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Healthcare: Pharmaceuticals, Biotech and Medical Devices Industries

Introduction

What if you could go to work each morning knowing that your efforts would help people lead healthier and longer lives? That is the feeling that the individuals working in the healthcare industry experience every day. Innovative medical devices, and more efficient and effective drugs and drug delivery systems translate directly into faster recoveries, less pain, and greater freedom for patients. Additionally, innovations in medical equipment and drug development technologies provide physicians and other healthcare providers with the tools and treatment options that allow them to better care for their patients. The importance of engineering and the key role of engineers in bringing those improvements and innovations to the people who need them can hardly be overstated.

The healthcare industry is a large, global, and incredibly competitive arena. In truth, it's really three industries in one. First, there is the pharmaceutical industry, which both competes with and is in partnership with the younger but equally innovative biotechnology industry. Biotechnology - commonly called biotech - is where technology and biology intersect to utilize biological systems to create or improve products. As an industry, it came of age relatively recently, with breakthroughs such as the engineering of recombinant DNA in 1973 and the introduction of the industry's first fully achieved product - human insulin - in 1983. In the years following and right up until today, biotech has changed the face of healthcare (and, indeed, the world) time and time again with innovations in forensics, genetic testing, and cloning.

The third industry, and in many ways the center of engineering in the healthcare industry, is the medical device industry. This industry has improved diagnostics and patient care with products like MRI machines, artificial joints, and stents, and has also made many breakthroughs with combination pharmaceutical and device products.

The healthcare industry is constantly pushing the scientific

Educational Goals:

After completion of this module, you should:

- **Be familiar with the healthcare industry and the opportunities it offers**
- **Be prepared to start a productive and focused job search in the healthcare industry**
- **Have a greater understanding of the operations and standards that are used in the industry**

envelope and expanding the scope of the world's medical knowledge and abilities. We can only try to imagine what dramatic changes will result from the research and development being done right now, but we do know that engineers will find a vibrant and exciting future throughout the healthcare industry in areas such as R&D, product and facility design, manufacturing, quality assurance, and much more. The development of an idea into a viable, reliable, and accessible product can be a complex process - but to see a new idea or product become a reality and know that it will change countless lives for the better is incredibly satisfying.

This module should give you an idea of trends in the industry, who the key players are, and how you can get started on a path to a promising and fulfilling career.

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Industry Scope

So how are the different areas of the industry defined? What are the similarities and differences between them?

Pharmaceutical Industry

We'll start with the pharmaceutical industry. This sector is dominated in both size and scope by large companies often referred to as Big Pharma. Many of these giant companies that are based in the U.S. are concentrated east of the Mississippi. Additionally, several are based in Switzerland, Germany, France, and Japan. Regardless of where they are based, however, these large companies (and in fact, many of the mid-sized firms), are increasingly global in reach. This globalization is fairly recent considering the industry's age, and has occurred primarily through mergers and acquisitions. While there are arguments for and against globalization of pharmaceuticals, no one can deny that this trend has changed the face of the industry. Companies (and eventually patients) have benefited from this extended reach into more markets because the additional income generated provides funding for further research and development. Also, access and the availability of important and life-saving drugs to impoverished nations, though not as comprehensive as many would like, has risen dramatically.

With global sales figures reaching $643 billion in 2006, the pharmaceutical industry is one of the most profitable industries in the world, and the U.S. pharmaceutical industry leads the way. Its prominence has been achieved in large part through significant investment in research and development (R&D). Of course, any cutting-edge industry has robust R&D sectors, but compared with other industries a relatively high proportion of the pharma budget goes into R&D. As a result, the marketplace is constantly changing and expanding, with new products and new uses for existing products announced regularly. Expansion like this is likely to translate into a robust job market for some time to come.

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Industry Scope

Biotechnology Industry

The biotechnology industry is smaller and much younger than the pharmaceutical industry, but despite starting almost 100 years later, biotech is transforming the world of drug discovery and development in ways - like gene-based technologies that attack and diagnose disease - that would have been hard to imagine even a few years ago.

In general terms, biotechnology refers to the use and modification of living organisms (like animals, plants, and bacteria) for purposes related to human health or the environment. When it first started to take shape, "biotech" was defined as "genetic engineering" a technology first discovered in academia and developed in start-up tech companies. Since then, it has expanded to encompass solutions to environmental and agricultural issues. Some examples of healthcare-related products coming out of the biotechnology industry include diagnostics and drugs that specifically target disease on the genetic level. More explicitly, because biotechnology allows us to study the genetic material of viruses and bacteria (such as those responsible for hepatitis or SARS, for example), we can use this information to develop diagnostic tests allowing us to detect the disease first, and then develop solutions to cure or suppress the disease. It is advances in biotech that have shaved years off of the drug approval process, and biotech products that provide special materials for manufacturing more effective medical devices.

From its roots in the U.S., biotech has evolved into a worldwide industry. While in the mid-1990s nearly two-thirds of this industry was based firmly in the U.S., the landscape today is very different. Europe now has 41 percent of the industry's total companies, compared to only 33 percent in the U.S.* The incredible growth in the Asia-Pacific market (fueled by an expanding region-wide outsourcing market, as well as by market expansion in the Australian and Japanese markets) means that the number of firms in this area is on the rise as well.

However, the U.S. remains very much at the center of the biotech world. Most of the publicly traded biotech companies are based in the U.S., and in terms of funding, revenue, R&D expenses, and employment the U.S. still holds the lead. The companies themselves are not large, as the majority of biotech firms have less than 50 employees and only a very small percentage have over 500.

The industry is moving steadily towards profitability, with revenues having increased from $8 billion in 1992, to $60 billion in 2005, to $70 billion in 2006. The revenue value of the global biotechnology market is estimated to reach $226 billion by the year 2010.** Like the pharmaceutical industry, biotech has been undergoing a spate of mergers and acquisitions, and this has increased the reach and scope of many of the larger biotech firms. But the industry has also seen an increase in specialization, with companies forming around interests such as contract research and manufacturing, vaccines, information technology and bioinformatics, traditional medicines, and stem cells.

So despite being smaller and younger than the pharmaceutical industry, biotech is a strong force in the healthcare arena. According to the Biotechnology Industry Organization, there are more than 370 drugs and vaccines currently in clinical trials targeting diseases such as Alzheimers, AIDS, arthritis, and diabetes, and it is biotechnology that allowed years to be shaved off development times for these and other important drugs. It's not only new treatments that are associated with breakthroughs in biotechnology, but new ways to utilize or manufacture existing drugs. These improvements will continue to save time and money, with the result that more people will have greater access to the help they need.

* Ernst & Young “Beyond Borders: Global Biotechnology Report 2005”
**RNCOS report “US Biotech Market Analysis” and bio.org industry stats.


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Industry Scope

Medical Device Industry

The medical device industry has transformed disease detection, cut down on the use of invasive treatment options, reduced recovery times, and enabled patients to resume active, productive lives more quickly. There are few areas and specialties in medicine that are not impacted by the work being done in this important sector.

Medical devices in the broadest sense have been around for centuries - arguably since the invention of the thermometer in 1603. But medical devices as we understand the phrase today might be traced more accurately to the discovery of x-rays in 1895. From that point on, the medical device industry never looked back. Products and equipment produced today include relatively inexpensive items like disposable syringes and home pregnancy test kits to multi-million dollar robotic surgery systems and M.R.I. diagnostic machines. Trend watchers and industry reports indicate that cardiovascular products in particular - pacemakers, angioplasty balloons, and stents - will experience notable growth in the foreseeable future as the aging population expands.

The medical device industry is currently generating over $150 billion in revenues, and though a handful of the companies that make up the sector are relatively sizeable (though nowhere near the size of the Big Pharma firms), the vast majority are really quite small***. In fact, according to the Advanced Medical Technology Association, an industry trade group, more than 80% of medical technology companies have fewer than 50 employees.

The companies that make up the medical device industry tend to “cluster around particular areas where other high tech industries are found. In the U.S., this means that, though you can find healthcare companies in many parts of the country, you'll find concentrations of these companies in California, Massachusetts, Florida, New Jersey, and Minnesota. Like the rest of the healthcare industry, the medical

device industry is experiencing tremendous growth globally - and the same “clustering can be seen in those markets. For example, in Germany - the largest of the European medical device markets - the cluster is around the Baden-Wuerttemberg. Though the European market is second only to the U.S. market, tremendous expansion and growth of this sector can be seen in the Asia-Pacific markets - not only regarding manufacturing itself but in terms of outsourced R&D and as a very valuable source of suppliers.

In the next decade, innovations in medical technology and engineering will fundamentally change the health-care landscape, providing new solutions to address chronic diseases and conditions and revolutionize the way treatments are administered. The medical device industry will expand as it races to keep pace with consumer demand and as it continues to develop the equipment that will foster breakthroughs in the healthcare industry, so engineers of all kinds will find challenges and opportunities here that they could never hope for elsewhere.

*** *Source: Medical Product Outsourcing 2006*


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Industry Operations

Overview

Due to the nature of the products they develop, all sectors of the healthcare industry are subject to a great deal of regulation. Administering the regulations is the responsibility of the Food and Drug Administration (FDA), which has oversight throughout the product development process, as well as a mandate to review the manufacturing and QA process on an ongoing basis.

Developing safe and effective new drugs and medical devices is a long, intricate, and multi-phase process and there is a tremendous investment of time and personnel involved in moving a drug from R&D to the marketplace. Engineers are involved throughout the process, so its critical that they understand FDA regulations and take them into consideration.

The approval process for drugs and medical devices differ considerably, due to the more physical interaction with the human body of devices, as opposed to the more chemical interaction of drugs. For medical devices, the first step involves determining the class of the device and that decision will determine the process from that point on. The FDA classifications of medical devices are assigned by the risk the medical device presents to the patient and the level of regulatory control the FDA determines is needed to legally market the device. As the classification level increases, so too does the risk and regulatory control.

The drug development and approval process, like the medical devices approval process, is overseen by the FDA but the process for drugs involves many more phases and can take considerably longer. A full drug development and approval process can take up to 12-15 years, though in special circumstances, the FDA has used an abbreviated process for drug testing and approval called "fast-tracking". The “fast track” designation is applied to products that demonstrate the

potential to treat or answer unmet medical needs of a serious or life-threatening condition. For example, a number of treatments for AIDS and various forms of cancer have been fast-tracked in recent years in the hope that this will bring these valuable treatments to market more quickly.

Naturally, over the course of a process cycle as long as that, many, many people are involved. Bringing a drug to market involves the work of countless professionals with a variety of skill sets and interests, including a variety of those in the engineering fields. At every phase, engineering excellence and attention to detail ensure the process is consistent, safe, and effective.

To give you an idea of what is involved, we'll next go through a typical phase-by-phase description of the FDA drug-approval process.


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Industry Operations

Discovery and Preclinical Trials

Pharmaceutical companies are continuously analyzing thousands of compounds, seeking the ones that will offer the best therapeutic value. Once they have identified the target compounds they wish to pursue, they begin six to seven years of preclinical testing, during which time the company undertakes lab studies for synthesis and purification of the drug and conducts animal testing. The purpose of this phase is to assess safety, side effects, and appropriate dosages.

Out of thousands of compounds tested, only a handful will be promising enough to lead the company to file an Investigational New Drug Application (IND). If the IND is approved by the FDA and by an IRB (Institutional Review Board, an overseeing body representing the institution in which the research takes place, such as a hospital or university), the manufacturer may begin the Phase I clinical testing.

The importance of the design engineer when it comes to the testing facilities used to conduct these early stages of development can't be stressed enough. The facilities and equipment developed must adhere to strict safety standards and maintain consistent performance over a long period of time. Redesigns may be required as compounds perform in unexpected ways, and the engineer will be called upon to do their part in maximizing the efficiency and speed of the process.

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Industry Operations

Clinical Trials

Testing is multi-phased, tightly controlled, and may involve a large number of patients, and each phase can take several months to several years for completion. Trials are designed to assess the safety and effectiveness of a new product.

- **Phase I** is made up of short-term tests on a limited population of test subjects, generally about 20-50 healthy volunteers. The purpose of these trials is to evaluate the safety and dosages still further than was managed in the pre-clinical tests, and to assess the pharmacological and toxicological effect of the compound in humans.
- **Phase II** involves still relatively small-scale tests, though they are longer in duration and involve a slightly larger test population, generally around 100-300 volunteers. What the R&D teams are looking for in this phase are things like optimal dosage levels, effectiveness, and potential side effects.
- **Phase III** has the largest test population, typically 1000-3000 volunteers. In this phase, the effectiveness and side effects of longer-term use across a larger user base is studied. It is the results of this phase that will deliver the information used by the FDA for approval.

Like the preclinical testing, the clinical trials must also be conducted in controlled situations. The final results from the testing period must be analyzed in the same way and under the same conditions as the first results even if they occur years apart. It is the engineer who will ensure the facilities and equipment work consistently and reliably and that the compounds produced are consistent.

Once the sponsor has conducted sufficient trials to demonstrate the safety and efficacy of the drug, they submit that information—along

with information on manufacturing specifications, drug stability and bioavailability, and suggested packaging and labeling—as a "new drug application" (NDA) to the FDA.


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Industry Operations

Approval

The FDA does not directly test the products or processes that it regulates. Instead, it is the responsibility of the company seeking to bring a new drug to market to submit information (the NDA) to the FDA proving that a new drug is safe and effective. The NDA is then reviewed by teams of FDA employees, including physicians, statisticians, chemists, pharmacologists, and other scientists, who assess the validity of the sponsor's claims. FDA inspectors also examine the facilities in which the sponsor intends to manufacture the drug.

After that, the drug may be approved for marketing or it may be declared "approvable" which means that there are remaining issues to be worked out between the FDA and the sponsor. These are usually relatively small items such as the FDA requiring more information or a change in the labeling.

Of course, it's possible that the drug will be declared "not approvable," meaning the submitted studies were insufficient to prove the drug's safety and/or efficacy.

Approval is not the end of oversight for drugs and medical devices. Because consumer safety is an ongoing concern, so is the regulation process. Over time, the FDA gathers safety information as the product is used and adverse events are reported. Depending on the details of those reports, it will occasionally request changes in a labeling, or if adverse events appear to be systematic and serious, the FDA may withdraw a product from the market.

For more information on the role of the engineer in getting new drugs and treatments to market, please see the Job Functions section of this module.

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Industry Operations

Industry Standards

We have already discussed the impact and influence the FDA has on the industry. In addition, there are also industry standards that provide guidance and direction to engineers working to achieve the most effective manufacturing and design process. These standards are written by experts with knowledge and expertise in the field and may run from just a few paragraphs to hundreds of pages.

Standards are not unique to this industry, of course. They promote safety, reliability, productivity, and efficiency in almost every industry that relies on engineering components or equipment. Some of the organizations providing standards and Good Manufacturing Practices (GMPs) to the engineers in the healthcare industry include:

- American National Standards Institute (ANSI)
- American Society of Mechanical Engineers (ASME)
- American Society for Testing and Materials (ASTM)
- Institute of Electrical and Electronics Engineers (IEEE)
- International Organization for Standardization (ISO)
- International Society for Pharmaceutical Engineering (ISPE)
- Consumer Healthcare Products Association (CHPA)
- United States Pharmacopoeia (USP)
- Institute for Nutraceutical Advancement (INA)
- Association for the Advancement of Medical Instrumentation (AAMI)

As previously mentioned, the healthcare industry is subject to government regulations by the FDA. These regulations are applied to a wide variety of products, and cover testing, manufacturing, validation, investigation of complaints and failures, annual re-evaluation of products, and testing of specific components and ingredients.

These regulations are administered by various sections of the FDA. The Center for Drug Evaluation and Research (CDER) is the FDA organization responsible for drug evaluation and approval. Even before approval, the labs and development facilities, clinical trials, and plans for production facilities may be subject to review by FDA inspectors. After approval, the responsibility for ensuring that firms adhere to the terms and conditions of approval shifts to the FDA's Office of Regulatory Affairs (ORA) which sends out field investigators and analysts to make periodic unannounced inspections of drug production and control facilities.

For more information about the specifics of the development process and the regulations related to them, you can check out the FDA's online information dealing with medical devices and drug development process.


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Industry Role of the Engineer: Job Functions

Overview

As you have now seen, the drug and medical device development process is quite complex. At every stage of that process, engineers are playing an important role. They are designing work environments and processes that set the tone for the whole project. They are working with scientists and other researchers to develop testing procedures and building prototypes, taking the plans from the page and making them 3-D. As the projects mature, they are testing to ensure that issues like safety and productivity are addressed thoroughly, while at the same time making sure that neither undermines the other. It is the efforts of all these engineers in all these capacities that create a successful and exciting development process.

Your engineering background qualifies you to perform in a variety of engineering job functions. The job functions are similar to those in other industries and offer you the opportunity to follow a path that aligns with your interests and strengths.

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Industry Role of the Engineer: Job Functions

Research & Design

Engineers are in at the ground floor when a potential new product is considered. At this early stage, they are considering the best configurations, processes, and designs to meet the target goals. In this industry, engineers also concern themselves with biocompatibility issues for implanted devices, materials within devices, and of course the interaction of the compounds in new pharmaceutical products.

Design engineers are not the only engineers you'll find in the Research & Development (R&D) department. Though it may be years before any product is ready for manufacturing or packaging, it is at this point that process and packaging engineers are introduced to the mix. Packaging engineers - though their deliverable is very much an end product - are involved with R&D, manufacturing, marketing, regulation, and purchasing. The packaging of any product in any industry must be suited to the product, serve the marketing goals of the company, and be cost effective. But packaging in the healthcare industry presents some unique challenges for the packaging engineer. Whatever they develop must comply with FDA regulations, addressing issues of shelf-life stability, labeling regulations, quality management, and packaging machinery that maintains product purity and safety.

Also in R&D, process engineers are needed to develop a small-scale version of manufacturing processes that are designed to ensure a consistent, unadulterated process. Sterilization is a concern at all phases of industry operations and all engineers in this industry make it a top priority. “Test early and often” might very well be the mantra of many of these exacting professionals. If a process proves viable in the small-scale and remains viable throughout scale-up of the clinical trials, it has a better chance of gaining FDA approval when it is implemented for full-scale manufacturing.

Since engineers in this field are most likely working as part of a larger

multidisciplinary team that includes non-engineers --researchers, medical professionals, fabricators, and other technicians -- it will be important that the engineering design intent is communicated as clearly as possible as prototypes are developed and tested. The documents and materials used to communicate that intent might include drawings and specifications covering materials, preliminary and scaled-up manufacturing plans, as well as validation procedures, timelines, cost analyses, and material and vendor sourcing.

As in many industries, computational methods and modeling used during the R&D phase allow engineers to predict structures and functions of complex systems, as well as analyze complex data sets. And it's not just medical devices that are being modeled. Biomedical engineers are able to design physiologically accurate dynamic models that respond to real-time input and stimuli. A computerized cardiac simulation system, for example, will run samples and compile results faster and in far greater numbers than in any human tests. This can lead to more targeted treatments for patients and improved outcomes.


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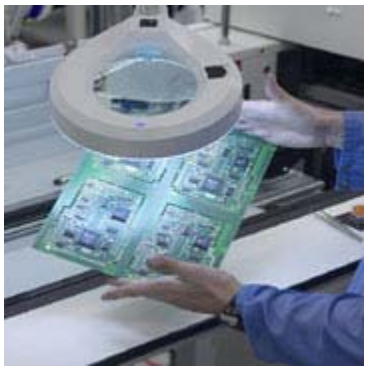
Industry Role of the Engineer: Job Functions

Production & Quality Assurance



Production or manufacturing engineers can be found in almost any industry you'd care to name, and quite a few of their responsibilities and concerns are the same across the board. Companies are always interested in shortening and improving their production or distribution operations so you'll generally find engineers doing system analysis and evaluation to meet the company's goals. But the production engineers in the healthcare industry have a particularly challenging job. In addition to making sure the production and distribution processes are as short and cost effective as possible, there are additional safety concerns and FDA regulations to adhere to. They perform laboratory studies of the manufacturing process and direct the scale-up of processes from the R&D phase to the full-scale manufacturing production processes required to produce a final product.

The manufacturing process for drugs or medical devices starts in the early phase of the development process. It starts small and gradually gets bigger - being re-evaluated at each stage. Even after the FDA approval has been given for the product itself, as well as for the manufacturing process, the production engineer is still needed for routinely reviewing the process, developing proposals for improvements, and searching for new vendors and materials - all with an eye toward tailoring a more cost-effective process for full-scale manufacturing. Even after a drug has been on the market for some time, advances in technology can bring down the cost of manufacturing, and, as a result, the cost of the product itself.

During testing and in the earliest phases of manufacturing, quality assurance and validation engineers will perform a thorough assessment of the system or facility design and ensure that it meets all requirements and specifications. This work is extremely important, in view of the fact that FDA approval is required to even begin manufacturing. As manufacturing moves forward, these engineers

(working closely with the production engineers and other team members) follow the production process closely and make sure that the product meets the highest standards of safety and quality mandated by the FDA.

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Industry Role of the Engineer: Job Functions

Specializations

In larger companies with more employees, you may find that the workplace structure allows narrower job scope and encourages specialization. In smaller companies, you may find they need everyone to wear more than one hat. Another option for someone looking to specialize is to consider a career with one of the engineering consulting firms that specialize in working with pharmaceutical clients. You might end up becoming a validation and compliance specialist or an operations expert.

Engineers in the industry will also find that there are a number of well-established specialty areas, such as bioinstrumentation, biomechanics, tissue and genetic engineering, rehabilitation engineering, and many others. Below is a description of some of the different areas.

- **Bioinstrumentation** uses measurement techniques to develop devices used in diagnosis and treatment of disease. These devices, like electrocardiograms that record the electrical activity of the heart and electroencephalograms that examine the nervous system, respond to signals generated from a biological, physiological, or other human sources.
- **Biomechanics** applies classical mechanics to biological or medical problems. It includes the study of motion and material deformation. Some of the most exciting developments in the field - robotic limbs, for example - have come from this specialty.
- **Biomedical imaging** includes far more these days than x-rays. It includes MRI, ultrasound, CT, PET, near infrared (NIR), electrical impedance, and optical coherence tomography. These technologies are used across a wide spectrum of the medical field, including early disease

diagnosis and treatment, radiotherapy, physiological computation and modeling, surgical management, and rehabilitation systems.

- **Clinical engineering** brings the engineer and engineering into the hospital itself. Clinical engineers develop medical instrumentation and work directly with medical personnel to adapt instrumentation to the specific needs of physicians, surgeons, and hospitals.

- **Drug delivery** challenges engineers to find ways to improve delivery strategies, ideally resulting in fewer invasive procedures, reduced dosages, and easier ways for patients to monitor their condition and manage their own treatment. As new materials and technologies are found and developed, delivery systems are tweaked and redesigned to take advantage of these innovations.

- **Nanotechnology** engineers develop devices, diagnostics, and therapeutics on the nano scale. Advances in this area are being made in molecular imaging, gene therapy applications, DNA sequencing, and drug delivery systems.

- **Rehabilitation engineering** is a particularly fast-growing field. People in this area work to address issues connected with physical and cognitive impairments of patients. They might be working on prosthetics, modifications for homes and workspaces, adapting transportation vehicles, or developing new technologies to assist in mobility and communication.

- **Tissue engineering** focuses on what's happening at the cellular level, and works to create replacements of portions or whole tissues and organs that are biocompatible with the patient. An example of this would be tissue engineering a meniscus - a delicate cartilage in the knee that is often torn by athletes.

Of course, there are many more specialty areas, and in many instances these areas interact and overlap. A biomedical engineer from an applied field will use knowledge gathered by biomedical engineers working in other areas. A bio-imaging specialist will find that the advances in nanotechnology align well with their own work. No matter what your specialty or what phase of the process you find yourself in, you'll find engineering is at the center of creative design, problem solving, efficiency, and safety.


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Companies

Many of the large pharmaceutical firms are closely connected with the biotech or medical device companies or are involved directly in all three sectors themselves. This list represents many of the primary key players in each field.

Private Industry—Pharmaceuticals
- Abbott Laboratories
- Astellas Pharma
- AstraZeneca
- Bayer AG
- Boehringer-Ingelheim
- Bristol-Myers Squibb
- Daiichi-Sankyo
- Eisai
- Eli Lilly & Co.
- GlaxoSmithKline
- Johnson & Johnson
- Merck & Co.
- Novartis
- Novo Nordisk
- Pfizer
- Roche
- Sanofi-Aventis
- Schering-Plough
- Takeda Pharmaceutical
- Wyeth

Private Industry—Biotech
- Amgen
- Biogen Idec
- Chiron Corp.
- Genentech
- Genzyme Corp.
- Gilead Sciences
- MedImmune
- Millennium Pharmaceuticals
- Serono
- ImClone

Private Industry—Medical Devices
- Baxter International
- Boston Scientific
- GE Healthcare
- Masimo
- Medtronic
- Optical Dynamics Corp.
- Philips Medical Systems
- Siemens Medical Solutions

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Companies

Government

The FDA and its various departments, the U.S. Public Health Service, the Veterans Health Administration, and the Department of Agriculture all have positions relevant to an engineer interested in combining the field of pharmaceuticals with a career in public service.

Engineers working at the FDA review, evaluate, and report on data as part of the FDA process to determine the safety and efficacy of medical products. They evaluate not only the test results being reported by the petitioning company, but they examine the test methods and manufacturing plans as well. They may work in various departments such as the Office of Science and Engineering Laboratories or the Center for Devices and Radiological Health, to name a few.

At the Department of Heath and Human Services, engineers are on staff to advise on the planning, design, acquisition, and construction of research, research support, and administrative facilities used by the department and its divisions, such as the National Institutes of Health.

Engineers at the Veterans Affairs and Health Administration serve in many capacities. Manufacturing and process engineers might be involved in facility design, advising on redesigning, implementing, and maintaining the complex and critical medical equipment intended to serve ever-changing patient and medical priorities. Or they might be biomedical engineers charged with finding solutions to problems associated with the lower limb kinematics and musculoskeletal forces during human locomotion.

So a full spectrum of engineering careers can be found in public service. The best place to start looking if you think this is the path you want to follow would be USAJobs, the governments' centralized job search and career website. It is maintained by the Office of Personnel

Management and simplifies the process of finding a federal job by posting job listings from all federal units in one location.


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Industry Outlook

Overview

So what does the future of healthcare look like? Overall, the future looks very bright indeed.

While it's true that we are all affected by fluctuating economic conditions, the healthcare industry as a whole is fairly stable. There will always be a market for over-the-counter and prescription drugs, diagnostic kits, routine vaccines for infants and children, antibiotics, analgesics, and other symptom-easing drugs. Similarly, medical devices from MRIs to stents and blood pressure or glucose monitoring equipment for home use will always be in demand, and require new equipment and instruments. As a result, while many industries were affected by the economic downturns in 2001, the pharmaceutical industry came through it better than most.

The industry has also had a recent string of successful "blockbuster" drugs and medical devices hit the market and found itself on an upward trend. This trend is expected to continue as demand for medical treatments and supplies increases with the expansion and aging of the population. Other factors expected to increase the demand include: greater personal income, changing scope of drug coverage by health insurance programs, the rising health consciousness and expectations of the general public, and a more industry-friendly regulatory environment that has streamlined the FDA approval process for "priority" drugs intended to address catastrophic or incurable illness like AIDS or different forms of cancer.

So what does this increased demand mean in the form of jobs and opportunities for engineers? Well, the Bureau of Labor Statistics (BLS) assessment states:

> The number of wage and salary jobs in pharmaceutical and medicine manufacturing is expected to increase

> by about 26 percent over the 2004-14 period, compared with 14 percent for all industries combined. Pharmaceutical and medical manufacturing ranks among the fastest growing manufacturing industries. Demand for this industry's products is expected to remain strong.... Unlike many other manufacturing industries, the pharmaceutical and medical manufacturing industry is not highly sensitive to changes in economic conditions. Even during periods of high unemployment, work is likely to be relatively stable in this industry.
>
> *-Bureau of Labor Statistics, U.S. Department of Labor, Career Guide to Industries, 2006-07 Edition, Pharmaceutical and Medicine Manufacturing*

Job functions in pharmaceuticals tend to be similar across the sectors but there are notable differences. Company size is one factor that makes a difference. Over half of the jobs in the industry are found in the larger firms. It's not that smaller firms aren't hiring; they certainly are. It's more a matter of volume. A single Big Pharma company might employ hundreds of thousands of people, whereas in biotech, which industry-wide has only 200,000 employees, the majority of firms have less than 50 employees and only a very small percentage have over 500. This difference in size can also play a part in what sort of company culture a firm has. You'll find that the larger, more established firms have a more traditional, corporate structure (and the hierarchy that goes with it), whereas the smaller biotech firms tend to be more egalitarian and less structured.

Another difference is company focus. Though R&D is a critical and important division in companies across the industry, biotech has a greater percentage of its resources focused on this phase than the big pharmaceuticals, simply because, as relative newcomers, they are just reaching the point where their first products are maturing.


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Industry Outlook

Partnerships

Industry Partnerships
Though in some ways they are competitors, there is a growing cooperation between the large pharmaceuticals, biotech, and medical device firms. Why would Big Pharma, with its massive market share, and a smaller firm looking to break into the market work together? Well, Big Pharma has the infrastructure in place to bring manufacturing online quickly and has already established footholds in the marketplace. Biotech firms don't have the size or resources to match those kinds of established assets but they are smaller and may have less institutional baggage than an older, established firm. That can translate into a more flexible outlook and a more agile R&D effort.

Sometimes apparent rivalries can lead to win-win situations. The new product might enhance something already being sold by Big Pharma, or the potential success of the new biotech product might be so great, and sales predicted to be so high, that a manufacturing deal might be extremely lucrative. It's a delicate balance between independence and survival.

Industry - Academia Partnerships
In addition to inter-industry cooperation, there is a great deal of cooperation and partnership between industry and academia. Many universities have robust research centers where much of the initial discovery process is done. When a promising compound is found or developed, it can be licensed to an industry player. Academia brings to the table valuable insights into the fundamentals of human disease, and industry provides the knowledge and tools to take these findings and turn them into practical applications for the benefit of patients and the medical community. Where academia provides expertise in patient care and clinical judgment, industry provides knowledge in clinical-trial design, data analysis, and regulatory affairs. The healthcare industry is one of the leading sources of funding for

academic research, and in return for that funding industry gains insight into its products from the experts and pioneers of academia. This synergy can often result in exciting prospects for new treatments and improvements on existing ones.

But it has also been a matter of growing concern in the past few years. The ties between industry and academia have become, in the opinion of some, too close and too tied to economics. The question of integrity and potential misconduct has arisen in some cases and IRB committee members have been skeptical of the academic researcher having financial ties or interests in the company petitioning on behalf of a new product. These questions are being examined by the FDA, the industry, and academia with revised guidelines and procedures being set out to clarify positions and prevent conflict of interest from undermining the potentially life-saving solutions all are working towards.


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Industry Outlook

Legal Issues

Over the last few years, there have been a number of high-profile legal actions related to a class of drugs known as COX-2 inhibitors. These cases - involving some of the largest companies in the industry - have received a great deal of media coverage and, due to the complexity of the cases, may go on for many years. In addition to the legal cases, the FDA also has investigated these issues, and in each case the companies involved have worked with the FDA to protect and inform the public as fully as possible.

As in many industries, there have been legal cases regarding accounting procedures and other financial misdealings. All of these legal issues have an impact on the reputation and public perception of the companies in question and of the industry as a whole, but they are the exception and not the rule. The healthcare industry, by and large, is considered to be well run, a valuable contributor to the economy, and (most importantly) an ally of the public in the fight to improve healthcare and the lives of people worldwide.

Other lawsuits becoming more prevalent in the industry deal with the issue of patent infringement. It is a complicated issue involving intellectual property, the globalization of the industry, the rise of generics, and access and availability for poor or developing nations. The healthcare industry invests a great deal of money into R&D as we have seen. It is only natural that they wish to protect and get a return on their investment. Changes to the FDA regulations in the past two decades have made it easier for generics to be brought to market and, as the time between the approval of a generic and the end of the primary drug's patent gets shorter, patent battles become more common.

Some drugs that are in high demand across the developing world are often products that are still under patent but which aren't necessarily the most cost effective for their companies to produce in large

quantities. This has led many of the nations most in need of these medical supplies to relax their restrictions on the development of “copies.” In that case, the driving force behind the infringement isn’t profits as much as it is saving lives, and it involves not only the patent laws of the originating company but of the global marketplace as a whole. It’s not an issue that is going away anytime soon and it’s not something where the solution -- if found -- will be easily implemented. But in the larger scheme of things, it is being managed as effectively as possible so that it doesn’t prevent other, equally important progress to be made on other products


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Mapping Your Career in the Industry

Educational Preparation

College/University Coursework
You don't need a biomedical or pharmaceutical engineering degree in order to get started in this industry. There are many opportunities available to graduates with degrees in other engineering disciplines like chemical, computer, electrical, or mechanical engineering. The majority of engineering programs - regardless of specialty - include core curriculums that will enable the recent graduate to work in any of the job functions discussed in previous sections. If, however, you want to start pursuing this specific path right away, consult with your academic advisors and consider coursework related to the field such as:

- Biomechanics
- Biomedicine for Engineers
- Chemistry for Engineers
- Clinical Development and Engineering
- Computational Methods in Biology
- Image Processing and Reconstruction Tomography
- Instrumentation in Biology and Medicine
- Introduction to Micro and Nanobiotechnology
- Orthopedic and Rehabilitative Engineering
- Pharmaceutical Facility Design and Maintenance
- Pharmaceutical Reaction Engineering
- Principles of Pharmacokinetics and Drug Delivery
- Process Engineering in the Pharmaceutical Industry
- Regulatory Science for Scientists, Engineers, and Managers
- Statistics
- Validation & Regulatory Affairs

Internships, Co-ops & Research Experiences
Work experience will always count in your favor, especially in an industry where networking is so central to your career development path. The Biomedical Engineering Alliance for Industrial Internships

offers a centralized site where companies and research institutions post internships, co-ops, and jobs in biomedical engineering firms. Also listed there are university-based research opportunities.

Research experience at a university will also make you a stand-out candidate when it comes time to get a job. Aside from opportunities in the engineering departments, there are many valuable experiences awaiting engineers in biology and material science departments that will prepare you for a career in the healthcare industry. Even if your plan is to specialize in something like validation processing, working in a biochemistry lab or on cancer research studies will enhance your understanding of the types of facilities and work processes you will encounter and the sort of issues your work will address.


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Mapping Your Career in the Industry

Finding the Right Job

A job search actually starts long before you send the first resume. It starts with prep work. If you want to make the right impression at that first interview or have your resume stand out, you have to know the industry and the things that make it unique. How will you find out what areas to focus on and where each company's interests and strengths lie? With research.

Research
Get to know the industry - the trends and current events - and get to know more about the key players and firms in the field as well. Which company has had a recent blockbuster drug? Which firm just bought out which? Which CEO has just stepped down? Begin by scanning your local newspaper's business section as well as the Wall Street Journal, but don't neglect the rest of the paper. Pharmaceuticals are not only big money but they are big news as well; you'll find they receive attention in science sections and can often be at the heart of front-page stories.

There are also online news feeds and aggregators that specialize in particular industries. Some news feeds, industry specific and general, that you might consider subscribing to include:

- Bizjournals (the online media division of American City Business Journals, the nation's largest publisher of metropolitan business newspapers) provides an industry specific selection of feeds. They have general healthcare feeds as well as biotechnology and pharmaceutical industry feeds.
- Medical Device Network
- PharmaceuticalTechnology.com
- The New York Times, like many major newspapers, has several feeds that would be relevant, including the health policy, business, and science feeds.

- Yahoo! and other web portals have detailed lists of news feeds in areas like business, technology, and health.

The next set of publications you should review regularly are the industry trade magazines, such as *Pharmaceutical Manufacturing, BioPharm International, The Gray Sheet,* and *Medical Design Technology Magazine*. Magazines like these report on all aspects of the industry and can help focus your search and help you target specific companies.

More industry news sources can be found in the Industry Resources section in this module.

Once you have your industry sources established, you can start researching the companies you intend to target. Don't forget that one of the best sources of information about a company is the company itself. Most companies have websites that include not only information on product lines but also company history and links for employment opportunities. For a list of leading companies in the industry, check out the Companies section in this module. For more information on researching companies and identifying targets for your search, review our Career Planning module.

On-campus Resources
Many companies visit campus for recruiting purposes. Your university Career Services Office should be able to tell you what companies are coming and when. They might also be able to provide information and contacts related to internships. For more information on using these on-campus options, review our Career Planning module.

Networking
On the whole, the healthcare industry does less on-campus recruiting than other industries, and a single online job listing might potentially draw thousands of applicants. This makes networking even more important for people looking to get into this field. Many people dismiss networking as simply "asking around" but it's much more than that - it can be the key to getting in the door and standing out from the crowd. You might hear of job openings that are not yet being advertised or about people who plan to leave a job in the near future. Another advantage is that being able to associate yourself with someone known to the hiring manager means you will have an edge in your first interview over the applicant who is just one of many names on a list.

For tips and suggestions on effective networking, review our Career Planning module.

Online Job Listing Sites
You can certainly find industry jobs on the large, general job-listing sites like Monster.com or careerbuilder.com, but winnowing down the list to the jobs in areas you want to focus on can be time consuming. Still, these resources are very comprehensive and it's worth looking at them - if only to get a sense of the range of engineering positions that are available at any given time.

If you want to start off with more focus, you can check out these sites specifically aimed at those looking for positions in the industry:

- Biomedical Engineering Network
- Biomedical Jobs
- Biospace
- Jobscience
- Mass High Tech biotechnology listings
- Mass High Tech pharmaceutical listings
- Medzilla
- PharmaManufacturing.com's Career Center
- Sciencejobs
- Scientific Search

As mentioned, an important source of online job information is the company websites themselves. Check back regularly in the careers sections. A list of leading companies and links to their websites can be found in our Companies section.


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Mapping Your Career in the Industry

Staying Current and Getting Ahead

In an industry where innovation is happening every day, it's extremely important to keep up with the latest news. Stay subscribed to those newsfeeds and keep up on your trade publication reading. No company, no matter how large, operates in a void. Keep abreast of what's happening, not only in your own company but with the competition as well.

Continuing Education
Success in pharmaceuticals also means keeping your skills sharp and your knowledge current with continuing education options like online classes, seminars, and conferences. The industry as a whole places a heavy emphasis on continuing education for employees, and many firms provide classroom training in safety, environmental and quality control, and technological advances. Trade magazines and professional societies like the ones in our Industry Resources section are a great place to start when you want to advance your career.

Networking as an Ongoing Practice
Several larger companies within the healthcare industry have formal rotation programs that offer new graduates an opportunity to experience more than one aspect of the firm and get a broader view of the industry as a whole. Not only will these programs expose you to different areas of the company, they'll bring you into contact with more people from different departments as well.

Networking is a valuable career development tool that can help you move up the career ladder. If you have the opportunity to participate in your company's rotation program or to attend industry meetings and conferences, take advantage of it.

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Industry Resources

Reading: Magazines, Journals and Websites

- BioSpace
- Biomedical Engineering Central
- Pharmaceutical Engineering
- Medical Device Link
- Medical Design Technology Magazine
- Medical Device Daily
- Pharmaceutical Manufacturing
- Chemical & Engineering News
- Pharmaceutical Processing
- Endovascular Today
- The Gray Sheet
- Medical Device and Diagnostic Industry Magazine

Many industry organizations and associations have websites with articles and white papers addressing issues facing companies and people in pharmaceuticals and biotech. We've listed several below.

Professional Societies and Associations
Professional societies offer the opportunity to meet and network with industry professionals. ASME has a Bioengineering Division whose activities can be of tremendous help in making valuable contacts and staying abreast of new developments in the bioengineering industry. The Division's technical activities are organized through the Fluid Mechanics, Design & Rehabilitation, Heat & Mass Transfer in Biotechnology, Cell & Tissue Engineering, and Solid Mechanics Technical Committees.

Many other industry-related organizations offer information on careers, industry information, and events that can be invaluable not only as you start your job search but even later on as you seek to take your career to new levels. Some you might want to check out include:

- American Institute for Medical and Biological Engineering (AIMBE)
- Biomedical Engineering Society (BMES)
- Biotechnology Industry Organization (BIO)
- IEEE Engineering in Medicine and Biology Society (EMBS)
- International Association for Pharmaceutical Technology (APV)
- International Federation of Pharmaceutical Manufacturers Associations (IFPMA)
- International Society for Pharmaceutical Engineering (ISPE)
- Medical Device Manufacturers Association (MDMA)
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- Pharmaceutical Research and Manufacturers of America (PhRMA)


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Healthcare: Pharmaceuticals, Biotech and Medical Devices Industries

Industry Summary

The healthcare industry provides excellent employment prospects for engineers looking for a challenging and rewarding career. The industry continues to grow and innovate, which gives engineers working in the field a chance not only to get ahead but to make a real difference in people's lives. Whether you are looking for the excitement and flexibility of a biotech start-up, a more structured, stable workplace like those found with Big Pharma, or the special engineering challenges of the medical device sector, you will find positions where your skills and passion can match up well in each of these areas.

The medical product development processes are long and complicated ones, and they don't always end the way you might wish. There are always going to be drugs and medical devices that don't get approved or don't work out as they are tested and investigated. To have worked so hard and so long on something that doesn't make it will be hard. But there will be the other times when it all comes together. There will be those times when you and your team have found something new that will alleviate pain or a new way of using a treatment that will speed recovery—and at those times, you will know that you made the right choice and that you have one of the most satisfying careers an engineer can have.

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