How to Prevent Workforce Shortages in the US Biotechnology Industry

by Clifford S. Mintz

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Despite humble beginnings, the biotechnology industry has become one of the most vibrant sectors of the American economy. In 2001, the industry spent $15.7 billion on research, and sales of biotech products exceeded $35 billion in 2002 (1). According to a report by the US Commerce Department, the market for biotechnology products is expected to reach $45 billion by 2006. Currently, more than 350 biotech drug products and vaccines are in human clinical trials, and hundreds more are in early development in the United States alone (1).

Recent surveys conducted by the Biotechnology Industry Organization (BIO) (1) and the accounting firm of Ernst & Young (2) estimate that approximately 1457 biotechnology companies operate in the United States. These companies employ about 191,000 people in high-value jobs (1). Moreover, an additional 286,000 jobs are generated by companies that provide goods and services to the biotech industry. There is no doubt that the biotechnology industry has finally come of age.

JOBS IN BIOTECHNOLOGY

Biotechnology drug development is an inherently complex and labor-intensive process (Table 1). Typically, it takes between 10 and 15 years to develop, gain regulatory approval for, and bring a successful biotechnology product to market. Accordingly, every step of the biotechnology drug development process offers ample employment opportunities. Examples of the types of jobs available at different stages of the biotechnology drug development process are shown in Table 2.

Historically, most jobs at biotechnology companies have been in drug discovery. However, during the past 15 years the emphasis has shifted from drug discovery to drug development and commercial manufacturing. This shift has created an enormous number of jobs in analytical chemistry, pharmacology, toxicology, regulatory affairs, bioprocess development, validation, quality control, quality assurance, clinical trials management, and large-scale manufacturing.

THE ETIOLOGY OF WORKFORCE SHORTAGES

The biotechnology industry has grown at an extraordinary rate in recent years, doubling in size between 1993 and 2000 (1). This rapid expansion resulted in an

Table 1: Biotechnology drug development timeline

	Development (eight to 12 years)				
	Preclinical	Clinical trials (five to seven years)			
Discovery (two to six years)	(three to five years)	Phase I	Phase II	Phase III	Manufacturing
Gene cloning	Bioprocess bevelopment	Safety	Dosage	Clinical benefits	cGMP production
Protein expression	Scale up		Efficacy	Therapeutic	Quality control
Assay development	ADME and toxicology			Efficacy	Quality assurance
Animal models of disease	Analytical methods				Quality systems management

Table 2: Job opportunities in the biotechnology drug development process

	Development		
Discovery	Preclinical	Clinical trials	Manufacturing
Automation and robotics scientists	Analytical chemists	Clinical data managers	Analytical chemists
Biochemists	Biomedical engineers	Clinical operations personnel	Bioprocess scientists
Bioinformatics and genomics	Bioreactor scientists	Clinical research associates	cGMP technicians
Biomedical engineers	Formulation scientists	Drug safety personnel	Marketing personnel
Biophysicists	Pharmacologists	Nurses	Quality assurance specialists
Computational chemists	Process chemists	Pharmacologists	Quality control specialists
Data managers	Regulatory affairs personnel	Physicians	Regulatory affairs personnel
Medicinal chemists	Toxicologists	Regulatory affairs personnel	Sterile fill personnel
Molecular biologists	Veterinary personnel	Statisticians	Validation specialists

enormous increase in job opportunities at biotechnology and related companies (Figure 1). Workforce shortages began to appear as early as 1996 in Massachusetts and California (3). According to several reports, the number of jobs in biotech far exceeds the number of skilled and qualified individuals to fill them (4, 5). A report issued by the New Jersey Department of Labor predicts a 28% increase in the number of biotechnology and life sciences jobs in New Jersey over the next seven years (6). Similar increases in employment opportunities have been projected for California, Maryland, North Carolina, and Wisconsin (4–6).

Students Unprepared: At the same time, student preparedness in math and science has been declining in the United States for more than a decade. A 2002 study conducted by members of the John J. Heldrich Center for Workforce Development at Rutgers University found that nearly half (46%) of all New Jersey high school juniors and seniors have taken no science honors or advanced placement courses, and more than half (56%) of those students said they were unfamiliar or not very familiar with the types of jobs available in the biotechnology and pharmaceutical industries (7). Similar results have been reported in other biotech-rich states such as Massachusetts, North Carolina, and California (4, 6). Finally, in a 2003 national polling study commissioned by Bayer Corporation, nine out of 10 respondents said they do not believe that today's students have the "math and science skills necessary to produce scientific excellence required for homeland security and economic leadership in the 21st century" (8).

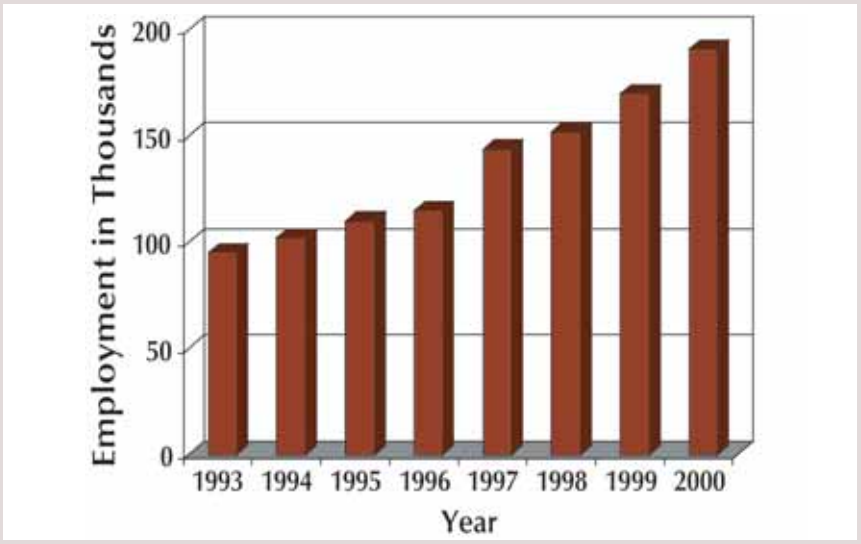
No single factor explains America's poor state of scientific preparedness. Some contributing factors are

- inadequately or poorly trained primary and secondary education science teachers
- the perceived difficulty of secondary and postsecondary education programs in science and math
- lower wages garnered by scientists than by other professionals.

Interestingly, not only are American students poorly prepared for careers in science, they are also unlikely to pursue them. According to recent surveys and polls conducted by various academic institutions, fewer US-born high school graduates and undergraduate college students are choosing careers in science and engineering than as compared with a decade ago (7, 8). Industry experts predict that if current job trends continue, US-based higher education institutions will not graduate enough people with adequate training in biotechnology to meet industry demand (7).

PhD Not Required: Another important but little-recognized factor that has contributed to biotechnology workforce shortages is the public misperception that a PhD degree is required to get a job in the industry. Many high school and undergraduate students have abandoned scientific careers in favor of other disciplines that do not require a PhD for employment. Ironically, during the past five years, the demand for employees who do

Figure 1: Increase in biotechnology jobs from 1993 to 2000



not hold PhD degrees has far outstripped the demand for individuals who have PhDs (9, 10).

The ongoing workforce shortages in the biotechnology industry have prompted many industry executives to publicly call for drastic improvements in biotechnology education and training in the United States. Despite this very public request, the biotechnology industry has invested very little money, time, or effort on American biotechnology education and training initiatives. Although several companies (such as Genentech, Promega, and Bio-Rad) have made biotechnology education and training a priority, the industry as a whole has been reluctant to play an active financial or instructional role in programs that promote biotechnology training.

Biotechnology Workforce Development Initiatives

Undergraduate Programs: In response to ongoing workforce shortages, many two- and four-year colleges and universities throughout the United States have created undergraduate training programs in biotechnology. Depending on the program, students who successfully complete their training receive a bachelor's degree, an associate's degree, or a certificate in biotechnology. The goal of these academically driven training programs is to expose high school and undergraduate students to the underlying scientific principles and practices of biotechnology to prepare them for jobs in the industry. Although such programs are timely and well-intentioned, they have been plagued by a variety of problems.

A majority of undergraduate training programs are funded by state and federal grants. Consequently, they lack adequate financial resources to sustain them over time. Unfortunately, many fail within two or three years of their implementation as grant support dwindles.

Many training programs suffer from chronic low enrollment. This is probably due to poor quality of the marketing and advertising campaigns used to recruit prospective students.

In many instances the academicians who created those programs have never held jobs in industry. Consequently, critically important topics such as good laboratory practices (GLPs), regulatory compliance, quality control and assurance, validation, and current good manufacturing practices (cGMPs) — all of which must be understood by individuals who work in the biotechnology industry — are conspicuously absent from many programs.

Unfortunately, most undergraduate programs do not offer job counseling, job interview training, or placement services to help students find jobs upon completion of their training. Not surprisingly, employment outcomes for program graduates are exceedingly poor.

Masters Degree Programs: In contrast with those undergraduate training programs, several highly regarded academic institutions such as the Georgetown University School of Medicine (http://nrr.georgetown.edu:591/BMB/biotech.htm), the University of Wisconsin–Madison (www.wisc.edu/grad/education/mas/040.html), and the University of Pennsylvania School of Engineering (www.upenn.edu/biotech) have created successful two year masters degree programs in biotechnology.

Unlike their undergraduate counterparts, these masters-level programs offer coursework frequently designed and taught by biotechnology company executives and employees. Moreover, the funds required to run them are derived almost exclusively from student tuition. This is important because it reduces reliance on external funding to staff and sustain them. Finally, enrollment in these programs is high and job outcomes for students are substantially better than those of undergraduate training programs.

For-Profit Ventures: During the past few years, several for-profit companies that specialize in industry-focused biotechnology training have formed, such as BioInsights, Inc. (www.bioinsights.com), SPI USA (www.spi.pt/seminar/about.html), LearningPlus (www.learningplus.com), and others. Increased demand for employees in biotech drug development and manufacturing has led those companies to focus on developing courseware on industry-specific topics such as GLPs, regulatory compliance, quality control, quality assurance, validation, and cGMPs. Such coursework (usually in the form of workshops and short courses) is typically developed by industry

professionals and designed to prepare individuals for jobs in biotechnology. At least one company uses professional recruiters to place qualified trainees into jobs at biotechnology companies. Unlike academic training programs, these companies do not offer degrees or certificates to their trainees. Nevertheless, they are committed to improving and increasing the size of the biotech workforce.

Averting Biotechnology Workforce Shortages

The demand for employees will continue to increase as more products gain regulatory approval. The existing US educational infrastructure cannot meet current labor needs of the industry. Fundamental changes must be made to the ways we educate, train, and prepare individuals for careers in the biotechnology industry.

Teacher Training: The most obvious place to start is to improve primary and secondary science teacher training. Most preservice and in-service science teachers today have never received any formal training in biotechnology. So it is not surprising that many high school students have never heard of biotechnology or the career opportunities it represents. To overcome this, all primary and secondary school science teachers must receive biotechnology training. This could be accomplished by adding biotechnology to preservice science teacher training and making biotechnology professional development mandatory for all in-service science teachers. Once teachers are properly trained and begin to incorporate biotechnology into primary and secondary school science curricula, biotech literacy should begin to improve among US elementary, middle, and high school students.

The introduction of biotechnology into primary and secondary school science curricula would be an important first step toward improving biotech literacy and awareness. However, curriculum changes alone may be insufficient to induce scientifically minded students to choose careers in biotechnology. Science teachers must also play more active roles in informing students about the plethora of high-value jobs available in the biotechnology industry. Ways in which science teachers could accomplish this include

- organizing biotechnology company–sponsored job fairs for middle and high school students
- creating school-sponsored biotechnology clubs and summer training academies
- regularly inviting scientists and executives from local companies to talk about career paths in the biotech industry.

Regardless of the method used, primary and secondary school students must be exposed to biotechnology as early as possible to begin to increase the size of the workforce.

Improvements to Existing Programs: The collapse of the information technology and manufacturing industries in the United States has forced many high school graduates, undergraduate students, and unemployed workers to consider alternative career paths. Career counselors, employment agencies, and outplacement companies frequently suggest the biotechnology industry as a possible alternative career choice. Unfortunately, the existing network of training programs cannot meet industry demand for new employees. Several approaches can be used in the short term to better prepare prospective employees for industry jobs.

Existing biotech training programs must increase the numbers of students that enter and graduate from their programs. This can be accomplished by drastically improving the quality of advertising and marketing campaigns used to promote them. In addition, training program administrators must work more closely with high school science teachers, human resource professionals, and others who can help identify people who may be interested in pursuing careers in biotechnology.

Local companies must be encouraged whenever possible to participate in training program course design and curriculum development. That guarantees creation of "industrial-strength" coursework that will help to better prepare students for jobs in industry. It also ensures development of courses in quality systems, regulatory affairs, bioprocess development, and manufacturing where job demand is greatest.

Industry professionals must be actively recruited as instructors to teach in training programs. Instructor knowledge of industry rules, regulations, and practices provides prospective employees with an accurate view of what will be expected of them when they graduate and get industry jobs.

Finally, courses that focus on job opportunities, résumé preparation and writing, and interviewing techniques must be included in these training programs to improve employment outcomes for graduates.

For-profit training companies will also help mitigate labor shortages in the biotechnology industry. However, many training companies are in their formative stages and cannot by themselves offer enough courses to curb existing biotechnology workforce shortages. One way they could have an immediate effect on biotechnology workforce development is by forming partnerships with existing academic training programs. The synergies offered by such partnerships are considerable. For example, academic training programs that lack industry-focused courses could rapidly and cost effectively add that type of coursework to their curricula by using courses developed by their corporate partners. Likewise, for-profit companies with limited infrastructure could take advantage of the physical spaces (classrooms and laboratories), organizational support, and financial resources of the educational institutions that house academic training programs. As an example of this business

model, BioInsights, Inc. recently entered into training partnerships with Mercer County Community College (www.mccc.edu) and Burlington County College (www.bcc.edu) in New Jersey and the Georgetown Medical School masters of biotechnology program in Washington, DC.

Americans are currently experiencing some of the highest unemployment rates of the past 25 years. Ironically, in this era of corporate downsizing and high unemployment, the biotechnology industry is facing critical workforce shortages. Surprisingly, industry — which stands to lose the most from ongoing labor shortages — has done almost nothing to support training initiatives in the United States. It is time for the biotechnology industry to take an active, visible role in workforce development. Without industry participation, the workforce shortages that have plagued US biotechnology companies in recent years are likely to continue into the future.

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