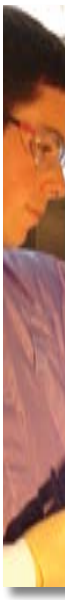
Biotechnology: An Industry for the Future

Environmental technicians at Novozymes North America in Franklinton, North Carolina, recycle nutrient-rich waste from manufacturing processes, spreading it in carefully controlled amounts as fertilizer on nearby fields. In the biotech future, more and more industrial chemical processes will rely on renewable resources instead of petroleum.



OPPORTUNITIES

Education for Biotechnology Opens Many Doors

In North Carolina, there are now nearly 20,000 people working in biotechnology companies. In addition, approximately 60,000 more are working in traditional chemical and pharmaceutical companies and specialty firms that provide services such as clinical trials management or engineering. All these companies may employ people with similar education and training in science, engineering, or manufacturing technology.

Completing a specialized biotechnology program at a community college or university opens many doors. Upon graduation, you will likely have many employment opportunities in the biotechnology industry, and in a broad group of bioscience and chemical companies employing individuals with similar sets of skills.

"...it is important to remember that biotech is the one industry that's poised to grapple with every major human and environmental challenge, from global hunger to global warming..." — G. Steven Burrill, *Biotech 2003 (Life Sciences: Revaluation and Restructuring)*

What Is Biotechnology?

It's in the news a lot and, because North Carolina is one of the nation's leading states in biotechnology, you may have seen headlines about new companies and jobs. But in fact, biotechnology has been around a long time.

Traditional biotechnology was (and still is) the use of living organisms to solve problems and make useful products. Domesticating crop plants and farm animals through selective breeding, and using yeast to make bread rise and produce wine are examples of traditional biotechnology.

New biotechnology: the use of living cells and their molecules to solve problems and make useful products.

New biotechnology is based on scientific advances over the last 50 years that have enabled us to understand how living organisms work—and how they can work for us. The key knowledge is an understanding of cells, the basic units of life, and—at a still deeper level—the molecules that make up cells.

Now, our understanding of how cells work makes it possible to create new varieties of plants with better nutrients for our diet, and the traditional fermentation processes used to make wine or beer have been re-tooled to produce cutting-edge pharmaceuticals for previously incurable diseases.

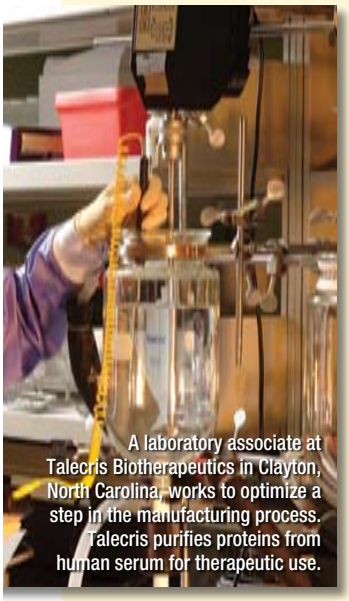
Biotechnology in Industry

When we use the term "biotechnology company" in this publication, we mean a company that uses biotechnology tools in its work. Since these tools can be used wherever living things are involved—and even where you might not think living things are involved—there is a broad range of industries where you might work in biotechnology.

You might work in:

- A pharmaceutical company developing new ways to cure cancer
- A chemical company making plastic from corn instead of petroleum
- An environmental company finding new microorganisms to clean up oil spills
- An agricultural company developing drought-resistant crops
- An energy company using fermentation to make ethanol for fuel.

A process technician inspects a bioreactor used to grow cells that produce a pharmaceutical product.

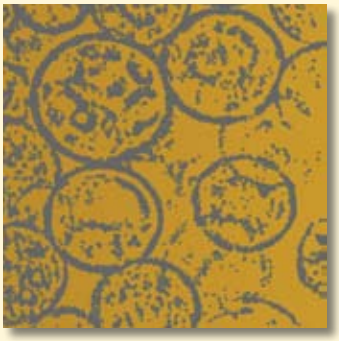


A laboratory associate at Talecris Biotherapeutics in Clayton, North Carolina, works to optimize a step in the manufacturing process. Talecris purifies proteins from human serum for therapeutic use.

Biotechnology's Toolbox

Biotechnology is not just one technology, but many. Biotechnology is a toolbox filled with many different kinds of living cells and their component molecules, and different ways to use them. Because there are millions of different species of plants, animals, and microorganisms in the world, each having cells and molecules with unique characteristics, there are a lot of potential tools in this toolbox! This is why biotechnology is so powerful and can be applied in so many different ways.

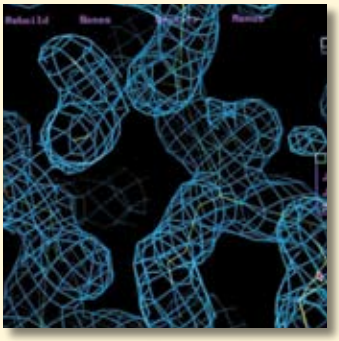
There are three basic kinds of biotechnology tools.



1. Working with Cells

A cell is the smallest unit of life. Some organisms (like yeast) have only a single cell; animals and plants can be made up of billions of cells. A typical human cell is less than a tenth the size of the period at the end of this sentence. Yet a single cell contains billions of molecules of many different kinds. You can think of a cell as a tiny chemical plant in which thousands of chemical reactions are going on every minute. This complex chemistry is what makes cells useful. For example, we can use chemical reactions in cells to break down pollutants or to synthesize antibiotics to cure infections.

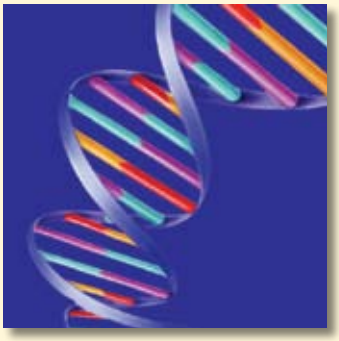
While a single cell can't produce enough of a product such as an antibiotic to do any good, we can grow billions of cells in bioreactors. This is called bioprocessing, and people who work in this field need to know biology, engineering, and manufacturing technology.



2. Working with Proteins

Many of the molecules in cells are proteins. These are the molecules that actually do the chemical work inside a cell and make it useful. Many of these proteins are enzymes. Even a simple cell such as a bacterium contains about 2,000 different proteins, each one with a unique job. When we use cells in a particular way—for example, to clean up an oil spill—we are actually using the enzymes made by the cells.

When we grow cells to make a useful product, the product is often a protein molecule. Protein products range from the enzymes added to laundry detergents, to insulin for diabetics, to vaccines used to prevent disease. Chemists, biochemists, and molecular biologists study the intricate structure of protein molecules and develop new ways to use these molecules.



3. Working with Genes

You probably know that DNA is the molecule responsible for inheritance. And you know from crime shows on TV that parts of our DNA molecules are unique to each individual. The sequences of chemical building blocks strung together to make up a DNA molecule are instructions, or blueprints, for a cell. These instructions, or genes, tell the cell how to make each of its proteins.

The DNA instructions are "written" in a chemical language called the genetic code. Because we have also learned how to change the code in DNA molecules, we can give a cell new instructions, telling it how to make the protein we want or how to do some other job. This is called genetic engineering. For example, geneticists have inserted the gene for a human protein called interferon into hamster cells that can be grown in bioreactors. The interferon is used to treat multiple sclerosis.

Biotechnology at Work

Because biotechnology can be used by many different companies, people who pursue the appropriate education, training, and skills to work in biotechnology will have many exciting career options.

Many industries are finding uses for the new tools provided by biotechnology. The health care industry is developing better ways to diagnose, treat, and prevent disease. The food and agriculture industries are rapidly adopting the tools of biotechnology. The "third wave" of biotechnology applications is just beginning to emerge in energy and the environment, where living cells and their molecules can help us develop new methods to clean up our environment, detect environmental contamination, and reduce our dependence on petroleum.

In addition to industry, biotechnology's toolbox is utilized in university research institutions and government agencies, such as the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the National Institutes of Health (NIH), the Department of Agriculture (USDA), the Federal Bureau of Investigation (FBI), and similar state agencies.

And There's More...

- Forensic scientists use DNA analysis and other biotechnology tools to solve crimes.
- Scientists around the world are collaborating to store DNA samples of endangered species and preserve the biodiversity that would be lost if these species became extinct.
- A protein that can absorb and degrade chemical nerve agents could become a new defense against bioterrorism.

Many beneficial applications of biotechnology are outlined in this publication. Nonetheless, some applications remain controversial. Throughout history, people often have been uncomfortable with new technologies. While technologies are not in themselves good or bad, sometimes a *particular application* of a technology concerns people. They may conclude that all applications of a specific technology are bad, overlooking many cases in which it can do great good. Before making decisions about a particular application, it is important to carefully study the scientific facts, the economic, sociological, and environmental balance of risks and benefits, as well as other ethical or legal issues that may be involved.

FIGHTING DISEASE

FASTER DIAGNOSIS: Biotechnology has made it possible to diagnose strep throat in minutes, rather than days. Some types of cancer can now be diagnosed with a simple blood test, rather than surgery.

NEW TREATMENTS: Biotechnology delivered the first new treatment for multiple sclerosis in over 20 years and the first new therapy for cystic fibrosis in over 30 years. In the future, defective genes or damaged cells may be repaired or replaced through the use of biotechnology.

BETTER PREVENTION: New vaccines help prevent hepatitis, meningitis, and influenza. New vaccines in food may eliminate the need for a trip to the doctor and a shot.

Protecting Babies And Children

Wyeth Vaccines, a business unit of Wyeth Pharmaceuticals, is dedicated to making life-saving vaccines, including those that eliminated smallpox and polio from the United States. Their Sanford, North Carolina, facility is continuing this legacy.

In the last decade, Wyeth's vaccines for meningitis, pneumonia, blood infections, and bacterial infections have significantly reduced infant and childhood mortality from these diseases around the world. Since Wyeth introduced its pneumonia vaccine for infants and toddlers, the incidence of the disease in children under two has declined by almost 80%.

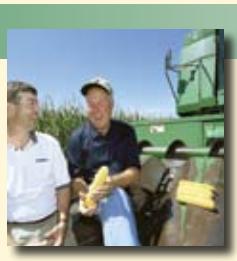
Approximately 1,500 people work at Wyeth's 325,000-square-foot facility in Sanford.

FEEDING THE WORLD

HARDIER CROPS: Innovative biotechnology solutions are creating crops that are more resistant to insects, diseases, and harsh weather, increasing U.S. farm income by more than $1.5 billion a year.

HEALTHIER ANIMALS: Biotechnology-engineered vaccines are available for parasites and infectious diseases. In the future, it may be possible to breed animals naturally resistant to parasites and disease.

BETTER FOOD: One of the first biotechnology foods was a tomato that could ripen on the vine for better flavor and still remain firm for shipping. Biotechnology can make food safer by reducing naturally-occurring toxins and allergens, as well as enhancing nutrient content and flavor.



Helping Farmers Prosper

Syngenta Biotechnology is a division of an international agricultural company committed to sustainable agriculture.

Sustainable agriculture combines different methods to make agriculture both profitable and environmentally sound. By helping farmers get more out of their existing farmland through improved crops, Syngenta's products help farmers remain profitable while preventing deforestation.

Syngenta Biotechnology has developed a new type of corn that resists the corn borer, one of the most destructive crop pests in the world. It also markets soybeans that reduce the cost and environmental impact of weed control. The company employs approximately 250 people in Research Triangle Park, North Carolina.

SAVING OUR ENVIRONMENT

NEW FUELS: New "designer" enzymes from biotechnology labs are being used to manufacture bioethanol, a non-polluting fuel made from plant material that can be used in place of gasoline. Using renewable resources such as corn or agricultural waste to produce a cleaner fuel is a win-win benefit for the environment.

CLEANER AIR, WATER, AND SOIL: Plants and bacteria can be used to safely clean up oil spills and remove toxic chemicals and other pollutants from our air, water, and soil.

NEW MATERIALS: Researchers have genetically engineered cells so that they can use plant sugars instead of petroleum-based chemicals to create biodegradable plastics and polyesters. "Green plastics" made from corn are being used to manufacture packaging materials, clothing, and bedding.

Enabling Cleaner Manufacturing

Novozymes North America, Inc. uses environmentally friendly manufacturing processes to make environmentally friendly products. Novozymes harnesses the chemical productivity of microorganisms through fermentation to create over 600 enzyme products, many of these at its facility in Franklinton, North Carolina. These products are used in industry worldwide for everything from processing cotton to making "stone-washed" denim to brewing beer and treating wastewater.

Novozymes products used in treatment of cotton textiles result in a 25 percent to 30 percent reduction of the process's impact on the environment by lowering energy consumption and the release of acid wastes. In 2005, Novozymes received the Environmental Protection Agency's (EPA) Presidential Green Chemistry Challenge Award for their innovative use of biotechnology to make healthier fats and oils.

Novozymes employs about 400 people at its facility in Franklinton.

A Career with Many Choices

Biotechnology offers a wider range of career choices than many other fields. You can choose among different types of employers, different roles within an organization, different work environments, and different paths for future advancement.

Salaries

Whatever career path you choose, you can often earn a higher salary if you pursue that career in the field of biotechnology. That's because biotechnology companies often pay competitive salaries to attract and retain employees who have the specialized knowledge and skills they require. The career profiles on pages 10 through 21 provide information on salaries for specific careers in biotechnology.

A packaging technician in a clean room visually inspects vials for potential defects before they are filled with a sterile injectable pharmaceutical product.

A Choice of Employers

The knowledge and skills required for a job in biotechnology are highly transferable. In industry, you can work for a pharmaceutical, medical device, food, agricultural, or chemical company. You might also work for a government agency or in a university.

A Choice of Work

Biotechnology careers have expanded well beyond the research laboratory as innovative ideas move to practical applications in the marketplace. Today there are many different jobs you can do in a biotechnology or related bioscience company:

- As a scientist, you can research the structure of a human protein involved in disease.
- As a laboratory technician, you can do exciting experiments to learn about that protein.
- As an engineer, you can design, build, or supervise a biomanufacturing facility to make this new product.
- As a process technician, you can operate a three-story-high bioreactor growing thousands of gallons of cells that make the new protein.
- As a facilities technician, you can troubleshoot and repair equipment malfunctions to keep the process running smoothly.
- As a clinical research associate, you can oversee a large clinical trial to investigate the safety of this new pharmaceutical.

A Choice of Environments

Jobs are available in many different types of industries, companies, and organizations:

- You can work in a fast-paced business environment, a cutting-edge research lab, a high-tech manufacturing facility, or in a greenhouse or agricultural research station.
- You can work exclusively at one location or travel—even globally—on a regular basis to meet with customers or inspect manufacturing operations.
- You can wear a business suit, lab coat, protective gear, clean room gown, or coveralls and work boots.
- You can work a traditional 9-to-5, Monday-through-Friday schedule or work on different shifts.
- You can work in a city or small town. Biotechnology is a global industry—you can work anywhere in the world.
- You can work in a classroom educating future scientists and technicians.
- You can work mostly with your head to generate new ideas or solve problems; mostly with your hands to operate or fix things; or you can use mind and hands more or less equally.

A Choice of Futures

Because biotechnology is an evolving field, it holds excellent promise for long-term career growth:

- You can advance by pursuing a management position. Most employers offer two tracks for advancement. Technical managers are senior technical or scientific experts who manage technical activities. Corporate managers become more involved in the business side of the company.
- You can advance by obtaining additional education. Biotechnology requires life-long learning. You can pursue certification in a specific technical competency, or you can expand your knowledge more broadly by pursuing a higher degree. Community colleges and universities in North Carolina make it easy to get education part-time through distance learning, short courses, and degree programs tailored to the working adult.
- You can advance by moving from one type of job to another, within a company, or from one company to another. You can even move from industry to a government agency or educational institution, and vice versa.

How Biotech Products Are Made

From Laboratory to Market

In the preceding pages, you've seen the wide range of biotechnology products that are possible. But even though such products may be very different, most companies making a biotechnology product operate in a similar way. We'll look at the pharmaceutical industry as an illustration of the major functions involved in the discovery, development, and marketing of a new product.

Making a New Drug

A unique feature of the pharmaceutical industry is that it is tightly regulated by the Food and Drug Administration (FDA). This means that all employees, from top management on down, have to comply with regulations called Good Manufacturing Practices (GMPs). These regulations require disciplined attention to following standard operating procedures and documenting every step in the manufacturing process. Working in a GMP facility requires patience and attention to detail, but successful employees appreciate the need for strict controls when making products that affect people's lives.

A Summary of Job Roles and Responsibilities

The descriptions on the page at right provide a summary of the activities involved in each step of the process of making a pharmaceutical. Within these descriptions, a number of career areas are indicated in boldface. The pages that follow provide additional information on each of these areas:

- **Scientists** (pages 10-11)
- **Laboratory Technicians** (pages 12-13)
- **Engineers** (pages 14-15)
- **Process Technicians** (pages 16-17)
- **Maintenance and Instrumentation Technicians** (pages 18-19)
- **Corporate Scientific Professionals** (pages 20-21)

The roles of these employees in other kinds of companies making different products are in many cases similar to those described on the page at right.

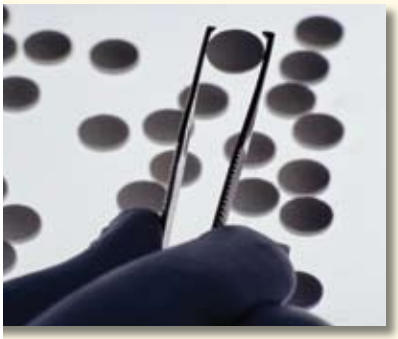
Process technicians at Diosynth Biotechnology prepare a bioreactor. By providing a controlled environment, a bioreactor is a life support system for the cells that grow within it.

1. Discovering and Developing a New Biotechnology Drug

A new product begins in the research laboratory, where **scientists** and **laboratory technicians** use biotech tools to learn about the causes of disease. Their discoveries lead to new ideas about how to combat disease. For example, a type of protein called an antibody might be a cure for a particular disease. Many different antibodies are then tested to see which one works best. Now various **corporate scientific professionals** get involved. *Patent attorneys* ensure the new drug idea is protected from competitors. *Medical and clinical personnel* design and conduct clinical studies to evaluate the safety of the new drug in patients while *regulatory experts* obtain FDA approval to market the new drug. *Marketing and business executives* evaluate its profitability. This whole process takes years.

2. Preparing to Make a New Drug

The processes used to make small quantities of drugs in a laboratory don't work to make the large quantities that will be sold. **Engineers** work with **process technicians**, **scientists**, and **laboratory technicians** to develop a large-scale manufacturing process for the new drug. In some cases, **engineers** must design and oversee construction of a new plant. Once the plant and equipment are ready, FDA regulations require everything be tested to make sure the system will produce a drug to meet set standards. This is called *validation*, and requires the expertise of specialists in this field as well as **engineers**, **technicians**, and **scientists**.



3. Making a New Drug

Process technicians operate all the equipment required to make the new product. To make this antibody, they grow cells in huge stainless steel tanks surrounded by a maze of piping, pumps, and automated control hardware. **Engineers** supervise the process. **Maintenance and instrumentation technicians** keep the plant systems and equipment running smoothly. **Laboratory technicians** test samples of the drug and the manufacturing environment to make sure that the drug produced is safe and meets all standards. **Scientists** often assist experienced manufacturing teams to solve problems or improve the process.

4. Getting the New Drug to Patients

Corporate scientific professionals play leading roles in getting the new drug to the patients who need it. *Medical writers* prepare the drug labeling and other information to be used by physicians and patients. *Sales and marketing professionals* are responsible for marketing the new drug and assessing the extent to which it meets physician and patient needs. *Regulatory experts* ensure that the company's sales and advertising practices comply with FDA regulations. *Technical sales and customer service personnel* work with physicians and patients who have questions or problems with the new drug. **Scientists** continue to look for ways to improve the drug.

5. Ensuring Patient Safety

While ensuring patient safety is a critical part of every step described above, **corporate scientific professionals** also play important roles in ensuring patient safety even after the product is in a customer's hands. *Medical and clinical personnel* evaluate the safety of the new drug and review reports of side effects submitted by physicians once the product is on the market. *Regulatory experts* ensure that side effects are reported to the FDA. **Scientists** and **laboratory technicians** monitor drug quality to ensure that no changes have occurred to the new drug that might affect its safe use by patients.