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# VAULT CAREER GUIDE TO BIOTECHNOLOGY

# VAULT CAREER GUIDE TO BIOTECHNOLOGY

CAROLE MOUSSAU
AND THE STAFF OF VAULT

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# THE SCOOP

# Overview of Biotech

CHAPTER 1

## What is Biotechnology?

Biotechnology, or biotech for short, refers to the use of biological processes to either make products or solve human problems. Biotech processes have been used for thousands of years, yet the industry we know today is scarcely more than a quarter century old. Bread, cheese, and beer all products made from microorganisms have been part of the human diet for 6,000 years. But it was not until the 1970s that scientists began to apply components of these microorganisms at the molecular level to solve human problems in a variety of spheres, including medicine, agriculture, and industry. Due to this breadth of applications, the term biotechnology gradually gave way to the more accurate biotechnologies, a collection of techniques that apply cellular and molecular characteristics and processes to solve human problems.

### How does biotech work?

Biotech products are based on two basic phenomena. First, nearly all life is similar at the cellular and molecular level. Second, the cells and molecules have very specific functions and tasks. The basic genetic material DNA, (deoxyribonucleic acid), which provides the instructions cells need to replicate and perform cellular tasks, and proteins, which provide the building blocks for performing the cell s tasks, are the two fundamental components of biotechnology products. Because these instructions are the same across all cells, technologies based on DNA can be applied across all cell types. And because cells and molecules have specific tasks, specific products can be developed for these tasks, often with more reliability and predictability than conventional pharmaceutical products.

### Interesting biotech factoids

The biotechnology industry has tripled in the 1990s. By May 2002, it had a market capitalization of $224 billion. In 2002, a total of 1,466 companies employed over 142,900 people in the US alone. Of those companies, 318 are publicly held. Over 325 million people have benefited from the more than 130 FDA-approved drugs and vaccines produced by the industry. Over two-thirds of these drugs were approved in the last six years. A research-driven industry, US biotech companies spent $16.3 billion on R&D in 2002, with the top five spending an average of $89,400 per employee in 2000. The scale of

this effort has produced over 350 products and vaccines in clinical trials, which target over 200 diseases, including cancer, diabetes, multiple sclerosis, and AIDS.

The industry s productivity reaches across several industrial sectors. Biotech companies have produced hundreds on medical diagnostic tests, including tests to detect the AIDS virus and home pregnancy tests. In agriculture, the industry has made foods such as papaya and soybeans more widely available and has produced hundreds of biopesticides and other agricultural compounds. Biotech products are also helping clean up the environment of hazardous waste and rendering industrial processes (e.g., chemicals, paper, textiles, etc.) cleaner and more energy efficient. Finally, the exciting new technique of DNA fingerprinting is making significant contributions in law enforcement and forensic science, in addition to anthropology and wildlife management.

## Where is Biotechnology Applied?

The biotech industry is diverse: there s room for a wide diversity of talent. This is exciting, since the industry employs people in virtually every scientific discipline, as well as in the traditional business functions. For example, scientists specializing in biology or chemistry can find work in basic or discovery research; while engineers can focus on the operations or manufacturing functions or on industrial processes. Increasingly, as the industry matures, demand for people with accounting and finance skills will also increase.

### Healthcare

Biotech products and techniques can be found in four major areas of healthcare, including: biopharmaceuticals, gene therapy, diagnostic testing, and tissue replacement.

Therapeutic drugs and vaccines made using biotech techniques are referred to as biopharmaceuticals, and are likely to become the leaders in the treatment of a plethora of disease conditions. Areas of active research include autoimmune disorders, cancer, cardiovascular diseases, genetic defects, infectious diseases, nephrology, and neurological disorders. Specifically, biopharmaceuticals targeting anemia, cancer, heart disease, impotence, infectious diseases, lysosomal storage disorders, multiple sclerosis, psoriasis, and rheumatoid arthritis will likely be the most prevalent in the remainder of the decade.

Most biotech research in the development of pharmaceuticals is essentially a two-step process. Because the human proteome (the full complement of proteins in human beings) is composed of several hundred thousand proteins, each with a specific function in the cell, biotech researchers first begin by identifying those proteins most likely to be responsible for the formation of a specific disease. Such a protein then becomes the target. To date, some 500 targets have been identified, with almost 5,000 more possible by the middle of the decade. The field of endeavor that studies the human proteome is called proteomics; its goal is to understand the role of proteins in the formation of disease. Once a target has been identified, the second step can begin the creation of therapeutic agents that can react with the protein to alter the pathway of a disease process.

Biotech products based on proteomics include protein-based drugs (administered by various modes of injection), such as monoclonal antibodies that may bind to cell surface receptors, and orally available small-molecule drugs (administered as a pill or capsule) that modulate cellular signaling.

A sister field to proteomics is genomics, the study of the human genome the full complement of genes in a human being. In addition to mapping genes, genomics seeks to determine their nucleic acid structures and understand their functions. Estimated at between 30,000 and 120,000, genes like proteins form a base from which additional targets can be identified. Gene therapy employs agents specifically directed against genetic targets.

Together, proteomics and genomics are reshaping the drug development landscape of the modern biopharmaceutical industry and rendering the process of creating therapeutic agents more precise, more efficient, and more predictable.

Biotech techniques are also being applied in diagnostic testing. Among the tests currently available are monoclonal antibody-based tests, genetic probes, DNA amplification, and agents to improve in vitro diagnostic imaging. Finally, biotechnology applications are being used to replace diseased or destroyed tissues. The technique is based on a substance called tissue plasminogen activator (TPA), made in the inner lining of blood vessels. TPA s main function is to prevent abnormal blood clotting.

## Agriculture

With the world s population expected to reach 10 billion people by 2030, according to United Nations estimates, agricultural biotech is poised to make a major contribution to the problem of feeding the world. Indeed, some

estimates predict that the world s food supply will have to double to keep pace with this increase in population. Biotech based foods, biopesticides, and plant and veterinary disease diagnostics are some of the areas of application of biotechnology in agriculture. These products and methods are used to increase crop yields, decrease required input resources (e.g., water and fertilizer), and create environmentally friendly pest control methods.

Rather than rely on the traditional but more costly and inefficient methods of crossbreeding and hybridization, farmers now use biotechnology techniques to improve crop yields and enhance the quality of food products. These techniques are more precise and selective in that single genes with known and desired characteristics can now be moved to a plant, making the plant s growth characteristics much more predictable. In addition, depending on the gene inserted often from a bacterium the plant will also be hardier and more resistant to diseases and pests.

Based on microorganisms, biopesticides are toxic to targeted pests and are able to control pest populations that have developed resistance to standard chemical pesticides. One example is the Bt (bacillus thuringiensis) bacterium, which is lethal to the European corn borer, an insect responsible for $1.2 billion in crop damage in the US annually. Biotechnology techniques are also being used to enhance the tolerance of plants to herbicides, which will kill the weeds that often grow alongside crop plants but not harm the plant. This is useful because traditional sprayed herbicides are expensive, reduce crop yields, and are not environmentally friendly.

Biotechnology has improved the nation s livestock by enhancing animal health and productivity. Veterinary disease diagnostics help treat and prevent disease in animals. Improved quality of feed helps meet the dietary needs of livestock. Animals and plants are also being used as factories for producing pharmaceuticals and chemicals. The two immune system proteins, interferon and interleukin-2, are made naturally in cattle. Potatoes and bananas have been used to produce vaccines to treat a variety of diseases, including cholera, hepatitis B, and food poisoning bacteria. Such plant-based pharmaceuticals are much more cost-effective to produce and distribute than traditional counterparts. They can, therefore, become more widely available to both developed and developing countries.

## Food processing

In the food processing industry, microbial starter cultures, enzymes, and vitamins are being used to create food products that require fermentation,

such as beer and cheese. More importantly, biotechnology techniques are being incorporated in food contamination test kits that help detect E. coli and the Norwalk virus.

## Industrial processing

Biotechnology techniques are also being applied to a wide variety of industrial processes, including:

Organic chemicals
Energy production
Mineral recovery
Waste-stream reduction
Bioremediation
Enzymes
Bioelectronics

In manufacturing and synthesis, conventional chemical engineering processes are giving way to technologies to create a variety of products. Enzymes are being used to convert cellulose to sugar, and from there, ethanol, an alternative fuel for transportation energy. Additional products from the conversion of cellulose include bulk, fine, and commodity chemicals and polymers. Bio-based products are carbon-neutral and hence do not contribute to global warming. They are also biodegradable, and make use of renewable resources, as opposed to fossil fuels. The benefits of this shift in manufacturing techniques include better economics (i.e., lower costs, higher profits), less pollution, and conservation of resources.

In other activity, genes in microbes are being modified to produce enzymes for underground injection to complete newly drilled oil wells. Bioprospecting refers to the search for microbes with unique profiles to be used in industrial processes. In the growing field of environmental biotechnology, the technique called bioremediation uses microbes and enzymes to clean up pollution.

Biotechnology is being applied to the forestry industry, a $400 billion industry, to increase its productivity. This is particularly important since global demand for wood products in 2010 is expected to be about 20 percent higher than the current usage of 1.9 billion cubic meters (UN Food and Agriculture Organization). Biotech processes are helping increase growth rates and render more efficient the conversion of solar power into wood production. In addition, biotech processes are helping produce trees that are

healthier, more insect- and disease-resistant, and less vulnerable to forest pests.

Enzymes produced by biotechnology provide the forestry industry with the means to pretreat and soften wood chips, remove pine pitch from pulp, bleach pulp without chlorine, de-ink recycled paper, help convert wood processing waste to produce energy, and remediate contaminated soils.

## Regulation of the Biotech Industry

Several agencies of the US government regulate the activities and product introductions of the biotech industry; some have overlapping responsibility. The Food and Drug Administration (FDA) reviews and approves biotech products in the healthcare sector, much like it does for the pharmaceutical industry. The FDA approves the safety of all foods and new food ingredients. In addition, all producers are required to ensure the safety and quality of anything they introduce into the food supply.

Three major events are shaping the regulatory environment in the biotech healthcare arena. First, in reaction to criticism that it was acting too slowly, the FDA moved the review of biologic drugs from the Cneter for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation and Research (CDER) in September 2002, thus bringing the review of all human therapeutics under one roof. This move was supported by the Biotechnology Industry Organization (BIO), a major industry group, which also expressed optimism that its review process will be expedited. Second, the appointment of Dr. Mark McClellan as the FDA s new Commissioner in October 2002 filled a two-year vacancy, one which some observers had noted may have delayed approval of new products. And third, in August 2002, the FDA announced a new plan to improve the quality and safety of manufactured drugs. These actions combined will help stem and hopefully reverse the decline in approval of new products and shorten the timeframe needed for approval. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), new product approvals have been declining from 53 in 1996 to 24 in 2001 and timeframe needed for approval grew from 11.7 months in 1998 to 16.4 months in 2001.

In addition to rigorous testing, the FDA requires labeling of any food product produced from genetically altered sources, especially when the nutritional composition of the end product has been significantly

affected. Any use of a known allergen must also be disclosed on the label.

The US Department of Agriculture (USDA) regulates agricultural products produced by the food industry, setting standards to ensure that new crops created through biotechnology techniques are at least as safe and that pesticides and herbicides are at least as effective as those grown conventionally. Over 5,000 field trials have been conducted on over 20,000 plots in the US since 1988.

The Environmental Protection Agency (EPA) oversees growing of plants with pest-protection characteristics and coordinates with the USDA and FDA, using its own statutes, and establishes allowable food residue tolerance levels for any new compounds.

# Biotech History and Trends

## Young industry, explosive growth

The biotechnology industry has experienced phenomenal growth over the last quarter century. Its first phase can be traced all the way back to 1750 BC, when the Sumerians used yeast to brew beer. As early as 500 BC, the Chinese used mold as an antibiotic. In the 1860s, Gregor Mendel worked on gene transmission in plants, initiating the study of genetics. In the 20th Century, an agricultural engineer coined the term biotechnology in 1919. In 1928, penicillin was discovered. In 1953, Watson and Crick discovered the structure of DNA.

The following two decades from 1960 to 1980 saw a rapid acceleration in knowledge. The first synthetic antibiotic was available in 1960. The first mouse-human cells were fused in 1965. The genetic code was cracked in 1966. By the 1970s, methods to cut and paste genes were developed. By 1981, the first transgenic animals were bred.

By 1983, the first artificial chromosome was made followed rapidly by genetically engineered plants in 1985, the use of microbes to clean up environmental pollution (oil spills) in 1986, and the first patent for a genetically altered animal in 1988.

In the 1990 s, the first non-viral full gene sequence was completed in 1995, followed by the unveiling of the cloned sheep Dolly in 1997, and the near-completion of mapping of the human genome in 2002.

This dizzying acceleration of knowledge has created a burgeoning industry with an increasing number of commercial products, which, despite the stock market downturn in the last two years, is poised to undergo significant growth in the remainder of the decade and onward in the 21st century. In other words, this is an exciting time to be thinking about and preparing to get into the biotech industry.

## Key trends

Despite the downturn in stock price valuations since the spring of 2000, the future of biotech remains intact. But the industry is being impacted by several broad structural changes, technological transformation, demographic shifts, and the emergence of new tools.

Perhaps the most significant change lies in the evolution of new business models for biotech entities. Although venture capital funding in 2002 was above that in 2001, the post-crash slump has forced a re-examination of how biotech companies are being kept alive as economic entities. Original models that did not project earnings until 10-15 years after a company is founded have given way to more pragmatic models that seek to introduce revenue streams much earlier, largely by creating a network of alliances between specialty biotech companies and larger pharmaceutical companies with established sales and marketing infrastructures.

Furthermore, the number of publicly traded companies has declined through mergers and acquisitions, as the industry consolidates both within itself and across to pharmaceutical companies. In 2001, there were some 631 public biotech companies; in 2002 that number shifted downward to 613 public companies. The most significant mergers occurred within the industry: Amgen, Inc. acquired Immunex Corp., makers of Enbrel for rheumatoid arthritis, for approximately $17.8 billion; MedImmune Inc. bought Aviron in January 2002, makers of FluMist influenza vaccine, for $1.6 billion; and in February 2002, Millennium Pharmaceuticals Inc. completed purchase of COR Therapeutics Inc., makers of Integrilin for acute coronary syndromes and patients undergoing percutaneous coronary intervention, for $1.8 billion. Analysts believe that this trend is likely to continue, as companies merge, restructure, or simply go out of business.

The trend toward consolidation is also coupled with the continued globalization of the industry, as companies seek out the best alliance partners from both domestic and foreign pharmaceutical companies, and as the latter gobble up biotech companies to expand their product portfolios.

Increasingly, companies are listed on US and foreign exchanges to expand investor bases. The explosion of Internet-based communication has facilitated scientific collaboration around the world. Finally, governments across the United Kingdom, European Union, and Scandinavia and Asia are increasingly cognizant of the need to invest in early-stage biotechnology companies as part of their economic development strategy. In the US alone, funding for basic research for the National Institutes of Health has doubled to $23 Billion over the last five years.

The trend toward globalization has created a need to harmonize the global regulatory environment, as lack of consistency in patent and intellectual property protection has hampered the entry of Western companies and kept valuable biopharmaceuticals from reaching needed markets.

Within the context of these global trends, several additional forces are shaping the industry. The biotech industry is expected to grow at a rate in the high teens for the remainder of the decade, according to the Standard & Poor industry surveys. This anticipated growth is great news both for those starting a career in biotech or for more experienced professionals, who will find more opportunities. Growth will likely come from the major, more established biotech companies, since they have product sales, full pipelines, and stable fundamentals. In contrast, the smaller, emerging companies are likely to continue to struggle. S&P has identified several broad industry trends, which are fueling this expected growth in revenues, including:

Development of new biologic therapies
Favorable demographics
Analytical tools companies struggling
Emerging integration tool in bioinformatics

Development of new biologic therapies, particularly for the treatment of cancer, is likely to fuel the most significant growth in the coming years. With some 500 biotechnology-related drugs in clinical trials as of 2002 and some 400 agents targeted for cancer treatment alone, biotechnology is set to make a major mark in oncology. In 2001, Cancer drugs Procrit, Epogen, Intron A, Neupogen, and Humulin reached $1 billion each in revenues and in 2002, Rituxan, Enbrel, and Remicade achieved the same benchmark.

In addition to cancer, the industry has ongoing research in many disease conditions exacerbated by aging, including autoimmune disorders, cardiovascular diseases, genetic defects, infectious diseases, nephrology, neurological disorders, lysosomal storage disorders, multiple sclerosis, psoriasis, and rheumatoid arthritis. The search for new biopharmaceuticals

plays is important in making the US healthcare system more efficient, since biopharmaceutical drug therapy is less costly and less invasive than surgical alternatives and can be self-administered by the patient. As a result, the burden on the healthcare system is reduced via shorter stays in acute care facilities, such as hospitals, fewer doctor visits, and less convalescent time in nursing homes.

From a demographic perspective, of the 281 million people in the US population today, approximately 62 million constitute the 45-to-64 year old age group the Baby Boom generation. While the US population is expected to increase 8 percent between 2001 and 2010, this cohort will expand by 26 percent over the same period. It is by far the fastest growing segment of the overall population. In addition, with life expectancy in 1999 at 76.7 years and climbing, aging baby boomers are creating a rapidly growing market for aging related disease treatments based on biotechnology.

Furthermore, according to the census bureau, the over-65 year old population is expected to more than double between 2001 and 2030, which will represent 13 percent to over 21 percent of the overall population. Since senior citizens now account for approximately 33 percent of pharmaceutical consumption, their growing numbers can only bode well for the prospective demand for the industry s products.

Thus, by focusing its research on the four leading causes of death in the US heart disease, cancer, cerebrovascular disease, and chronic lower respiratory disease the biotech industry is set to bring to market biopharmaceuticals for which there is an expanding base of demand.

A new field, bioinformatics, stands out as particularly promising in managing and interpreting the masses of data generated by genomic and proteomic research. Bioinformatics refers to the use of advanced databases and computer analysis tools to perform queries and simulations, cross-reference and compare data, archive test results, and collaborate. This new field has spawned academic programs and is one of the promising new career paths created by the industry.

# Developing New Drugs

CHAPTER 2

## Major Tools and Techniques Used in Biotechnology

The biotech industry employs a host of tools and techniques to develop new drugs. Having a basic understanding of these will help you understand how the industry obtains data and acquaint you with the companies that specialize in these analytical tools. Although some of the minor players have been hit hard in the last two years, the major players Applied BioSystems Group, Invitrogen Corp., Millipore Corp., and Waters Corp. have introduced new products and continue to be profitable.

| Tool/Technique | Description | Leading Company |
|---|---|---|
| Genomic databases | Databases that compile information on the characteristics, expression, and function of genes and proteins, the features of single nucleotide polymorphisms, aspects of medicinal chemistry, and drug screening. | Celera Genomics Group and Incyte Genomics Inc. |
| Biochips | Miniature slide or plate that allows researchers to perform tests to understand the structure and function of genes and proteins. | Affymetrix |
| High performance liquid chromatography (HPLC) | HPLC provides a more automated way to separate proteins than do 2-D gels or isotope-coated affinity tags but is not as sensitive as these methods. | Waters Corp. and Agilent Technologies |
| Isotope-coded affinity tags (ICAT) | A newer, more sensitive method for labeling proteins, ICAT can detect proteins that 2-D gels might miss. | Applied Biosystems Group |
| Mass spectrometry (MS) | Instruments that measure the mass-to-charge ratio of peptides (protein fragments) and allow scientists to quantify the characteristics of proteins. | Applied Biosystems, Waters, and Thermo Electron Corp. |
| 2-D gels | Used to separate thousands of proteins from cell or tissue samples. After separation onto a gel, protein characteristics are analyzed by specialized computer software. | Amersham Biosciences |
| X-ray crystallography | Used to determine the three-dimensional structure of a protein, as part of the search for small-molecule drugs targeting specific cellular pathways, which may interrupt a protein s synthesis. | Structural Genomix Inc. and Syrrx Inc. |

# Ethical Issues in Biotech

Because it is grounded in the use of living organisms to produce drugs and food, the biotech industry has been grappling with ethical issues as more and more products become available. Remarkably, the nascent industry proactively moved to regulate itself as early as 1973, shortly after Drs. Herbert Boyer and Stanley Cohen successfully recombined DNA by forming the Recombinant DNA Advisory Committee (RAC) to explore the consequences of this achievement and to investigate the risks involved in conducting research in this area. During the next decade, as basic research moved toward product development, the industry again acted proactively by formulating and adopting safety standards for industrial manufacturing using organisms derived using recombinant DNA technology. Today, work on stem cells, cloning, and the development of genetically modified crops are the main sources of controversy.

## Stem cell research

The stem cell controversy derives from the potential power of these undifferentiated embryonic cells to become differentiated into virtually any type of cell found in the human body. Scientists have the ability to maintain and focus the development of such cells to replace existing cells that are either cancerous or which have lost their capacity to function normally due to accidents and/or disease. Thus, in addition to cancer, patients suffering from diabetes, stroke, brain and spinal cord injuries, as well as diseases associated with aging, can potentially have a new source of healthy cells. The consequences of successfully implementing this vision have raised enough questions that the NIH issued a policy in 2000 that would allow some research under strict federal oversight. In August 2001, the Bush administration restricted the policy somewhat but permitted continued federal funding. Subsequently, the NIH has issued update guidelines to the industry to implement the new policy.

## Cloning

Cloning refers to the laboratory replication of genes, cells, or organisms from a single entity, meaning that exact copies of genes can be made. Although the National Bioethics Advisory Commission (NBAC), with industry agreement, has acknowledged the moral, ethical, and safety consequences of this activity, there is, nevertheless, one strand of cloning research that is supported by the industry.

Therapeutic cloning or somatic cell nuclear transfer (SCNT) refers to the use of undifferentiated cells that are genetically identical to those of a patient, and hence have no potential of incurring rejection. Such cells can develop into new tissues targeted to replace diseased tissues and offer promising new treatments for Alzheimer s, Parkinson s, heart disease, and many cancers.

## Food and agriculture controversy with the European Union

Perhaps the most heated debate, however, surrounds the development and marketing of genetically altered crops. Agricultural scientists have long experimented to develop varieties of crops among them soy, corn, cotton, etc. that are hardier, more disease and pest resistant, and more nutritious. Success in this area has been remarkable: by 2002, a full 74% of the total US soybean crop acreage, 71% of cotton, and 32% of corn used biotech breeding methods. Biotech has also produced fruits and vegetables (e.g., tomatoes and raspberries) that are longer lasting and less prone to disease. Aquaculture has produced salmon and other fish that breed faster and cost less. Overall, the biotech food market is estimated to expand 18 percent to $5 billion by 2005.

Yet despite these advantages, concerns remain both at home and abroad. In July 2003, critics took to the streets in Sacramento, CA, decrying the use of terminator genes and raising the possibility that cross-pollination of genetically altered foods with those grown in the wild will harm plant diversity and pose unknown health dangers to humans who consume them. Also in July 2003, the European Union (EU) recently ended the five-year moratorium on genetically altered crops it imposed in 1998 to have time to study health and safety concerns and to develop a system of tracing and labeling biotech foodstuffs. The EU requires such crops have clear labels. The US, along with Argentina and Canada, formally requested a panel of experts from the World Trade Organization (WTO) to rule the EU guidelines illegal. The US and its allies claim that the guidelines are cumbersome, difficult to implement, and constitute a trade barrier. American farmers claim they lost some $300 million per year in lost corn exports. The US seeks full and unconditional acceptance of biotech-based foodstuffs.

## Recent Products

The U.S. Food and Drug Administration (FDA) has approved several new products for marketing in the last few years. In May 2001, the FDA gave Novartis marketing approval for Gleevec for treating patients with chronic myeloid leukemia, a cancer drug developed through rational drug design. In 2002, Gleevec gained approval for gastrointestinal stromal tumors, and may prove applicable to other forms of cancer. In May 2003, the FDA approved Gleevec® for use in pediatric CML (chronic myeloid leukemia) patients, an indication that includes children as well as adults.

In October 2001, the FDA granted Gilead Sciences approval to market Viread® for the treatment of HIV infection in patients being concurrently treated with other anti-retroviral agents and who were also showing signs of HIV-1 viral replication despite ongoing anti-retroviral therapy. Approval of this drug has been a boon for Gilead Sciences, whose second-quarter 2003 revenues significantly exceeded projections, due largely to sales of Viread®.

In 2002, Amgen received FDA approval to market Aranesp® for the treatment of anemia in patients with nonmyeloid malignancies, and where the anemia is caused by chemotherapy that is administered concomitantly. Aranesp® also reduces the need for transfusions. Since its approval, it has eroded sales of Procrit®, made by Johnson & Johnson. Amgen, the world s largest biotech company, hopes revenues from sales of Aranesp® will help double its 2002 revenues, to $10 billion, by 2005.

In December 2002, as a result of its purchase of Immunex, Amgen also gained the right to market Enbrel, a billion-dollar drug for the treatment of rheumatoid arthritis, polyarticular-course juvenile rheumatoid arthritis and psoriatic arthritis. By July 2003, the FDA s Arthritis Advisory Committee recommended Enbrel as the first biologic treatment for ankylosing spondylitis, since ongoing clinical trials showed improved spinal mobility and pain management.

In 2003, Genzyme gained both the European Commission and FDA approval to market Aldurazymeâ, the first specific treatment for people people suffering from mucopolysaccharidosis I (MPS I), a progressive, debilitating and life-threatening disease caused by an inherited deficiency of alpha-L-iduronidase, a lysosomal enzyme. This drug is the result of a collaborative effort by Genzyme and BioMarin.

In 2003, the FDA also approved Fabrazyme, an enzyme replacement therapy to treat patients with Fabry disease, a genetically inherited condition based on lysosomal storage disorders that has broad symptoms and can manifest in

various degrees of severity. Fabrazyme is one of several new drugs whose approval was fast-tracked by the FDA in response to calls for more expedient drug approval processes. An expensive drug, financing for Fabrazyme has recently been met with resistance from state-funded drug programs. In July 2003, the Health Department of Ireland refused to approve additional financing to make the drug available for its citizens, arguing that Fabrazyme could cost up to 200,000 Euros per patient per year.

In March 2003, the FDA granted Roche Laboratories approval to market FUZEON , for the treatment of HIV-1, under an accelerated six-month priority review process. It is the first in a new class of drugs called fusion inhibitors, which keep the HIV virus from getting into cells. FUZEON , combined with other anti-retroviral agents is indicated for patients already being treated for HIV-1 and who exhibit signs of HIV-1 replication despite ongoing anti-retroviral therapy. Roche Laboratories entered into a co-marketing agreement with Trimeris, Inc. to market FUZEON .

In June 2003, the FDA granted Genentech approval to market Xolair, the first humanized therapeutic antibody for asthma and the first approved therapy designed to target the IgE antibody, a key underlying cause of the symptoms of allergy-related asthma. Xolair is manufactured by Genentech and co-marketed by Genentech, Novartis Pharmaceuticals, and Tanox, Inc.

## The Drug Discovery, Testing, and Approval Process

The drug discovery, testing, and approval process in the United States is the most rigorous in the world, often taking years and hundreds of millions of dollars. The central goal is to provide the public with medications that are both safe and effective. The major steps in the process are the same for both regular and biopharmaceuticals and are listed below, followed by the average number of months required to obtain FDA approval. It s important to understand this process because it provides the framework around which all biopharmaceutical products are shepherded from the laboratory ultimately to the marketplace.

Discovery

Preclinical testing

Phase I

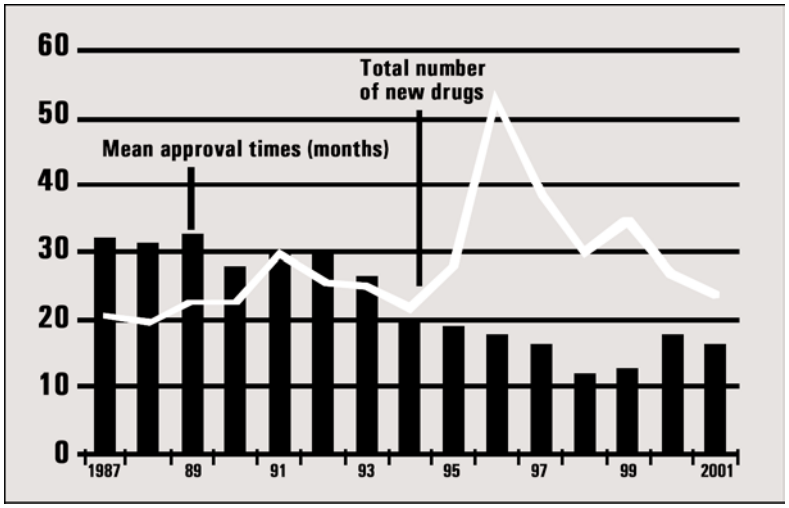
Phase II

Phase III

FDA Review and Approval

Post-marketing Testing

## FDA Review Times




*Source: Pharmaceutical Research and Manufacturers of America*

The biotech industry continues to be intensively focused on discovery research the basic R&D from which potential product candidates are identified. The discovery phase can be broken down into several steps. Understanding how discovery research proceeds will provide you with a broader perspective, especially if you are considering a career in the laboratory.

## Discovery

| Step | Description |
|---|---|
| Identify Target | Focus is on identifying genes and their respective products, which are suspected to cause a specific disease. **Goal: Find and isolate potential areas for therapeutic intervention.** |
| Validate Target | Once the target has been identified, its role in the disease must then be understood. Techniques such as differential gene expression, tissue distribution analysis, and protein pathway studies help verify a genetic target s role in disease formation. **Goal: Understand the target s role in disease** |
| Develop Assay | A drug candidate screening process or assay is then developed to detect the activity that potential drug treatments have on the target molecule. An ideal assay is cost-effective, fast, accurate, easy to perform, quantitative, and amenable to automation. **Goal: Find a way to test a potential drug s effect on the target** |
| Conduct Primary Screening | Compounds are then identified that have a minimum level of effect or activity against the target molecule. Drug developers then include these hits in subsequent screens. This step is often automated. **Goal: Find active drug candidates or hits** |
| Conduct Secondary Screening | Results from the primary screen are confirmed. In addition to its activity, the candidate drug s potency and selectivity are also determined. Drug developers this identify the candidate drug molecule with the most promising pharmacologic profile. Secondary screening is often done manually and is thus more costly than primary. **Goal: Find the most promising drug candidates** |
| Optimize Leads | Once the most promising candidates have been identified, yet another screening step is made to identify the most promising candidate relative to safety and therapeutic efficacy. The products of these screens are incorporated in new libraries of compounds. This step can incorporate 10 or more iterations over previously screened groups. **Goal: Identify the drug candidates or leads with the best safety and therapeutic efficacy profiles.** |

## Preclinical Testing

| Step | Description |
|---|---|
| Preclinical studies | Leads are then submitted to a set of FDA-mandated animal tests before clinical trials on humans can begin. Animal testing is used to assess a lead s potential carcinogenicity and other toxicity. Other pharmacologic properties of the compound are also tested. The results of testing in this phase are incorporated in an Investigational New Drug Application (INDA), which is submitted to the FDA before human clinical testing commences. **Goal: Assess the drug s toxicity in animals** |

## Clinical Testing

| Step | Description |
|---|---|
| Phase I | The candidate drug is administered is small doses initially to a relatively small number of healthy people to test its safety. If proven successful, the dosage is slowly increased to determine the candidate drug s safety at higher levels. **Goal: Test the safety of the drug** |
| Phase II | The candidate drug is then administered to patients suffering from the disease the drug is intended to treat. Phase II tests seek to evaluate the drug s effectiveness and safety, includes a larger population of subjects and a longer test period than Phase I. **Goal: Test the efficacy of the drug** |
| Phase III | Testing here is the most complex and rigorous and often involves even larger groups of ill patients, who are monitored closely to determine the candidate drug s efficacy and identify adverse reactions. Tests are often double-blind and randomized with placebo control to remove the possibility of bias. **Goal: Verify the drug s safety, effectiveness, and optimum dosage regimens** |

The results of this rigorous process are sobering. For each 20 drugs entering clinical testing,

On average, 14 complete Phase I

Of those, 9 complete Phase II

One or two survive Phase III

This means that only 5-10% of candidate drugs submitted for clinical trials are approved for marketing, making the US drug approval process the most restrictive in the world.

## FDA Review and Approval

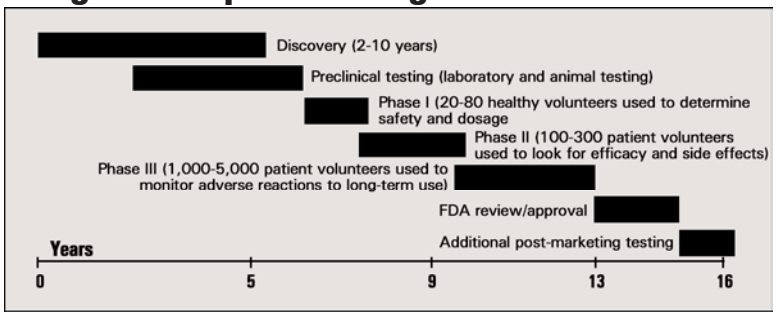
| Step | Description |
|---|---|
| Filing of Biologics License Application (BLA) or New Drug Application (NDA) | The BLA and NDA are summaries of all aspects of a candidate drug s profile and intended use. They are compiled by the manufacturer and submitted to the FDA. BLAs and NDAs contain complete details on the molecular structure and formulation, the results of all phases of testing, production methods, labeling content, and intended patient use.<br>BLAs and NDAs sometimes exceed 100,000 pages of text. Typically, the FDA requires 18 months to approve a drug after the manufacturer submits these documents. |

### Post-Marketing Testing

| Step | Description |
|---|---|
| Additional indications | After introduction into the marketplace, the manufacturer often submits supplemental NDAs to obtain approval of a drug for other additional indications. |
| Post-launch monitoring | The FDA continues to monitor a drug after it enters the marketplace. If side effects show up when a drug is in wide use, the FDA may request an additional phase (Phase IV) of testing to determine the long-term effects of a drug. |
| Regulatory measures | The FDA may order a product recall if either the safety or efficacy of a drug is questioned. This can happen under several circumstances, including defective packaging, misleading labeling, failure to meet disintegration or content uniformity tests, loss of sterility, subpotency, or lack of evidence of effectiveness. |

The following diagram illustrates the drug development process for both regular and biopharmaceuticals.

## Drug Development Stages




*Source: Pharmaceutical Research and Manufacturers of America*

# ON THE JOB

# Departments and Career Paths

CHAPTER 3

## Departments in a Biotechnology Company

Whatever the size, biotech companies are organized by departments, which in turn are homes to one or several functional groups:

| Department | Fuctional Group |
|---|---|
| Research and Development (R&D) | Discovery Research, Bioinformatics, and Animal Sciences |
| Operations | Process/Product Development, Manufacturing and Production, and Environmental Health & Safety |
| Quality | Quality Control, Quality Assurance, and Validation |
| Clinical Research | Clinical Research, Regulatory Affairs, and Medical Affairs/Drug Information |
| Finance & Administration | Finance, Administration, Information Systems, and Legal Counsel |
| Business Development | Business Development and Marketing/Sales |
| Project Management | Available in all departments |

Smaller companies, which are more focused on research and do not yet have products on the market, may not have some of the functional groups listed above. In addition, some functional groups such as finance and administration may be combined in the smaller to mid-size companies. As companies grow and commercialize products, their organizational structure grows organically, and groups within each department become more formal.

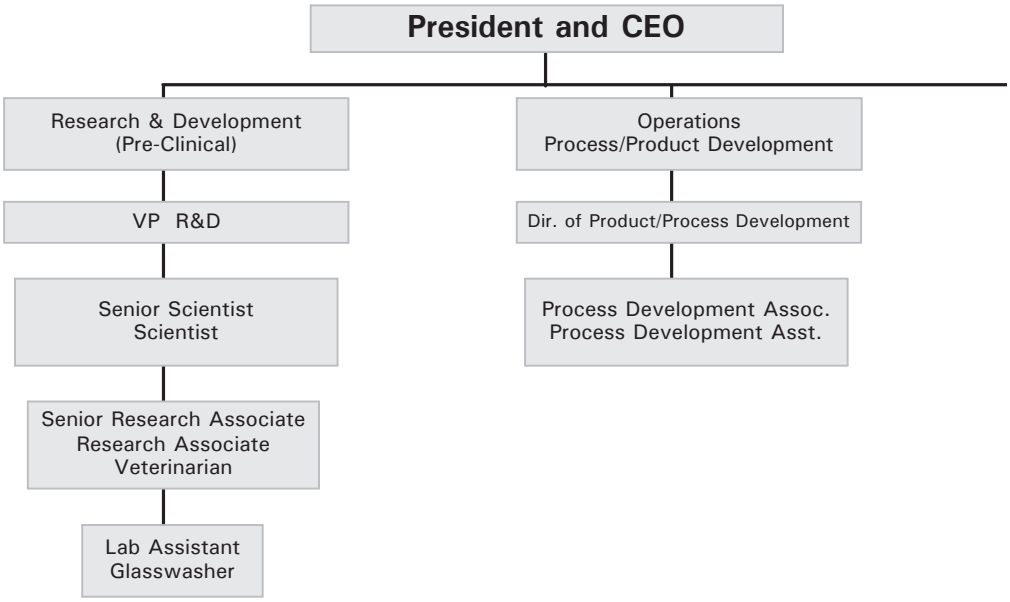
*Source: Mass Biotech Council, Biotech Industry Organization*

## Career Paths

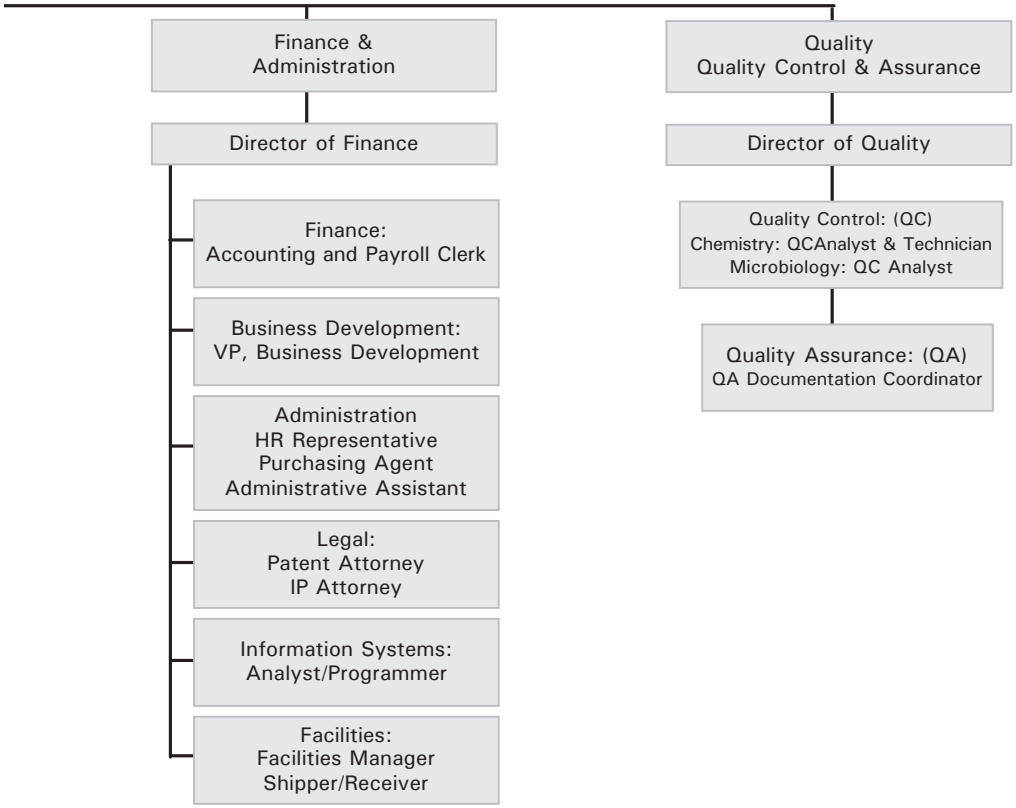
As you think about a career in the biotech industry, it is useful to identify the general area (or areas) where your primary interests and aptitudes lie. The career paths below provide some guidance on how you might chart a career path. Note that the charts build on one another, with more groups evolving as a company grows from a small organization (fewer than 50 people) to a medium-size organization (51-300 people) to a large organization (Over 300 people).

In a small company, only the most basic functions are filled and career tracks are either rudimentary or non-existent. Typically, a small company does not yet have a product to commercialize, and thus, does not need manufacturing capacity or marketing groups.

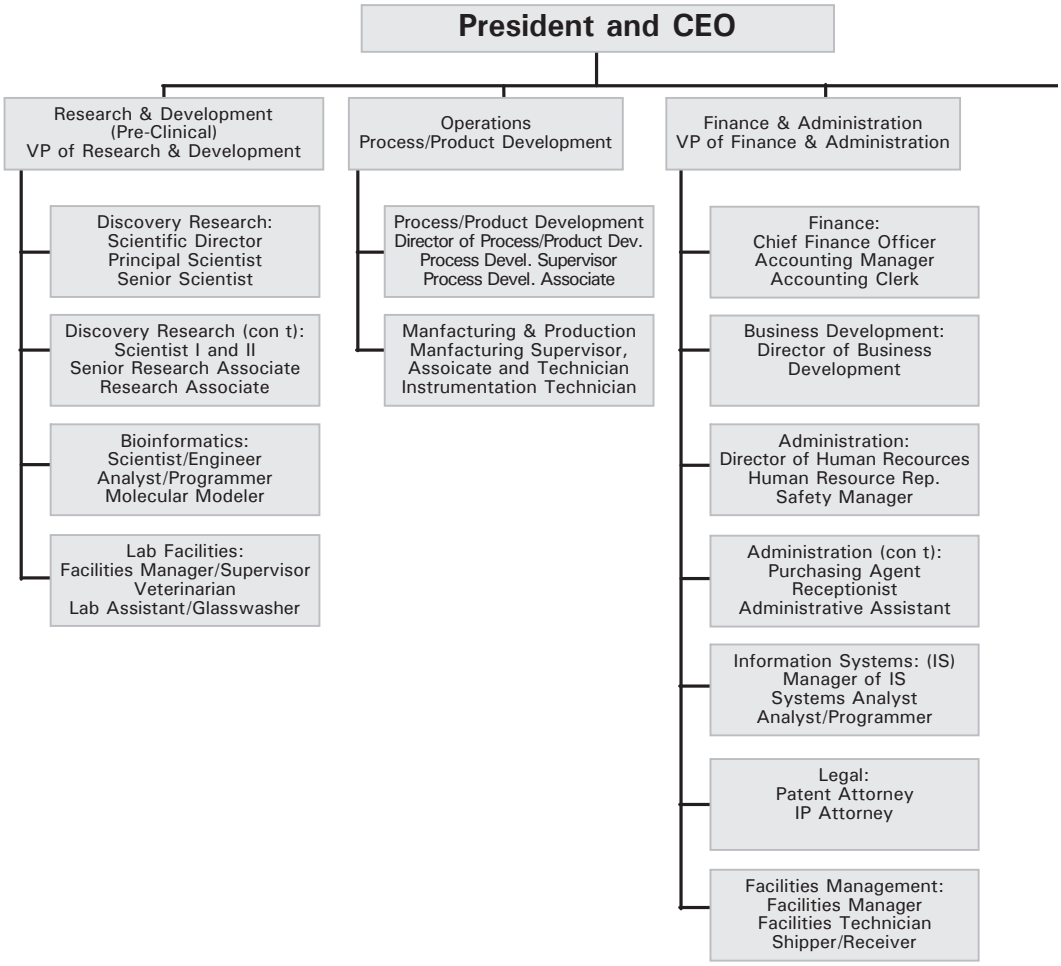
## Small Company Organization Chart

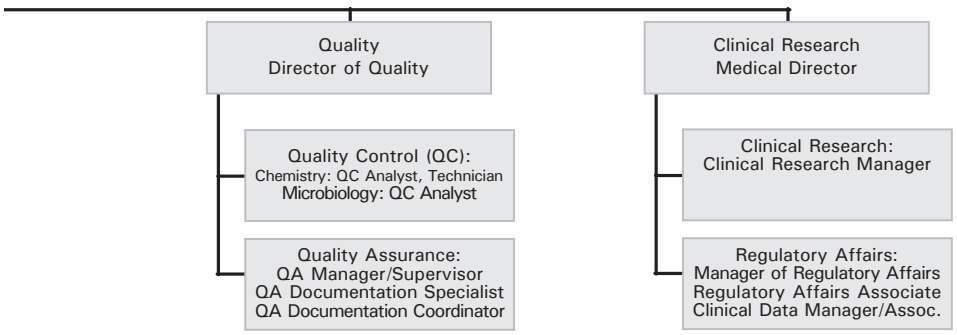



As a company grows from a small to a medium-size firm, its R&D expands and its manufacturing capacity takes form. Administrative functions needed to support these efforts also grow. Clinical research which typically involves testing drug candidates on humans and regulatory affairs groups round out the areas needed to bring a product to market. At this stage, career tracks firm up and a hierarchy forms in each group.


Finance &
Administration
Director of Finance
Finance:
Accounting and Payroll Clerk
Business Development:
VP, Business Development
Administration
HR Representative
Purchasing Agent
Administrative Assistant
Legal:
Patent Attorney
IP Attorney
Information Systems:
Analyst/Programmer
Facilities:
Facilities Manager
Shipper/Receiver
Quality
Quality Control & Assurance
Director of Quality
Quality Control: (QC)
Chemistry: QCAnalyst & Technician
Microbiology: QC Analyst
Quality Assurance: (QA)
QA Documentation Coordinator

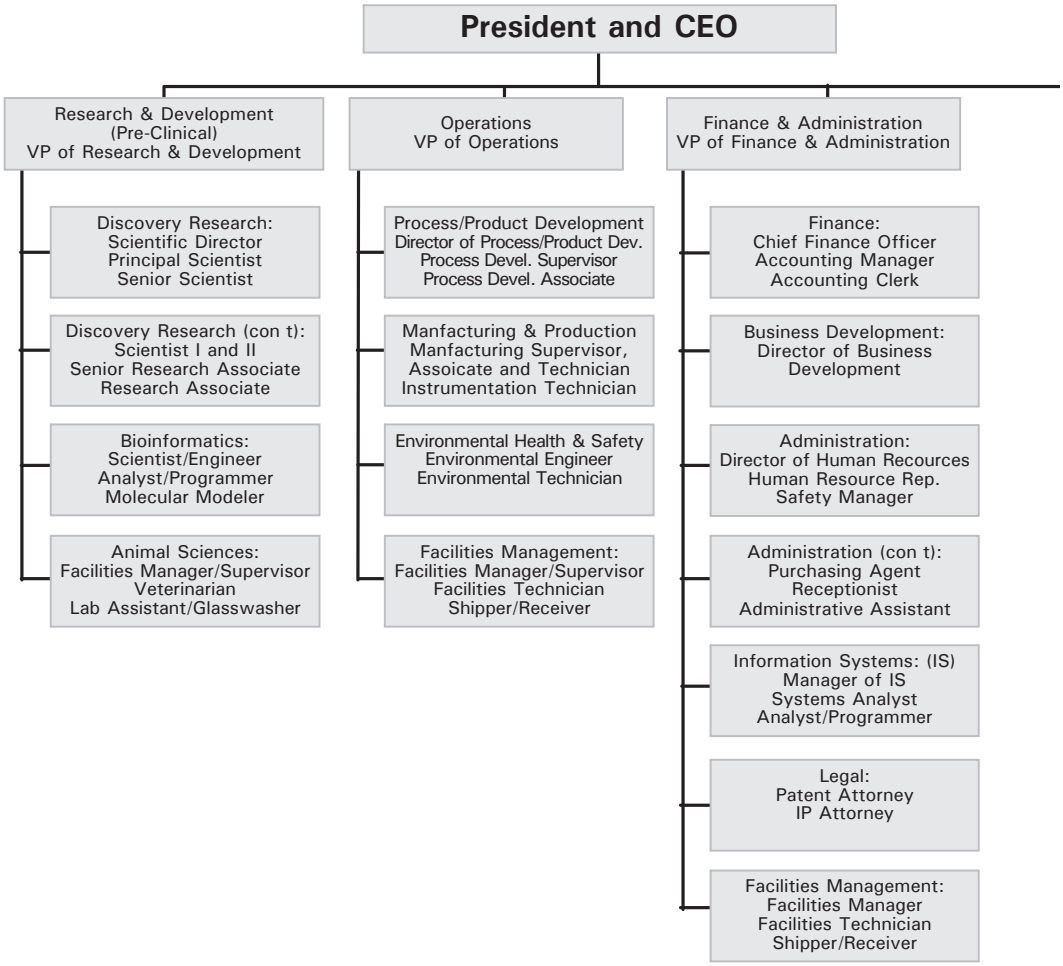
## Medium-Sized Company Organization Chart

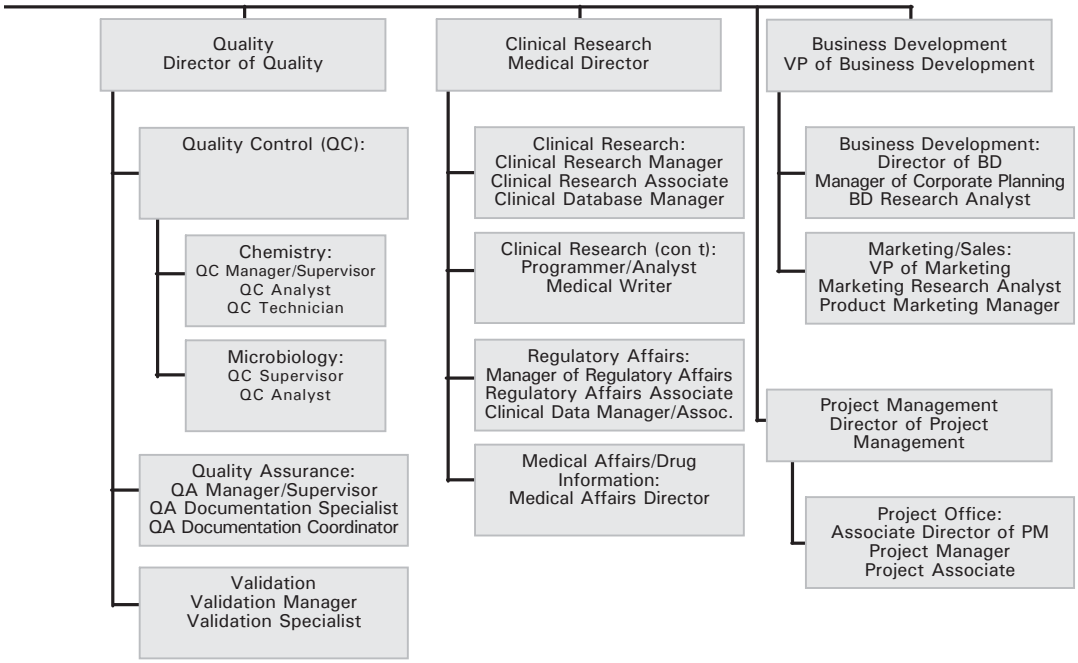





When a company becomes large, career tracks formalize and more layers are added in each group. In R&D, discovery research staff expands and a separate group dedicated to managing animal testing facilities usually forms. In addition to manufacturing capacity, the company also becomes concerned with meeting environmental health and safety guidelines. A Bioinformatics group in R&D and Data Validation group in Quality help manage the massive amounts of data generated by the research groups. In addition, Business Development is often promoted to the senior management level and a separate project management office is created to oversee special projects that don t naturally fit into any of the traditional formal functions.

## Large Company Organization Chart






*Source: Organization structures derived from Mass Biotech Council charts.*

# Science-Related Careers

## CHAPTER 4

Jobs in the biotech industry fall into two general classifications: scientific and non-scientific. This section gives job descriptions and required education and experience levels. The salary ranges included are approximate and based on a survey conducted by the Mass Biotech Council in 2001; the ranges are expected to be valid for the 2002-04 period. In addition to salary, companies also include a package of benefits specific to each company. Some companies provide stock options (depending on the job classification) and most companies encourage continuing education.

Because the biotech industry is still in its infancy, most jobs are found in the R&D function. As products emerge from the clinical trials pipeline and become approved for manufacturing typically a 10 to 15 year process many new jobs in manufacturing, sales, and marketing are likely to be created. In fact, according to the Mass Biotech Council, the number of manufacturing related jobs are expected to increase sharply in the next few years, with over 1,000 new jobs in New England alone. This means that college students interested in a career in biotech manufacturing are facing good prospects for entry-level jobs.

# Discovery Research

## Vice President of Research and Development

The VP of R&D is the highest-ranking position in the R&D function.

| Management | Technical | Other |
|---|---|---|
| Sets strategic scientific objectives, develops operational plan, and oversees R&D organization.<br>Creates the organizational structure that supports strategic objectives. Directs major functions and assigns managerial responsibilities to each group.<br>Provides leadership and direction on all research activities, initiation of new projects, and development of policies within function.<br>Acts as final decision-maker on all administrative and operational issues. | Represents company in technical issues. Initiates new technologies and processes. | Manages scientific and technical career development of employees. |

| Education | Experience | Salary Range |
|---|---|---|
| PhD, scientific discipline | 15 years of management experience | Over $175K |

## Scientific Director and Associate Scientific Director

The two-tier Scientific Director job is the next highest-ranking position in the R&D function and is more focused on managing operations.

| Management | Technical | Other |
|---|---|---|
| Directs research efforts of one to several groups within R&D organization.<br>Conducts long- and short-term planning.<br>Interfaces with management of other functional areas, including business and manufacturing.<br>Makes final decisions on operational issues.<br>Generates strategies and tactics to implement scientific and business objectives.<br>Monitors and evaluates completion of projects.<br>Develops budgets for all aspects of R&D function. | Conducts and collaborates with others on basic research.<br>Collaborates on patent applications and manuscripts for publication.<br>Represents R&D function in internal managerial and external customer points of contact. | Conducts briefings and technical meetings for internal management and external customer contacts.<br>Participates in attracting and obtaining new business contracts. |
| **Education** | **Experience** | **Salary Range** |
| PhD, scientific discipline | 10 to 12 years of management experience | $99K to $175K |

## Principal Scientist and Senior Scientist

The scientist position is a key scientific researcher position in the R&D function. The top two and lower two tiers are described separately. Top-tier scientists (principal scientist and senior scientist) are recognized as scientific experts within the company and are expected to have broad knowledge of state-of-the-art principles and theories. Often exceptionally talented and creative, they are also expected to help set the scientific direction of the company and make significant contributions to new research initiatives.

| Technical | Administrative | Other |
|---|---|---|
| Initiates, directs and executes R&D that is critical to corporate strategies and image.<br>Investigates feasibility of applying scientific principles to projects and programs.<br>Plans and executes laboratory research.<br>Applies and/or develops highly advanced technologies, scientific principles, theories and concepts that may be new to the industry. | Participates in development of patent applications.<br>Contributes to scientific literature and conferences.<br>Acts as key spokesperson to customers on corporate capabilities and future efforts.<br>Serves as consultant to top management in long-range corporate planning of new areas of research | May manage and direct professional development of research group.<br>May be instrumental in attracting and obtaining major new contracts and/or grants. |

| Education | Experience | Salary Range |
|---|---|---|
| PhD, scientific discipline | 5-10 years of experience in research | $85K to $132K |
| Post-doctorate | 12-15 years of related experience | N/A |
| MS | 8-10 years of experience in research | N/A |

## Scientist I and II

The scientist job is the senior researcher position in the R&D function. At this level, scientists are expected to be experts in their fields and possess in-depth knowledge of the theories and concepts in their areas of expertise. They are also expected to be able to apply these concepts to solve a broad range of complex problems of interest to the company that employs them.

| Technical | Administrative | Other |
|---|---|---|
| Initiates, designs, develops, executes and implements scientific research projects.<br>Investigates feasibility of applying a wide variety of scientific principles to potential inventions and projects.· May coordinate interdepartmental activities and research efforts. | Serves as in-house and outside consultant.<br>in development of patent applications.<br>Contributes to scientific literature and conferences.<br>May act as leading technical contact on projects requiring cross-functional coordination. | May manage and be responsible for professional development of research group.<br>Provides intra/inter-group scientific leadership and training.<br>Acts as mentor and/or project leader. |

| Education | Experience | Salary Range |
|---|---|---|
| PhD, scientific discipline | 0-5 years of experience in research | $60K to $90K |
| MS | 8-10 years of experience in research | N/A |

## Principal Research Associate, Senior Research Associate and Research Associate

The three-tier research associate position provides key laboratory research support to the scientist-level staff in the R&D function and often requires post-graduate training.

| Technical | Administrative | Other |
|---|---|---|
| At Principal level, often acts as primary investigator of independent research projects where own judgment is applied toward developing tools and techniques.<br>At the Senior level, performs scientific experiments in collaboration with others.<br>Develops and implements tools and methods to meet scientific objectives of organization.<br>Exercises own discretion in completing experiments at all levels.<br>Is familiar with scientific literature and can select methods to apply to own projects. | Serves as in-house and outside consultant.<br>in development of patent applications.<br>Contributes to scientific literature and conferences.<br>May act as leading technical contact on projects requiring cross-functional coordination. | May manage and be responsible for professional development of research group.<br>Provides intra/inter-group scientific leadership and training.<br>Acts as mentor and/or project leader. |

| Education | Experience | Salary Range |
|---|---|---|
| BS/MS | 2-8 years of regulatory affairs experience in biological and pharmaceutical products | $38K to $70K |
| MS | 0-5 years of regulatory affairs experience | N/A |

## Research Assistant

The research assistant job is an entry-level laboratory research position in the R&D function.

| Technical | Administrative | Other |
|---|---|---|
| Performs research and laboratory tasks that support projects of senior scientific staff.<br>Often has some discretion in the carrying out of technical tasks.<br>In performing experiments, makes observations, gathers and analyzes data, and interprets results. | Works under direct supervision of group leader.<br>Prepares various technical reports. | Able to read and understand scientific literature in own field or research. |
| **Education** | **Experience** | **Salary Range** |
| AS/BS or equivalent in a scientific discipline | Minimum of 0-2 years of laboratory experience | $32K to $48K |

# Bioinformatics

## Scientist/Engineer

The scientist/engineer job in bioinformatics is one of biotech s hot new jobs in the R&D function. It requires expertise in any one of several basic science disciplines as well as knowledge of programming languages and databases.

| Technical | Administrative | Information Technology |
|---|---|---|
| Develops gene discovery algorithms for integrating sequence-based/functional knowledge about genes to help scientists analyze and interpret gene-expression data.<br>Analyzes DNA information and identifies opportunities for innovative solutions to analyze and manage biological data.<br>Assists in developing software and custom scripts to automate data retrieval, manipulation, and analysis; application of statistics, and visualization tools.<br>May manage processes involved in database design, interface design, and information processing. | Initiates and manages external relationships and collaborations with academic and commercial parties, evaluation of third party products and technologies, and management of acquisition and implementation.<br>Provides leadership in the development, evaluation, and deployment of gene centric information systems.<br>Works with others in developing statistical and probabilistic methods for gene clustering/analysis. | Proficient in programming languages like C/C + +, Perl, SQL, HTML, and JAVA and has knowledge of mixed operating systems environments (e.g., UNIX, Windows NT, Sybase, Oracle, etc.)<br>Has working knowledge of public domain bioinformatics data sources, public sequence databases, sequence assembly tools and gene expression analysis software. |

| Education | Experience | Salary Range |
|---|---|---|
| MS or PhD in Bioinformatics, Statistics, Biochemistry, Mathematics, Molecular Biology or Computer Science, Computational Chemistry, or related field | 1-4 years of industry experience | $75K to $100K |

## Analyst/Programmer

The analyst/programmer job provides more focused computational analysis support in the R&D function.

| Technical | Administrative | Human Resource |
|---|---|---|
| Designs and develops software, databases, and interfaces used to analyze and manipulate genomic databases.<br>Collaborates with Production to develop high- throughput data processing and analysis capability, design and implement data queries, novel algorithms and/or visualization techniques.<br>Maintains large-scale DNA databases.· Prepares data for other scientists.<br>Monitors new data from public databases and cleans loaded data to satisfy quality control criteria. | Provides technical and scientific customer support.<br>Helps guide, implement, and maintain further improvements to Bioinformatics software.<br>Works with others to diagnose and repair problems with bioinformatics software. | Fluent in at least one of the following: C/C + +, Perl, SQL, HTML, and JAVA.<br>Has working knowledge of relational databases and system administration.<br>Familiar with public sequence databases and standard sequence analysis tools. |
| **Education** | **Experience** | **Salary Range** |
| MS/PhD or equivalent experience in Molecular or Computational Biology, Computer Science, Mathematics/Statistics, Bioinformatics, or related field | 1-3 years of experience developing computational biology applications | $60K to $100K |

## Molecular Modeler

The molecular modeler position is focused on using computational techniques to help identify biologically active molecular structures; the position supports a company s discovery research in the R&D function.

| Technical | Administrative | Other |
|---|---|---|
| Provides molecular modeling support for discovery research.<br>Applies computational techniques to identify and optimize the number of hit/lead compounds.<br>Demonstrates expertise in molecular modeling of small molecules in rational drug design (QSAR and Structure based design, predictive Drug Absorption, Distribution, Metabolism and Excretion (ADME), and/or library design in a drug discovery setting). | Acts as leader in molecular modeling or computational design group<br>Interacts with scientific staff to perform various functions, including developing new methods, designing ligands, developing pharmacophores, designing and analyzing libraries of molecules, developing models for virtual screening and application of Quantitative Structural Activity Relationships (QSAR), determining protein structures, and performing molecular simulations. | Demonstrates strong familiarity with principles of medicinal chemistry and commercial modeling software packages, database searching, docking and scoring functions.<br>Has some knowledge of systems administration. |

| Education | Experience | Salary Range |
|---|---|---|
| PhD degree in chemistry, biochemistry, computational chemistry or a related field | 5+ years of industrial experience | $60K to $100K |

# Animal Sciences

## Facility Manager/Supervisor

The Facility Manager/Supervisor in Animal Sciences oversees the facilities needed to house and care for animals used in experimentation in the R&D function.

| Administrative | Technical | Other |
|---|---|---|
| Supervises the activities and staff of the animal facility.<br>Ensures a smooth-running animal facility including stability of the lab environment, proper functioning of all equipment, appropriate levels of all supplies, and environmental monitoring (e.g. live sentinel).<br>Processes requests for animals to be purchased<br>Allocates space, time and resources for the animals. | Sets and maintains a high standard of animal husbandry according to AALAC guidelines<br>Optimizes animal handling techniques based on scientific requirements of animal projects and Good Laboratory Practices (GLP). | Hires, develops, manages, and appraises the animal facility staff. |

| Education | Experience | Salary Range |
|---|---|---|
| BS in biological sciences or equivalent | 5 years of experience in animal husbandry | $60K to $80K |
| AALAS certification at a technologist level preferred | 3+ years of supervisory experience in an animal facility in a biotech and/or pharmaceutical company | $60K to $80K |

## Veterinarian

The veterinarian job is focused on the care of laboratory animals used to test drug candidates in the R&D function.

| Technical | Administrative | Other |
|---|---|---|
| Diagnoses, treats, and monitors laboratory animals during the research stage of new drug therapies/discoveries.<br>Observes and documents animal behavior, testing and vaccination of animals<br>Performs autopsies.<br>Works with scientists to analyze complications during new drug treatments/applications. | Consult on the breeding, feeding and maintenance of animals. | Requires experience in a biotechnology or clinical research environment. |

| Education | Experience | Salary Range |
|---|---|---|
| Doctor of Veterinary Medicine (DVM or VMD) degree and a license to practice | 2-3 years of laboratory, veterinary, and/or animal experience | $100K to $150K |

## Lab Assistant

The lab assistant job is and entry-level laboratory position in the R&D function. It provides a candidate with a general exposure to the laboratory environment.

| Technical | Administrative | Other |
|---|---|---|
| Performs various research/laboratory tasks and experiments under general supervision.<br>Works on moderately complex assignments where judgment is required in resolving problems and making routine recommendations.<br>Maintains equipment and inventory levels of supplies.<br>May make detailed observations, analyze data and interpret results. | Writes reports, summaries, and protocols.<br>May participate in troubleshooting and calibration of instruments. | May assist in training of entry-level employees. |

| Education | Experience | Salary Range |
|---|---|---|
| High School diploma, preferably a biotechnology certificate | 1-2 years of laboratory experience | $24K to $33K |
| AS or equivalent experience with a scientific background | | |

## Glasswasher

The glasswasher helps provide laboratories with needed equipment to carry out R&D functions. It requires only a minimum of education and provides general exposure to a technical environment.

| Technical | Administrative | Other |
|---|---|---|
| Washes and dries glassware and distributes it to various laboratories to use in research.<br>Maintains glass washing facility and performs routine maintenance on glass washing equipment.<br>Sterilizes equipment in an autoclave. | Works on semi-routine assignments. | Is able to reorganize work after deviations from standard practices. |

| Education | Experience | Salary Range |
|---|---|---|
| High school diploma or equivalent | 0-2 years of laboratory experience | $22K to $29K |

# Non-Science Careers

CHAPTER 5

While most jobs in the biotech industry are in the R&D function, there are plenty of exciting non-science careers, including business careers in marketing, sales, business development and more. Here s a look at some of the major career paths.

## Marketing/Sales

### Vice President of Marketing

The Vice President of Marketing fulfills the marketing management role in the business development function. As companies bring products to market, the sales/marketing function becomes differentiated from the business development function. The primary focus of the head of marketing is to launch products. As products emerge from the R&D pipeline, the marketing of biopharmaceuticals will be a promising career path for candidates with MBAs.

| Management | Other |
|---|---|
| Develops and implements strategic and tactical marketing programs to drive revenue growth and product contributions.<br>Identifies business issues and creates solutions to drive brand performance.· Develops brand strategies and manages implementation of brand campaigns and programs.<br>Monitors brand revenue and expense forecasts to achieve revenue and earnings targets.<br>Manages all vendor and agency relationships to achieve maximum Return on Investment (ROI) on all marketing programs.<br>Maintains and develops marketing staff.<br>Provides appropriate direction to field sales team to assure optimal execution of all programs. | Works with research professionals to provide commercial input to the development of new products.<br>Works with Corporate Development, Project Management and senior management on strategic planning and product development issues. |

| Education | Experience | Salary Range |
|---|---|---|
| BS in scientific fieldMBA highly desirable | At least 2 years of strategic marketing experience and 4 years of marketing experience in a biotechnology / pharmaceutical business development environment. | |

## Marketing Research Analyst

The marketing research analyst focuses on understanding the wants and needs of customers and potential customers. Increasingly quantitative, this position requires statistical skills and both verbal and written communication skills.

| Management | Technical | Other |
|---|---|---|
| Provides information on marketed and pipeline products, including assessment of strategic direction and marketplace analysis.<br>Uses primary and secondary qualitative and quantitative market research data to create financial models and provide analytical support to existing and new marketing and sales strategies.<br>Researches market trends, awareness, adoption and attitudes of newly launched products.<br>Analyzes provider, patient and other relevant data sets to support targeting strategies for sales and marketing promotions. | N/A | Advises management on competitive activities and strategies<br>Performs market research to support business development.<br>May interface with external partners, vendors or clients.<br>May be expected to deliver regular communications and/or briefings. |
| **Education** | **Experience** | **Salary Range** |
| BS in Economics, Econometrics, Statistics or financial analysis | 1-3 year s experience in data analysis and marketing research in a healthcare/pharmaceutical environment. | |

## Product Marketing Manager

| Management | Technical | Other |
|---|---|---|
| Manages all aspects of product marketing, product strategy and development, strategic planning and creation and implementation of marketing strategies.<br>Develops business cases for new/existing product initiatives, launch plan creation, management of product life cycle, and high level technical and sales support to internal and external groups.<br>Provides direction to sales training to identify training needs and interfaces with Sales Managers and Sales Consultants to identify and address product issues/opportunities.<br>Works with Market Research to develop sales forecasts and identify primary and secondary market research needs.<br>Manages marketing resources. | N/A | Builds and sustains relationships with internal and external customers.<br>Contributes to product definition, product feature positioning, forecasting, competitive analysis, solution pricing, and development of marketing materials. |

| Education | Experience | Salary Range |
|---|---|---|
| BS or MS in life sciences or a related discipline; MBA is desirable | 3-5 years experience in marketing with emphasis on market strategy, product development and business case analysis in a life science research environment. | |

# Project Management

## Director of Project Management

The two-tier director of project management position (companies often have directors and associate directors) fulfills the managerial role in the project management function. It requires an understanding of Chemistry, Biochemistry, Medical or Pharmaceutical Regulatory Affairs and proven experience in managing interdisciplinary development teams. In addition, it is also expected that a Director have a basic understanding of drug development processes and strategies.

| Management | Other |
|---|---|
| Oversees all aspects of project development.<br>Coordinates and develops yearly programs, strategic plans, and annual project budgets.<br>Provides direct input into corporate strategic planning, development management processes, critical path issues/solutions, resource management, and project management from conception through development cycle.<br>Manages multiple global cross-functional project teams.<br>Reports project status to executive management.<br>Collaborates with senior project managers, functional directors, and managers to ensure integration of project, company, and functional goals in reaching milestones and timetables.<br>Ensures that resources assigned to projects are adequate to meet program objectives.<br>Monitors project expenses against budget.<br>Works with project managers and project teams to identify risks, contingencies, and alternatives. | Identifies issues that may delay product or project and recommends appropriate action to be taken.<br>Supports team function and project managers.<br>Manages all project and client communications |

| Education | Experience | Salary Range |
|---|---|---|
| BS/MS, PhD preferred in life sciences and MBA degree is preferred for Director. | At least 8 years of experience in a pharmaceutical or biotechnology environment | $110K to $145K |
| For Associate Director BS/MS in life sciences, MBA or Post-Graduate Level science degree | At least 5 years of project management experience in a pharmaceutical or biotechnology environment | |

## Project Manager

The project manager carries the bulk of the responsibilities of managing a company s projects and is the senior individual contributor position in the project management function.

| Management | Technical | Other |
|---|---|---|
| Manages all daily project management activities, including project schedule development, project budget, team leadership, intra-division liaison, project communication, staffing activities, status reporting, and resource plan development.<br>Identifies and tracks critical path/activities, risks, contingencies, and alternatives.<br>Supervises and mentors team members<br>Ensures team members understand scope and requirements of project. | N/A | Records meeting minutes, tracks action items, prepares meeting agendas, coordinates global and sub-team activities.<br>Disseminates project information. |

| Education | Experience | Salary Range |
|---|---|---|
| BS in scientific disciplineMBA a plus . | At least 3-5 years of staff management or supervisory experience in a pharmaceutical or related industry | $70K to $90K |

## Project Assistant

The Project Assistant job is an entry-level position in the project management function.

| Management | Technical | Other |
|---|---|---|
| Performs departmental project management activities under the supervision of a project manager.<br>Collects project plan updates<br>Maintains or modifies project plan documentation<br>Prepares and distributes project status reports. | N/A | Assists project manager in identifying and scheduling project deliverables, milestones, and required tasks<br>Assists in establishing standards for project reporting and documentation. |

| Education | Experience | Salary Range |
|---|---|---|
| BS in scientific discipline | At least 3 years of experience in pharmaceuticals or a related industry | |

## Vice President of Business Development

The Vice President of Business Development is the most senior manager in the Business Development function. Initially a part of Finance and Administration in small companies, this function usually becomes fully differentiated in the organization chart as a company becomes grows.

| Management | Technical | Other |
|---|---|---|
| Provides leadership and direction for all financial and strategic relationships of the company.<br>Identifies, evaluates, and pursues specific strategic and financial prospects of new market opportunities.<br>Directs assessment of future markets and licensing potential<br>Coordinates commercial input to specific programs.<br>Establishes new scientific and strategic partnerships, joint ventures, and alliances.<br>Manages partnership activity (e.g., tracking, documentation, and status reporting of collaborations).<br>Establishes and implements development strategies to support commercialization and licensing strategies. | N/A | Communicates with other senior officers to achieve goals and milestones.<br>Oversees planning and execution of market strategy.<br>Manages the creation of presentation and other marketing materials for professional meetings, seminars, and conferences. |

| Education | Experience | Salary Range |
|---|---|---|
| MBA Degree in scientific discipline | At least 8 years of business development experience in a biotech/pharmaceutical environment. | |

| Additional Requirements | |
|---|---|
| Dealing with corporate partners<br>Negotiating and completing agreements<br>Understanding of due diligence, asset valuation, alliance integration, and portfolio management | Extensive contacts in the pharmaceutical / biotechnology industrial community relevant to the licensing of targets, leads, and drugs. |

## Director of Business Development

The Director of Business Development is the second most senior position in the Business Development function and is directly in line for the top spot. The scope of this job is similar but somewhat narrower than that of the VPs and more focused on overseeing the day-to-day operations of the BD function.

| Management | Technical | Other |
|---|---|---|
| Manages identification, evaluation, and development of pharmaceutical and biotechnology prospects for new business opportunities.<br>Develops proposals and term sheets for prospects<br>Manages day-to-day aspects of closing, including utilization of legal counsel and coordination with other business and human resource functions.<br>Scans the marketplace by performing market research, analyzing new market opportunities, and pursuing new business opportunities.<br>Organizes, tracks, documents, and reports on status of all prospects in the business development pipeline. | N/A | Participates in developing and executing marketing strategy.<br>Prepares presentation and marketing communications materials.<br>Participates in developing strategic partnerships, joint ventures and alliances.<br>Participates in identifying technology and intellectual licensing opportunities. |

| Education | Experience | Salary Range |
|---|---|---|
| BS, scientific disciplineMBA strongly preferred | At least 8 years of experience in pharmaceutical and biotechnology companies. | |

| Additional Requirements | |
|---|---|
| Selling, networking, and negotiating contracts at the executive level within the drug discovery and development areas. | Strong business acumen, organizational, and analytical skills . |

## Manager of Corporate Planning

| Management | Technical | Other |
|---|---|---|
| Manages financial planning processes (e.g., long-term and strategic planning; short-term and tactical planning).<br>Designs and implements financial planning processes.<br>Participates in setting targets and planning guidelines.<br>Assists CFO in crafting and presenting key messages regarding company s financial plans and outlook to internal and external audiences.<br>Conducts competitive analysis. | N/A | Reports on key events that might have significant impact to future business.<br>Provides finance support for key functions including IT, HR, Legal, Business Development, and Finance.<br>Completes special projects for CFO. |
| **Education** | **Experience** | **Salary Range** |
| BS/BA in any fieldMBA preferred | At least 8 years of financial planning and analysis experience | |

## Business Development Research Analyst

The Business Development Research Analyst job is the entry-level position in the Business Development function. It requires, however, a high degree of education and can be a great opportunity to gain exposure to the business issues facing a biotech company.

| Management | Technical | Other |
|---|---|---|
| Creates periodic market analysis and competitive intelligence reports.<br>Assists Director in meeting goals and advising senior management in defining and developing investment growth strategies (e.g., assess and pursue expansion, acquisition, and partnering opportunities; manage activities and processes for diversification and business growth).<br>Works with internal and external counsel to evaluate intellectual property of licensing and acquisition candidates.<br>Secures licenses required for ongoing discovery and development operations and for maintaining long-term partner relationships. | N/A | Provides recommendations to facilitate partnering decisions.<br>Negotiates and maintains agreements with investigators and their institutions. |

| Education | Experience | Salary Range |
|---|---|---|
| BS in scientific fieldMS or PhD preferred | At least 3-5 years experience in biotechnology / pharmaceutical business development or licensing. | |

| Additional Requirements |
|---|
| Experience in strategy consulting, investment banking or corporate partnering/deal making desirable |

# Information Systems

## Manager of Information Systems

The Manager of Information Systems (MIS) job provides managerial leadership for the IS function.

| Management | Technical | Other |
|---|---|---|
| Manages information systems and computer resources for organization.<br>Oversees organization s Computer Operations, Systems and Programming, Technical Support Services, Communication Network, and User services.<br>Acts as a liaison between senior management and computer staff.<br>Manages department s budget. | Develops disaster recovery plans and manages back-up and security systems.<br>Manages user requirement definition and development, application development, system configuration and testing, installation, implementation of ongoing support, system enhancements / upgrades and bug fixes. | Hires, trains, and supervises information systems staff.<br>Responsible for the introduction of new systems and hardware/software rollouts. |

| Education | Experience | Salary Range |
|---|---|---|
| BS in Computer Science or Business AdministrationMS or MBA may be required for senior level positions in larger companies | At least 5-8 years of MIS management experience. | $80K to $90K |

| Additional Requirements |
|---|
| Knowledge and experience of process modeling, reengineering and systems analysis. |

## Systems Analyst

The Systems Analyst job is the senior hands-on position in the IT group. It is more focused on understanding the systems needs of business units and on identifying suitable solutions.

| Technical | Administrative | Other |
|---|---|---|
| Designs, customizes, and implements new software.<br>Supports existing legacy and packaged software systems.<br>Interprets business needs into functional requirements and program specifications, defines business process flows, develops prototype screens and reports for new/existing system enhancements, and builds test plans, test criteria and scenarios.<br>Collaborates with Analysts/Programmers to drive and oversee development and implementation process.<br>Supports all phases of system testing, user training and system deployment, and assists in creation of related documentation.<br>Provides on-going application support, research and diagnostics on all production systems and manages the entire lifecycle for IT deliverables. | Provides technical support to business unit by analyzing new software programs and hardware equipment and conducting cost/benefit analysis. | Provides strategic advice to business units by developing business processes/procedures and identifying enabling systems/technologies . |

| Education | Experience | Salary Range |
|---|---|---|
| BA/BS in Computer Science | At least 3-5 years of business/systems analysis experience, preferably in a biotechnology or pharmaceutical environment. | |

| Additional Requirements | |
|---|---|
| Demonstrated success implementing packaged software and strong knowledge of the full Systems Development Life Cycle .<br>Strong analytical and problem-solving skills. | Broad understanding of technology and solid understanding of the appropriate application of various technologies. |

## Analyst/Programmer

The Analyst/Programmer job is hands-on computer support position in the IT group. This entry-level professional job is most suitable for computing enthusiasts and can lead to more senior positions in the IT group.

| Technical | Administrative | Other |
|---|---|---|
| Designs, develops, codes, tests, debugs, and documents programming applications to satisfy requirements of one or more user areas.<br>Typically provides 24-hour daily production and technical support to assigned systems.<br>Provides comprehensive consultation to business units, business analysts and IT management and staffs at the highest technical level.<br>Provide programming and proper usage support to users of business systems.<br>Contributes to all aspects of application development, system configuration, system testing, installation, and implementation of system enhancements/upgrades and bug fixes. | Assists with the creation and modification of custom reports, specified by users. | Perform User Acceptance Testing and End User training.. |

| Education | Experience | Salary Range |
|---|---|---|
| BS in Computer Science or related area | At least 3 years of programming experience in a scientific or technical environment. | $65K to $75K |

### Additional Requirements

Proficiency in programming languages like C/C++, Perl, SQL, HTML,and JAVA and knowledge of mixed operating systems environments (e.g. UNIX, Windows NT, Sybase, Oracle etc.).

Structured programming skills, problem-solving abilities, and strong diagnostic capabilities.

Extensive knowledge of relational databases, commercial report writers, and proficiency in PC software..

## Librarian

In addition to library services, the Librarian is also required to have software management skills. As biotech companies grow, the Librarian fulfills both a valuable reference function and a key organizational role for a company s scientific and legal staff.

| Technical | Administrative | Other |
|---|---|---|
| Assists Library Services Manager in all library operations (e.g., acquisition and organization of print and electronic resources, references services, long range planning for the library, and staff orientation in the use of electronic information resources including integrated library systems, web browsers, and search engines). | Manage software (e.g., migration of source code and files to production systems, management and maintenance of version control, release and migration documentation, access authorization for developers, testers, etc.).<br>Manage deployment of software releases or rollouts. | Conducts statistical, financial, scientific, patent and/or business information searches. |

| Education | Experience | Salary Range |
|---|---|---|
| BS/MS in Science and/or MSL (Masters in Library Science) | At least 1-3 years of experience in a pharmaceutical or biomedical library. . | |

| Additional Requirements | |
|---|---|
| Knowledge of non-traditional information resources (e.g., CD-ROMs, online databases, and the Internet). | Other requirements (if applicable) include working knowledge of software version control, release, and migration packages. |

# Legal

## Patent/Intellectual Property (IP) Attorney

The patent/intellectual property (IP) attorney works to protect a biotech company s valuable proprietary technology often a company s most important asset.

| Legal | Technical | Other |
|---|---|---|
| Works as in-house counsel in the preparation and prosecution of patent applications, development and maintenance of the company s IP, and development of intellectual property strategies and policies.<br>Reviews, negotiates, and drafts license, research, technology, and material transfer agreements for IP consideration and protection.<br>Reviews IP provisions of contracts and assists in rendering opinions on contract validity and infringement.<br>Collaborates with licensing counsel to draft opinions and develop legal strategies.<br>Oversees all aspects of copyright, trademark, and litigation matters. | N/A | be responsible for supervision of patent support staff.<br>Interacts with scientists and counsels in-house clients on contract, commercial, and intellectual property issues. |

| Education | Experience | Salary Range |
|---|---|---|
| JD degree (Juris Doctorate)BS in Science or related field, advanced degree preferred | 10 years of experience in all aspects of US/Foreign intellectual property and patent laws relating to biotechnology. | $130K to $140K |

| Additional Requirements | |
|---|---|
| Must be admitted to practice before a state bar in the US patent Office.<br>Experience with biotechnology and/or pharmaceutical patent prosecution, contract work and technology licensing. | Intellectual property strategy development and implementation. |

## Labor/Employment Law Attorney

The labor/employment law attorney provides expertise in issues relating to the employer-employee relationship. This role become increasingly important as a company s workforce grows and becomes more diverse.

| Legal | Technical | Other |
|---|---|---|
| Provides legal representation, counseling, and guidance in employer-employee issues (e.g., labor relations, employment discrimination, occupational safety and health, affirmative action, unemployment compensation, wage and hour regulation, and wrongful discharge).<br>Represents company before courts, administrative and arbitration tribunals, and during collective bargaining negotiations and labor arbitrations.<br>Counsels company in employee benefits law (e.g., retirement plans, welfare benefit plans and executive compensation programs; statutory and regulatory compliance; governmental filings and representation before regulatory agencies; pension and welfare funds issues; and employee benefits litigation).<br>Advises management on employment issues [e.g., hiring and firing, contract interpretation, non-compete, confidentiality and separation agreements, sexual harassment, Family and Medical Act (FMLA) and Fair Labor Standards Act (FLSA)]. | N/A | Works with employer to ensure compliance with new federal and state employment statutes and regulations. |

| Education | Experience | Salary Range |
|---|---|---|
| JD degree (Juris Doctorate)BS in Business Administration or related field | 3-5 years of labor and employment litigation experience in a large law firm or a combination of law firm and corporation. | |

| Additional Requirements | |
|---|---|
| Strong practice experience in Title VII, ADA, FLSA, WARN, OSHA, FMLA, wrongful termination, discrimination claims and traditional labor law. | Knowledge of current legislative and regulatory changes in employment. |

## Contract Attorney

The contract attorney provides the expertise needed to understand the creation and implementation of contracts, a function that is particularly important in the biotech industry since most companies enter into various legal arrangements with other entities both to provide specialized research services and to receive sales/marketing support from larger companies with established product distribution infrastructures.

| Legal | Technical | Other |
|---|---|---|
| Provides legal counsel and service on corporate, regulatory, judicial, and legislative issues.<br>Drafts contracts, amendments, subcontracts, subleases, and non-standard agreements.<br>Analyses contracts, RFPs/RFQs, product acquisition agreements, and commercial leases from other firms.<br>Negotiates optimal terms.<br>Identifies risk exposure.<br>Advises executive management on contractual obligations and issues.<br>Interfaces with Contracts Department to escalate contract risks.<br>Establishes and maintains document control management procedures. | N/A | Keeps current on legislative issues, statutes, decisions, and ordinances of judicial bodies.<br>Examines legal data to determine advisability of defending or prosecuting lawsuit. · Provides legal guidance to staff.<br>Sometimes acts as agent in various business transactions. |

| Education | Experience | Salary Range |
|---|---|---|
| JD degree (Juris Doctorate)<br>BS in Business Administration or related field | At least 3-5 years of experience in commercial litigation. | |

| Additional Requirements | |
|---|---|
| ·Familiarity with legal requirements of contracts | Knowledge of contract regulatory law |

# Facilities Management

## Facilities Manager

The facilities manager provides managerial oversight for a biotech company s buildings as opposed to its animal testing facilities. As a company grows, the group responsible for maintaining physical facilities becomes logically organized in the Finance and Administration function.

| Management | Technical | Other |
|---|---|---|
| Manages design, planning construction and maintenance of equipment, machinery, buildings, and other facilities.<br>Plans, budgets, and schedules facility modifications (e.g., estimates on equipment, labor, materials, etc.).<br>Oversees coordination of building space allocation and layout, communication services, and facilities expansion. | N/A | May have responsibility for health and safety standards. |

| Education | Experience | Salary Range |
|---|---|---|
| BS or equivalent | 5 years of experience in maintenance trades. Knowledge of building codes. | $60K to $88K |

### Facilities Technician

The facilities technician fulfills specific day-to-day tasks required in keeping laboratory equipment and building utilities running smoothly.

| Management | Technical | Other |
|---|---|---|
| Performs daily monitoring, repair, and preventative maintenance activities on critical systems and facility equipment.<br>Troubleshoots, install, and modernizes new and existing systems, including refrigeration equipment, water systems, HVAC systems, and electrical systems.<br>Documents repairs, adjustments, and replacement of equipment and/or components per GMP standards. . | N/A | Provides input and corrections to Standard Operation Procedures (SOPs).<br>Assists engineering in evaluating new equipment or technology. |
| **Education** | **Experience** | **Salary Range** |
| AA/AS or Certificate of Completion in a 2-year technical school in mechanical/electrical fieldOr High School Diploma | At least 5 years of experience in GMP maintenance | $25K to $46K |

### Shipper/Receiver

The shipper/receiver position ensures the efficient movement of supplies and equipment used by a biotech company.

| Management | Technical | Other |
|---|---|---|
| Loads or unloads, checks, stores, moves, and records movement of supplies, raw materials, equipment and products to and from internal departments, external suppliers and/or customers. | N/A | Prepares bills of lading, invoices, requisitions and other documents.<br>Routs shipments, reviews receipt of all materials and verifies quantities.<br>Ensures outgoing shipments are packaged according to specification. |
| **Education** | **Experience** | **Salary Range** |
| High School Diploma or equivalent | Some previous experience and knowledge of shipping and couriers. Valid Driver s License. | $25K to $40K |