Under the Microscope

Biotechnology Jobs in California

Employment Development Department
Labor Market Information Division
Information Services Group
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June 2004

Note to readers: Although the report is dated June 2004, the occupational wages and growth trends cited in the Biotechnology Careers section of this report have been updated, and are current as of December 2007.

Biotechnology Careers

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Executive Summary

Biotechnology uses living organisms and their components to make products.

Mention biotechnology and many people think of the latest drugs being developed to treat a wide variety of illnesses. However, biotechnology comprises much more. Its products include drugs for humans and animals, medical diagnostics and health-related services, and agricultural products.

A look into the factors driving growth in biotechnology shows that a population that is both increasing, as well as growing older, translates into a greater demand for drugs and medical devices. In response, more than 175 biotechnology drugs have been approved since 1982. Also boosting the industry is a need for agricultural products that will increase crop yields and curb the need for herbicides, veterinary medicines to care for pets and livestock, and environmentally-friendly industrial products.

Biotechnology workers are found in many traditional industries, depending on the type of product or research conducted. The two major industries employing biotechnology workers are Drugs, and Research and Testing.

Growth industry

Nine industries account for most biotechnology-related occupations. Biotechnology research offers promise of revolutionary applications for environmental management, biomedical devices, instrumentation, agricultural products, food processing, human and veterinary medicines, and pharmaceutical manufacturing.

California—with more than 400 biotechnology firms—leads the country, having about twice the number of firms as the second leading state. Most biotechnology jobs in California are located in the four major biotechnology regions: San Diego, Los Angeles/Orange, the San Francisco Bay Area and Sacramento/Stockton.

Economic effect

Today, California's biotechnology firms employ an estimated 100,000 workers. By 2015, the industry may employ as many as 250,000 workers. And this is only part of the story; studies suggest the 'job multiplier' for biotechnology is about 1.9, meaning that almost two additional jobs are created elsewhere in the nation's economy for every job created directly in biotechnology.

The War on Terrorism means more money for the biotechnology industry. The federal government has allocated $1.6 billion to the National Institutes of Health for biodefense research and development (R&D) in fiscal year 2004, with more to come in the future.

The total value of all publicly-traded biotechnology companies in the United States in early 2003 was $206 billion.

Biotechnology occupations defined

Occupations described in this report represent jobs and titles in the biotechnology industry. The 36 occupations are clustered into seven major work activities within the industry: Research and Development, Clinical Research, Manufacturing and Production, Regulatory Affairs, Quality Systems, Information Systems, and Marketing and Sales. To assist students, job seekers, and counselors each career note gives an overview of the following:

- Tasks specific to the job
- Transferable skills, knowledge, and abilities needed
- Training and education requirements
- Average earnings
- California employment and outlook
- Additional sources of information, such as associations and licensing agencies

Tables compare occupations

The report contains charts and tables that display biotechnology occupations in several ways, such as by educational requirements, work activity, interests, and alphabetically. These include average statewide earnings, employment, and outlook information, both statewide and by industry. An appendix lists biotechnology-related academic programs in California.

Career guidance

The report includes a section designed to help career explorers determine whether or not they are suited to the biotechnology field. It encourages readers to answer questions about themselves, describes the work environment, and discusses interests and values common to the industry.

Introduction

A new industry

On April 2, 1953, *Nature* published a letter by James Watson and Francis Crick that would revolutionize the world—a description of the structure of the molecule of deoxyribonucleic acid; perhaps better known as DNA.[1] Considered one of the most important discoveries in biology, their letter ushered in a new era in the life sciences, one marked by fundamental discoveries in genetics, medicine, biology, and agriculture, and changing our understanding of virtually every aspect of living organisms. That single discovery can be said to have directly led to the establishment and growth of an entire industry—biotechnology.[2]

Mention biotechnology, and many people think of the latest drugs being developed to treat cancer, heart disease, Alzheimer's, neurological disorders, and a wide variety of other illnesses. Yet, biotechnology encompasses much more. New, more robust, varieties of agricultural crops—resistant to disease, easier to harvest, faster growing—have come from biotechnology research. Biotechnology has also led to better ways to manufacture products, including drugs, foods, petroleum products, and mining, among others. It offers an improved way of making diagnostic agents, chemical products, and disease preventatives that will benefit California and its citizens.

This guide will look at both the biotechnology industry and many of its occupations.

Biotechnology cuts across many industries

Biotechnology uses living organisms and their components to make products. These products include drugs for humans and animals, medical diagnostics, agricultural products, and health-related services.

The products and services coming from the biotechnology industry truly represent the frontiers of a marriage between science and industry. The fruits of the industry have already had a significant impact on the traditional pharmaceutical industry, and have the potential to revolutionize medicine, agriculture, drug manufacturing, and veterinary science.

Biotechnology industry facts

- California, with more than 400 biotechnology firms, leads the country in the number of biotechnology firms. This is more than twice the number of firms as Massachusetts—the second leading state.[3]
- The War on Terrorism means more money for the biotechnology industry. The federal government has allocated $1.6 billion to the National Institutes of Health for biodefense research and development in fiscal year 2004, with more to come in the future.[4]
- Most biotechnology jobs are located in the major biotechnology regions in California: San Diego, Los Angeles/Orange, the San Francisco Bay Area and Sacramento/Stockton.
- The total value of all publicly-traded biotechnology companies in the United States in early 2003 was $206 billion.[5]

Biotechnology industry facts *(continued)*

- Like any evolving industry, biotechnology is subject to significant upturns and downturns in employment, revenue, sales, and stock pricing.
- Revenues for the biotechnology industry have increased more than sevenfold from 1989 to 2002. This represents a 16 percent compound annual growth rate.[6]
- More than 175 biotechnology drugs received Food and Drug Administration (FDA) approval by 2003.[7]
- Job opportunities exist for workers who have associate and bachelor degrees in information technology and the biological and laboratory sciences, although many require a masters or doctorate.
- About two-thirds of biotechnology firms employ 135 workers or fewer.[8]

History of Biotechnology

Although many people think that biotechnology is a relatively new industry, elements of biotechnology have been with us since the beginning of recorded history.[9]

Biotechnology Milestones

8000 B.C.E.	Humans domesticate crops and livestock.
4000–2000 B.C.E.	Yeast harnessed to leaven bread and ferment beer.
1865	Gregor Mendel, an Austrian monk, publishes studies showing the inheritance of biological traits in pea plants.
1953	James Watson and Francis Crick discover the double-helix structure of DNA.
1973	Stanley Cohen and Herbert Boyer pioneer the techniques to manipulate DNA to make new genes in bacteria.
1974	Cesar Milstein and Georges Kohler develop monoclonal antibodies, specific antibodies that can be made in large quantities.
1978	Human insulin produced artificially using recombinant DNA.
1982	Genentech's Humulin, made from genetically modified bacteria, is the first biotechnology drug to be approved by the Food and Drug Administration.
1983	PCR, the polymerase chain reaction technique to make unlimited copies of genes, is developed. It later becomes a significant tool in research, diagnostics, and police forensics.
1986	First genetically engineered vaccine for humans, the hepatitis B vaccine, developed. Also, the first biotechnology cancer drug is produced.
1990	The Human Genome Project (an effort to map all of the genes in humans) is launched.
1997	Researchers in Scotland achieve the first cloning of a mammal from an adult cell—a sheep named Dolly.
1998	Researchers first grow human embryonic stem cells.
2000	The rough draft of the human genome DNA sequence is completed.

[1]Watson, J. D. and Crick, F. H. C., “Molecular Structure of Nucleic Acids,” *Nature*, April 25, 1953, pp. 737–738. Retrieved from <http://www.nature.com/genomics/human/watson-crick> (April, 2004).

[2]Noble, Ivan, “’Secret of life’ discovery turns 50,” BBC NEWS Online, February 27, 2003, <http://news.bbc.co.uk/go/pr/fr/-/2/hi/science/nature/2804545.stm> (April, 2004).

[3]Ernst & Young, *Resilience – America’s Biotechnology Report 2003*, July 2003, p. 4.

[4]American Association for the Advancement of Science, “NIH Budget Growth Slows to 2 Percent in FY 2004,” February 25, 2003, <http://www.aaas.org/spp/rd/nih04p.pdf> (April, 2004).

[5]Biotechnology Industry Organization, “Biotechnology Industry Statistics,” n.d., <http://www.bio.org/er/statistics.asp> (April, 2004).

[6]Ernst & Young, p. 7.

[7]Biotechnology Industry Organization, “Editors’ and Reporters’ Guide 2003–2004,” June 2003, <http://www.bio.org/er/BiotechGuide.pdf> (April, 2004).

[8]Biotechnology Industry Organization, “The United States Is The World’s Leader in Biotechnology,” quoted by Biotechnology Industry Organization, “Biotechnology Industry Organization on Bayh-Dole and Technology Transfer Before the President’s Council on Science and Technology Office of Science and Technology Policy,” Washington, D.C., April 11, 2002, p. 6. Retrieved from <http://www.bio.org/ip/pdf/bd20020509.pdf> (April, 2004).

[9]Biotechnology Industry Organization, “Editors’ and Reporters’ Guide 2003–2004,” pp. 9–15.

Biotechnology—An Overview

Research and production in an evolving industry

The biotechnology industry has evolved to encompass several major areas of research and production:

- Agricultural products
- Biomedical devices
- Environmental management
- Food processing
- Human and veterinary medicines
- Instrumentation
- Pharmaceutical manufacturing

Biotechnology growth and development ultimately flows from discoveries in basic research. As this basic research is undertaken, the discoveries that result from it are published in one or more of the hundreds of worldwide scientific journals.

Once promising ideas are identified, companies may be formed, or licensing agreements may be worked out. This is how creative research can be turned into breakthrough biotechnology products. The rewards for such breakthrough products can be immense. The first monoclonal antibody to gain FDA approval, Rituxan, was such a drug, reaching blockbuster status early, and earning almost $1.5 billion in sales in 2003.[1]

Revenues, of course, ultimately drive the industry. In some cases the needs and the opportunities are obvious—human therapeutic products that will treat disease and alleviate suffering can satisfy pressing needs. Medicines to treat major life-threatening diseases, such as cardiovascular disease and cancer, can readily attract capital investment. Sometimes, research breakthroughs can point to process changes that significantly lower production costs.

Cuts across many industries

Depending on the type of biotechnology product or research conducted, biotechnology workers are counted within many traditional industries.[2] These include the following:

- Drugs
- Drugs and Sundries
- Engineering Services
- Management and Public Relations
- Medical, Dental Laboratories
- Medical Instruments
- Measuring and Controlling Devices
- Professional and Communications Equipment
- Research and Testing

(See Appendix B for a list of the industries involved in biotechnology.)

Important areas of current research

There are many specialized areas of biotechnology research that have excited scientists and others in the field and hold the promise of significant benefits to mankind over the coming decades. These include:

- Agriculture
- Bioprocessing technology
- Bioterrorism
- Cell culture
- Cloning
- Industry applications
- Microarrays

The following paragraphs further define these specialized areas of research.

Agriculture

Genetically-modified foods are food products modified in the laboratory to either add beneficial characteristics to a food product or subtract undesirable ones. An example would be changing the genetic structure of a food crop to withstand higher doses of an herbicide, allowing farmers to better control weeds and achieve higher crop yields. Other changes might include increasing the nutritional content of a food by adding genes to create nutrients missing from people's diets.

In a way, man has been modifying food crops for thousands of years, by crossbreeding plants with desirable characteristics. Modern techniques, however, can squeeze into months what might have taken many years of selective breeding to achieve similar goals. Also, they can transfer genes in ways that are not possible with traditional crossbreeding techniques.

It's not just a matter of economics. With the world's population pushing past six billion and expected to grow by over 70 percent in 50 years, farmers have to make major efforts to feed a rapidly growing population.[3] Here are some of the changes that researchers are trying to make to help meet these demands:

- Better yield
- Disease resistance
- Drought and/or cold tolerance
- Herbicide tolerance
- Higher nutritional content
- Improved taste and appearance
- Pest resistance
- Pharmaceutical drugs from plants
- Phytoremediation (use of plants to pull contaminants from the soil)

Bioprocessing technology

Bioprocessing technology broadly refers to the use of cells or cell products to make a useful product. An excellent (and ancient) example is the use of yeast to bake bread and similar products, as well as to brew beer and ferment wine. Components of cells are often used in the industry; enzymes are most frequently used. Enzymes are catalysts very commonly used in manufacturing, because they allow reactions to occur at temperatures and atmospheric pressures that exist in the natural environment.

Cells and cell products are used today to help make medicines for humans and animals, as well as products used in industry and food processing. In the future, this technology will help make complex drugs that will help treat disease and allow for longer and healthier lives. It will also make our lives more comfortable as new manufactured goods, foods, and cleaning products make an appearance in the marketplace.

Bioterrorism

The terrorist attacks on September 11, 2001, coupled with anthrax-laced letters sent out several months later, made it clear that the nation's air, food, and water supply are potential avenues for bioterrorism. The biotechnology industry has been quick to act in addressing the potential along with government and the academic community. Currently, research is being done to find treatments for anthrax, smallpox, bubonic plague and other biological agents that might be used by terrorists.

In January 2003, President George W. Bush announced the 'Project Bioshield Initiative' to fund programs to help fight bioterrorism. It is estimated about $6 billion will be allocated to fund the project over the next 10 years. Among other goals, the program seeks to encourage the development of necessary medical countermeasures against a chemical, biological, or nuclear attack.[4]

Cell Culture

Cell culture is the technique of growing cells outside of a living organism. Cells might be plant, insect, or mammalian in origin. Plant cell culture can produce products with therapeutic value in a clean, controlled manner. This technique is used to produce some drugs, as well as compounds that are used as coloring and flavoring agents in the food processing industry.

Cloning

Cloning has been popularized in both fact and fiction, but at its most basic it represents nothing more than making a new organism that has the same nuclear genetic blueprint as the original organism. Cloning can be divided into two major areas, reproductive cloning and therapeutic cloning.

Reproductive cloning. This process is similar to that of identical twins who share the same genes, except that it is artificially initiated. Although cloning is most well known when it involves large animals, such as Dolly the sheep (the first clone of a domestic animal) many living organisms, such as cells, plants or animals can be cloned.

Cellular clones are distinct families of cells grown in culture. Different cell lines have different features that are useful in molecular biological applications. These cells are a fundamental tool of biotechnology research, development, and product manufacturing.[5] They are used in therapeutic applications such as monoclonal antibodies and diagnostic testing. They can be used in the laboratory to create new plants with different genetic features.

Cloning (continued)

The cloning of various animals grabbed headlines over the last decade. Although the cloning that brought Dolly instant renown is the most well known, it was newsworthy only because genetic material from an adult cell was used, a feat many scientists did not believe was possible. Today, cloned research animals are commonplace and rarely make the news.

One potential use for animal cloning may be the use of genetic material to clone rare or even extinct animals. In 1998, for example, a rare breed of cow was cloned. In 2002, the first clone of an endangered species was a baby gaur, a type of wild ox native to Asia. And in 2003, a baby banteng (an endangered wild cattle indigenous to Southeast Asia) was born.[6] Some scientists are even trying to clone extinct animals such as woolly mammoths, who died out thousands of years ago, but whose remains have been frozen in the permafrost in Siberia. So far, finding suitable DNA has proven to be elusive, though animals that have gone extinct in the past century may have intact DNA. DNA is a complex molecule that can break down fairly quickly after an organism dies. Fantasy aside, it is very unlikely that cloned dinosaurs will inhabit a 'Jurassic Park.'

Therapeutic cloning. Cellular clones are also the basis of the process of therapeutic cloning which is the use of clone-derived stem cells to treat diseases such as heart disease, Parkinson's disease, Alzheimer's and paralyzing injuries such as those involving the spinal cord. This therapy, which is experimental, involves creating cloned cells using a human egg cell, implanting the nucleus from a skin or other cell from a patient, removing stem cells from the dividing group of cells, and growing many stem cells from those cloned cells. These stem cells are then injected into diseased or injured organs, where it is hoped they will begin to function as normal heart, brain or other tissue.[7]

Another technique that promises similar results is the process of growing stem cells that are already present in the body. It seems that there are many types of stem cells in adults, including stem cells that give rise to blood cells, neural cells, and skin and hair. Stem cells have even been found in fatty tissue. These stem cells are also thought to be able to replace damaged organs or tissues.

In time, it might be possible to use one of these techniques to grow entire new organs to replace damaged ones. Already researchers think they might be able to grow new teeth to replace those lost or diseased.[8] This area of research is called 'tissue engineering.' Any human application of such techniques is many years away.

General industry applications

Biotechnology is increasingly viewed as a more gentle way of making general industrial products that formerly required harmful chemicals for which disposal was difficult. Since many biotechnological components, such as enzymes, work at ordinary temperatures and pressures, these agents may produce the same products at a lower cost and in a way that is more environmentally friendly.

Microarrays

Microarrays are very important diagnostic and research tools that represent a unique way of studying DNA and proteins. DNA 'gene chips' are fabricated so that thousands or even tens of thousands of DNA molecules are laid out, or arrayed, on glass slides as tiny spots. Each spot may contain thousands of cloned (identical) DNA molecules that make up a single gene or part of a gene. To detect whether a particular gene is active or 'expressed' in a cell, a gene chip is prepared that has most of the cell's DNA. A solution of molecules that can attach to DNA is then introduced that indicates whether that gene is expressed, as well as its relative quantity. These molecules have been 'tagged' with a dye that glows under a laser. The resulting pattern can provide a picture of the active genes within the cell.

There are many uses for gene chips. One frequent way gene chips are used is to compare healthy and diseased cells. This enables scientists to see the difference in gene expression between the two cells.

Protein microarrays work in a similar fashion. But since they have the potential to tell us which proteins are active, they can help describe what genes do. DNA is a template, a set of instructions that tells a cell how to make proteins. Proteins are much more complex than DNA, because instead of being in a simple double helix configuration, proteins are folded in a very specific way. If they are misfolded, they will not work, or may even cause disease. The potential of using protein microarrays are immense and worth the extra effort to study them. For example, protein arrays can tell us what proteins are associated with early-stage cancer, allowing for early detection when cancer is generally more curable. They may also tell us which drugs work best in which individual, since our proteins can vary between family members and as we age.

Safety and ethics

As with any new or emerging technology, questions arise as to the safe and ethical use of biotechnology. The three areas that appear the most controversial are genetically modified foods, cloning, and embryonic stem cell research. Some people are concerned about genetically modified organisms. Although breeding experiments have been going on for thousands of years (for example, all breeds of dogs are the result of breeding efforts that started with the wolf), modern genetic manipulation can introduce DNA from species that could never interbreed. For example, human genes have been inserted in the nucleus of different animals so they can produce human proteins. Some scientists believe that this genetic manipulation could be an important source of drugs to treat human diseases. Perhaps in the future so-called 'pharm' animals will represent a new biotechnology frontier.

The controversial aspect of embryonic stem cell research is the source of the cells—generally leftover cells from *in vitro* fertilization procedures. Political discussions have limited federally funded research on these cells to 64 existing embryonic cell lines.

[1]Genetech, Investor Financials, “Historical Product Sales.” Retrieved from <http://www.gene.com/gene/ir/financials/historical/rituxan.jsp> (April, 2004).

[2]U.S. Department of Labor, Occupational Safety and Health Administration, *Standard Industrial Classification System Search*. Retrieved from <http://www.osha.gov/oshstats/sicser.html> (April, 2004).

[3]U.S. Census Bureau, ”Total Midyear Population for the World: 1950-2050.” Retrieved from <www.census.gov/ipc/www/worldpop.html> (April, 2004).

[4]The White House, Home News & Policies, “DHS Announces FY 2005 Budget,” February 2, 2004. Retrieved from <http://www.whitehouse.gov/news/releases/2004/02/20040202-7.html> (April, 2004).

[5]New Scientist, ”Cloning FAQs.” Retrieved from <http://www.newscientist.com/hottopics/cloning/cloningfaq.jsp> (April, 2004).

[6]BBC News UK Edition, ”Endangered Animal Clone Produced,” April 9, 2003. Retrieved from <http://news.bbc.co.uk/1/hi/sci/tech/2932225.stm> (April, 2004).

[7]Biotechnology Industry Organization, ”The Value of Therapeutic Cloning for Patients.” Retrieved from <http://www.bio.org/bioethics/tcloning.asp> (April, 2004).

[8]BBC News World Edition, ”New teeth ‘could soon be grown,‘” May 3, 2004. Retrieved from <http://news.bbc.co.uk/2/hi/health/3679313.stm> (May, 2004).

The Biotechnology Industry Outlook

Drug approvals increase

The biotechnology evolution continues despite its peaks and troughs. One industry group estimates that over 175 biotechnology drugs have been approved since 1982. For the decade of the 1980s, 15 biotechnology drugs were approved in the United States. For the decade of the 1990s, 90 biotechnology drugs were approved. Since 2000, 71 biotechnology drugs have already been approved.[1]

Growing and aging population

Industry growth is driven by supply and demand; the supply representing the tremendous amount of basic and directed scientific research being done at the academic and industry level, and the demand being the unmet needs of a growing population. Combined, these two forces, together with sufficient funding from government, charities and industry, have paved a course for an overall growth in the number of biotechnology firms and workers.

A closer look into the factors driving growth in biotechnology shows that the aging of the population translates into greater demand for drugs and medical devices. Also driving growth is a need for agricultural products that will increase crop yields and curb the need for herbicides, veterinary medicines to care for pets and livestock, and for industrial applications.

Recent biodefense funding

The federal budget allocated $1.6 billion to the National Institutes of Health for biodefense efforts in fiscal year 2004, with more to come in the future.[2] The biotechnology industry will get a share of this novel source of funding, adding employment opportunities to the industry.

The “industry”

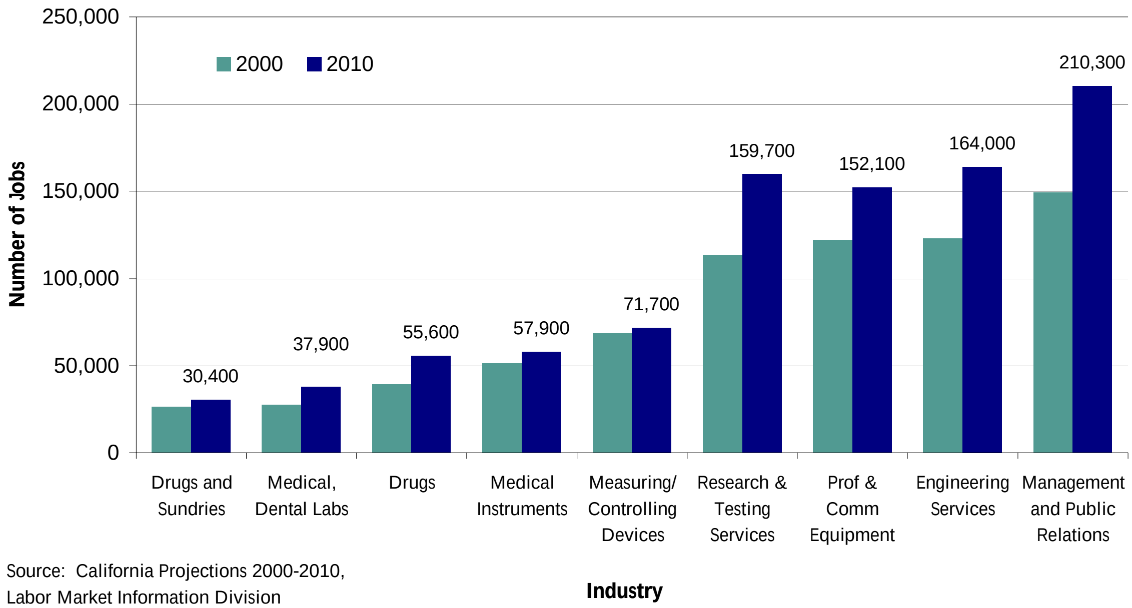
Although described as a singular industry, biotechnology cuts a wide swath across a number of industries, as described in the overview—agriculture, pharmaceuticals and medicine, food processing, manufacturing, and more. What is in common is that each uses living organisms to produce products and services. What differs is the application of the living organisms, and where the process stands in the research and development cycle.

The bulk of our analysis is based on the retiring Standard Industrial Classification (SIC) system, as California‘s industry projections of employment using the North American Industry Classification System (NAICS) have not yet been completed. For the purpose of this release, we will attempt to bridge the gap by describing the industries using SIC, and providing a crosswalk between the two classification systems. (See Appendix B for the crosswalk.) Once the NAICS industry projections have been completed (in late 2004), we will release an addendum to this report clarifying the industry relationships using that classification system.

Nine industries involved in biotechnology are displayed in Exhibit 1. Exhibit 1 shows projected growth in these industries between 2000 and 2010. Biotechnology-related industries have continued to expand despite the recent economic downturn. Biotechnology-related industries are projected to grow by over 30 percent by 2010, adding an estimated 219,000 new jobs.

Exhibit 1

Growth of Industries that include Biotechnology



Source: California Projections 2000-2010, Labor Market Information Division

Bulk of employment in two industries

It is important to note that biotechnology jobs account for a fraction of total employment in the above nine industries. Even the two industries with the largest numbers of potential biotechnology workers—Research and Testing, and Drugs—are chiefly populated with workers not engaged in biotechnology work.

Exhibits 2 and 3 below illustrate employment totals of the 36 occupations focused in this report relative to remaining employment in the two industries. It is also important to note that some workers in biotechnology are not described in this report and fall into the "all other" employment in these charts. These workers generally perform tasks non-specific to the industry such as clerical, janitorial, or accounting.

Exhibit 2

Biotechnology Occupations in Research and Testing Industry

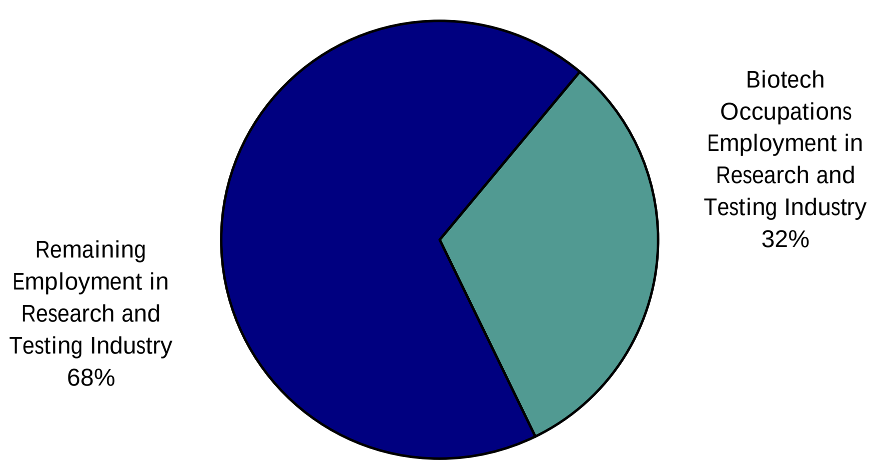
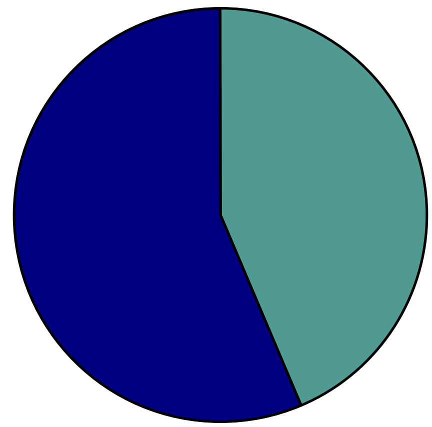


Exhibit 3 **Biotechnology Occupations in the Drugs Industry**



The remainder of employment within these industries includes cross-industry occupations such as management, support, and janitorial staff. Appendix C arrays the 36 selected occupations by these two industries, along with current and projected employment through 2010, and assorts the occupations by the levels of education and training required. As noted above, the education and training requirements for these occupations range from high school to doctorate degree.

[1]Biotechnology Industry Organization, "Editors' and Reporters' Guide 2003-2004", June 2003. Retrieved from <http://www.bio.org/er/approvedyear.asp> (April, 2004).

[2]American Association for the Advancement of Science, "NIH Budget Growth Slows to 2 Percent in FY 2004," February 25, 2003.

The Biotechnology Industry in California

Growth in California and the nation

Today, California's biotechnology firms employ an estimated 100,000 workers. By 2015, the industry may employ as many as 250,000 workers.[1] In 2003, out of the 1,466 biotechnology firms nationwide, almost 440 were located in the State, representing nearly 30 percent of the U.S. biotechnology market.[2] Moreover, the impact of biotechnology on the entire economy is much greater. Studies suggest the 'job multiplier' for the biotechnology industry is larger than for most industries, with one estimate suggesting about 1.9 additional jobs are created in the nation's economy for every one job in biotechnology.[3]

For the nation as a whole, biotechnology continues to grow. The total number of biotechnology firms in the United States was about 1,200 in 1992; by 2001, that total had grown by about 20 percent. During that span, employment nationwide rose from about 79,000 to about 190,000.

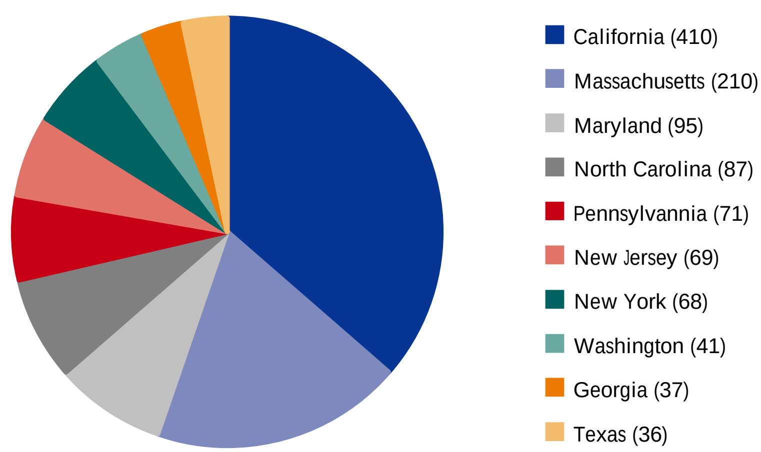
Revenues for the biotechnology industry have grown substantially; they increased by more than 600 percent from 1989 to 2002. This represents a 16 percent compounded annual growth rate. The number of biotechnology products on the market has increased from 2 in 1982 to more than 175 in 2003.[4]

Medical biotechnology firm numbers

According to the California Healthcare Institute, about 225,000 persons worked in the biomedical industry (of which biotechnology is a part) in California in 2002, earning about $13 billion in salaries.[5]

Exhibit 4

Medical Biotechnology Firms: Top Ten States by Number of Firms in 2002



Source: Daniel Pollak, "California's Bioscience Industries: Overview and Policy Issues."

Major biotechnology regions in California

There are four major Biotechnology centers in the State: San Diego and Los Angeles/ Orange areas in Southern California, and the Bay Area and Sacramento/Stockton areas in Northern California. Major Biotechnology centers have several characteristics in common:

- Major research universities and leading research institutions
- An abundance of talent at all levels of bioscience and biotechnology
- A large reservoir of experience from such industries as computers, pharmaceuticals, medical devices, and electronics
- The availability of funds to invest in high technology

What California firms are working on

California firms are working in the following biotechnology fields:

Human Diagnostics: Companies are engaged in producing medical devices to test for genetic and infectious diseases. Genetic diseases, such as sickle-cell anemia, cystic fibrosis, and Alzheimer's disease, are those in which heredity plays a major role. Infectious diseases, like human immunodeficiency virus (HIV), hepatitis B and C, and influenza are those caused by person-to-person exposure to bacteria or a virus. Examples of diagnostic products are tests for blood screening for various diseases, materials and equipment used to analyze samples of blood and other bodily fluids, and tools to locate defective genes that cause hereditary diseases.

Human Therapeutics: Companies produce materials and pharmaceuticals to treat illnesses. Therapeutic products include genetically engineered proteins used to lessen the effects of heart attacks and to slow or halt the growth of cancer cells of patients with leukemia. Several companies are developing vaccines to treat acquired immunodeficiency syndrome (AIDS) and the diseases that are associated with AIDS. Genetically engineered growth hormones are being used to treat dwarfism, and other genetically engineered materials are commonly used to treat anemia and organ transplant rejection. Other diseases that are being treated or prevented through biotechnology include other forms of cancer, diabetes, and hemophilia.

Agricultural and Veterinary: Animal scientists have developed methods for breeding and raising farm animals so that they can be more efficiently raised, resulting in lower production costs. Products of Biotechnology include treatments and tests for farm animal diseases such as those found in cattle, sheep, and pigs. Vaccines have been developed to prevent diseases such as foot-and-mouth disease in cattle, tapeworm in sheep, and dozens of other types of bacterial infections and viruses found in animals throughout the world.

What California firms are working on (continued)

Food/Chemical: Companies are marketing products developed by scientists that detect food-borne microbes and toxins and test for chemical contamination. Genes have been developed to be added to food crops to provide natural protection against insect pests. Genetically engineered enzymes have been used in producing high fructose corn syrup that is used as a sweetener in a large number of prepared foods and beverages and in producing enzymes for making cheese. Scientists are also working on plants that are drought and frost resistant.

Environmental: Bacteria have been developed to clean up oil spills and chemical leaks from storage tanks by rendering the toxic materials or hazardous substances harmless. Experts have said that this area of biotechnology offers great promise. Bacteria are also used in cleaning wastewater of harmful chemicals and in detoxifying or reducing industrial waste at its source.

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[1]Daniel S. Levine, "Hayward State center to grow biotech workers," *San Francisco Business Times*, March 12, 2004.

[2]Ernst & Young, *Resilience — America's Biotechnology Report 2003*, July 2003, p. 3.

[3]Ernst & Young, *The Economic Contributions of the Biotechnology Industry to the U.S. Economy*, p. 5. Retrieved from <http://www.bio.org/news/ernstyoung.pdf> (April, 2004).

[4]Biotechnology Industry Organization, *Editors' and Reporters' Guide 2003–2004*, June 2003, p. 5.

[5]Price Waterhouse Coopers LLP and the California Healthcare Institute, *Biomedicine: The Next Wave for California's Economy — 2002 Report on California's Biomedical R&D Industry*, 2002, p. 14. Retrieved from <http://www.pwcglobal.com/technology/lifesciences/CA%20Biomed%20R&D%20Survey%202002_Statewide.pdf> (April, 2004).

Evolution of a Drug:
An Example of the Biotechnology Process in Action

Paradigm shift

California biotechnology firms create and produce new pharmaceutical products in the same fashion as firms around the world. It is a complex, time-consuming, and very expensive process to bring an idea or a discovery from the mind of the researcher to the lab, and ultimately, to the consumer.

According to a 2003 report by the Tufts Center for the Study of Drug Development, "While the rate of new drug approvals in the U.S. doubled over the past three decades, annual research and development (R&D) spending has increased more than 12 times in inflation-adjusted dollars, leading firms to adopt a new R&D paradigm that stresses better, faster, and cheaper. Blockbuster drugs may be a desirable goal, but they require large user populations to generate large revenues. Genomic-based medicine will focus on smaller patient groups, heightening the emphasis on rapid and innovative product development."[1]

Research and development

A company's first steps in producing and marketing a new product involve the process of R&D. During R&D, small-scale experiments take place as scientists and laboratory staff work together to develop new products that offer promise. At this point, the number of staff is usually quite small. Typically, an R&D team would consist of scientists, research associates, laboratory assistants, and technicians. Because research is the primary function of the organization at this stage, most lead scientists possess Ph.D.s while other research associates and technical support staff members have bachelor's and master's degrees.

Research and development is a lengthy process that often lasts many years for each product. Research scientists concentrate on new discoveries, while other scientists and technical staff engage in process development and the scaling up of production resources to conduct full-scale manufacturing.

Research and development uses far fewer workers than manufacturing. Where R&D employs highly educated scientists, engineers, and support personnel, manufacturing generally does not require the same advanced educational requirements.

Limited production

Actual production begins at the R&D stage when small amounts of the product are needed for testing and various experiments, including, perhaps, human clinical trials. Production at this point includes cell culture and fermentation, where the desired cells and cell parts are grown, primary recovery where the product is captured for further processing, and the purification and packaging of the product into bulk form.

Clinical trials

A company must then prove to the U.S. Food and Drug Administration (FDA) that its product is safe and effective. After receiving permission from the FDA, clinical trials may begin testing the drug. During this phase, production of the product takes place in a pilot plant or in an expanded section of the laboratory. A small number of workers may be employed to operate this small manufacturing facility and to conduct clinical research.

Current Good Manufacturing Practices

Before receiving FDA approval for manufacturing and marketing of drugs and medical devices, a company must establish that its product can be manufactured consistently, and the production processes adhere to FDA and U.S. Environmental Protection Agency (EPA) regulations relating to the current Good Manufacturing Practices (cGMPs).[2] The FDA periodically inspects manufacturing facilities to make sure these regulations are followed.

Role of the FDA

As many as fifteen years may pass from the time a product is first conceived, developed, and tested before it finally receives regulatory approval from the FDA for manufacturing. Of course, some drugs never make it through clinical trials. And the longer the process, the more expensive. A 2002 Tufts Center study shows the average cost to develop and win market approval for a new drug in the U.S. is over $800 million. The FDA has put into place relatively new procedures called 'accelerated approval programs' that can trim years from the process. For example the Chronic Myelogenous Leukemia (CML) drug Gleevec was approved in less than three months after FDA received the drug's application. Of course, many years of research and trials came before the drug was submitted for approval.

Manufacturing

Upon receiving permission from the FDA, the manufacturing process is expanded to produce large quantities of the product that may include creating a manufacturing facility. Additional staff is hired for the manufacturing process, including technicians, operators of production and packaging equipment, quality systems personnel, and workers involved with product distribution.

At this stage of operation, the company hires more technical personnel with bachelor's or master's degrees, and fewer with Ph.D.s. Employment opportunities also increase for technicians who have associate's degrees from community colleges, as well as for support staff with high school diplomas or above.

Marketing and sales

The final component of the development of a drug or medical device is its marketing and sales. These activities ultimately provide the fuel on which the company runs. Without getting the drug into the hands of the professional or consumer, drug development, in a sense, is simply an interesting (and expensive) experiment.

Biotechnology companies have several options when it comes to marketing a drug.

- Market a new drug themselves.
- License the drug to another, often larger, company.
- Agree to be purchased by another firm.
- Forge an agreement with another company to jointly market the drug.
- Sell the new drug outright to another company.

Marketing and sales (continued)

Since many biotechnology companies are small, they frequently cannot effectively market a new drug. The advantages of joining forces with a company employing an established sales force are many and include the cost savings by utilizing an existing sales staff, one that has already established relationships with physicians, hospitals, and other customers. Pharmaceutical companies also often have a technical staff in place that can answer questions about drugs and medical devices, and, if necessary, travel to off-site locations to maintain and repair medical equipment. Marketing staff can also coordinate training and educational seminars necessary to familiarize customers with all aspects of a product.

Some large biotechnology companies (and pharmaceutical companies who have developed biotechnology products in house) have made the decision to retain the marketing and sales functions. The advantage of selling a product that was developed by the firm include closer connections between the customer and the researcher, greater control over product sales, and a potential for retaining more of the product's profit.

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[1]Tufts Center for the Study of Drug Development, PhRMA, *Outlook 2003*, 2003, p. 1.

[2]U.S. Food and Drug Administration, Center for Drug Evaluation and Research, 21 Code of Federal Regulations. Retrieved from <http://www.fda.gov/cder/dmpg/cgmpregs.htm> (April, 2004).

Occupational clusters

The occupations detailed in this report are grouped into seven major categories. They are:

Research and Development: This cluster consists of basic and applied research in the field of biotechnology. Research results in a gain of knowledge and understanding of a physical or biological process; development is the application of that knowledge to create new and improved biotechnological products. Integral to this process is the development of theory, the testing of hypotheses, the creating of models, and the clarification of knowledge. Research and development is done in the laboratory, greenhouse, an animal care facility, and in a field of agricultural crops, among others.

Clinical Research: Research done in a clinical setting. Generally this involves clinical trials of pharmaceuticals investigated for use by humans, but veterinary drugs are also tested before being approved for use in domestic animals and livestock.

Manufacturing and Production: Once a new drug or biotech product or device is developed, it must be manufactured if the company is to put its new knowledge to work to increase company revenue. In some cases, manufacturing and production is subcontracted to a different company. The manufacturing of pharmaceuticals and medical devices must meet standards set by the Food and Drug Administration, called the current Good Manufacturing Practices (cGMP). Good Manufacturing Practices (GMPs) are regulations that describe the methods, equipment, facilities, and controls required for production.

Regulatory Affairs: Drugs and medical devices cannot be sold in the United States unless they meet standards for safety and efficacy. There are steps that companies must take in order to prove that their particular products meet those requirements. An important part of this approval process involves clinical trials in which small numbers of patients are given the drug to establish safe dosing, as well as whether the trial drug is more effective than standard treatment. These workers may work closely with government officials.

Quality Systems: Quality control is vital in the manufacturing of important products such as pharmaceuticals or medical devices. Drugs, medical devices and other biotechnology products must meet government standards for purity and efficacy. Quality factors are part of manufacturing design parameters. Monitoring products to ensure they meet company and regulatory standards is another aspect of this area of biotechnology.

Information Systems: Computer databases and data storage are necessary to maintain the vast amount of information regarding the research and development of new biotechnology drugs and medical devices. Modern research, development and manufacturing organizations run on information. The organization of this information is crucial to the biotechnology industry. Poor organization and access to this information can prove fatal to a company.

Occupational clusters (continued)

Marketing and Sales: Product research and development are important, but a company needs to sell its products and services to remain in business. Biotechnology is no exception. However, since the industry offers highly specialized products and services, marketing and sales can prove to be challenging. A background in relevant technology and sciences, as well as a knack for sales and marketing, is often a requirement that biotechnology companies seek out. As in many technical businesses, marketing and sales personnel often work closely with the customer to help solve his or her problems with the company's products.

Individual occupation description format

The occupations described in the careers section which follows are representative of those found in the biotechnology industry. Administrative occupations in the biotechnology industry are not included in this guide. These occupations are found in most industries, and their duties, entrance requirements, and wages are similar to those found in other industries. Not all occupations are found in all companies, and job descriptions, education, experience requirements, and wages will differ between companies.

Each biotechnology career guide answers questions about the following categories:

Job Title: These titles reflect jobs commonly found in a biotechnology company. Alternate titles are job titles that might also be used by industry to describe the same job.

What They Do: This is a brief job description that lists responsibilities and day to day tasks.

Skills/Knowledge/Abilities: These are examples of some of the major skills, knowledge, and abilities necessary for a worker to successfully carry out the job.

Training Requirements: These are the minimum educational and work experience required by the industry for the job described. For many jobs, higher levels within a single occupation require more education and/or experience. Information in this section comes from job specifications in California biotechnology firms, recruitment Web sites, and other published data. Requirements stated often do not concur with those reported in the Bureau of Labor Statistics Occupational Training and Education Levels, largely because the federal data represent average requirements for these occupations across all industries.

Wages: A wage range is usually cited. The lower end of the wage range reflects the wages typically paid to entry-level workers. The higher end of the wage range reflects the pay for those workers with two to three years of experience in the job described. Wage data were obtained from the California Occupational Employment Statistics Survey and represent the occupation's wage across all industries, not exclusive to biotechnology firms.

California Outlook: These figures represent the projected growth of jobs in the occupation throughout California in all industries including biotechnology. Projections data are estimated using past industry employment trends, projected industry growth, and the occupational staffing patterns which array occupations across industries.

Occupational Codes: This report includes, where possible, appropriate occupational codes from the Standard Occupational Classification (SOC) system to provide a means of referencing other materials. "NA" indicates that codes were not found in the SOC system.

Additional Sources of Information: This section lists local and national associations or state licensing agencies and contact information.

Biotechnology: Is it for you?

Clues

Students and job seekers may wonder about a career in biotechnology. The following information may help as one considers the 35 occupations described in this report. If you answer yes to the following questions about yourself, you may find biotechnology a satisfactory field of work.

What is important to you?

Is it important for you to

- Use your imagination to find new ways to do something?
- Work with mathematics or statistics?
- Search for and discover new facts and develop ways to apply them?

School subjects

Have you liked and done well in one or more of the following school subjects?

- Animal Science or Husbandry
- Horticulture
- Zoology
- Chemistry
- Advanced Mathematics or Calculus
- Forestry
- Physiology
- Biology
- General Science
- Statistics

Leisure activities

Have you enjoyed any of the following as a hobby or leisure-time activity?

- Belonged to a 4-H, FFA, or garden club
- Bred animals
- Conducted experiments with plants
- Experimented with a chemistry set
- Performed experiments for a science fair
- Raised or cared for animals
- Read medical or scientific magazines
- Studied plants in gardens, parks, or forests

Work environment

Are you comfortable with the following factors common to the biotechnology work environment?

- Working indoors
- Importance of being exact or accurate
- Spending time sitting or standing
- Spending time using your hands to handle, control, or feel objects, tools, or controls
- Wearing common protective or safety equipment

Exploring biotechnology

The following table “Interests for Biotechnology Careers” arrays the 36 biotechnology occupations by interest types to assist career seekers to select occupations suited for them. Appendix A lists the biotechnology careers by occupational cluster. An alphabetical list of biotechnology occupations is in the Table of Contents. Appendices C and E display the occupations by education and training requirements.

Do biotechnology occupations match your interests?

These two pages look at biotechnology occupations through an "interest" lens. Interests generally refer to the like or dislike of activities. Human personalities and work environments can be classified into the six broad categories of vocational personalities and environments described on these two pages. You function best and find job fulfillment in work environments that are in harmony with your personality.

REALISTIC OCCUPATIONS frequently involve work activities that include practical, hands-on problems and solutions. They often deal with plants, animals, and real-world materials like wood, tools, and machinery. Many of the occupations require working outside, and do not involve a lot of paperwork or working closely with others.	Animal Handlers Animal Technicians Assay Analysts Biochemical Development Engineers Clinical Research Associate Instrumentation/Calibration Technicians Laboratory Support Workers Library Assistants Manufacturing Engineers Manufacturing Technicians Microbiologists Plant Breeders Process Development Associates Process Development Engineers Production Planner Schedulers Quality Control Engineers Research Associates Sales Representatives Scientific Programmer Analysts Scientists Validation Technicians
INVESTIGATIVE OCCUPATIONS frequently involve working with ideas, and require an extensive amount of thinking. These occupations can involve searching for facts and figuring out problems mentally.	Animal Technicians Assay Analysts Biochemical Development Engineers Biostatisticians Clinical Research Associates Manufacturing Engineers Manufacturing Research Associates Microbiologists Plant Breeders Process Development Associates Process Development Engineers Production Planner Schedulers Quality Assurance Analysts Quality Assurance Auditors Quality Control Inspectors Quality Control Engineers Research Associates Safety Specialists Sales Representatives Scientific Programmer Analysts Scientists Medical (Technical) Writers
ARTISTIC OCCUPATIONS frequently involve working with forms, designs, and patterns. They often require self-expression and the work can be done without following a clear set of rules.	Medical (Technical) Writers Graphic Designers

Do biotechnology occupations match your interests? (continued)	
Individual personalities and occupations both blend more than one interest area. Read the definitions of each interest area. Biotechnology occupations that would likely satisfy the interest area are listed next to the definition. More than one interest group may fit you. An occupation may also appear in more than one group.	
SOCIAL OCCUPATIONS frequently involve working with, communicating with, and teaching people. These occupations often involve helping or providing service to others.	Animal Technicians Customer Service Representatives Library Assistants Safety Specialists Sales Representatives
ENTERPRISING OCCUPATIONS frequently involve starting up and carrying out projects. These occupations can involve leading people and making many decisions. Sometimes they require risk taking and often deal with business.	Customer Services Representatives Process Development Associates Production Planner Schedulers Manufacturing Engineers Quality Control Engineers Safety Specialists Sales Representatives
CONVENTIONAL OCCUPATIONS frequently involve following set procedures and routines. These occupations can include working with data and details more than with ideas. Usually there is a clear line of authority to follow.	Assay Analysts Biostatisticians Customer Service Representatives Documentation Coordinators Instrumentation/Calibration Technicians Library Assistants Manufacturing Research Associates Manufacturing Engineers Process Development Associates Production Planner Schedulers Quality Assurance Auditors Quality Control Analysts Quality Control Inspectors Quality Control Engineers Research Associates Sales Representatives Scientific Programmer Analysts Scientists Validation Technicians

Preparing for Jobs in Biotechnology

Skills needed

Employers in the biotechnology industry have stated that there are many skills and abilities they look for in entry-level workers. Some of these include the following:

- Ability to work as a team member.
- Knowledge of Good Laboratory Practices (GLP).
- English language skills: to communicate and understand written and spoken instructions and directions, conduct record keeping, and maintain log books.
- Use of basic math: add, subtract, multiply, and divide using whole numbers, fractions, and decimals; solve problems using percentages, metric system conversions, and ratios. Highly level technical jobs will require competency in college level mathematics.
- Use of computers for word processing, producing spreadsheets, and manipulating data.
- Ability to understand and follow instructions such as governmental regulations and company policies relating to safety, production practices and laboratory procedures.
- Attention to detail.
- Recognition of problems and reporting them.

Education

High school: Students preparing for careers in biotechnology should be prepared to complete high school courses such as chemistry, biology, and mathematics. Laboratory experience and training is especially important to develop the basic skills that will be needed on the job or to succeed in course work at community college and university levels. A strong base in the high school sciences and mathematics, in addition to the development of communication skills, is especially necessary to prepare students for employment if they wish to enter the workforce upon graduation from high school.

Community college-employer partnerships: Some community colleges, industry organizations, and companies have established or are attempting to forge partnerships to provide training to prospective biotechnology technicians. For those who are interested in careers as scientists in California, almost all community colleges offer courses in the biological sciences, and about one-third of them offer programs, courses, or certificates in biotechnology.

Students should work closely with their instructors, counselors, and advisers throughout their years in high school and college to plan their academic programs and to assess their opportunities in the industry. Companies may be willing to hire interns, and many will consider interns who have completed high school, graduates with associate degrees, and students attending community colleges.

Training

Most biotechnology companies provide in-house training following employment; however, it would be more realistic to expect training from a combination of sources: employers, colleges and universities, and technical schools. Schools in the California Community College, California State University and University of California systems, and private institutions throughout the state offer numerous courses ranging from biology and the biological sciences to biochemistry, bioengineering, and biomedical physics to molecular and cellular biology.

Career clusters

Students should be aware that the biotechnology industry continually changes as it develops new products. The mix of workers in the manufacturing stage will differ from the worker mix in research and development. Some companies may eventually specialize in R&D while others may concentrate more on manufacturing. A company specializing in R&D will tend to hire fewer workers than a manufacturing facility. It will also hire mainly scientists, engineers, and a small number of technicians to develop and test their products. When a company reaches the manufacturing stage, it then hires more workers to staff technical, clerical, administrative, sales, and maintenance positions.

Exhibit 5: Biotechnology Careers at a Glance

Occupation Clusters	Education	Growth 2000–2010[1]	75th Percentile Hourly Wage[2]
Research and Development Occupations			
Greenhouse Assistants*	High School	23%	$16.95 to $22.56
Laboratory Support Workers*	High School	-2%	$8.43 to $16.48
Laboratory Assistants*	Certification or Associate	28%	$21.96 to $22.56
Plant Breeders*	Bachelor's	22%	$16.95 to $34.49
Research Associates (R&D)*	Bachelor's	34%	$28.28 to $42.59
Research Scientists*	Doctorate	34%	$28.28 to $42.59
Clinical Research Occupations			
Animal Handlers	High School	34%	$11.97
Animal Technicians	Certification or Associate	44%	$11.94
Biostatisticians	Master's	13%	$42.48
Bioinformatics Specialists*	Master's	99%	$42.28 to $50.04
Clinical Research Associates*	Bachelor's	28%	$35.92 to $39.24
Medical (Technical) Writers	Bachelor's	30%	$38.03
Manufacturing Occupations			
Assay Analysts*	Certification or Associate	35%	$21.96 to $22.37
Biochemical Development Engineers	Bachelor's	21%	$49.96
Instrumentation/Calibration Technicians*	Certification or Associate	3%	$18.06 to $29.44
Manufacturing Engineers	Bachelor's	6%	$43.18
Manufacturing Research Associates*	Bachelor's	21%	$33.91 to $43.18
Manufacturing Technicians*	Certification or Associate	9%	$11.02 to $18.66
Process Development Associates*	Bachelor's	15%	$34.20 to $43.18
Process Development Engineers*	Bachelor's	8%	$43.18 to $49.96
Production Planner Schedulers*	Bachelor's	14%	$22.74 to $43.18
Regulatory Affairs Occupations			
Documentation Coordinators	High School	19%	$15.52
Documentation Specialists	Bachelor's	34%	$47.73
Quality Systems Occupations			
Microbiologist	Bachelor's	41%	$33.91
Quality Assurance Auditors	Bachelor's	12%	$29.96
Quality Control Analysts	Bachelor's	12%	$29.96
Quality Control Engineers	Bachelor's	6%	$43.18
Quality Control Inspectors	High School	-1%	$18.06
Safety Specialists	Bachelor's	24%	$33.16
Validation Technicians	Certification or Associate	-1%	$18.06
Information Systems Occupations			
Library Assistants	High School	27%	$16.18
Scientific Programmer Analysts	Bachelor's	59%	$41.18
Marketing and Sales			
Customer Service Representatives	Bachelor's	34%	$18.44
Graphic Designers	Bachelor's	29%	$27.70
Sales Representatives	Bachelor's	14%	$45.67
Technical Services Representatives	Bachelor's	23%	$22.56

*Wages and employment reported for these occupations represent a sum of two or more Standard Occupational Classification (SOC) categories that together more fully describe the job within the biotechnology industry.

[1]See individual occupation descriptions for details about estimated number of job opportunities.

[2]The 75th percentile wage means that 75 percent of workers earn less than the 75th percentile wage and 25 percent of workers earn more. A range of wages in the 75th percentile wage column represents the spread among all the SOC categories that represent the biotechnology occupation.

Source: EDD/LMID's Employment Projections by Occupation 2000–2010 and Occupational Employment Statistics Survey, 2004.