

# The Industry Pilot Series™: Biotechnology in the US

The Industry Pilot Series™ provides readers with an in-depth overview of key industry sectors. Identifying industries that genuinely interest you is a key, and often overlooked, aspect of effective career planning. Industry Sectors covered thus far include: Financial Services, Healthcare, Homeland Security, and Biotechnology. Excerpts for each are available free at [SilverCareerManagement.com](http://SilverCareerManagement.com).

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# What Is Biotechnology?

Break biotechnology into its root words and you have *bio*—the use of biological processes; and *technology*—to solve problems or make useful products. Using biological processes is hardly a noteworthy event. We began growing crops and raising animals 10,000 years ago to provide a stable supply of food and clothing. We have used the biological processes of microorganisms for 6,000 years to make useful food products, such as bread and cheese, and to preserve dairy products. Why is biotechnology suddenly receiving so much attention?

During the 1960s and '70s our understanding of biology reached a point where we could begin to use the smallest parts of organisms—their biological molecules—in addition to using whole organisms.

A more appropriate definition in the new sense of the word is this:

“New” Biotechnology—the use of cellular and biomolecular processes to solve problems or make useful products. We can get a better handle on the meaning of the word biotechnology by simply changing the singular noun to its plural form, biotechnologies.

Biotechnology is a collection of technologies that capitalize on the attributes of cells, such as their manufacturing capabilities, and put biological molecules, such as DNA and proteins, to work for us.

The table below will give a glimpse of the various areas which are directly benefiting from biotechnology revolution.

<i>Applications of Biotechnology</i>		
<i>Healthcare</i>	<i>Veterinary</i>	<i>Agriculture</i>
<i>Pharmaceuticals</i>	Genetic engineering	Diagnostics
Therapeutics	Monoclonal antibodies	Biopesticides
Vaccines	Recombinant interferons	Microbial diagnostics
Gene therapy	Transgenic animals	Environmental adaptations
Growth & other hormones		Genetically modified foods
Pharmacogenomics		Natural fertilizers
<i>Diagnostics</i>	<b><i>Industrial biotechnology</i></b>	Nutraceuticals
Biosensors	Energy conservation	Transgenics
DNA probes	Pollution reduction	
Monoclonal antibodies	Waste reduction	<b><i>Forestry biotechnology</i></b>
Polymerase chain reaction	Bioelectronics	Genetic engineering
Genomics/proteomics	Organic chemicals	Biological pest control
Biological instrumentation	<b><i>Environmental biotechnology</i></b>	Tissue culture propagation
<i>Biological devices</i>	Bioremediation	Transgenic plants
Drug-coated stents	Biotreatment	
Microdevices	Immunoassays	<b><i>Marine biotechnology</i></b>
Bone growth devices	Microbial mining	Biomedical research
Cartilage regeneration	Environmental monitoring	Food supply
Tissue replacement		Therapeutics
Wound healing devices	<b><i>Food Processing</i></b>	
Skin grafts & wound closures	Microbial starter cultures	
	Enzymes and vitamins	
	Food contamination tests	

<b>Diagnostics</b>	Gene analysis Integrated therapies Expression analysis	
<b>Immuno therapy</b>	Therapeutic vaccines for cancer & infectious diseases	
<b>Genomics</b>	Explosion of new targets for drug discovery	
<b>Pharmaco-Genomics</b>	Customization of medicine Rational patient selection for clinical trials	
<b>Proteomics</b>	High throughput validation of gene products	
<b>Gene Therapy</b>	<i>DNA</i> Direct transfer Vector mediated Live virus	<i>RNA</i> Anti sense Ribozymes RNA ligands
<b>Cell based therapies</b>	Nervous system repair Tissue regeneration Immune reconstitution	

The table shows some of the healthcare fields where biotechnology is making its presence felt directly.

The table below gives a forecast of the advances expected in the field of biotechnology over the years

<b>In 10Years</b>	* Genetic testing for 25 common conditions * Doctors begin practicing genetic medicine * Gene therapy successful for some conditions
<b>In 20 Years</b>	* Gene-based designer drugs for common diseases such as diabetes and high BP * Cancer therapy will be targeted to molecular fingerprint of the tumor * Genetic diagnosis and treatment of mental illness
<b>In 30 years</b>	* Genes involved in aging fully catalogued * Complete genomic sequencing of individual will be routine
<b>In 40 years</b>	* Individualized preventive medicine available and largely effective * Average life expectancy of 90 years

## Industry trends

### Food, animal and agricultural biotechnology

Humans have always relied on plants and animals for food, shelter, clothing and fuel, and for thousands of years farmers have been changing them to better meet our evolving needs. Society's demand for resources provided by plants and animals will increase as the world's population grows. The global population, which numbered approximately 1.6 billion in 1900, has surged to more than 6 billion and is expected to reach 10 billion by 2030. The United Nations Food and Agriculture Organization estimates world food production will have to double on existing farmland if it is to keep pace with the anticipated population growth. Biotechnology can help meet the ever-increasing need by increasing yields, decreasing crop inputs such as water and fertilizer, and providing pest control methods that are more compatible with the environment.

Biotechnology has broad applications in industry. The 1995 Biotechnology Guide U.S.A. lists 32 different industry sub-categories of biotechnology. The top 10 are listed in Table below. Only 9.1 percent of firms in biotechnology are primarily involved in plant agriculture.

	Category	Number of companies involved	Percent of total
1	Therapeutics	330	32.5
2	Clinical diagnostics	201	19.8
3	Plant agriculture	92	9.1
4	Reagents	83	8.2
5	Specialty chemicals	68	6.7
6	Environmental testing / treatment	49	4.8
7	Animal agriculture	42	4.1
8	Testing / analytical services	38	3.7
9	Immunological products	36	3.5
10	Equipment	28	2.8

According to Kidd, "total U.S. agricultural biotechnology" revenues jumped \$50 million to \$460 million from \$409.8 million in 1993. A more conservative estimate by Frost & Sullivan, market intelligence firm, placed 1993 revenues for the "U.S. agricultural biotechnology industry" at \$107.5 million. Dibner (1995) predicted food and agricultural biotechnology sector sales to increase rapidly to \$10 billion by 2000, when perhaps 40 percent of U.S. farmers would be under contract to grow some kind of value-added (biotechnologically modified) crop. Frost & Sullivan's prediction, again more conservative, for year 2000 sales of agricultural biotechnology was about \$2 billion. However, 1994 was the sixteenth consecutive year of measured losses for a surveyed group of 15 agricultural biotechnology research firms which together tallied a negative \$102 million in earnings for 1994, a figure that was up almost \$53 million from negative \$153.7 million in 1993. Clearly there is a discrepancy in the figures here between an enormous biotechnology market and a small, struggling "U.S. agricultural biotechnology industry". The problem, it seems, is that such estimates do not cast their nets widely enough to catch all the business going on in agricultural biotechnology, and are limiting themselves to just the loss-making entrepreneurial biotechnology research sector.

### ***Classes of firms involved in plant agricultural biotechnology***

In order to be both clear and comprehensive about what is the agricultural biotechnology industry, six major industry classifications can be identified which include firms involved in the development and marketing of biotechnologies for applications in plant agriculture:

**1. Biotechnology Research and Development (R&D) firms:** often referred to as **new biotechnology firms** or **NBFs**. These consist primarily of small science-based firms with only a few to a few-hundred employees and with very high ratios of R&D spending per employee. Characteristically they are recently founded, usually located near large research universities, often headed by Ph.D. scientists, are typically financed by venture capital in their early phases and most remain privately held. Few of the largest and most successful have gone public or have been sold to large corporations with interests to acquiring specific research capabilities. Among of the best known of these agro-biotechnology R&D firms are Agracetus, Calgene, Ecogen, Mycogen, and Plant Genetic Systems.

**2. Agricultural products companies:** These groups consists of corporations, such as Cargill, and are primarily involved in grain processing, the manufacture and distribution of herbicides, pesticides, and fertilizer, and the supply of other agricultural products, equipment, and services. Some are specialized to particular types of agriculture.

**3. Seed companies:** These often go hand-in-hand with agricultural business. Despite the considerable overlap, seed firms have been historically somewhat distinct: a situation deriving from these firms' specialization in the breeding and production of hybrid and improved crop seeds.

4. The fourth industry classification consists of firms whose core business is in **pharmaceuticals**, but which have large divisions and subsidiaries in agricultural products, crop protection, and seeds. As a result of the virtual revolution of biotechnology in this class of industries, many of these firms today are styling themselves as "life sciences" companies, fully encompassing pharmaceutical, nutritional, and agricultural businesses.

5. The fifth group consists of those large **chemical corporations** which have traditionally had secondary agrochemical interests. There has been somewhat of a tendency for chemical firms to move away from biotechnology in agriculture, in deference to the greater biotechnological expertise of the pharmaceutical firms. Significant involvement is still found with Dow, DuPont, ICI, Lubrizol, and others. Monsanto is an example of a traditional chemical company that diversified into pharmaceuticals and has since likewise emerged as a "life sciences" company.

6. **Food corporations:** Product research and development has long driven such giants as Procter & Gamble and Unilever to employ any and all technologies relevant to the improvement of their core product businesses, including biotechnology. Campbell Soup and Frito-Lay have focused biotechnology efforts on improving those particular crops (tomatoes and potatoes, respectively) on which their food products depend most heavily.

### **Improving Crop Production**

The crop production and protection traits agricultural scientists are incorporating with biotechnology are the same traits they have incorporated through decades of crossbreeding and other genetic modification techniques: increased yields; resistance to diseases caused by bacteria, fungi and viruses; the ability to withstand harsh environmental conditions such as freezes and droughts; and resistance to pests such as insects, weeds and nematodes.

### **Natural Protection for Plants**

Through science, we have discovered that plants, like animals, have built-in defense systems against insects and diseases, and we are searching for environmentally benign chemicals that trigger these natural defense mechanisms so plants can better protect themselves. Biotechnology has also opened up new avenues for working with nature by providing new biopesticides, such as microorganisms and fatty acid compounds, that are toxic to targeted crop pests but do not harm humans, animals, fish, birds or beneficial insects. A biopesticide farmers (including organic farmers) have used since the 1930s is the microorganism *Bacillus thuringiensis*, or Bt, which occurs naturally in soil. Using biotechnological tools, we can transplant the genetic information that makes the Bt bacterium lethal to certain insects (but not to humans, animals or other insects) into plants on which that insect feeds.

### **Herbicide Tolerance**

Herbicides are sprayed over crops to eliminate undesirable weeds. Often, herbicides must be applied several times during the growing cycle, at great expense to the farmer and possible harm to the environment.

Using biotechnology, it is possible to make crop plants tolerant of specific herbicides. When the herbicide is sprayed, it will kill the weeds but have no effect on the crop plants. This lets farmers reduce the number of times herbicides have to be applied and reduces the cost of producing crops and damage to the environment.

### **Resistance to Environment Stresses**

While plant breeders have successfully incorporated genetic resistance to biotic stresses into many crop plants through crossbreeding, their success at creating crops resistant to abiotic/environmental stresses has been more limited, largely because few crops have close relatives with genes for resistance to these stresses. The crossbreeding limitation posed by reproductive compatibility does not impede crop biotechnology; genes found in any organism can be used to improve crop production. As a result, scientists are making great strides in developing crops that can tolerate difficult growing conditions. For example, researchers have genetically modified tomato and canola plants that tolerate salt levels 300 percent greater than non-genetically modified varieties.

### **Environmental and Economic Benefits**

Beyond agricultural benefits, products of crop biotechnology offer many environmental and economic benefits. As described above, biotech crops allow us to increase crop yields by providing natural mechanisms of pest control in place of chemical pesticides. These increased yields can occur without clearing additional land, which is especially important in developing countries. In addition, because biotechnology provides pest-specific control, beneficial insects that assist in pest control will not be affected, facilitating the use of integrated pest management. Herbicide-tolerant crops decrease soil erosion by permitting farmers to use conservation tillage.

According to the National Center for Food and Agricultural Policy's (NCFAP) 2004 report, in 2003 the 11 biotech crop varieties adopted by U.S. growers increased crop yields by 5.3 billion pounds, saved growers \$1.5 billion by lowering production costs, and reduced pesticide use by 46.4 million pounds. Based on increased yields and reduced production costs, growers realized a net economic impact or savings of \$1.9 billion. The Conservation Tillage Information Center (CTIC) at Purdue University found out in a study that the increase in conservation tillage associated with herbicide-tolerant crops decreases soil erosion by 1 billion tons of soil material per year, saves \$3.5 billion per year in sedimentations costs and decreases fuel use by 3.9 gallons per acre.

### **Forest Biotechnology**

Throughout the world, wood provides us with fuel, construction materials and paper, and its supplies are dwindling rapidly. Wood products are currently a \$400 billion global industry, employing 3 million people. Demand for wood products is expected to increase, even as major economies, such as Europe and Japan, are unable to grow enough trees to meet their current demand. According to the U.N. Food and Agriculture Organization, world demand for wood products in 2010 will be about 1.9 billion cubic meters, almost 20 percent higher than it is now. We must attempt to meet that demand without cutting down the world's remaining forests.

### **Increasing Productivity**

Biotechnology can be used to create disease- and insect-resistant trees and to increase their growth rates. Scientists are also learning how to use biotechnology to improve the efficiency with which trees convert solar energy into plant material and to shunt more of that energy into wood production and less into pollen, flowers or seeds. All of these methods of increasing productivity should decrease the pressure on natural forests. However, developing trees through the use of biotechnology is a lengthy undertaking because trees take a long time to grow. So, researchers are looking to other methods for increasing productivity. For example, they are using a biotechnology process in a fungus to fight diseases that infect trees and are working on improving the microorganisms that live on tree roots and provide trees with nutrients, such as nitrogen-fixing

bacteria increase the nutrients available to soybeans and alfalfa. In addition, biopesticides have also been used extensively to control forest pests, and we expect progress in insect cell culture to boost the number of biocontrol agents available for forest insect control.

### **Environmental Benefits**

Perhaps a more important economic role for biotechnology in this industry will be found in its changing the way we convert trees to useful products. Extensive research is being conducted to increase a tree's amount of cellulose, the raw material for papermaking, and to decrease the amount of lignin, a tough molecule that must be removed in papermaking.

Traditionally, removing lignin from trees has required harsh chemicals and high energy costs, so changing the cellulose: lignin ratio genetically has important environmental implications, as does increasing the growth rate of trees. Because trees absorb carbon dioxide, any advance that allows us to increase tree yields without cutting down forest could have significant positive effects on global warming. Other environmental benefits that biotechnology is providing to the forestry industry include enzymes for

- Pretreating and softening wood chips prior to pulping.
- Removing pine pitch from pulp to improve the efficiency of paper-making.
- Enzymatically bleaching pulp rather than using chlorine.
- De-inking of recycled paper.
- Using wood-processing wastes for energy production and as raw materials for manufacturing high-value organic compounds.
- Remediating soils contaminated with wood preservatives and coal tar.

### **Healthcare and Pharmaceutical Industry**

Biotechnology tools and techniques open new research avenues for discovering how healthy bodies work and what goes wrong when problems arise. Knowing the molecular basis of health and disease leads to improved and novel methods for treating and preventing diseases. In human health care, biotechnology products include quicker and more accurate diagnostic tests, therapies with fewer side effects and new and safer vaccines.

#### **Diagnostics**

We can now detect many diseases and medical conditions more quickly and with greater accuracy because of the sensitivity of new, biotechnology-based diagnostic tools. A familiar example of biotechnology's benefits is the new generation of home pregnancy tests that provide more accurate results much earlier than previous tests.

Many tests are portable, so physicians conduct the tests, interpret results and decide on treatment literally at the patient's bedside. Tests for strep throat and many other infectious diseases provide results in minutes, enabling treatment to begin immediately in contrast to the two or three day delay of previous tests.

Biotechnology has also decreased the costs of diagnostics. A new blood test, developed through biotechnology, measures the amount of low-density lipoprotein (LDL), or “bad” cholesterol, in blood. Conventional methods require separate and expensive tests for total cholesterol, triglycerides and high-density lipoprotein cholesterol. Also, a patient must fast 12 hours before the test. The new biotech test measures LDL in one test, and fasting is not necessary.

We now use biotechnology- based tests to diagnose certain cancers, such as prostate and ovarian cancer, by taking a blood sample, eliminating the need for invasive and costly surgery.

In addition to diagnostics that are cheaper, more accurate and quicker than previous tests, biotechnology is allowing us to diagnose diseases earlier in the disease process, which greatly improves a patient’s prognosis. Most tests detect diseases once the disease process is far enough along to provide measurable indicators. Proteomics researchers are discovering molecular markers that indicate incipient diseases before visible cell changes or disease symptoms appear. Soon physicians will have access to tests for detecting these biomarkers before the disease begins.

The wealth of genomics information made available by the Human Genome Project will greatly assist doctors in early diagnosis of hereditary diseases, such as type I diabetes, cystic fibrosis, early-onset Alzheimer’s disease, and Parkinson’s disease—ailments that previously were detectable only after clinical symptoms appeared. Genetic tests will also identify patients with a propensity to diseases, such as various cancers, osteoporosis, emphysema, type II diabetes and asthma, giving patients an opportunity to prevent the disease by avoiding triggers such as diet, smoking and other environmental factors.

### **Therapeutics**

Biotechnology will make possible improved versions of today’s therapeutic regimes as well as treatments that would not be possible without these new techniques. Biotechnology therapeutics approved by the U.S. Food and Drug Administration (FDA) to date are used to treat many diseases, including anemia, cystic fibrosis, growth deficiency, rheumatoid arthritis, hemophilia, hepatitis, genital warts, transplant rejection, and leukemia and other cancers.

### **Using Natural Products as Therapeutics**

Many living organisms produce compounds that have therapeutic value for us. For example, many antibiotics are produced by naturally occurring microbes, and a number of medicines on the market, such as digitalis, are also made by plants. Plant cell culture, recombinant DNA technology and cellular cloning now provide us with new ways to tap into natural diversity.

As a result, we are investigating many plants and animals as sources of new medicines. Ticks could provide anticoagulants, and poison-arrow frogs might be a source of new painkillers. A fungus produces a novel, antioxidant enzyme that is particularly efficient at mopping up free radicals known to encourage tumor growth. Byetta™ (exenatide), an incretin mimetic, was chemically copied from the venom of the gila monster and approved in early 2005 for the treatment of diabetes. PRIALT® (ziconotide), a recently approved drug for pain relief, is a synthetic version of the toxin from a South Pacific marine snail.

The ocean presents a particularly rich habitat for potential new medicines. Marine biotechnologists have discovered organisms containing compounds that could heal wounds, destroy tumors, prevent inflammation, relieve pain and kill microorganisms. Shells from marine crustaceans, such as shrimp and crabs, are made of chitin, a carbohydrate that is proving to be an effective drug-delivery vehicle.

### **Replacing Missing Proteins**

Some diseases are caused when defective genes don't produce the proteins (or enough of the proteins) the body requires. Today we are using recombinant DNA and cell culture to produce the missing proteins. Replacement protein therapies include

- Factor VIII—a protein involved in the blood-clotting process, lacked by some hemophiliacs.
- Insulin—a protein hormone that regulates blood glucose levels. Diabetes results from an inadequate supply of insulin.

### **Using Genes to Treat Diseases**

Gene therapy is a promising technology that uses genes, or related molecules such as RNA, to treat diseases. For example, rather than giving daily injections of missing proteins, physicians could supply the patient's body with an accurate instruction manual—a nondefective gene—correcting the genetic defect so the body itself makes the proteins. Other genetic diseases could be treated by using small pieces of RNA to block mutated genes.

Only certain genetic diseases are amenable to correction via replacement gene therapy. These are diseases caused by the lack of a protein, such as hemophilia and severe combined immunodeficiency disease (SCID), commonly known as the "bubble boy disease." Some children with SCID are being treated with gene therapy and enjoying relatively normal lives. Hereditary disorders that can be traced to the production of a defective protein, such as Huntington's disease, are best treated with RNA that interferes with protein production.

Medical researchers have also discovered that gene therapy can treat diseases other than hereditary genetic disorders. They have used briefly introduced genes, or transient gene therapy, as therapeutics for a variety of cancers, autoimmune disease, chronic heart failure, disorders of the nervous system and AIDS.

### **Cell Transplants**

Approximately 10 people die each day waiting for organs to become available for transplantation. To circumvent this problem, scientists are investigating ways to use cell culture to increase the number of patients who might benefit from one organ donor. Liver cells grown in culture and implanted into patients kept them alive until a liver became available. Patients with type 1 diabetes were implanted with insulin-producing cells from organ donors into the subjects' livers. Eighty percent of the patients required no insulin injections one year after receiving pancreatic cells; after two years, 71 percent had no need for insulin injections. In another study, skeletal muscle cells from the subject repaired damage to cardiac muscle caused by a heart attack.

Expensive drugs for suppressing the immune response must be given if the transplanted cells are from someone other than the patient. Researchers are devising new ways to keep the immune system from attacking the transplanted cells. One method being used is cell encapsulation, which allows cells to secrete hormones or provide a specific metabolic function without being recognized by the immune system. As such, they can be implanted without rejection. Other researchers are genetically engineering cells to express a naturally occurring protein that disables immune system cells that bind to it. Other conditions that could potentially be treated with cell transplants are cirrhosis, epilepsy and Parkinson's disease.

### **Stimulating the Immune System**

Using biotechnology, proteins can now be produced in sufficient quantities to be marketed as therapeutics. Small doses of biotechinterleukin-2 have been effective in treating various cancers and AIDS, while interleukin- 12 has shown promise in treating infectious diseases such as malaria and tuberculosis.

Researchers can also increase the number of a specific type of cell, with a highly specific function, from the cellular branch of the immune system. Under certain conditions, the immune system may not produce enough of the cell type a patient needs. Cell culture and natural growth factors that stimulate cell division allow researchers to provide or help the body create the needed cell type.

Cancer vaccines that help the immune system find and kill tumors have also shown therapeutic potential. Unlike other vaccines, cancer vaccines are given after the patient has contracted the disease, so they are not preventative. They work by intensifying the reactions between the immune system and tumor. Despite many years of research, cancer vaccines have not yet emerged as a viable strategy to fight cancer. Nonetheless, researchers are optimistic that this kind of approach to battling cancer would be a major improvement over the therapies used today.

### **Suppressing the Immune System**

In organ-transplant rejections and autoimmune diseases, suppressing our immune system is in our best interest. Currently we are using monoclonal antibodies to suppress, very selectively, the type of cell in the immune system responsible for organ-transplant rejection and autoimmune diseases, such as rheumatoid arthritis and multiple sclerosis. Patients given a biotechnology-based therapeutic often show significantly less transplant rejection than those given cyclosporin, a medicine that suppresses all immune function and leaves organ-transplant patients vulnerable to infection.

Inflammation, another potentially destructive immune system response, can cause diseases characterized by chronic inflammation, such as ulcerative colitis. Two cytokines, interleukin-1 and tumor necrosis factor, stimulate the inflammatory response, so a number of biotechnology companies are investigating therapeutic compounds that block the actions or decrease production of these cytokines.

### **Regenerative Medicine**

Biotechnology permits the use of the human body's natural capacity to repair and maintain itself. The body's toolbox for self-repair and maintenance includes many different proteins and various populations of stem cells that have the capacity to cure diseases, repair injuries and reverse age-related wear and tear.

### **Tissue Engineering**

Tissue engineering combines advances in cell biology and materials science, allowing us to create semi-synthetic tissues and organs in the lab. These tissues consist of biocompatible scaffolding material, which eventually degrades and is absorbed; plus living cells grown using cell culture techniques. Ultimately the goal is to create whole organs consisting of different tissue types to replace diseased or injured organs.

The most basic forms of tissue engineering use natural biological materials, such as collagen, for scaffolding. For example, two-layer skin is made by infiltrating a collagen gel with connective tissue

cells, then creating the outer skin with a layer of tougher protective cells. In other methods, rigid scaffolding, made of a synthetic polymer, is shaped and then placed in the body where new tissue is needed. Other synthetic polymers, made from natural compounds, create flexible scaffolding more appropriate for soft-tissue structures, like blood vessels and bladders. When the scaffolding is placed in the body, adjacent cells invade it. At other times, the biodegradable implant is spiked with cells grown in the laboratory prior to implantation.

Other major tissues being engineered by researchers is **biohybrid kidney**

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