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The BIO Market for Engineering Management

Introduction

Due to new genetic engineering breakthroughs, the aging of "Baby Boomers" in the United States, and increased business opportunities in the application of life sciences, the biomedical field is one of the fastest growing segments in engineering. This level of growth suggests that there might be great opportunities for growth within Master's degree programs in Engineering Management. The questions are: Who are these new engineering and science students that might gain from an Engineering Management Master's degree, and is there an opportunity to target these new prospective students? The second question is: Which industries might want to hire these new graduates? In this paper, the term BIO is defined as all the healthcare industries that might be interested in these new graduates, including developers, manufacturers, and distributors of medical products, equipment, and services. This includes pharmaceutical firms, hospitals, and governmental agencies that investigate, regulate, or provide health services. The purpose of this paper is to highlight to the Engineering Management educational community the opportunity to address a new growing market. This paper provides a historical background of BIO, investigates the various degrees that might prepare these BIO engineers before they earn their Master's of Science Degree in Engineering Management, and the industries where this might be useful.

Historical background

The pharmaceutical industry has been in place since ancient times. People have always been looking for medicines to cure diseases and illnesses. The pharmaceutical industry is currently a much regulated industry in this country and its regulation began in 1906 when the FDA was founded. The FDA plays a major role in the pharmaceutical industry by providing security to the users and eliminating dangerous medicines. In 1938, the ingestion of "Elixir of Sulfanilamide" led to the deaths of 107 adults and children. Due to these deaths, the 1938 Federal Food, Drug, and Cosmetic Act was passed, giving the FDA considerably increased power to regulate on behalf of the public. Originally its control was limited to prescription medicine, but in 1961, over-the-counter drugs also became regulated by the FDA. The following year, safety and efficacy data began to be required for new drugs.¹

The pharmaceutical industry is experiencing significant growth. In 2005, the U.S. pharmaceutical market reached \$252 billion in revenues, a seven percent increase from 2004. Globally, sixty-four companies (72.6% of the global pharmaceutical market) achieved sales greater that \$1 billion. The top ten pharmaceutical companies generated revenues of \$252 billion and make up more than 40 percent of the total market. The top five companies included: Pfizer with a market share of 7.4%, GlaxoSmithKline with a market share of 5.6%, Sanofi-Aventis with a market share of 5.6%, AstraZeneca with a market share of 4.0%, and Johnson and Johnson with a market share of 3.7%. By 2010, the global pharmaceutical market is expected to grow at a compounded annual growth rate of 6.9% to reach \$842 billion in 2010.²

Biotechnology is the other major driver in the current growth of the BIO industry. James Watson and Francis Crick are usually credited with the start of biotechnology. In 1953, they published their manuscript describing the double helical structure of DNA. However, it wasn't until 1976 that the first biotechnology company, Genentech, was founded. Four years later, genetically engineered human insulin was considered the first biotechnology product on market.³

The biotechnology industry has been on a rapid increase since the early 1990s. Since 1993, U.S. healthcare biotechnology revenues have increased from \$8 billion to \$39 billion in 2003. As of December 31, 2003, there were 1,473 biotechnology companies in the United States employing 198,300 people.⁴ In 2005, the top ten biotechnology companies all had revenues higher than \$1 billion, an increase in all ten from 2004. The top three companies included: Amgen with revenues of \$12.4 billion, Genentech with revenues of \$6.6 billion, and Genzyme with revenues of \$2.7 billion.²

The engineering field has been slow to engage in this dynamic industry; however, this started to change with the growth of the biomedical engineering discipline. The National Institute of Health (NIH) is often credited with the creation of biomedical engineering more than fifty years ago.⁵ However, it is the Whitaker Foundation that is usually credited with its explosive growth during the last few decades. Not only was it the largest financial supporter of biomedical engineering education and research, it developed a strategy that turbocharged the discipline's growth. The Whitaker Foundation was founded in 1975, and instead of funding projects gradually to ensure its long term survival, it decided the U.S. needed a viable bioengineering discipline. The foundation developed a plan to invest all their capital in a short period of time making substantial grants to thirty new biomedical engineering departments throughout the U.S. in a major way so that they could afford to hire faculty and build the needed facilities. They also provided funding to almost 1,500 young researchers to help them start their careers in biomedical engineering.⁶ Since 1989, seventy-five institutions have received gifts from \$750,000 to \$18 million toward their biomedical engineering programs. This contributed to the rapid rise in biomedical engineering programs during the five year period between 1995 and 2000. During this five year period, the number of biomedical engineering programs doubled from approximately twenty-five to fifty.⁷ As planned, the foundation used up all their funds and is now defunct.

During the last two decades, biomedical engineering has made tremendous strides. According to the United States Department of Labor, the numbers of biomedical engineering jobs will increase by 31.4 percent through 2010 with overall job growth averaging 15.2 percent.⁸

The demand for BIO

In the context of new health solutions based on improved knowledge of human genetics, improved materials, pharmaceutical products, and a source of biomedical engineers, the United States is facing an aging population, with the graying of the "Baby Boomers" who need and demand more health products and services. In 2004, Americans spent \$2 trillion on healthcare. This cost was equivalent to 15% of the United States' total output of goods and services for that year.⁵ "Baby Boomers" are classified as the generation born during the period of increased birth rates between 1946 and 1964. In 2004, the average annual healthcare expenditures for

Americans between the ages of 45 and 54 was \$2,695. As expected, as the population aged, the average annual healthcare expenditures increased. The average for Americans between the ages of 55 and 64 increased to \$3,262 and for people 65 and over, it was \$3,899.⁹ In 2006, the oldest of the baby boomers turned 60 years old, and as baby boomers continue to age, the need for healthcare and new biomedical technologies will continue to increase.

As the BIO industry has grown, there has been a great demand for new products and processes. There was a well-developed scientific community involved in this industry, but it was not well served by engineering. Engineers who entered this field were trained in one of the other traditional disciplines and learned the biological disciplines as they got involved to solve the problems. Consequently, many engineering solutions were developed by MD's and scientists who saw the needs even though they were not trained in engineering or business. As these BIO enterprises grow and they learn how to make effective use of biomedical engineers, the technical development needs will be better met than they have before. However, there is an increasing need for professionals to manage the technical projects, programs, and organizations. This market need could be met by bioengineers who earn a Master's Degree in Engineering Management. These professionals would not only understand engineering and life-science issues, but also management and strategic issues.

The Massachusetts Biotechnology Education Foundation is a non-profit company that promotes and supports science and biotechnology education in Massachusetts. In the May 1, 2005 issue of Genetic Engineering News, Cora Beth Abel, the Vice President of MassBioEd stressed that clinical and project management were the two areas most in need of workforce development. She was quoted as saying: "Project Management is another critical shortage. Biotech employees, whether in the lab or the executive suite, need this knowledge of how science and business fit together."

Engineering Management has been meeting the demand for engineering re-education for decades. Engineering Management was first established at the University of Missouri-Rolla in 1965 and has been growing.¹⁰ According to a survey performed at Portland State University, the number of academic institutions worldwide offering Engineering Management and Technology Management degrees has increased dramatically from 32 in 1976 to 250 in 2003. This growth reflects the need in a wide range of industries for engineers that are educated in management. However, there is an opportunity to address the educational needs for engineers to manage in these growing BIO industries. Since this is a new and growing area, it may be valuable for Engineering Management departments might consider targeting a few key BIO industries. This would facilitate the program modifications that might be criteria for success. Depending on the targeted industries, specific action can be taken. For example, changes can be made to current classes, new classes can be introduced, or new emphasis areas can be created to prepare these students.

Who are the students that might be targeted?

The following section provides a sample of the major academic disciplines that students might benefit from a Master's degree in Engineering Management.

Biomedical Engineering. The National Institute of Health (NIH) created a working definition of biomedical engineering on July 24, 1997: "Biomedical engineering integrates physical, chemical, mathematical, and computational sciences and engineering principles to study biology, medicine, behavior, and health. It advances fundamental concepts; creates knowledge from the molecular to the organ systems level; and develops innovative biologics, materials, processes, implants, devices, and informatics approaches for the prevention, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health." Biomedical engineers take classes in all basic sciences as well as classes in almost every area of engineering, such as electrical, mechanical, and materials engineering.

Bioengineering. Bioengineering has both medical and non-medical applications. When referring to bioengineering in the medical context, bioengineers "apply engineering principles to understanding the structure, function, and pathology of the human body."⁵ Bioengineers are very important to the pharmaceutical industry, playing a large part in drug discovery and development.

Clinical Engineering. Clinical engineers are sometimes considered a branch of biomedical engineering. The role of clinical engineers is to "use engineering concepts and technologies to improve and manage patient-oriented health-care delivery systems in hospitals and clinics by selecting, maintaining, and testing medical instruments and machines, by training personnel in their use, and by ensuring that systems do not interact in ways that may be detrimental to patients and hospital staff."⁵ The American College of Clinical Engineering (ACCE) refers to the clinical engineer as a "technology manager". Knowledge of business is extremely important as required duties include financial or budgetary management, service contract management, data processing systems for managing the medical equipment, and coordination of service agreements and in-house operations.¹¹

Hospital/Healthcare Administration. Hospitals and clinics are businesses that require considerable management and technical expertise. The U.S. Department of Labor states that people in the area of hospital administration "must be prepared to deal with evolving integrated healthcare delivery systems, technological innovations, an increasingly complex regulatory environment, restructuring of work, and an increased focus on preventative care."¹² As hospitals become more and more technologically advanced, it will be beneficial for administrators have this "engineering" knowledge in order to stay competitive and have the latest advancements.

Orthopaedics. There are many specialty areas that also provide a great opportunity, such as orthopaedics. The American Academy of Orthopaedic Surgeons describes the scope of orthopaedics as encompassing "disorders of the body's bones, joints, ligaments, muscles, and tendons."¹³ Orthopaedics is a specialty area within biomedical engineering in which artificial joint replacements are designed. To accomplish this, orthopaedic biomedical engineers "analyze the friction, lubrication and wear characteristics of natural and artificial joints; they perform stress analysis of the musculoskeletal system; and they develop artificial biomaterials (biologic and synthetic) for replacement of bones, cartilages, ligaments, tendons, meniscus and intervertebral discs."⁸ These products are then sold, usually to doctors and surgeons, who must understand both the pros and cons to each individual implant for the safety of the patient.

What industries might want to hire the graduates?

The following section provides a sample listing of major industries that might gain from hiring BIO students with a Master's Degree in Engineering Management.

A major opportunity lies with firms that seek to innovate within the BIO arena, as they build and distribute biomedical devices, research equipment, manufacturing equipment, and services to all of the BIO players. This is a very large group of firms that are responding to the needs of our aging population and growing opportunities due to technological advancement. In the August 16, 2006 issue of <u>Business Week Online</u>, the article "From Bench Top to Bedside" focuses on ten innovative medical devices that either improve existing treatments and devices or solve new problems. Mary Beth Privetera, a faculty member at the University of Cincinnati's Medical Device Innovation and Entrepreneurship Program said: "There's a new focus on innovation and ideas that change health care for the patient."¹⁴

The beginnings and growth of the biotechnology industry have already been discussed; however, there are many, and sometimes conflicting, definitions for biotechnology. In 1992, the Convention on Biological Diversity defined biotechnology as "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products and processes for specific use."¹⁵ A more specific definition for biotechnology is: "a collection of technologies, for instance genomics, proteomics, combinatorial biology and chemistry, and high-throughput-screening, which causes a rapid advance in all the traditional life sciences, particularly in the pharmaceutical R&D process."³

The beginnings and growth of the pharmaceutical industry have also been discussed. This industry focuses on the development and introduction of new drugs to market. Individuals involved in pharmaceutical marketing and sales must not only have a very strong knowledge of marketing, but also of the pharmaceutical products and the processes utilized to produce them. It is also valuable that salespeople understand the competitive position of their product which can be obtained through "taking part" in product research and development.

Consulting is another area of opportunity since these new BIO firms will likely create a large demand for consulting. These firms will need to deal with advanced and expensive technologies and will often not be able to hire the required expertise. These firms are also young and growing which generally implies that they will have limited financial resources. At the same time, global competition will require fast and effective action. All these factors tend to increase the need for consultants.

Traditionally, hospital systems have been made up of doctors, nurses, and administrators. With the importance of medical breakthroughs, many hospitals conduct research on-site. Additionally, many efforts are being made to improve hospital processes. Sridhar B. Seshadri is the Vice President of Planning and Process Excellence for Stanford Hospital and Clinics and is representative of this career opportunity. Although currently working in a management role, Seshadri started his career in healthcare as an engineer. In an interview, Seshadri states: "Our focus is to improve those operational processes that 'envelop the clinical event'."¹⁶

As part of a marketing class at the University of Missouri-Rolla, a number of students investigated the demand within hospitals for engineers with not only a knowledge and education in the biomedical discipline but also in business. Ten hospitals were contacted; and five hospitals responded. The students interviewed human resource managers who were in the position to know their hiring practices and needs. Four U.S. hospitals were contacted by phone, while a hospital in Saudi Arabia was contacted by email. All hospitals stressed the importance of formal management training. When asked about the engineering management degree program, four out of five surveyed were not familiar with it. When asked about the need for engineers who are knowledgeable about the biomedical discipline as well as business, most respondents stated that they were sure there was a need, but were not very knowledgeable on the subject. The investigator also found that smaller independent hospitals were unlikely to be able to afford to hire these types of engineers. The opportunity exists with very large hospitals and hospital systems.

Conclusion

Future research in this area includes quantification of these opportunities with segmentation and estimated growth rates of the prospective students and industries that are likely to have a need for these graduates. It is expected that some of these segments will have much greater opportunities for our graduates and the identification of these segments is very important for the department to develop effective plans.

With the large number of growing BIO industries, technology management expertise is a necessity. This provides a great opportunity for Engineering Management departments to supplement education in this area, if they take the initiative. Engineering Management has a large role to play, educating BIO professional students to prepare them to manage these new activities. Engineering Management departments should investigate this growth opportunity and take action to develop appropriate educational products.

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