 20,000 people. In addition, tens of thousands of North Carolinians work in companies that provide goods and services in support of biomanufacturing and related pharmaceutical manufacturing.

Biomanufacturing jobs pay well. Entry-level bioprocess technicians typically earn \$25,000 to \$30,000 and move up to \$50,000 after five years. The average salary for these positions in North Carolina is well above the average pay for other manufacturing jobs, which are generally declining in number. In 2003, the average annual wage for employees at biopharmaceutical manufacturing businesses in North Carolina was \$70,567, according to the N.C. Employment Security Commission.

A growing industry

As more biopharmaceuticals and other products of biotechnology move from the laboratory to the marketplace, the demand for biomanufacturing capacity is expected to increase. North Carolina is well positioned to capture a large share

of this growing market. The North Carolina Biotechnology Center, in partnership with the state Department of Commerce and other organizations, is aggressively promoting the retention, expansion, and attraction of biomanufacturing companies.

In recent years three major biopharmaceutical manufacturers — Diosynth RTP, Biogen Idec and Merck & Co. — were brought to North Carolina. Diosynth, one of the world’s largest contract biomanufacturers, carries out process development and drug production for biopharmaceutical companies. Biogen Idec, which operates one of the world’s largest cell-culture facilities, manufactures the multiple sclerosis drug Avonex® and the psoriasis drug Amevive®. Together, these two companies have created about 1,000 new jobs for North Carolinians, and both continue to expand. Merck broke ground in October 2004 for a vaccine-manufacturing plant in Durham that is expected to employ at least 200 people when it comes online in 2008.



MANUFACTURERS OF PHARMACEUTICALS AND DIAGNOSTICS

COMPANY	PRODUCTS	LOCATION
Alpharma USPD	Pharmaceuticals	Lincolnton
Banner Pharmacaps	Pharmaceutical gel caps	High Point
Baxter Healthcare IV Systems	Intravenous solutions	Marion
Bespak	Drug-delivery devices	Apex
BioMerieux	Diagnostic kits	Durham
Carolina Medical Products	Ointments, powders, non-injectable solutions	Farmville
Cytosol Ophthalmics	Sterile balanced salt solutions	Lenoir
Eisai Pharmatechnology	Alzheimer’s drug	RTP
Eon Labs	Broad range of products in solid, oral dosage forms	Wilson
GBF Medical Group	Diagnostic kits	Greensboro
GlaxoSmithKline	Drug formulation and packaging	Zebulon
Hospira	Injectable solutions and drugs	Rocky Mount
Leiner Health Products	OTC pharmaceuticals	Wilson
Medtox Diagnostics	Drug testing kits	Burlington
Merck Manufacturing	Pharmaceuticals	Wilson
Microban Products	Anti-microbial polymeric additives	Huntersville
NittaGelatin USA	Gelatin powder for pharmaceuticals and food	Fayetteville
Novo Nordisk Pharmaceutical Industries	Human insulin formulation and sterile filling	Clayton
Purdue Pharmaceuticals	Pain relief and asthma drugs	Wilson
Shionogi Qualicaps	Pharmaceutical gel caps	Whitsett
TriPath Imaging (+ TriPath Oncology)	Medical reagents	Burlington (Durham)
Tyco Healthcare Mallinckrodt	Acetaminophen	Raleigh
Vintage Pharmaceuticals	Pharmaceuticals	Charlotte

Other biomanufacturing plants with established operations in North Carolina also have expanded. They include Wyeth Vaccines, which operates one of the world’s largest vaccine facilities in Sanford, and Newco Plasma Services Biotherapeutics (formerly Bayer), which operates the world’s largest blood fractionation plant in Clayton. Several new biomanufacturing plants also are coming online in North Carolina. In 2004 Biolex opened a therapeutic protein biomanufacturing plant in Pittsboro, Embrex dedicated a poultry vaccine plant in Laurinburg, AlphaVax announced plans to build a human vaccine plant in Durham, and KBI BioPharma, a contract biomanufacturer, opened biopharmaceutical development services laboratories in Durham.

Preparing the work force

Biomanufacturing plants are complex operations that typically run 24 hours a day, seven days a week, under stringent regulation by the Food and Drug Administration. Having highly trained technicians who can operate these plants efficiently and in compliance with FDA rules is crucial to the growth and success of biomanufacturing companies.

CONTRACT MANUFACTURING SERVICE PROVIDERS

COMPANY	SERVICES	LOCATION
AaiPharma	Broad range of analytical and manufacturing services	Wilmington
Cardinal Health	Analytical services	Morrisville
DSM Pharmaceuticals	Bulk chemical synthesis, fill and finish, and aseptic filling services	Greenville
Hospira	Sterile solutions and emulsions for infusion and nutrition therapy	Clayton
Harmony Labs	Development and manufacture of topical pharmaceuticals and cosmeceuticals	Landis
LabCorp	Clinical laboratory services	RTP, Burlington
Metrics	Analytical services	Greenville
Pharmacore	Organic chemical synthesis	High Point
Pisgah Labs	Organic chemical synthesis	Pisgah Forest

Industry, government and academia are working to plan and implement a nationally unique training program through the North Carolina Biomanufacturing and Pharmaceutical Training Consortium, a partnership of universities, community colleges, industry and the Biotechnology Center. The program will address training across all the relevant scientific, technical and engineering disciplines at all levels from Certificate or Associate Degree to Ph.D. The goal is to train 2,000 to 3,000 students each year.

North Carolina State University in Raleigh will build and equip a \$36 million Biomanufacturing Training and Education Center (BTEC) scheduled to open in January 2007. Plans call for a 100,000-square-foot plant that will provide hands-on experience in a pilot scale, Good Manufacturing Practices (GMP) environment similar to an industrial setting. North Carolina Central University in Durham will receive \$19.1 million for the Biomanufacturing Research Institute and Technology Enterprise (BRITE) to open in January 2007. BRITE will include a 65,000-square-foot research laboratory and classroom facility that will conduct research, teach and train at all levels in biotechnology and biomanufacturing. The North Carolina Community College System will receive \$9.4 million for BioNetwork, a network of six centers statewide that will train workers in biotechnology, pharmaceutical and life sciences and will channel students into the BTEC and BRITE programs for additional training.

Funding is being provided by the non-profit Golden LEAF, a foundation that underwrites economic development activities using half of the state’s tobacco settlement money. Golden LEAF committed \$60 million in 2003. The General



Building a biomanufacturing community

The state's work force training initiative is part of a highly capable infrastructure that supports the biomanufacturing industry in North Carolina and makes the state an attractive location for biomanufacturing companies. The biomanufacturing community includes several architecture,

"We're determined that North Carolina will have the world's best-trained work force for biomanufacturing."

— **DR. LESLIE ALEXANDRE,**
PRESIDENT AND CEO
NORTH CAROLINA
BIOTECHNOLOGY CENTER.

construction, engineering, instrumentation and consulting firms that design, build, upfit and validate bioprocessing plants in compliance with FDA requirements. It also includes a dynamic chapter of the Society of Life Science Professionals, a large and active chapter of the International Society of Pharmaceutical Engineers, and a Bioprocessing and Process Development Focus Group. The Focus Group, sponsored

by the Biotechnology Center, provides a dedicated forum for process development scientists and engineers in the state to discuss issues, challenges and developments in biomanufacturing. Other specialized networking groups for entrepreneurs and scientists further enrich the intellectual infrastructure.

BIOMANUFACTURERS

COMPANY	PRODUCTS	LOCATION
Ajinomoto USA	Amino Acids	Raleigh
AlphaVax	Vaccines	Durham
Archer Daniels Midland	Citric acid	Southport
Argos Therapeutics	Therapeutic vaccines	Durham
Biogen Idec	Multiple sclerosis and psoriasis drugs	Research Triangle Park
Biolex	Therapeutic proteins	Pittsboro
Corn Products International	High-fructose corn syrup and starch	Winston-Salem
Diosynth RTP	Contract biopharmaceutical manufacturing	Research Triangle Park
Embrex	Poultry vaccines	Laurinburg
Greer Laboratories	Allergenic extracts, vaccines	Lenoir
KBI BioPharma	Contract biopharmaceutical manufacturing	Durham
Merck & Co.*	Vaccines	Durham
MWG	Synthetic nucleic acids	High Point
Newco Plasma Services Biotherapeutics	Blood and plasma-related therapeutics	Clayton
Novozymes	Industrial enzymes	Franklinton
Wyeth Vaccines	Vaccines	Sanford

* Merck broke ground in October 2004 with a 2008 completion date.

Assembly is expected to provide ongoing operational funds. Industry is providing millions of dollars of in-kind services and equipment.

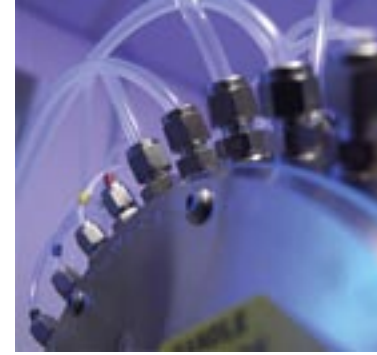
In addition to this training initiative, the Biotechnology Center has worked with industry and the North Carolina Community College System to develop the BioWork® course for training entry level bioprocess technicians in bioprocess, pharmaceutical, and chemical manufacturing. This 128-hour course, taught by the community colleges, covers basic science, cGMP, and manufacturing technology, giving students the background they need to learn quickly and effectively on the job. The course is offered to the public and is used by companies for in-house training of new hires and incumbent workers.

Several community colleges have Associate of Applied Science degree programs in biotechnology; bioprocess, chemical, and pharmaceutical manufacturing technology; and laboratory technology. And many university departments across the state have B.S. degrees or areas of concentration in all the foundational disciplines supporting bioprocess and pharmaceutical manufacturing.

The state's training initiatives have earned wide recognition for North Carolina's biotechnology work force. The Milken Institute's 2004 Biotech Index report ranked the Research Triangle area No. 1 in the nation in human capital and biotechnology work force.

Contact us

For more information about biomanufacturing opportunities in North Carolina, contact Dr. Ken Tindall, Senior Vice President for Science and Business Development. For information on work force training, contact Dr. Kathleen Kennedy, Vice President of Education and Training.



Biomanufacturing

A HIGH GROWTH INDUSTRY
FOR NORTH CAROLINA'S
21ST CENTURY ECONOMY



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04-081 CA 01/2005