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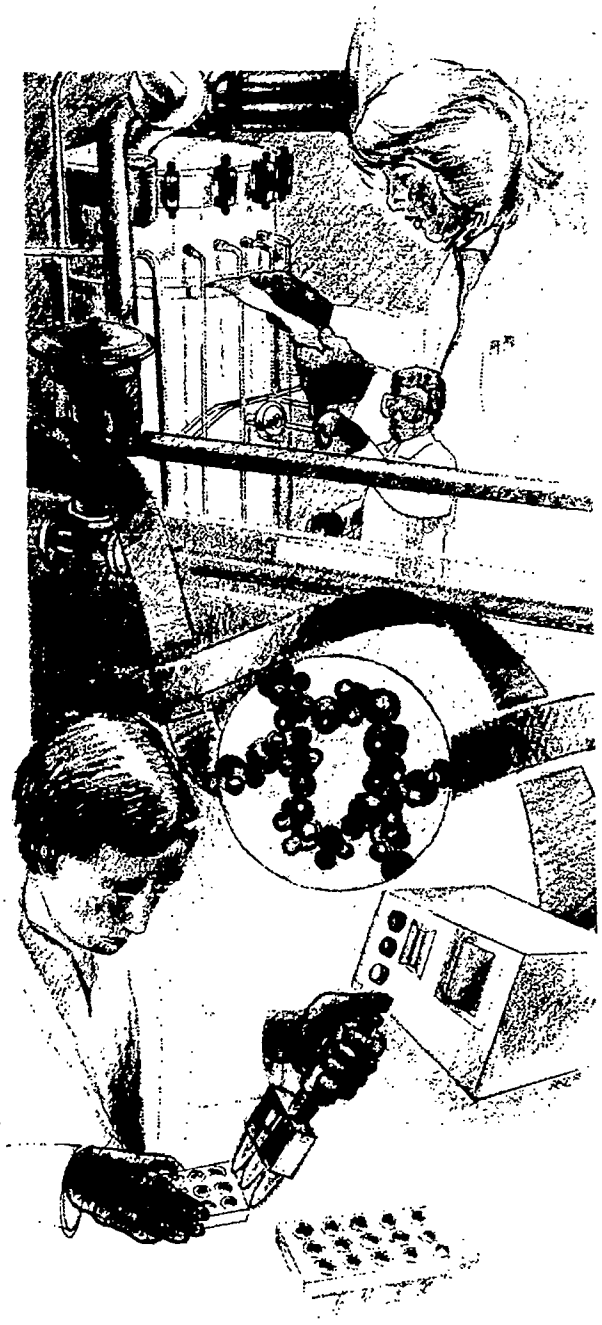
ABSTRACT

A study examined the nature and requirements of biomanufacturing work force development in Massachusetts. The jobs created by biotechnology and skill requirements for the different levels of biotechnology jobs were analyzed. Next, study task force members visited 23 companies throughout Massachusetts and interviewed a wide selection of personnel, including company presidents, scientists, human resource personnel, trainers, "line" technicians, and manufacturing supervisors. Respondents were asked to rate the importance of 155 competencies. At least 90% of the competencies related to work habits and interpersonal relationships, communication, math, and technology received ratings of "required" or "good to know." Chemistry skills were generally considered more important than biology skills. The following issues pertaining to incorporating biotechnology into the K-12 curriculum were discussed: teacher needs, teacher training, resources for teachers, sex equity strategies, strategies for grades K-5 and 6-8, and a model curriculum for technical training. Job quality and opportunities for women and other minority groups in the biomanufacturing industry were examined. Task force members formulated 20 recommendations regarding state, job training, and educational initiatives. (Includes 21 tables.) (MN)

BIOMANUFACTURING IN MASSACHUSETTS: AN ASSESSMENT AND EDUCATIONAL ANALYSIS



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by

Minuteman Regional Vocational
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BIOMANUFACTURING IN MASSACHUSETTS
An Assessment and Educational Analysis

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Summary

The phenomenal rate of growth in the number of biotechnology firms in Massachusetts over the past twenty years continues to stimulate interest and attention on the part of investors and policy makers who are becoming increasingly aware of the vast potential of this industry. World class universities, research institutions, and hospitals are generally recognized as the state's key strengths in fostering its impressive core of R & D oriented biotechnology start-up enterprises. Industry observers, however, have consistently stressed that scaled-up production and manufacturing stages of biotechnology-based products will require a different set of enabling factors which may not be currently available in the state or the region. This report addresses one of the most significant enabling factors in industrial biotechnology development, which is the availability of a qualified biomanufacturing workforce.

This report relates the results of a survey study undertaken by the Minuteman Regional Vocational Technical School on behalf of the Massachusetts Department of Education for the purpose of gaining an up-to-date perspective on the nature and requirements of biomanufacturing workforce development. It provides an overview of the industry trends as they relate to workforce needs. The study approach is described and research results are presented. Specific recommendations are offered to governmental agencies, industry, and educational institutions challenged with meeting the workforce needs in a timely and cost effective manner.

The authors of this report argue that if we are to adequately meet the skilled workforce demands of the industry, we will do so through a combination of traditional and non-traditional approaches. Workforce development must strive to provide for the acquisition and refinement of specific competencies. The newness and uniqueness of modern biomanufacturing requires a close working relationship between the industry and the training institutions. Biomanufacturing competencies must be identified and understood in terms common to both the industry and the training institutions. Competency-based training objectives must build upon current experience and draw upon a variety of existing technical and scientific disciplines; particularly in the engineering and life sciences areas.

Since it appears to be true that biotechnology firms are creating new jobs and paying high average salaries to their workers, the implicit assumption is that biotechnology will be like the computer industry and generate many jobs and help the economy rebound. Previous studies have found that job growth will actually be modest relative to the computer industry, and that the average wage for low-skilled production workers in Massachusetts biotechnology is less than the average for all manufacturing industries in the state. However, new jobs are available, and Massachusetts needs the jobs and other economic benefits (such as innovation, investment, and taxes) created by biotechnology. Furthermore, a well-trained workforce will help attract and keep biotechnology companies in Massachusetts.

Most members of the Massachusetts workforce do not qualify for biotechnology jobs at present because they do not have the level of education and skills required by this industry. Many biotechnology jobs require a bachelor's degree, which most Massachusetts workers do not have. However, jobs in production operations in mature biotechnology companies typically require a semi-skilled educated worker with a high school diploma or an associate's degree.

Education is not the only barrier to job access. The current biotechnology workforce tends to be more homogeneous than the total workforce for all industries. People of color are virtually absent from the laboratories, and are represented in very small numbers in production areas of most biotechnology firms (greatly varying from firm to firm). Women are present in biotechnology laboratories in larger proportions than other high tech industries but are under-represented in senior management occupations. Vocational-technical education and community college programs may be the most effective way to prepare a more diverse workforce for the new jobs in biotechnology companies.

Biotechnology is a new and unique industry. There are important differences among biotechnology firms as well as between biotechnology and other high tech industries. In general, many of the comparisons made between biotechnology and other high tech industries in terms of employment are simply not true. While biotechnology is a growth industry which will lead to certain public benefits, it has special characteristics and needs that must be understood by those who wish to enhance the benefits by supporting the industry. Massachusetts must understand those characteristics in order to effectively plan for biotechnology economic development.

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SECTION I: INTRODUCTION

Industry Overview

Rarely has a new technology generated as much hope and controversy at the same time as has biotechnology. One reason for hope is that biotechnology will make great improvements in human health. In addition, many state leaders are excited about biotechnology because of its promise to bring economic growth, especially employment. The following section reviews the biotechnology companies. It describes the industry and its employment potential for low- and semi-skilled labor.

In the following discussion low-skilled means that a high school diploma is required, but generally no additional experience. Semi-skilled means that special training and/or an associate degree is required, High -skilled means bachelors degree or higher. For ease of presentation, non-degreed is used to combine low- and semi-skilled. Degreed means education including and beyond the bachelor's level.

What follows are the results and analysis of a study of the employment benefits to low- and semi-skilled labor in biotechnology. The focus is on low- and semi-skilled workers because they represent the largest segment of the workforce, and they have suffered from recent changes in the availability and quality of work during the last several decades. We need to better understand the opportunities of new technologies and industries like biotechnology for this segment of the labor force. Government's role in helping this segment of the labor force is to seek ways to enhance job access and upward mobility through skill development.

Before summarizing the characteristics of the industry and its manufacturing jobs, a short definition of biotechnology is provided, along with a brief discussion of some of the larger and controversial issues surrounding biotechnology. The controversies arise because certain biotechnology applications pose serious ethical and environmental dilemmas. These issues should not be entirely overlooked when one is considering how to support the industry in order to enhance employment and other benefits.

What is Biotechnology?

People have been putting cells to work for centuries. Whenever we make beer or bread, we harness the productive capabilities of yeast and in a sense, are practicing biotechnology. However, our understanding of plant and animal cells reached a critical turning point in 1953, when Watson and Crick discovered the structure of DNA (deoxyribonucleic acid), the molecule that carries the genetic information governing the growth, maintenance, and reproduction of most living systems. This knowledge helped scientists to understand how proteins (molecules composed of amino acids) and other naturally occurring substances in the cells, can be used to treat and even prevent disease.

Biotechnology is the collection of techniques that use naturally occurring substances and life processes to produce a wide range of products and services for applications in human health, animal health, and agriculture. The best known of these techniques is called gene splicing (or recombinant DNA), because it allows for the combination of segments of DNA from different organisms. Microbes into which genes have been spliced may be commercially valuable because they can produce useful proteins in larger and purer quantities than can be obtained economically from other sources.

Perhaps the most successful example of a product obtained through genetic engineering is human insulin. Prior to human insulin, the only other sources of insulin for diabetic patients were pigs and cows. However, some people were allergic to the insulin taken from these animals. When scientists first managed to get genetically engineered bacteria to grow human insulin in a test tube in 1978, biotechnology achieved its first major victory.

Biotechnology is beginning and may continue to have a large, positive impact on human health care in terms of diagnosing, curing, and even preventing disease. While other technologies have had significant effects on the quality of human life, none has come so close to controlling the biological basis of life itself. Because of its power, there are many debates over how to use the technology and how to eliminate or minimize its potential dangers.

Social Issues

Since the beginning, a number of concerns have surrounded biotechnology. Some of these concerns are ethical in nature, while others are ecological. Ethical dilemmas have arisen with rapid advancements in diagnosis due to biotechnology. Biotechnology has enabled more

precise diagnosis of certain diseases based on the presence or absence of a certain gene associated with the disease. Today, it is possible to accurately diagnose many diseases for which there are no known cures. The dilemma arises when we consider whether people should be informed that they carry a gene associated with a disease for which there is no known cure. Can society protect that same individual from possible discrimination (i.e., by employers or insurance companies)?

Another set of controversies having to do with biotechnology involves the environment. Microbiologists and ecologists continue to debate how to measure and manage the risk of an accidental release of genetically engineered microbes into the environment. Microbiologists say the risk is too small to measure and therefore insignificant, while ecologists argue that the effects of releasing genetically engineered microbes into the environment should be fully explored before they occur. These and other issues will continue to be debated and must be reflected in an up to date educational training program.

Biotechnology and Economic Development

Economists and planners are also interested in biotechnology, because they associate it with other high-tech industries which have bolstered the US economy and employed many people during a time when many traditional industries were in decline. During the mid-80s, industry forecasters predicted that the biotechnology industry would reach $100 billion in revenues by the turn of the century. While this estimate may turn out to be overly optimistic, it nonetheless caused many states to develop strategies to capture the economic and employment benefits associated with biotechnology. Biotechnology represents a major technological innovation that will give U.S. companies an advantage over competitors in the world economy. Competitive companies are expected to grow quickly and employ many people.

In its 1988 report, the Office of Technology Assessment counted 33 states with specific funding allocations for biotechnology. The importance of biotechnology in state economic development strategies was likewise observed by researchers at the University of California, Berkeley in a national survey (Blakely, 1988) (OTA, 1988).

There are two expectations typically associated with high tech strategies. One is that high tech firms are innovative and competitive and will therefore help stimulate economic revival for regions that host them (Osborne,

1989). The second is that these firms will provide many new job opportunities (Birch, 1979). The UC Berkeley survey of state biotechnology policies confirmed the existence of this second expectation. Creating 'skilled-jobs' topped the list of policy objectives of supporting biotechnology. (Blakely, 1988). However, there is an important distinction between research and development (R&D) and manufacturing. Typically, we expect R&D to employ mostly high-skilled workers, while manufacturing employs more low- and semi-skilled workers. If states are concerned with creating jobs, we would expect them to target manufacturing as one of their top policy goals. However, supporting biotechnology manufacturing as opposed to R&D was at the bottom of the list of policy objectives in the Berkeley survey. Nearly one quarter of the respondents claimed that biotechnology manufacturing (again, as opposed to R&D) is 'not very important' or 'not important at all.'

It appears that states have their priorities reversed. Biotechnology R&D will generate fewer jobs than manufacturing, and those jobs will not be accessible to low- and semi-skilled labor. Therefore, Massachusetts would simultaneously improve its competitiveness and its helping of non-degreed labor by preparing workers for biotechnology manufacturing.

Biotechnology is especially important to Massachusetts because the state has the nation's third highest number of biotechnology firms. Estimates of total 1990 annual revenues for these firms ranges between $263 million (Ernst & Young, 1990, p. 89) and $1.3 billion (MCEC/PFI,1990). Federal research dollars help fuel the science on which the industry is based, and Massachusetts medical research institutions and universities get a large share. Local receipts of federal funding rose from $317 million in 1981 to $503 million in 1988 (Boston Redevelopment Authority, "Outlook for the Nineties," 1990).

Biotechnology is also important because the state's economy is presently experiencing a severe slowdown. Unemployment in Massachusetts averaged nearly 9.0% during the first quarter of 1991, nearly double the rate of the previous year and higher than the national average. Due to its promise and good timing, biotechnology is attracting special attention from political leaders and the media. Local leaders have encouraged the hope that biotechnology will help the state's economy to recover.

At a Mass. Biotechnology Council (MBC) meeting held in Boston during the Fall of 1991, Governor William Weld

of Massachusetts stated that he was optimistic about the role biotechnology will play in the Massachusetts economy and promised to help make Massachusetts "the best place in the country for biotechnology." He also issued a plea for biotechnology to stay at home. "During the transition from research to development to manufacturing, I ask you to stay in Massachusetts," said Governor Weld. "Our taxes are likely to go down and our fiscal, economic, and educational policies are aimed at trying to make this a hospitable place for you to be creative in your business and successful in your chosen field."

Assumptions about job growth were also reiterated by Dr. James M. Howell, consultant and former chief economist of the Bank of Boston. He argued that the Massachusetts, and especially the Boston economy has become a knowledge-based economy in which young, high-technology firms are the engines of future growth. He counts biotechnology among the high-technology firms (Howell Report, November 1990).

"As these firms are created, the achievement of high and rising levels of productivity, the continuous upgrading of product design and quality and the aggressive pursuit of new market segments will be quickly translated into new jobs and high incomes for residents of the city and state."

SECTION II: JOB DESCRIPTIONS: NON-DEGREED

Introduction

This section designates those job categories that are most likely to be experienced by a highly skilled, well trained Biomanufacturing Technician. The task force team deemed it appropriate to include a brief background on those job categories that are cited and alluded to throughout this report.

Laboratory Assistant

Performs a variety of research/laboratory tasks and experiments under general supervision. Works on assignments that are moderately complex and where judgment is required in resolving problems and making routine recommendations. Maintains laboratory equipment and inventory levels of laboratory supplies. May make detailed observations, analyze data, and interpret results, write experimental reports, summaries, and protocols. May be responsible for limited troubleshooting and calibration of instruments and assisting in training of entry-level employees.

Education/Experience: Requires a High School diploma, AA degree or equivalent experience with a scientific background. Minimum work experience of 1-2 years related laboratory experience with a High School diploma, or 0-2 years with an AA degree.
Salary: $19,000 - $27,000.

Laboratory Support

Responsible for washing and drying glassware and distributing it to appropriate locations within the laboratories. Maintains glass washing facility and performs routine maintenance on glass washing equipment. May sterilize glassware and other laboratory items in an autoclave. Generally works on assignments that are semi-routine in nature. Requires ability to reorganize deviation from accepted practices.

Education/Experience: Requires a High School diploma or equivalent. Should have a minimum of 0-2 years laboratory experience.
Salary: $15,000 - $21,000.

Cell Culture and Fermentation Manufacturing Assistant

Responsible for assisting manufacturing in specific product-related operations in bacterial fermentation (i.e. *Ecoli*). Operates and maintains production equipment as it relates to bacterial fermentation (i.e. bioreactors, cell harvest, and separation operations). Weighs, measures and checks raw materials to assure proper ingredients and quantities. Prepares media and buffer components. Maintains records to comply with regulatory requirements. Assists with in-process testing.

Education/Experience: Requires a High School diploma, AA degrees or equivalent experience, plus a minimum of 0-2 years related work experience in a manufacturing environment.
Salary: $18,000 - $26,000.

Purification Manufacturing Assistant

Assists manufacturing in production - scale protein purification and manufacturing of final products. Weighs, measures and checks to assure batches manufactured contain proper ingredients and quantities. Maintains records with good manufacturing procedures (GMPs), regulatory requirement, and standard operating procedures. May assist with in-process testing to assure batches meet specifications.

Education/Experience: Requires a High School diploma, AA degree or equivalent experience, and a minimum of 0-2 years of work experience in a manufacturing environment.
Salary: $18,000 - $26,000.

Aseptic Fill Manufacturing Assistant

Responsible for manufacturing and packaging of future and existing products. Operates and maintains small production equipment. Weighs, measures and checks to assure batches manufactured contain proper ingredients and quantities. Maintains records with good manufacturing practices (GMPs), regulatory requirements, and standard operating procedures. May assist with in-process testing to assure batches meet specifications.

Education/Experience: Requires High School diploma, AA degree, or equivalent and a minimum of 0-2 years of work experience in a manufacturing environment.
Salary: $18,000 - $26,000.

Quality Control Inspector

Performs a wide variety of inspections, checks, tests, and sampling procedures for the manufacturing process. Performs in-process inspection and documents results. Monitors critical equipment and instrumentation. Writes and updates inspection procedures and checklists as necessary.

Education/Experience: Requires a High School diploma, AA degree or equivalent experience with a scientific background, and a minimum of 1-2 years in quality control systems, with knowledge of good manufacturing practices (GMPs).
Salary: $21,000 - $32,000.

Quality Assurance
Documentation Clerk

Responsible for providing clerical and administrative support related to documentation system requirements. Audits all documentation manuals to assure they are accurate, up-to-date, and available to appropriate personnel. Maintains filing of all master documents.

Education/Experience: Requires a High School diploma, AA degree or equivalent experience, and a minimum of 0-2 years experience, preferably in documentation or quality control/assurance.
Salary: $19,000 - $30,000.

SOURCE:
The Massachusetts Biotechnology Industry/Education Resource Directory, Bay State Skills Corporation, pp. 63, 66, 68.

SECTION III: JOB CREATION

This section presents an overview of the job creation process in biotechnology production where most low- and semi-skilled jobs are created. Recent surveys provide current and future estimates of production jobs, but they do not explain how jobs are generated at different stages of product development. The major findings from these surveys suggest that:

1. Biotechnology production does not employ large numbers of people, but new jobs are being created.

2. Production occurs in three distinct phases—research and development, clinical trials, and commercial manufacturing. It takes place at the lab bench during R&D. During clinical trials, it typically moves into a separate space or pilot plant within the same facility. Finally, commercial manufacturing often requires a separate facility.

3. The number of production jobs increases between R&D and clinical trials, and skill levels begin to drop. The average pilot plant employs slightly more than 40 people, 2/3 of whom have at least a bachelor's degree.

4. For a given product the number of production workers required for commercial manufacturing is not necessarily higher than for manufacturing in the pilot plant (depending on automation and potency of product). The average commercial plant employs 53 persons, almost 60% of whom have less than a bachelor's degree.

5. Some firms may pursue strategies that do not lead to growth in production employment in Massachusetts.

6. Production is already beginning to leave the state, and many firms will be making critical location decisions during the next 2-3 years.

Next, the focus is given to production employment. National and state data on production jobs are reviewed, and that is followed by an analysis of the job generation process at the plant level for both therapeutic and diagnostic products. The fourth section explores several limitations on employment growth, including firm strategies and location decisions. Issues of skill requirements, access to jobs by women and minorities, and job quality are considered later.

Two problems are important to keep in mind while reading this section. The first is to define 'high tech.' There are many definitions of high tech, but we mean those industries for whom the proportion of engineers, computer scientists, life scientists, and mathematicians exceeds the manufacturing average. Secondly, we define biotechnology sectors. Biotechnology is typically broken into two market segments: therapeutics and diagnostics. A national survey by Ernst & Young, a private consulting firm serving the biotechnology industry, suggests that growth in production employment will occur more rapidly with diagnostic products due to the shorter product development which is more than half that of therapeutic products (Ernst & Young, 1987).

Does Biotechnology Create Many Jobs?

Counting jobs in the biotechnology industry is difficult. First of all, biotechnology is a process used in many industries: primarily pharmaceutical, chemical, food and agriculture. Second, there are companies that were founded with the sole purpose of exploiting biotechnology processes (referred to in this study as dedicated biotechnology firms, or DBFs), while other companies may use biotechnology processes for some but not all of their products. Finally, there are companies that make equipment used in the biotechnology industry.

The decisions about which companies to include in estimated total jobs and whether to count all employees or just those who are engaged in biotechnology processes leads to different estimates of employment. For example, there are two annual estimates of biotechnology employment at the national level (see tables 3.1 and 3.2). The Bureau of the Census estimates that in 1990 there were 28,700 employees in diagnostic (SIC 2835) and non-diagnostic, or therapeutic (SIC 2836) sectors. Ernst & Young estimated that there were nearly 50,000 employees in biotechnology in 1990. The accuracy depends on the biotechnology definition used, and on the availability and believability of data for the categories included.

Based on the government's 1990 estimate, biotechnology in the U.S. is very small. It represents only 16%, by employment, of the entire drug industry. It is even smaller when compared to the computer and semiconductor industries which employed almost 28 times as many people in 1990. However, since 1988, computers and semiconductors have shown job losses, whereas biotechnology, mainly the drug sector, added jobs. Computers and semiconductors are mature industries, while biotechnology is in its infancy.

Official government estimates of employment in biotechnology in Massachusetts are not available , but several surveys have attempted the task. The local estimates range (see table 3.2) from 13,600 to 17,585. Regardless of the estimate used, biotechnology represented less than half of one percent of total employment in Massachusetts in 1990 (see tables 3.3, 3.4), and approximately 6.4% of all high tech employment. High tech employed 212,200 people in 1990, down from 238,600 in 1988 (see table 3.5).

Job losses in high tech between 1988-90 were twice the estimated number of total employees in biotechnology as of 1990. Even if the most optimistic projections for growth of Massachusetts biotechnology are correct and employment reaches 80,000 (see table 3.2) by the turn of the century, biotechnology will employ barely half of what high tech employed during the 1980s. Biotechnology employers are the first people to agree with this assessment.

"Biotechnology is not going to be the kind of industry, from a production staffing point of view, that will be equivalent to the DECs and Wangs of this world. It isn't a labor intensive kind of thing. A lot of it is automated. You're harvesting your product from processes that don't require an assembly line type of an approach."

Jobs in Biotechnology Production

Estimates of the number of biotechnology production jobs in the U.S. in 1990 were 14,300, exactly half of all biotechnology jobs (see table 3.3). In Massachusetts, Feinstein Partners Inc. estimated that 3,264 of 13,600 of biotechnology jobs were in production, which represents one quarter of the biotechnology workforce. The proportion of production jobs to all jobs in the national estimate may be inflated due to inclusion of older companies that have larger production workforces, and are counted because some fraction of their business is biotechnology. Feinstein forecasts that production jobs in Massachusetts

will increase 686% by the year 2000. This means that the number of production jobs might increase from 3,264 (24% of total biotechnology workforce) in 1990 to 25,655 (32%) by 2000.

Stages of Production

Production occurs in three distinct phases during the life cycle of a product. Between each phase, the number of employees changes, with the largest increase typically occurring during scale-up, the period when the company goes from producing small to large quantities of a products. Not all products are alike, and so not all production processes are alike. There are significant differences between therapeutic and diagnostic products, that mostly have to do with regulatory controls and the complexity of the production process. Also, there can be variation among therapeutic products due, again, to regulatory controls, but also to product concentration and potency, and automation.

Each of these characteristics influences employment and will be discussed in this section, but first, we should briefly review the production process itself to provide background. In so doing, we will use the therapeutic market segment as the basis for the description, because it helps to clarify the different employment outcomes. However, later, in the section, an example of employment growth during the product development cycle of a diagnostic product will be given.

Like all drugs, biotechnology products are heavily regulated. These regulations demarcate the three stages in the production process. Before a vaccine or therapeutic treatment can be sold in the U.S., a company must demonstrate that it is safe and effective and can be manufactured consistently. Before a drug can be tested in clinical trials, an Investigational Drug Application (IND) must be filed with the Food and Drug Administration (FDA). If tests show that the product is safe and effective, then a second permit, the Product License Application (PLA), is granted. In addition, the manufacturing process itself must be validated to show that the product can be produced consistently and meet current good manufacturing practices (GMPs). After PLA and validation, the product can be made and commercially marketed (see table 3.4).

Research & Development: Laboratory Bench

The first stage of production occurs during R&D when small quantities of product are needed for laboratory

investigations. Quantities in the range of 1 - 50 liters can be produced at the same lab bench where R&D occur. This phase may last up to a year or more for a therapeutic product.

There are usually fewer production steps in R&D than later stages, since the end result is not a finished product. Steps include: 1) cell culture and fermentation, where desired cells, or cell parts (i.e. proteins), are grown, 2) primary recovery, where the product is captured, and 3) purification of product into bulk form. Production is usually carried out by several scientists and engineers, with the assistance of one or two non-degreed people who wash glassware, care for laboratory animals, and/or prepare solutions. Total staffing is probably not more than 5 individuals.

Clinical Trials: The Pilot Plant

The second stage of production occurs after an IND permit is granted and can take up to several years. At this time, larger quantities of product (50-100 liters, depending on the potency) are needed to supply clinical trials. Production may expand to several benches within the lab, or move into a separate pilot plant, usually in the same building. Pilot plants are not large. Generally, they range in size from 5,000 to 20,000 square feet.

A series of process steps begins to take place in the pilot plant. These steps include, but are not limited to, the following:

1. Formulation, where the bulk product is stabilized for delivery into the bloodstream.
2. Filling, where the product is put into one of several forms (i.e. capsules, vials, freeze dried, etc.
3. Packaging, where the product is boxed, labeled, and shelved.

The production process in a pilot plant is still undergoing development and change; it is not yet routine.
At this time, a plant manager is hired, along with several supervisors, as many as 10 process operators, a quality control (QC) specialist, one or two filling technicians, two utility specialists who maintain packaging and shipping, if required. Total staffing might reach as many as 50 people, most of whom will be degreed or semi-skilled. Based on a local sample, the average workforce in the pilot plant is estimated at 41 employees, two-thirds of whom are degreed (see table 3.4). Because economies of scale have not been fully achieved, pilot plants are often more labor intensive than commercial facilities.

Manufacturing: The Commercial Plant

When a PLA permit is received, production goes through scale-up, during which time the biological, chemical, and engineering issues associated with increasing production by factors of 10X, 100x, or even 1000X, are worked out. However, this increase from the pilot scale is usually not linear and presents serious technical challenges. Typically, a separate and dedicated commercial facility is established in the range of 200,000 to 540,000 square feet.

While fermentation volume may reach as high as 100,000 liters, scale-up does not mean that the number of employees increases in proportion to the product. The same person who operated a fermenter with a 10-liter capacity, can be trained to operate a fermenter with a 10,000-liter capacity. Process steps do not change appreciably but are made routine and followed religiously to avoid the risk of losing federal license to manufacture.

After the commercial facility is created, the pilot facility is likely to be assigned a new product for process development. Some employees from the pilot facility may move to the commercial facility, but most of the staff for the commercial facility will be new hires. Additional utility technicians, process operators, and packaging and distribution people will be added. Total employment may increase beyond the pilot plant or it may actually decrease due to economies of scale and automation. Based on estimates from several firms, the average employment in commercial plants would be 53 persons (see table 3.5).

Other Variables Affecting Growth

There are a number of other variables that affect employment levels in the biotechnology plant. Broadly, these variables fall into two categories: those over which companies do exercise much control, and those over which they do not exercise control. In the first grouping are those qualities inherent in the product (concentration and purity) and regulatory requirements. The second grouping includes things like automation, company goals, and strategies.

Product Concentration

The Biotechnology revolution enabled certain products to be produced in much greater quantity, concentration, and purity than were possible before using traditional

processes. In this respect, the technology is labor saving. If a product is very potent to begin with, then fewer employees are needed to grow adequate amounts of it. A highly concentrated product may actually require fewer employees when it is manufactured in a commercial facility than in the pilot plant. In other words, if 1,000 effective doses can be obtained from 1 liter of material, versus 10 doses, then scale-up allows fewer employees to produce large quantities of the product.

Product Differences

Some products are more labor intensive than others because they require extra processing steps. Occasionally, chemical modifications must be made. All of these additional steps require extra hands, thus increasing the number of employees to be hired.

Other products require extra processing steps due to regulatory restrictions. This is the case with biopharmaceuticals, which are injected into the bloodstream. The FDA requires additional steps and precautions to ensure purity and consistency. As a result, more inspectors must be hired, as well as quality control and quality assurance personnel. By contrast, manufacturing antibiotics is simpler because they are not as regulated (see table 3.9). One plant manager estimated that biopharmaceuticals employ 1/3 to 1/2 more workers than antibiotics.

Regulations also pertain to diagnostic products. Those used outside the body (in vitro) are not as strictly regulated as those used inside the body (in vivo). Another difference between diagnostic and therapeutic products is that diagnostics tend to have more pieces to package. Therefore, manufacturers of diagnostic products often hire more people for packaging, distribution, and warehousing. The addition of employees for a diagnostic product is shown in Table 3.6. Most of the 11 people added in the commercial phase are assemblers.

Automation

The incentives to automate biotechnology production include reducing the labor cost, and improving consistency and accuracy of data collection used to show compliance with federal regulations. Those interviewed said that automation is widely practiced and likely to increase in the future. One employer explained the incentives and limitations of automating production for her company as follows:

"The number of people you decide to hire in production and how much you streamline depends on how much you automate. The issue we have with automation in diagnostics is that you have a short product life cycle, which discourages automation. Having said that, I would say that our products are fairly automated...We have chosen to automate first those processes that are the most labor intensive that we saw ourselves continuing to utilize for several years..(But) in real small lots you still fill by hand."

Company Strategies and Alliances

Biotechnology employment growth in Massachusetts will also depend on business strategies. Ernst & Young (1990) reports that companies tend to pursue one of five key strategies (see table 3.2), not all of which lead to large employment growth. The common goal among large firms is to become a fully integrated company, including developing their own production infrastructure. This strategy is likely to lead to employment growth. However, not all companies plan to become fully integrated. The top two strategies among small firms are to develop products which can be licensed by other companies, or to be acquired by another company. Neither of these strategies is likely to result in increased job growth in the near term (*Ernst & Young, 1990, see table 3.7).

One of the most common strategies used by biotechnology firms is the strategic alliance. Alliances are struck for purposes of research, production, marketing, and/or sales. U.S. biotechnology companies say they engage in three strategic alliances on average (Ernst & Young, 1990, p. 39). Most alliances are formed in order to take advantage of the partner's marketing capability, but 17% of the companies use alliances for manufacturing (see table 3.8). Production employment in Massachusetts is hindered when a firm chooses to license its technology to a company that manufactures its product outside the state. Currently, most of the products developed by Massachusetts biotechnology firms are being manufactured outside the state by large pharmaceutical and chemical companies.

Licensing may decline in the future if companies develop internal production and marketing capabilities of their own. However, if the strategy becomes a permanent fixture (as warned by Blakely and Nishikawa, 1990), then we are likely to see production growth in Massachusetts inhibited to a degree. One experienced CEO stated that his company's use of alliances is changing.

"Four or five years ago, 90 percent of what we were working on in the research pipeline had already been licensed. Today, that's reversed. We own worldwide rights to 90 percent of our R&D today. We'll do more licensing, we'll do more deals, but they will be more strategically than economically driven. James Vincent, CEO, Biogen, (Ernst & Young, 1990, p. 103)."

In reflecting on what he would do differently today, another CEO from Massachusetts said,

"I would have insisted on complete manufacturing rights on all licensing deals, and have moved faster to retain clinical development control. Gabe Schmergel, CEO, Genetics Institute, (Ernst & Young, 1990, p. 103)."

Biotech Location

Alliances are not the only strategy currently limiting employment growth in biotechnology production in Massachusetts. Some firms are choosing to establish manufacturing facilities outside the state. There are also signs that firms will do their manufacturing offshore. Three of the eleven firms participating in this study have manufacturing facilities or warehouses in other states, and three have manufacturing facilities overseas (see table 3.9).

Despite the beginnings of decentralization, most biotechnology firms are still concentrated in the Cambridge area. They want to remain close to the universities where many of their founders teach, and where they can tap scientific advances as soon as they happen.

Cambridge, however, may not be ideal for manufacturing, because land is scarce and expensive. Companies also mention their concern about the regulatory environment.

"Cambridge is a very constraining environment. Are we going to have an environment that is conducive to setting up a production facility, or are we going to have environmental issues that would be too overwhelming to allow us to stay here, versus going to Rhode Island, New Hampshire, Puerto Rico, or Ireland? Our preference would be closer proximity than to have to get on an airplane to go see the production facility."

Cambridge is not the only hot spot in Massachusetts. Worcester, which boasts several universities and a teaching hospital, is home to half a dozen biotechnology companies. Town leaders have put together a set of regulations that companies find attractive. With help from the state, Worcester created a science park for biotechnology

companies. BASF, one of the world's largest corporations chose Worcester to establish their newly created bioscience laboratory. Local BASF officials speak with enthusiasm about Worcester.

"Worcester had the infrastructure that no one else had. It had the Biotechnology park all set up to lure biotechnology companies. They had the legislation in place. Worcester city fathers and business people were ready for biotechnology—encouraging, and wooing biotechnology. It was ready made for us. We didn't have to wait for regulations and laws concerning biotechnology research. It was all there, and they wanted it. The Worcester community is extremely supportive."

While Massachusetts still retains its appeal as a hotbed for science, firms are looking outside the state as they mature, plan production facilities, and plan strategies for entering world markets. They do not have to wait to learn what other states and countries have to offer. A number of executives interviewed for this study mentioned that they were regularly contacted, and occasionally offered tempting deals, by more aggressive state governments.

There are trade-offs to keeping operations in the same vicinity. One biotechnology executive expressed the view that commercial production facilities should be far enough away from R&D to prevent the R&D from influencing production.

"Once you're up doing commercial manufacturing, you want to be sure you're not doing research. A lot of people argue the opposite. They say they like to have their manufacturing close to their R&D so it will be easier to put in different new technologies and techniques. I think that's dangerous, because when you're doing manufacturing on a commercial scale, you want to make sure you do it the same way, every day, all the time. You want to do that on a pilot scale to get everything worked out, because going in to change your process and getting the FDA to accept it is not trivial."

By no means is this philosophy true for every company. One of the state's largest therapeutic producers has kept all of its facilities in Cambridge. A production manager there said he would not want a dedicated commercial facility to be more than one hour away from the R&D operations, due to the need for frequent visits. However, two production managers from other therapeutic companies were not adamant about keeping facilities in the same state.

Because the regulatory requirements for diagnostics are less severe, these companies seem more content with present facilities. Both diagnostic firms in the sample have all of their operations contained within one building. A chief executive officer from one of these firms offered a rule of thumb about expansion and relocation for a diagnostic company.

"For a diagnostics business up to $50 million in sales, I'd just as soon have it all under one roof. I think that there are significant benefits...I mean, these aren't anvils we're making, so you just can't ship a blueprint up to Ottawa and have them read the blueprint and go make the anvils. These are very delicate biological systems, and they're changing all the time...and from time to time they don't work...So to be able to have the development scientist and the production scientists sit down and do problem-solving together without having to charter airplanes—I think—is a distinct benefit.

Beyond that, you might have administration and distribution under one roof in Massachusetts, and take both production and development and put them in Bellbrook, Ohio or somewhere. But I think I'd keep those two (production and development) together, and this is based on my experience at (another diagnostic firm), where one of my predecessors decided to split up R&D and production and it was disastrous. It almost spelled the end..."

Agriculture may be different from therapeutics and diagnostics. While most of the agricultural biotechnology firms in Massachusetts are still in R&D, Biotechnica International, the state's largest player in agricultural biotechnology, decided to relocate to the Midwest. The only agricultural company in this study said unequivocally, that when the company reaches commercial production for its agricultural product,

"...we would not do manufacturing in Massachusetts. One of the issues is raw material. The material we use is a corn gluten protein, so we want to be close to where they mill the corn..."

Europe and Puerto Rico are likely to be winners of biotechnology production facilities in the future. One CEO explained the reason his company opened shop in Europe:

"If you are to succeed, you must access that marketplace. To do so, a company must have a manufacturing presence in Europe. It's much easier to get products into the international markets if they're made locally there. U.S. made products take much longer."

Puerto Rico is equally attractive to companies because of tax advantages and a large pharmaceutical infrastructure on the island. More than 85 pharmaceutical companies have operations in Puerto Rico, manufacturing about half of all pharmaceutical products sold in the U.S. In a recent Boston Herald story, one company executive said that:

"We would jump to Puerto Rico in a New York second if Massachusetts does not provide us with some sort of incentives, because Puerto Rico does."

Conclusions

1. The absolute numbers of production jobs created by biotechnology in Massachusetts are quite small. Even the most optimistic forecasts, should they be realized, project that biotechnology will employ fewer than half of what computer and semiconductor manufacturers employed in the state during the 1980s.

2. Biotechnology production creates more jobs than R&D, and it mostly creates jobs for low- and semi-skilled labor. Therefore, if the state is going to target this industry, it must develop effective strategies for supporting biotechnology manufacturing. One vital part of this strategy is a well-trained, highly skilled, available workforce.

3. The critical growth in production for non-degreed labor comes as clinical trials end and scale-up to commercial production begins.

4. Employment volume varies with product, market segment, and firm strategy. Some companies are more likely to generate manufacturing jobs than others.

Table 3.1

MASSACHUSETTS BIOTECH SAMPLE
By Market Segment

11 COMPANIES - 1991

Product Sector	Study % of sample	MBC Survey % of sample	E&Y Survey % of sample
Therapeutic	43%	41%	35%
Diagnostic	49%	39%	28%
Agriculture	8%	8%	8%
Suppliers	---	12%	29%
Total	100%	100%	100%

Source:

Peter Feinstein, Inc, "An Assessment of the Massachusetts Biotechnology Industry", October, 1990.

Table 3.2

GROWTH ESTIMATES FOR MASSACHUSETTS BIOTECH FIRMS
Total Employment, Production Employment, and
Percentage Growth 1990-2000

	1990	1993	1995	2000
Total Employment				
Feinstein	13,600	21,352	—	79,968
EDIC	17,585	—	30,422	—
Production Employment				
Feinstein	3,264	6,300	—	25,655
EDIC	—	—	—	—

Percent Increase from 1990

	1993	1995	2000
Total Employment			
Feinstein	57.0%	—	488.0%
EDIC	—	73.0%	—
Production Employment			
Feinstein	93.0%	—	686.0%
EDIC	—	—	—

SOURCE: Peter Feinstein, Inc., 1990, (N = 66, all are members of the Mass. Biotech Council)

Economic Industrial Development Corporation, "Growth in the nineties: Prospects for Strategic Economic Development in Boston", January, 1991.

Table 3.3

US TRENDS AND FORECASTS IN BIOTECH & OTHER HIGH TECH INDUSTRIES

Total Production Employment

EMPLOYMENT	1987	1988	1989	1990	1991	Percent Change 1987-88	1988-89	1989-90	1990-91
Production workers (000)	79.6	81.4	82.3	83.4	83.7	2.3%	1.1%	1.3%	0.4%
2833 Medicinals & botanicals	6.1	6.2	6.2	6.4	6.3	1.6%	0.0%	3.2%	-1.6%
Paarmaceutical preps	59.9	61.6	62.2	62.7	62.9	2.8%	1.0%	0.8%	0.3%
2835 Diagnostic substances	6.8	7.3	7.6	8	8.1	7.4%	4.1%	5.3%	1..2%
2836 Bio prod ex diagnostic	6.8	6.3	6.3	6.3	6.4	0.0%	0.0%	1.6%	1.6%
3571, -2, -5, -7 Computers & Peripherals	101	105	105	103	101	4.0%	0.0%	-1.9%	-1.9%
367 Electronic Components (including Semiconductors)	330	343	333	327	320	3.9%	-2.9%	-1.,8%	-2.1%

SOURCE: U.S. Department of Commerce: Bureau of the Census: International Trade Administration (ITA). Estimates and Forecasts by ITA
1988 Advance data from the 1988 Annual Survey of Manufacturers
1989 Estimate
1990 Estimate
1991 Forecast

Table 3.4

BIOTECHNOLOGY INDUSTRY
Approval Cycle for a Medical Therapeutic Product

PHASE	GENERAL ACTIVITY	TIME SPAN
(Preclinical)	Research and testing on animals for efficacy and toxicity as well as replicating production.	1-2 years
IND	Filing of "Investigative New Drug" application. New data requests could require 6-12 months of additional testing	1-2 months
(Clinical Trials)		
Phase I	Tests on healthy humans at multiple centers to determine product safety.	1-2 years
Phase II	Tests on limited group with the medical problem to determine product safety.	1 year
Phase III	Test of large numbers of patients to determine product efficacy.	2-3 years
Final FDA Approval (NDA)	Collection, correlation, preparation and submission of test data and product review.	1-2 years
	TOTAL	6-10 years.

Source: "Biotechnology Industry Analysis, " S. Brainard, M. Podsedly, and L. Sutlif. Boston College Graduate School of Management. Chestnut Hill, MA. 1989.

Table 3.5

BIOTECH EMPLOYMENT GROWTH
Pilot & Commercial Plants
Therapeutic Firms

	Company	Company	Company	AVERAGE PLANT	
Total employees	40	33	50	41	100.0%
Degreed	28	29	25	27	65.9%
Non-degreed	12	4	25	14	34.1%
AVERAGE COMMERCIAL PLANT					
Total employees	40	70	50	53	100.0%
Degreed	12	53	5	23	43.4%
Non-degreed	28	17	45	30	56.6%

SOURCE: Case Studies of 3 Mass Biotech firms, 1991.
Data are based on estimates.

Table 3.6

EMPLOYMENT GROWTH FOR DIAGNOSTIC PRODUCT
by Each Production Stage
by Workforce Degree

	R&D	Clinical	Commercial	Total
Total employees	3	2	11	16
Degreed	3	2	0	5
Non-degreed	0	0	11	11

SOURCE: Based on case product for MA diagnostic firm, 1991.
Data are based on estimates.

Note: Degreed = bachelor's plus
Non-degreed = less than bachelor's

Table 3.7

BIOTECH FIRMS AND PLANS FOR CONSOLIDATION
Within the next 5 years
by Company Size

	To Acquire a Smaller Firm	To be Acquired By a Larger Firm	To Merge With an Equal-Size Firm
Small 1-50 employees	37.0%	48.0%	39.0%
Mid-Size 51-135 employees	54.0%	21.0%	17.0%
Large 136-299 employees	76.0%	30.0%	25.0%
Top Tier 300 + employees	74.0%	22.0%	22.0%
All Companies	47.0%	39.0%	32.0%

SOURCE: Ernst & Young, "Biotech 91: A Changing Environment"

Table 3.8.

REASONS FOR PARTNERING
Biotech Companies with Alliances in the U.S.

	Mktg. Ability	Capital Needs	New Products	Mfg. Ability	Science/ Techn'g
Diagnostic	83.0%	29.0%	19.0%	27.0%	10.0%
Therapeutic	59.0%	55.0%	10.0%	14.0%	17.0%
Ag-bio	46.0%	54.0%	17.0%	17.0%	80.0%
Supplier	71.0%	31.0%	38.0%	13.0%	80.09%
All Companies	64.0%	45.0%	20.0%	17.0%	15.0%

SOURCE: Ernst & Young "Biotech 91: A Changing Environment"

Table 3.9

LOCATION OF BIOTECH PRODUCTION FACILITIES
OF 11 FIRMS IN MASSACHUSETTS
Case Study - 1991

MASSACHUSETTS		
	Same Bldg. R&D	35.4%
	Separate Bldg. Same City	18.2%
	Separate MA Cities	27.3%
NON-MASSACHUSETTS		
	Separate State	27.3%
	Offshore	27.3%

SOURCE: Case Studies (1991)

SECTION IV: SKILL REQUIREMENTS

Introduction

1. The current biotechnology workforce is highly educated. Biotechnology employers are hiring nearly twice the proportion of degreed workers than are represented in the Massachusetts workforce.

2. Semi- and low-skilled jobs do exist in biotechnology firms, and their number will increase in the future.

3. Low- and semi-skilled jobs are more commonly found in mature firms than R&D firms, and in diagnostic firms than in therapeutic companies.

4. Sterile manufacturing techniques and familiarity with current Good Manufacturing Practices (GMPs) are production skills transferable to biotechnology. Some Massachusetts companies are hiring production workers with these skills from high tech and food processing industries.

5. In addition to education and experience, some entry level jobs require spoken and written fluency in English preventing some immigrants access to these jobs.

Are there jobs for non-degreed workers?

People often mistakenly assume that all jobs in biotechnology companies require an advanced degree in the life sciences. While it is true that the industry is very much on the cutting edge of recent advances in microbiology, commercial biotechnology firms must still employ people to manufacture their products in jobs that do not require 4 years of college.

Table 4.1 presents the research results on education requirements of biotechnology firms in our sample compared with the educational attainment levels of the entire Massachusetts labor force. Because the sample is based on case studies, we cannot generalize about all firms in Massachusetts, nor about other states. It is likely to err on the side of counting more non-degreed workers, because older firms (founded before 1982) were deliberately oversampled. Their workforce is likely to be more di-

verse, in terms of skill, than those of younger firms which we would expect to have a larger share of degreed workers.

In table 4.1, we see that the educational composition of the biotechnology workforce is very different than that of the entire Massachusetts workforce. While fewer than one-third of biotechnology workers are non-degreed based on this sample, almost two-thirds of the Massachusetts workforce is non-degreed. This difference suggests that a real skill mismatch exists between the industry and the state's workforce. Most biotechnology jobs will be inaccessible to most of the state's residents. However, at least one-third of all biotechnology jobs, possibly more if requirements relax as the industry matures, are accessible to workers with less than a bachelor's degree.

If we generalize based on the case studies, then nearly 30% of all jobs in current biotechnology firms do not require a bachelor's degree. If we apply this figure to the Feinstein estimates reported in section 3 (refer to table 3.2), then approximately 4,000 of 13,600 current jobs in biotechnology are accessible to non-degreed labor. Similarly, if growth projections for the year 2000 are accurate, then about 22,000 of the 75,000 + jobs will be accessible to non-degreed labor. However, education requirements are likely to change in favor of hiring more non-degreed labor, in which case the numbers of jobs mentioned above would be low end estimates.

Production jobs represent the largest share of all low- and semi-skilled jobs found in firms (usually 60% in the case studies). R&D includes several positions for low-skilled labor (i.e. glass washers) and semi-skilled positions (i.e. lab assistants, media preparation technicians, and animal care personnel), and administration includes clerical support, which can be both low- and semi-skilled. Clearly, production is the most important area of biotechnology activity if we hope to see jobs created for non-degreed workers.

Table 4.2 illustrates the differences between diagnostic and therapeutic firms in terms of educational attainment levels of the firms' workforce. On average, 25.5% of the total workforce of the three therapeutic firms in the sample were non-degreed, whereas 42.6% of all workers in the diagnostic company were non-degreed. All firms in this comparison are approximately the same age. However, the diagnostic company has been manufacturing for commercial sale for several years, while the therapeutic companies are either licensing production of their approved products, or are awaiting product approval.

Job Requirements for Production Occupations

Biotechnology firms distinguish between low- and semi-skilled workers. This distinction has been largely ignored in recent surveys of Massachusetts biotechnology companies. If surveys mention requirements for entry-level positions at all, they generally address semi-skilled, to the exclusion of low-skilled jobs. In order to plan to meet the present and future labor needs of the biotechnology industry, as well as to enhance job access, it is important to understand that there are different skill needs, and that these needs change over time.

The remainder of this section is divided into three parts. The first part describes the requirements for semi- and low-skilled jobs. The second part describes how skill requirements change as firms mature. The third part describes how hiring strategies have evolved over time, and how biotechnology firms have coped with skill shortages by hiring workers from other industries where workers have transferable skills.

Semi-skilled Production Jobs

Skill requirements vary according to the area of production and the level of responsibility. While job positions and job titles vary from firm to firm, there is a basic set of job categories in biotechnology production, which are listed and grouped by skill level in table 4.3

Semi-skilled positions exist in the areas of 1) process development, 2) cell-culture or fermentation, 3) separation and purification, 4) aseptic fill, 5) quality control and assurance, and 6) facilities operation. The semi-skill job titles are typically called manufacturing technician, instrument technician, and quality control inspector. Employers typically look for three types of people to fill semi-skilled jobs:

a) An applicant who has several years experience (but may not have an associate degree) in sterile manufacturing and with Good Manufacturing Practices (GMP). Sterile manufacturing is required by federal law for all human drugs to ensure safety and effectiveness. Workers must be familiar with the techniques and work environment.

b) An applicant who has an associate degree or skills training in biotechnology or related health fields (but may not have previous work experience) where sterile manufacturing and laboratory techniques are taught.

c) An applicant who has a special certificate or license, such as the American Laboratory Animal Technician's license (ALAS) for handling animals or fireman's license for boiler operation.

Aside from familiarity with federal GMP standards, employers say they want to hire people who understand the basic equipment including fermenters, cell harvesters, and centrifuges. To acquire this knowledge, says one employer,

"You don't need a four year degree person, but you want a skill level that's higher than just high school. The community college and vocational-technical educational system can be a major supplier of trained personnel."

Low-skilled Production Jobs

The areas of production that require less skill than those described above, are 1) facilities operation, 2) assembly, and 3) warehousing and distribution. Sometimes there are low-skilled, entry positions below the technician level in other process areas as well. These positions are usually called operator or manufacturing assistant.

Operators, and other entry-level positions, are involved in measurement and documentation, preparation and transference of solutions, and handling equipment and supplies.

"A manufacturing supervisor stated than an operators position does not require a rocket scientist to do it, but it does require someone who is detail oriented, who can read numbers, can understand decimal points, and can weigh raw materials."

English

Being able to do basic math and follow instructions is not all that is required of entry-level jobs, say biotechnology personnel executives. English skills are also required. Employers say that because of federal regulations, their employees must be able to communicate and understand written and spoken directions. Safety considerations were also given as a reason for requiring English skills. Several firms said they have had problems in the past with employees whose poor English skills detracted from the company's operations.

"We have a lot of foreign nationals in assembly who speak English, which is required for safety and instructions... because they have to understand Good Manufacturing Procedures. Every one of them has to understand that when you switch products, you literally have to clean up the whole area,

get rid of everything on the old lots, and then check to make sure that when the new batches come in they have the right serial numbers and so forth."

The English language requirement was a consistent theme throughout the interviews regardless of whether companies were serving diagnostic or therapeutic markets. While language fluency may not seem like an unreasonable prerequisite, it may exclude or limit immigrant workers, whose English skills may be poor, from gaining employment in certain skill areas in biotechnology.

Skills Change as Firms Mature

We saw in the previous section that production increases in proportion to R&D as firms mature. Likewise, the requirements for different skill levels also undergo changes as firms mature. It is important to recall the stages of product development to highlight the types of skills required at each stage. Opportunities for low- and semi-skilled labor increase with each stage. Table 4.4 shows how the percentage of non-degreed production workers rises from R&D to clinical to commercial based on data taken from the case studies. The reader should note that company C in table 4.4 is not yet fully commercial, so we could expect even higher levels of low-skilled labor than are seen at this point.

The skill changes are best described below by the employers themselves.

1) Research and Development - Laboratory Bench:
"I consider my entry level here (in R&D) to have a bachelor's degree. It's a much more highly educated population. Anybody in the lab doing research has to have at least a bachelor's degree. There are a couple of people in the animal lab facility who have an associate's degree. Every other single person within that lab has to have a bachelor's now and will in the future.

2) Clinical Trials - The Pilot Plant:
"For the pilot plant, that's different...the entry level here needs to be at least an associate's. We could probably get away with a lower level when it gets to production."

3) Manufacturing - The Commercial Plants:
"Once we get to the point where we'll need to have a fully developed production capability, we know we won't be staffing it with people with biology and bio-

chemistry degrees. It's not driven by the fact that you need people with those skills. You'll have some of those, but not a predominant number of them.

Plant managers were even more clear about the changes in skill requirements with each production phase than were the human resource people. One plant manager said that 1/3 to 1/2 of the pilot plant workforce would typically be non-degreed, while as much as 90% would be non-degreed in the commercial plant. Another manager said that the proportions of degreed to non-degreed in the pilot plant would be 70/30, and then reverse in the commercial plant.

Before a product can be approved for sale, the production process and facility have to be licensed. Because of federal requirements for product safety and consistency, commercial production processes become highly standard and routine. Procedures cannot vary without risking loss of federal licenses to manufacture and sell the product. As a result, skill levels are higher in the pilot plant where the process is evolving continually, and are lower in the commercial plant because production has become more routine and automated. The profile of commercial production also involves more low skilled employment because additional finishing steps are added including assembly and packaging, which require no more than a high school diploma.

Hiring Strategies Have Evolved Over Time

While product life cycle may offer the greatest explanation of the change in skill demands from R&D to commercial production, it does not capture the learning process which has occurred in older firms. Nor does it explain the variations in hiring strategies among firms at the similar stages of development. Previous surveys have missed the element of change occurring within the industry with respect to hiring practices. The biotechnology industry is relatively young and employers learn as they experiment with ways to meet their employment needs.

This section presents some of the hiring lessons learned by the older generation of firms in our sample (those founded before 1982). These lessons are important for understanding the industry. Firms have coped with their employment needs in several ways:

1. Hiring people from other states.
2. Substituting workers with bachelor's degrees where there is a short supply of experienced, but nonetheless non-degreed, workers.

3. Re-training workers from other local industries where transferable skills exist.

The main pattern that developed is that firms eventually choose to substitute non-degreed labor for workers with bachelor's degrees.

Since the beginning of biotechnology, there has been an unusually close alliance between universities and biotechnology firms. Many biotechnology firms were started by university professors and located near universities. One scientist, who worked with several DBFs (dedicated biotechnology firms) during the last decade, said that during those early years, *"we were like universities."* The industry-university ties may have influenced decisions about who to hire.

Another employer, with many years experience in personnel, gave this description:

"When we were very small, we thought that the person answering the phone should have a masters in science so that they could understand the questions being asked. It was that mentality!...If we have a choice between experience and education, we would probably take education."

When it came time to staffing production areas, many firms went to New Jersey and the Midwest to recruit experienced production workers, because there were a large number of pharmaceutical and chemical companies located there. But relocating people was costly, so firms decided that recruiting out-of-state was not an effective long term solution to labor needs. Their next strategy was to hire recent graduates from the universities.

There are several good reasons why firms hired bachelor's degree holders for production positions. Research scientists were used to working with undergraduate and graduate students. They wanted people who were familiar with the equipment and practiced good lab procedures. Furthermore, there has continued to be a large supply of people with BS degrees graduating from Boston area schools each year.

In addition, there is no pharmaceutical industry in the state from which to hire workers trained in sterile manufacture. If firms were going to have to train workers, they were more confident of training bachelor's degree holders than non-degreed people. The same employer stated:

"The reason we've actually gone after bachelors degrees at these levels is because we haven's been able to find trained workers. So, we thought that if it was an option of relocating an hourly paid person, or hiring a bachelors'-level person for a year or two (and who would then move on), we're going to take the bachelors first."

Indeed, the problem firms experienced with hiring bachelor's degreed people was that they did not stay with the company for a long period of time. The work the graduates were doing was relatively monotonous and the opportunities for advancement limited. Firms reported that people were leaving after one year because they were getting discouraged. While this strategy has worked over short term, companies know it would be too costly over the long term. Another problem with hiring recent college graduates is that while they may be familiar with laboratory equipment and procedure, they still need training with biotechnology equipment. One employer in a diagnostic firm said that he preferred not to hire recent college graduates because they required training that the company was not equipped to provide.

"This isn't a very good place to train people...Previous academic experience is interesting, but it's not particularly valuable. We take graduates at the entry level only."

Another strategy was to hire people with high school degrees with experience in industries where there was some skill compatibility. Employers have hired workers from industries where sterile manufacturing techniques and GMP practices were followed. Due to the lack of a developed pharmaceutical industry in the state, they hired operators from the food processing industry. However, employers explained that they had problems with some of the food industry workers. These workers were used to labor-management relations based on union contracts. This was an unacceptable basis of relations for the firms.

The current strategy among the largest firms is to hire a combination of people. These include holders of bachelor's degrees or associate degrees in biotechnology or biomedical studies, high school graduates who have taken a laboratory course, and workers from certain industries where skills many be transferable.

Skill Transferability from Other Industries

Employers are experimenting with hiring semi-skilled labor from other high-technology industries, such as

electronics, pharmaceutical, diagnostic, and chemical, as well as non-high tech industries, such as food processing. This may be good news to workers who have lost jobs in the high tech industry (see table 4.4).

There seemed to be more talk among firms about trying to hire workers from electronics than real attempts to do so. At least one major employer thought it would be feasible for this kind of workers to make the transition.

"We can get (production) people trained to operate in clean room environment in electronics, and transition them into skilled people who can work here. Having the background of a clean room environment is already an advantage for people who end up in production here...They ought to be available and trainable without it being a major issue."

While the majority of the employers in this study expressed the view that skilled workers from electronics and food industries were suitable for re-training in biotechnology, some disagreed. One employer expressed doubts about whether former electronics workers would be good candidates for biotechnology jobs. He favored people from agriculture, pharmaceutical, diagnostic, and food industries. Another employer expressed the view that production operators from other pharmaceutical industries were not as ideal as might be expected. However, this view seemed to be in the minority.

"In most cases they (production operators) haven't been in production facilities that equate to ours. They're making tablets. We're not necessarily making tablets. We're making vials of product which are harvested from different types of processes. But they do have experience in drug manufacturing."

Training and Future Shortages

The availability of people with special training in biotechnology production is new as of this year. The Bay State Skills Corporation, a Massachusetts economic development organization, together with biotechnology companies and several junior colleges, has designed and funded several pilot adult training programs for biotechnology workers.

These programs have been implemented at three local junior colleges and one vocational technical high school, Minuteman Tech, located in Lexington. The first series of biotechnology certificates will be awarded in 1992. While some of these graduates will go to work in medical research institutions, it is expected that the majority will work in the private biotechnology industry.

High school graduates do not need to have previous work experience, but employers prefer students who have taken one or two laboratory courses. The largest companies say they have the capability to train workers for their present needs. However, several companies expressed a concern that there could be a skills crunch in the near future as products in the regulatory pipeline gain federal approval. Once this happens, employers say they will need to hire more production workers. If several companies reach this stage at the same time, there will be a shortage of manufacturing technicians.

Given the mix of opinions, further research into the strategy of retraining workers from other industries might prove fruitful. On the other hand, there is an opportunity and need to train and educate young people and adults for future biotechnology production jobs. Both strategies offer new employment possibilities to a limited number of Massachusetts workers.

The analysis of skill requirements for low- and semi-skilled jobs in biotechnology production suggests that while there seems to be variation in how firms are fulfilling their employment needs, some patterns have also emerged. The implications of this analysis for low- and semi-skilled labor are as follows:

1. There are job opportunities in biotechnology for both low- and semi-skilled labor. These opportunities will increase as more firms mature in the next several years.

2. Because other options (i.e., hiring from outside the state, or hiring BS degreed workers for what are essentially low-skill jobs) are being ruled out, there appears to be a real opportunity to train a new workforce for biotechnology in Massac u-setts. These workers must include some recent high school graduates who have received skills training in various aspects of biotechnology.

3. There are opportunities in biotechnology for workers who have been laid off from production jobs in electronics or food industries, or who may be looking for a change.

4. Most firms neither have the resources nor the infrastructure to train large numbers of workers. There will be a skills crunch in the near future if the demand for skilled labor grows quickly and existing training programs will not adequately meet that demand.

Table 4.1

EDUCATIONAL LEVEL
Total Massachusetts Workforce vs. Biotech Workforce
(1990)

Highest Degree Attained	Percent
DEGREED	
Total MASS Workforce	33.1%
Biotech Workforce Sample	72.2%
NON-DEGREED	
Total MASS Workforce	66.9%
Biotech Workforce Sample	27.8%

SOURCE: Current Population Survey, Bureau of Labor Statistics, March 1990.
Mass. Biotech Sample, 4 firms, 1991

Table 4.2

HIGH VS. LOW SKILLED LABOR
Diagnostic and (3) Therapeutic Firms

DIAGNOSTIC

Highest Degree Attained		Percent
High Skilled Jobs (require BS or more)		57.4%
Low Skilled Jobs (require less than BS)		42.6%
	TOTAL	100.00%

(3) THERAPEUTIC FIRMS

Highest Degree Attained		Company A	Company B	Company C
High Skilled Jobs (require BS or more)		78.8%	77.5%	67.2%
Low Skilled Jobs (require less than BS)		21.2%	22.5%	32.8%
	TOTAL	100.0%	100.0%	100.0%

SOURCE: Case study data gathered from 4 firms, 1991
High skilled = bachelor's + required
Low skilled = less than bachelor's

Table 4.3

BIOTECH WORKFORCE BY MINIMUM DEGREE REQUIRED
Massachusetts: 1991

Job Descriptions	Minimum Degree				Starting Salary
	Ph.D	BS	AA	HS	
PRODUCTION					
Director	X				59,000
Fermentation					
Supervisor		X		X	31,000
Research Associate		X			27,000
Technician		X			21,000
Assistant				X	18,000
Purification					
Supervisor		X		X	31,000
Research Associate		X			27,000
Technician		X			21,000
Assistant				X	18,000
Aseptic Fill					
Supervisor		X		X	31,000
Research Associate		X			27,000
Technician		X			21,000
Assistant				X	18,000
Quality Control					
Supervisor		X			32,000
Engineer		X			32,000
Analyst		X			25,000
Inspector				X	21,000
Microbiology Supervisor		X			32,000
Microbiologist		X			24,000
Validation					
Supervisor		X			57,000
Technician			X		20,000
Quality Assurance					
Supervisor		X			47,000
Documentation Specialist		X			29,000
Technical Writer		X			23,000
Documentation Clerk				X	19,000

SOURCE: Bay State Skills Corporation, Biotech Directory 1991.
Salaries are average estimates provided by MA firms.

Table 4.4

INCREASE IN NON-DEGREED LABOR
by Stage of Product Development
by Date of Company Founding

	R&D	CLINICAL	COMMERCIAL
SKILL LEVEL	Company A (1989)	Company B (1981)	Company C (1981)
TOTAL EMPLOYMENT			
High Skilled Jobs	91.7%	78.8%	67.2%
Low Skilled Jobs	8.3%	21.2%	32.8%
	100.0%	100.0%	100.0%
PRODUCTION			
High Skilled Jobs	93.5%	60.0%	37.8%
Low Skilled Jobs	6.5%	40.0%	62.2%
	100.0%	100.0%	100.0%

SOURCE: Case study data gathered from 3 MASS firms, 1991
High-skilled = bachelor's degree + required
Low-skilled= less than bachelor's

SECTION V: COMPETENCY SURVEY BACKGROUND

As part of the assessment process for the biomanufacturing study, a skills and competency survey was conducted among industry representatives. The survey was developed by members of the Minuteman Task Force and representatives of the Biotechnology Advisory Committee. The survey was formulated to identify those technical, academic, and interpersonal competencies needed to enter and succeed within the manufacturing sector of the biotechnology industry.

The survey was unique in that it attempted to identify the generic competencies that are needed for successful employment in this sector of the industry. A total of 155 competencies that encompassed the technical, academic, and interpersonal skills were utilized in the industry survey.

Methodology

The data that were gathered as part of the competency survey are the direct result of personal interviews and communication with industry representatives. Initial company contacts were secured with the direct assistance of the Massachusetts Biotechnology Council and members of the Biomanufacturing Advisory Committee.

Members of the task force visited 23 companies and interviewed a wide selection of personnel. Among the respondents were vice presidents of manufacturing, scientists, human resource personnel, trainers, "line" technicians, and manufacturing supervisors. These individuals identified those tasks needed to perform specific duties. These tasks were then translated to those technical, academic, and interpersonal competencies needed to perform in the identified job category. Those being interviewed were asked to distribute additional surveys to other departments of the manufacturing sector.

Analysis

The responses from the Biotechnology Industry Survey have revealed the following data:

- Each competency in the survey was viewed as being vital for the effective job performance of a Biotechnology Manufacturing Technician.
- All work habits and interpersonal skills listed in the survey were identified as being vital for job performance.

- All communication competencies listed in the survey received a rating of 90% or better in category A, "good to know and/or vital for job performance."

- All math competencies listed in the survey received a rating of 90% or better in category A, "good to know and/or vital for job performance."

- About sixty five percent of the Chemistry competencies assessed were identified as being vital for the Biotechnology Manufacturing Technician, while the remaining thirty five percent of the stated competencies were identified as being "good to know" and somewhat important for job performance.

- Ninety percent of all technical competencies were identified as being "good to know" and "somewhat helpful" to the Biotechnology Manufacturing Technician, with more than one-half of these competencies identified as being "vital for job performance."

- The assessment of the Biology competencies indicated a split opinion regarding their importance for job performance. About one-third of the competencies were identified as being "vital", one-third were identified as being "somewhat helpful but not vital for job performance", and one-third were identified as "not being important or not necessary for job performance" but "good to know" and "somewhat helpful" for learning higher level skills and for further advancement in the field of Biotechnology Manufacturing.

Summary

In reviewing the overall response to the competency questionnaire, there were clearly discernible patterns that developed. First, competencies that are viewed as general, relevant to the work place, such as math skills, communications and human relations, and work ethic skills received scores of no less than 90% in the required or good to know for the job category. In addition, technical competencies T43 to T53, which deal with Good Manufacturing Practices and record keeping, received between a 95% to 100% ranking in the vital for job performance category. This data suggests that the industry perceives these skills as basic skills for the Biomanufacturing Technician.

In the basic sciences of chemistry and biology, chemistry skills were generally held to be more important than biology skills. Due to the fact that the chemistry competencies listed in the survey are less conceptual in nature than are the biology com-

petencies. Furthermore, the ability to correctly calculate the composition of solutions and communicate in the language of chemistry is, in fact, going to be more commonly encountered in the workplace than is the replication of DNA or listing the types of mutations and their causes. Also, the nature of the responses in these two categories may reflect a bias on the part of the individuals reporting, since most will be coming into this field generally with a stronger chemistry than biology background.

The technical competencies present a more mixed pattern and must be analyzed individually rather than in the broader context used above. The competencies T43 to T53, which were previously discussed, can be joined by T1, T2, T4 to T10, T18 and T19 as representing technical competencies sought by the biomanufacturing industry at large. The responses to the remainder of the technical competencies reflect the diversity of this technology. Since these companies range from small start-up companies with a primary focus on research and development to firms producing laboratory animals, diagnostic tools, or therapeutic products, a range of responses is to be expected.

In conclusion, the survey appears to have appropriately targeted the manufacturing side of the biotechnology industry. The majority of the competencies clearly represent the qualities that the biomanufacturing industry is requiring of its employees. The technical competencies that scored less than 85% as good to know or vital for job performance represent the diversity of this multifaceted industry. For some institutions, in such cases, curriculum should be planned around those competencies which the industry perceived as being of the most universally desired (i.e. competencies T1, T2, T4 to T10, T18, T19, T43 to T58, those pertaining to math skills, communications and human relations, work ethics, chemistry, and biology).

Employer Response
Performance Competencies
for the
Biotechnology Manufacturing Technician

A = Good to know and/or vital for job performance.
B = Not important and not necessary for job performance.
C = No Response.

The student upon completion of his/her study of the Biotechnology Manufacturing Program will be able to:

	A	B	C
T1. Follow appropriate safety procedures.	100%	0	0
T2. Demonstrate computer literacy and application with respect to the IBM and Macintosh operating systems. (i.e. word processing, spreadsheets, data bases).	97%	3%	0
T3. Produce drawings using CAD software.	41%	59%	0
T4. Identify and explain workplace applications of measurement fundamentals (i,.e. indicating instruments, digital meters, monitors, electrical symbols).	95%	5%	0
T5. Demonstrate the workplace application and use of temperature instrumentation (i.e. temperature scales, temperature measurement, thermocouples).	97%	3%	0
T6. Demonstrate the workplace application and use of pressure instrumentation (i.e. pressure elements, manometers, pressure transducers, differential pressure measurement).	90%	10%	0
T7. Demonstrate the workplace application and use of level and flow instrumentation (i.e. direct and indirect level measurement, flow rate meters and calculations, total flow meters, measurement conversion, mass flow measurement.	95%	5%	0
T8. Demonstrate the workplace application and use of pH instrumentation (i.e. pH monitors, pH probes).	97%	3%	0
T9. Demonstrate the workplace application of composition instrumentation (i.e., nutrient probes and measurement devices).	85%	15%	0
T10. Demonstrate the workplace application of dissolved gases instrumentation (i.e. O_2, and CO_2 probes, dissolved gas monitors).	85%	15%	0

T11. Demonstrate the workplace application and use of transmission instrumentation (i.e. pneumatic and electrical transmission). Demonstrate the workplace application and use of control measurement instrumentation (i.e. proportional control, adjustable, pneumatic, electric, hydraulic and control values).	77%	23%	0
T 12. Demonstrate the workplace application and use of robot control devices and interfacing systems.	61%	39%	0
T13. Demonstrate the workplace application and use of servo systems.	51%	49%	0
T14. Program a robot using the "on- line" and "off-line" programming methods.	46%	54%	0
T15. Analyze and service a variety of electromechanical devices (i.e., mechanical, fluid, pneumatic, optical, electrical, thermal, and control systems).	64%	36%	0
T16. Describe, analyze, and service the basic components of an electronic circuit.	59%	39%	2%
T17. Identify and draw electronic symbols and basic circuit diagrams.	56%	44%	0
T18. Read and interpret a flow chart.	95%	5%	0
T19. Identify process variable in industrial processes.	95%	5%	0
T20. Explain the differences between open loop control and closed loop control.	64%	36%	0
T21. Explain the importance of feedback in a closed loop control system including the concepts of set point and error.	69%	31%	0
T22. Describe the advantages of a standardized control room over a direct piping system.	59%	41%	0
T23. Identify the standard signals used in process control.	74%	26%	0
T24. Define the common terms used in control terminology.	72%	28%	0
T25. Describe the four most common types of controller action.	54%	41%	5%
T26. Define the range and span of an instrument.	82%	18%	0
T27. Explain the possible errors that can be found in signal measurement.	69%	31%	0
T28. Calculate the maximum error of an instrument given its percent error and range of operation.	79%	21%	0

T29. Explain how a flapper nozzle works.	39%	56%	5%
T30. Describe pneumatic signal transmission citing the basic similarities of the operations.	44%	56%	0
T31. Identify the graphs of linear and nonlinear transducers.	41%	59%	0
T32. Recognize the symbols used in process control diagrams.	67%	33%	0
T33. Recognize and use all four types of process control diagrams.	54%	44%	2%
T34. Describe and analyze a process control drawing for the elements, signal flow and process flow.	51%	49%	0
T35. Define control loop efficiency.	49%	51%	0
T36. Explain how to increase the sensitivity of a control system.	61%	39%	0
T37. Explain the advantage of proportional control over on-off control.	56%	44%	0
T38. Describe the advantage of a proportional plus reset controller over a proportional controller without reset.	49%	49%	2%
T39. List the elements in a single variable control loop.	51%	49%	0
T40. Explain what kinds of processes require a cascade control system.	54%	46%	0
T41. Identify the primary and secondary loops in a diagram of a cascade control system.	46%	54%	0
T42. State the sequence of loop tuning in a cascade control system.	44%	56%	0
T43. Using the regulations for good curent manufacturing practices, define the critical terms used in the pharmaceutical manufacturing industry.	95%	5%	0
T44. Explain the need for and demonstrate proficiency in workplace cleanliness.	100%	0	0
T45. Demonstrate the ability to follow standard operating procedures (SOP's) and explain their importance.	100%	0	0
T46. Demonstrate proper record keeping for production processes and product monitoring.	100%	0	0
T47. Properly maintain equipment log books.	100%	0	0

T48. Explain and demonstrate proficiency in using different procedures for sterilization of solutions.	92%	8%	0
T49. List and discuss the responsibilities of the Quality Control group.	100%	0	0
T50. Explain the general requirements of record keeping and reports, including how long such records must be kept.	100%	0	0
T51. Discuss the importance of SOP's and the Master Production and Control Records; describe what must be kept in the latter.	97%	3%	0
T52. Discuss the relation of SOP's to Batch Production and Control Records.	95%	5%	0
T53. Discuss the requirements for QC laboratory records, including requirements for records on reference standards and calibration of instruments.	100%	0	0
T54. Demonstrate the maintenance of cells in culture (i.e. monitoring growth, monitoring media, changing media, passing cells).	87%	3%	0
T55. Demonstrate preparation and appropriate sterilization of media and media components.	90%	10%	0
T56. Determine the concentration of proteins in solution.	92%	8%	0
T57. Perform chromatographic separation of 2 or more proteins.	85%	15%	0
T58. Demonstrate factors influencing enzyme activity (i.e. temperature, pH, and substrate concentration.	85%	15%	0
T59. Determine Km and Vmax of an enzyme.	74%	26%	0
T60. Determine the inhibitors of an enzyme.	72%	28%	0
T61. Determine mode of enzyme inhibition (i.e. competitive, non-competitive, or uncompetitive).	72%	28%	0
The student upon completion of his/her study of Chemistry will be able to:	**A**	**B**	**C**
C1. Perform conversions of known metric to other equivalent metric values to its metric or English equivalent (m, cm, mm, mL, L, µL, Kg, g, mg, µg, °C).	92%	3%	5%
C2. Express and solve a series of problems using exponential notation.	93%	5%	2%

C3. Demonstrate an ability to write and express **inorganic** chemical nomenclature.	85%	13%	2%
C4. Demonstrate an ability to write and express **organic** chemical nomenclature.	85%	13%	2%
C5. Write a balanced chemical equation.	85%	13%	2%
C6. Demonstrate an ability to perform mass-mass problems.	85%	13%	2%
C7. Demonstrate an ability to perform mass-volume problems.	88%	10%	2%
C8. Demonstrate an ability to perform calculations involving percentage composition of solutions.	95%	3%	2%
C9. Demonstrate an ability to perform calculations involving molar concentration of solutions.	93%	5%	2%
C10. Apply the principles of titration and know how to measure it.	88%	10%	2%
C11. Demonstrate an ability to prepare a solution of a specific concentration by diluting a solution of known concentration.	93%	5%	2%
C12. Prepare a liquid chromatography laboratory for the separation and analysis of high molecular weight compounds.	79%	21%	0
C13. Demonstrate a working knowledge of general laboratory techniques used in a chemical laboratory.	95%	5%	0
C14. Perform tasks in the chemical laboratory in a safe, disciplined and efficient manner.	97%	3%	0
The student upon completion of his/her study of Biology will be able to:	**A**	**B**	**C**
B1. Describe the structure of a polymer and explain how polymers are formed and broken down.	67%	31%	2%
B2. Describe carbohydrates and give examples of carbohydrates that are polymers.	70%	28%	2%
B3. Describe the structure and functions of lipids in an organism.	72%	26%	2%
B4. Describe the structure and functions of proteins in organisms.	88%	10%	2%
B5. Identify the structures in a typical cell and explain the function of each.	85%	13%	2%
B6. Demonstrate and explain the differences between anaerobic and aerobic processes.	83%	15%	2%

B7. Demonstrate and explain the process of fermentation.	80%	18%	2%
B8. Describe the function, composition, and structure of DNA and the three types of RNA.	80%	18%	2%
B9. Describe the process of replication of DNA.	77%	21%	2%
B10. Explain how DNA makes up the genetic code.	72%	26%	2%
B11. Describe the processes of transcription and translation.	67%	31%	2%
B12. Demonstrate an understanding of basic Mendelian Genetics.	57%	41%	2%
B13. Distinguish between structural and regulatory genes.	59%	39%	2%
B14. Describe the types of mutations and list causes.	49%	49%	2%
B15. Explain the usefulness of a pedigree.	34%	64%	2%
B16. Explain how genetic engineering results in recombinant DNA.	75%	23%	2%
B17. Distinguish between a bacteria and a virus and describe the structure of each.	88%	10%	2%
B18. Summarize the functions of hormones and how they are regulated.	62%	32%	2%
B19. Summarize and compare cellular and antibody immunity.	77%	21%	2%
B20. Explain the role of enzymes in metabolic pathways.	72%	26%	2%
B21. Demonstrate sterile techniques in laboratory processes such as in the isolation and culture of biologic materials.	88%	10%	2%

<u>The student upon completion of his/her study of Math will be able to:</u>

	A	B	C
M1. Add, subtract, multiply, and divide whole numbers, fractions, and decimal numbers.	100%	0	0
M2. Perform operations with directed (positive and negative) numbers.	97%	3%	0
M3. Round numbers.	95%	5%	0
M4. Apply metric units of length, area, volume, and capacity.	100%	0	0
M5. Solve problems using ratios and proportions.	100%	0	0
M6. Solve problems using percents.	100%	0	0

M7.Solve problems using powers and roots.	100%	0	0
M8.Solve and graph linear and non-linear equations.	95%	5%	0
M 9.Apply problem solving techniques.	98%	0	2%
M10.Estimate answers.	95%	5%	0
M11.Use graphs, charts, and tables.	100%	0	0
M12.Apply computer problem-solving analysis.	92%	8%	0
M13.Apply basic principles of quality assurance.	100%	0	0
M14.Use a calculator to solve problems.	100%	0	0

The student upon completion of his/her study of Communications will be able to:

General competencies	**A**	**B**	**C**
CH1.Use reading, writing, listening, speaking, nonverbal, and visual skills to solve job-related problems and to help perform on-the-job tasks.	100%	0	0
CH2.Move rapidly and effectively from one mode of communication to another.	100%	0	0
CH3.Communicate in a clear and concise manner.	100%	0	0
CH4.Use language, tone, style, format, and vocabulary appropriate for the purpose and audience.	97%	3%	0
CH5.Understand and correctly interpret literal and figurative meaning and be able to distinguish between them.	95%	5%	0
CH6.Interpret written or oral communication in relation to its context and the writer's or presenter's point of view.	95%	5%	0
CH7.Use relevant sources to gather information for written or oral communication.	92%	8%	0
CH8.Participate in formal and informal group discussions and decision making.	100%	0	0
CH9.Compose unified and coherent correspondence, descriptions, explanations, and reports.	95%	5%	0
Reading and Viewing Competencies			
CH10.Comprehend technical words and concepts that pertain to a particular occupation.	100%	0	0
CH11.Restate or paraphrase a written selection to confirm one's understanding of what was read.	95%	5%	0

CH12.Read and understand forms, diagrams, memos, and letters.	100%	0	0
CH13.Read and interpret data presented in tables, graphs, charts, maps, and blueprints alone or in combination with related texts.	100%	0	0
CH14.Adjust reading strategy to purpose and type of reading (skimming, scanning, reading in depth).	97%	3%	0
Writing and Visuals Competencies			
CH15.Find, read, understand, and use information from books, manuals, computer printouts, and other printed matter or electronic sources such as video terminals.	97%	3%	0
CH16.Recognize visual cues to meaning.	92%	8%	0
CH17.Compose logical and understandable reports and correspondence that meet accepted standards for grammar and spelling.	95%	5%	0
CH18.Review and edit written reports and memos.	95%	5%	0
CH19.Write logical and understandable phrases and sentences to fill out forms accurately.	97%	3%	0
CH20.Write summaries of processes and events.	97%	3%	0
CH21.Adjust the content, style, and vocabulary of writing to meet the needs of the audience (co-workers, subordinates, supervisors, customers/clients).	97%	3%	0
CH22.Use appropriate layout and format to enhance communication.	95%	5%	0
CH23.Prepare graphics (tables, diagrams, charts, graphs, drawing, maps, and photographs) for the purpose of communicating information.	93%	5%	2%
Listening and Nonverbal Communication Competencies			
CH24.Identify relevant information in oral messages.	97%	3%	0
CH25.Listen attentively to take accurate notes.	100%	0	0
CH26.Demonstrate courtesy when listening.	100%	0	0
CH27.Analyze information gathered from informal presentations.	97%	3%	0
CH28.Recognize nonverbal cues that influence the meaning of oral communication.	95%	5%	0

CH29.Determine when more information is needed and ask appropriate questions to gain information.	97%	3%	0
Speaking and Nonverbal Communication Competencies			
CH30.Prepare oral summaries for the purpose of informing.	97%	3%	0
CH31.Participate in group team discussions.	100%	0	0
CH32.Exchange ideas orally.	97%	3%	0
CH33.Recognize nonverbal cues of listener.	97%	3%	0
Work Habit Competencies			
CH34.Perform all tasks in a safe, disciplined, and efficient manner	100%	0	0
CH35.Maintain a good record of attendance and punctuality.	100%	0	0
CH36.Demonstrate ability to follow specific oral and/or written directions.	100%	0	0
CH37.Demonstrate proper personal hygiene and appearance.	100%	0	0
CH38.Fulfill requirements of a flexible and demanding work schedule (on-call status)	100%	0	0
CH39.Demonstrate concern for and attention to detail.	100%	0	0
CH40.Demonstrate the ability to organize, implement, and follow up designated operations and tasks.	100%	0	0
Interpersonal Competencies			
CH41.Communicate with superiors and coworkers in a direct and honest manner.	100%	0	0
CH42.Report errors, omissions, and/or malfunctions efficiently and according to company policy.	100%	0	0
CH43.Demonstrate the ability to perform effectively and cooperatively as a member of a production team.	100%	0	0
CH44.Demonstrate courteous and respectful relationships with fellow workers.	100%	0	0
CH45.Exhibit job performance that demonstrates a total commitment to company goals and objectives.	100%	0	0

SECTION VI: INCORPORATING BIOTECHNOLOGY INTO THE CURRICULUM: GRADES K-12

Introduction:

Contemporary biotechnology is the result of dramatic advances in molecular biology and particularly protein chemistry and the isolation and manipulation of DNA. The techniques of biotechnology and their underlying concepts have affected virtually every subdiscipline of biology, and are having a dramatic effect upon our daily lives. The teaching of biology needs to reflect these new techniques and the new perspective it gives us on a variety of problems.

Teacher Needs

The teaching profession must respond in innovative ways to the demands made by such a pervasive and rapidly changing field.

Teachers need to update their knowledge of the basic content areas, and identify the underlying concepts needed to understand contemporary biology. Content areas must be presented in a way that relate to the curricula needs of the teachers. Teachers need to see the connection between lab experiments and their curriculum. They must be able to relate specific content areas to everyday life and to broad scientific issues. They need articles that are written at the level appropriate for their needs, rather than those geared to the interests of scientific specialists.

Teachers need to upgrade their laboratory skills so that they can share with students their knowledge of the basic techniques of biotechnology. They need hands-on activities and experiments which can be used in their biology curricula.

Teachers need access to affordable and effective support materials in order to bring biotechnology into their classrooms. They need protocols and materials which they can take back to the classroom and use with a minimum of adjustment. Teachers may need access to professional expertise in order to realize these activities in the classroom. Articles which can be read by teachers or students are useful for putting together an effective lesson.

Applications of biotechnology provide opportunities for students to apply basic concepts to real-life problems and to

develop possible career interests. Teachers need opportunities to develop connections with universities, medical centers, and industry so that they can identify appropriate scientific applications in their community and adapt them to their curriculum needs.

In order to ensure that specific lessons will be utilized, teachers need to play a role in the selection and write-up of lesson plans. Teachers need a forum for the exchange of ideas and methods for the incorporation of biotechnology into their curriculum. A long-term relationship between the public schools and universities and industry is necessary so that teachers can have access to professional expertise.

Teachers need to examine their pedagogical beliefs and develop their instructional skills so that they are able to play an active role in bringing biotechnology into their curriculum in a manner appropriate to the level of their students.

The objectives outlined in this proposal are designed to provide teachers with the knowledge base, skills, and resources needed to develop and implement innovative teaching strategies to meet the educational challenges and opportunities presented by the field of biotechnology.

Teacher-Training

Teachers should be encouraged to introduce biotechnology into their classrooms by participating in a variety of preparatory workshops.

By participating in workshops, teachers should:

- Learn basic concepts of biotechnology
- Develop relationships with scientists
- Obtain written protocols for experiments and activities which can be used in their classrooms
- Find access to resources (equipment and written materials), necessary for implementation of these activities.
- Develop strategies for incorporating biotechnology into their particular curriculum.

It is also desirable to have a science specialist or curriculum coordinator who will work with administrators, and scientists to develop a series of lessons and activities for use in the workshop. The science specialist should be familiar with classroom teaching strategies, curriculum development, and the field of biotechnology.

An outline for developing typical biotechnology workshop sessions follows.

I. Introduction

Teachers are introduced to a specific content area.

II. The Experiment/Activity

Teachers will participate in a hands-on activity or experiment which illustrates the content area.

III. Applications to the Classroom

Teachers, scientists, and science educators determine how the content area explored in this session can be applied to their curriculum.

Teachers receive literature that deals with these techniques and their applications to everyday life. The teachers, scientists, and science educators discuss the following:

- Specific examples which demonstrate the use of this technique in contemporary biotechnology.
- How to obtain the resources necessary to bring this concept into their classroom.
- How to put this technique into a context of interest to their students.
- How to develop a curricula unit designed to teach this concept.

IV. Developing Lesson Plans

Teachers work in teams to prepare lesson plans which adapt the session's activities to their particular needs.

Resources for Teachers

The DNA Learning Center at Cold Spring Harbor Laboratory (N.Y.), conducts a course on the theory, practice, and application of recombinant DNA technology. This one week course is designed for high school and college science teachers and is held each summer at different locations around the country. The course curriculum and protocols have been published in the book, DNA Science: A First Course in Recombinant DNA Technology, by David Micklos and Greg Freyer.

Several workbooks are available to assist the high school teacher in developing lessons concerned with biotechnology. Advances in Genetic Technology was developed by the BSCS and is available from D.C. Heath and Company in Lexington, MA. An NSF Mosaic Reader, DNA: The Master Molecule, is published by the Avery Publishing group in Wayne, NJ. A Biotechnology Workbook is available from Prentice Hall. The

National Association of Biology Teachers in association with the North Carolina Biotechnology Center has put together a workbook of biotechnology activities developed by teachers. The Genetic Resource, a series of publications on the genetic applications of biotechnology is available from the Massachusetts Department of Public Health.

The Industrial Biotechnology Association provides a series of videos on biotechnology, suitable for use in the high school classroom. Literature concerning biotechnology can also be obtained from them, including the color pamphlet, "Biotechnology in Perspective". For information, contact IBA (Industrial Biotechnology Association), 1625 K Street NW, Suite 1100, Washington, DC 20006.

Experiment kits in biotechnology are available from scientific suppliers such as the Carolina Biological Supply Company. These kits are primarily suited for advanced level classes. A Bacterial DNA Extraction Kit provides materials for the isolation of DNA, so that students can spool and observe it, making it less mysterious. It is possible to isolate DNA without these kits, using instructions found in workbooks, such as that made available by the National Association of Biology Teachers. Carolina also sells a DNA Restriction Analysis Kit, which requires 37°C water baths, gel electrophoresis chambers, power supplies, and micro pipettes. Their gene Regulation Biokit allows students to observe repression and induction of the galactosidase gene in *Escherischia coli*. Similar equipment for biotechnology experiments is available from other suppliers, such as VWR and Owl Scientific, located in Arlington, Texas.

Regional workshops in biotechnology are often available for teachers and students. The Massachusetts Biotechnology Research Institute (MBRI) in Worcester has offered workshops for elementary and high school teachers. The Whitehead Institute in Cambridge has begun to offer a series of biotechnology-related events for teachers and students. Microcosmos, at Boston University, takes the approach that hands-on encounters with microorganisms are a fun way to excite students about science. Many of their activities are useful for elementary students as well as their older counterparts in the middle and high schools. These activities can be learned at frequent Microcosmos workshops or from their publication, Microcosmos: A Curriculum Guide to Exploring Microbial Space.

Good introductions to recombinant DNA technology are provided by the 1983 book, Recombinant DNA: A First Course, by James D. Watson, John Tooze, and David T. Kurtz, and Understanding DNA and Gene Cloning: A Guide for the Curious, by

Drlica. A Cartoon Guide to Genetics by Gonick and Wheelis provides information about classical and molecular genetics in an entertaining style, suitable for high school students of all levels. Judson's The Eighth Day of Creation and Invisible Frontiers, by Stephen Hall, provide excellent histories of the biotechnology industry. Many other books dealing with more specific issues of biotechnology have appeared in recent years.

Career Awareness

Increased self-awareness and career awareness should be basic goals of the science curriculum. The development of career awareness should be an integral part of the curriculum, and involve the resources of the school, family, and community.

The biotechnology curriculum should include student interaction with the professional scientific community. Students of all ages should have the opportunity for positive experiences with various science professionals, including women and minorities.

Lessons should be supplemented with field trips or visits by science professionals. Interactions with the science community should be integrated with ongoing activities in the curriculum for maximum effectiveness.

Awareness of the variety of available occupations in biotechnology is important, but not enough. Students should leave the public schools with a strong sense of their interests and learning/working styles, their educational goals, and how these correlate with a choice of career goals.

Sex Equity Strategies

Another challenge to the science educator is to help all students to realize their potential. Positive self-perceptions seem to be particularly important for promoting female equity in the sciences. In order to empower female and minority students in the sciences, the curriculum must incorporate the needs, values, and interests of these groups.

The relevance of biotechnology to daily life can be used to foster a positive attitude towards science and learning in all students. Material which addresses students' interests and needs can help teachers to relate to students as individuals, build students' sense of worth, and foster equity in the science classroom. Activities and case studies should be added to the existing curriculum.

Teachers should encourage females and minority students to play an active role in the science classroom by including activities and materials that reflect the interests and needs of these groups. Appropriate role models should be used to promote career awareness in females and minorities.

These objectives can be achieved if the biotechnology curriculum utilizes activities that are geared to a variety of learning styles. Activities should be hands-on, varied, and go beyond "cookbook" laboratory experiments utilizing sophisticated equipment. Teachers should be encouraged to incorporate appropriate math and writing skills into biotechnology activities. Articles relating to biotechnology appear in the press on a daily basis, providing the opportunity for students to research and write about a variety of subjects.

Outline - Academic

The following is an outline of a suggested high school unit on biotechnology. Particular pieces of this unit will fit well into other areas of the science curriculum, and teachers are encouraged to use parts of this unit as it fits their needs. Suggestions are made for adapting this biotechnology unit to the needs of elementary, middle school, and high school students, including vocational-technical classes.

1. What is Biotechnology? An Overview

In the broadest sense, biotechnology is the application of biology to meet the needs of mankind. However, the term "biotechnology" usually refers to the use of molecular biology, especially the manipulation of DNA, to solve problems facing our society.

An ancient and simple example of biotechnology is the preservation of milk by making cheese or yogurt. Making cheeses, yogurt, or root beer are activities,vel-high school biology classes, or even for students in middle school or elementary grades. The fast plants group at the University of Wisconsin has a recipe for making kim-chee, Korean pickled cabbage. This not only introduces students to biotechnology, but also to the process of fermentation and the culture of bacteria.

Contemporary biotechnology and its impact on biology, medicine, and society can be introduced through activities and discussions, that highlight specific application of the field. The isolation of DNA is a good beginning activity, making the subject matter more concrete for the students. High school students at all levels can follow the introductory activities with an examination of specific case studies, such as the ice-minus bacteria, the use of DNA fingerprints, or the development of a genetic marker for cystic fibrosis. The examples should be chosen so as to generate student interest. Activities must be kept appropriate for the age group and academic level of the class.

2. Proteins and Other macro Molecules:

An understanding of proteins is of fundamental importance to an appreciation of biotechnology. Much of biotechnology centers around the identification, study, and production of proteins and other macro molecules. The manipulation of DNA allows us access to these proteins.

Elementary and middle school students can perform simple studies of proteins used in everyday life, such as observing the digestion of jello by fresh pineapple juice or contact lens cleaner enzymes. These students can build simple models of proteins, using Slinkies, pop beads, or colored plastic links to represent the amino acids.

In a high school biology class, this section should stress the relationship between protein structure and function. The amino acid structure of proteins and the lock and key fit of enzymes and substrates, receptors and messengers, and antibodies and antigens are part of the basic high biology curriculum. Hands-on activities, including experiments and model building can be tailored to the level of the students. Enzyme structure and function may be studied through an experiment demonstrating the digestion of gelatin by the use of contact lens cleaners. Classes can discuss enzyme kinetics and analyze the effects of temperature and pH on enzyme activity.

Hormones and other chemical messengers can be studied through specific case studies, such as that of the endorphins and opiates. This type of case study can be used to advantage with standard and basic level students and can be followed up with model building activities. Monoclonal antibodies can be studied using specific examples, such as pregnancy test kits.

The basic concepts necessary for understanding protein behavior and the handling of proteins, such as the effects of pH, temperature, salts, and polar interactions can be covered to various degrees, depending on the level of the students. Advanced placement and vocational classes should provide a greater emphasis on techniques for the separation and purification of proteins. Techniques such as denaturation, column chromatography, absorption chromatography, and protein electrophoresis may be the subject of laboratory exercises. The effect of pH, temperature, and buffer selection may also be covered.

3. Genes are the Means: Mutations and the Genetic Code

An understanding of gene structure and function helps us to identify, isolate, and genetically engineer the production of proteins. Therefore, the next logical step in a unit on biotechnology is to introduce gene structure and mutation, and their application to biotechnology. Model-building is particularly suited to this section and can be adapted for middle school students all the way up through advanced placement classes.

High school students can study protein synthesis, the structure, replication, and translation of DNA, the structure and function of RNA, the genetic code, and the nature of mutations. Students may perform an experiment using the Ames test, a test used to identify mutations in bacteria.

4. DNA Fingerprints: Restriction Enzymes and Gel Electrophoresis

The study of DNA fingerprinting can be used to teach students about restriction enzymes and the technique of separating DNA fragments by gel electrophoresis. Both middle school and high school students can perform simple activities involving the cutting of paper representations of DNA.

A comparison between classic fingerprinting and DNA analysis is a good way to introduce the concept of DNA and genes to middle school students. It may be possible to get forensic experts from the community to visit and speak to students. This can be followed up by discussion of the relationship between DNA, traits, and differences between individuals. All levels of students can perform experiments involving the preparation and separation of DNA fragments by gel electrophoresis.

5. Genetic Diseases: Identifying Genes Using RFLP Analysis and Genetic Markers.

This section builds on the concepts of the previous topic. The use of restriction fragment length polymorphisms (RFLP) in identifying markers of genetic disease. Specific case studies can be researched by the students or by the teacher and presented to the students. RFLP analysis may be beyond the curriculum for middle school and standard level biology classes,

but a general discussion of genetic markers can be followed by the discussion of a specific case study, such as sickle-cell anemia. Students of all levels can participate by acting out debates centering around bio-ethical issues.

6. Bacterial Factories in Biotechnology: Recombinant DNA, Transfection and the Production of a Protein product:

A. Fermentation Technology

Fermentation experiments are an excellent way to introduce students of many age levels to cell culture and bacteria. These experiments can be tailored to a wide variety of students, from elementary school classes to advanced high school and vocational classes. Simple experiments can demonstrate the use of bacteria in the production of sauerkraut or kim-chee. More advanced classes can analyze the products of fermentation, study the effects of changing physical and chemical conditions on the growth of bacteria, and examine the design of fermentation vessels. Visits to biotechnology companies can be used to demonstrate fermentation technology and the culture of mammalian cells.

The concepts of sterile techniques and cell culture can be introduced to most students from the upper elementary grades through high school, through the culture of bacteria in the classroom. Elementary or middle school students can be provided with sterile petri dishes which they can infect with bacteria from their fingers. More advanced students can practice skills such as sterile technique, autoclaving, serial dilution, counting colonies, and the use and preparation of culture media.

B. Recombinant DNA and Bacterial Transfection

Once a gene is identified and isolated, it can be transfected to a bacterial or eukaryotic cell, allowing that cell to make a particular protein. Advanced placement students can use commercially available kits to perform a transfection experiment. This can be followed by a discussion of its application to specific areas of research. Students of other levels can build paper models of plasmids and recombinant DNA.

7. Putting it all Together: The Business of Biotechnology.

In this section, students examine the steps in generating a product based on the techniques used in biotech-

nology. Students, both at the middle school level and high school levels, may be asked to find articles from newspapers or periodicals concerning new products based on biotechnology. A site visit to a local biotechnology company would be appropriate for this section.

More advanced students should choose a product and demonstrate the steps they would follow to develop a process using the techniques used in biotechnology.

Strategies for the Primary Grades (K-5)

Biotechnology can be adapted to various age levels as long as the learning objectives are developmentally appropriate for the children. A priority for biotechnology education at this level is to foster a positive attitude towards learning and towards science. In the primary grades content is less important than promoting inquiry and the development of learning skills. Positive contact with scientists is also beneficial at this age.

Children at this age level are very concrete and have relatively short attention spans. The students should be kept working. For maximum effectiveness, activities must be hands-on with a minimum of lecturing and note-taking.

Activities need to be well-organized, but must allow for exploration and observation by the students. Observation is an important skill for students in the primary grades. Activities can begin with a period of careful observation, followed by discussion and experimentation. Other activities might begin with discussion or exploration and end up with a period of student observation.

Many of the concepts of biotechnology, such as the structure and function of proteins or cells, are fairly abstract. It is very important to begin with ideas or concepts of which the children already have some experience or understanding. Proteins can be studied through their use in food. Students can make cheese or study the protease in pineapple.

The use of analogy is often an effective way of teaching abstract of difficult concepts. Proteins can be demonstrated by the use of multicolored plastic links, each link representing an amino acid. Models like this need to be coupled with direct experiences. The students must be developmentally able to understand the analogy. For example, the cell can be represented as a pizza, with the

additions, such as mushrooms and pepperoni, representing the organelles. Some students below the fifth grade may actually believe that cells are small pizzas.

Strategies for the Middle Grades (6-8)

At this age the learning of skills and development of values is at lest as important as learning content. Science activities should foster inquiry-based learning. Biotechnology can be used to provide opportunities for students to develop their skills in analyzing choices and making thoughtful decisions. An interdisciplinary approach to biotechnology can help students develop skills in these areas while developing an interest in science. For example, biotechnology can be connected to new methods of diagnosis and the development of medicines and other treatments. Study of biotechnology can be used to bring up related ecological issues, such as the destruction of the rain forest and the importance of genetic diversity.

Students in the middle grades are at the onset of puberty, a time of physiological and developmental adjustment. Biological maturity precedes emotional and intellectual maturity. This is a time of anxiety and experimentation, when students are very concerned with relationships with peers and how they appear to others. Students at this age level want to develop an understanding of themselves and their relationships with others. The science curriculum needs to reflect these realities, focusing upon approaches which connect science content with these issues.

An exploration of biotechnology should be used to help the students develop the skills and knowledge so that they can begin to understand the changes occurring in their bodies and their relationships with others, and begin to make well considered choices for themselves. Many of the concept areas of biotechnolgy have direct connections to students interest in the functioning of the human body and interpersonal issues, such as fairness. Interdisciplinary approaches to biotechnology help to connect the content with these concerns of young adolescents. For example, a unit on genetics should include activities which foster a discussion of ethical and social issues and the making of choices.

At this age level, students concerns may make it difficult for them to concentrate. In addition, students at this age are concrete thinkers and do not deal well with uncertainty. For these reasons, activities must be hands-on with very clear and simple instructions and learning objectives.

Interaction with peers is particularly important at this age level. Working in groups is an effective way of organizing science laboratory sessions and other activities. Biotechnol-

ogy should be used to provide opportunities for students to communicate ideas, orally and in written form, and to recognize other viewpoints. The relationship between biotechnology and health, social and ecological issues can be used to provide students with these opportunities to share, discuss, and critically evaluate ideas.

At an age when students are so uncertain about themselves, opportunities for close relationships with adults are very important. Contact with scientists can mean a great deal to students of this age. If a scientist comes into the classroom, he/she should try to interact directly with the students in small groups, or in a one-on-one situation.

Suggested Topic Outline for Technical Training

I Introduction to Technology and Biotechnology

a. Career exploration (field trips/guest lecturers)
b. Concept of Biotechnology (video tapes, IBA)
    1. Regulatory Affairs
    2. Ethics in Biotechnology
    3. Work ethic skills
        a. Resource Skills
        b. Interpersonal Skills
        c. Informational Skills
        d. Systems Skills
        e. Technology Skills
c. Safety

II Process Concepts

a. Temperature Measurement
b. Flow Measurement
c. Level Measurement
d. Pressure Measurement
e. pH Measurement
f. Dissolved Gases (O2 and CO2)
g. Composition (cell density, nutrient, and waste products)

III Principles of Process Control

a. Recognition of Symbols
b. Control Diagrams
c. Control Loops
d. On-off, Proportional, Derivative, and Integral Control

IV Automation and Robotics

a. LEGO TC logo Projects
b. Introduction to Robotics
c. Fluid Control Systems
d. Electromechanical Devices
e. Servo Systems
f. Robot Control Devices
g. Robot Interfacing Systems
h. Automated Manufacturing Systems

V Computer Applications

a. IBM Systems:
    1. Basic Computer Functions
    2. Word Processing
    3. Database
    4. Spreadsheet
b. Macintosh Systems:
    1. Introduction to the Macintosh

VI Basic Electronics

a. Basic Components of an Electronic Circuit
b. Reading Wiring Diagrams
c. Test Equipment
d. Trouble shooting

VII Good Manufacturing Practices

a. Terminology
b. Regulations (Federal)
c. Hazards in the Workplace
d. Cleanliness
e. Master Production Records
f. Control Records
g. Standard Operating Procedures (SOP)
h. Batch Production and Control
i. Responsibilities of QC/QA

VIII Cell Culture and Product Production

a. Aseptic Techniques
b. Culture Media
c. Sterilizing Procedures
d. Bacteria Cell Cultures
e. Mammalian Cell Cultures
f. Growth Cycle
g. Induction of Product
h. Plant Cells

IX Product Isolation, Purification, and Testing

a. Whole Cell Products
b. Intracellular Cell Products
c. Extracellular Cell Products
d. Bulk Separations
e. Purification of Product
f. Chromatographic Methods
g. Concentrating Product
h. Packaging Product

X Product Monitoring

a. Assay of Bioactivity
b. Binding Properties
c. Enzymology
d. Electrophoresis

SECTION VII: ANALYSIS OF JOB QUALITY

This section analyzes case study material as well as secondary material to answer the question: Are these good jobs? Job quality can be measured in many ways. For purposes of this section, three aspects of job quality are examined:

- wages and other health benefits,
- opportunities for advancement, and
- worker safety.

The issue of worker safety is raised because there has been considerable controversy surrounding recombinant DNA research, in particular, the fear of worker exposure to genetically altered microbes.

Significant findings regarding job quality include the following:

1. Wages are comparable, but slightly lower than the average for all production workers in manufacturing industries in Massachusetts. Most companies provide full health coverage. Some firms offer other benefits, such as equity in the company and tuition reimbursement.

2. Opportunities for advancement are restricted by education or specialized training, and presents a real challenge to employees hoping to make a career in biotechnology. There is diversity of opinion among firms about the opportunities for advancement for a worker who only holds a high school diploma. However, most firms encourage and support their employees efforts to continue their education in order to expand opportunities.

3. There is concern that workers will be exposed to a number of biological, product, and process hazards, but generally the industry takes extensive precautions to prevent accidents.

Salary/Wages and Other

The Feinstein survey (1990) reported that the average salary for Massachusetts biotechnology firms was $30,700. However, one would expect the average salary to be high, given the large number of people working in research who have advanced college degrees. The high average wage for all workers does

hide the fact that the distribution of wages differs significantly depending upon job classification.

The 1990 Massachusetts Board of Higher Education Regents survey reported that people with an Associates degree or semi-skilled training could expect to earn between $18,500 and $24,000 with three years experience, and workers with a bachelor of science could earn between $22,000 to $28,000 with three years experience.

Because biotechnology production includes some highly educated workers, we can arrive at an estimate of the average production salary for non-degreed workers by excluding those positions for which a bachelor's degree (or more) is required (see table 7.1). From a private industry source, we estimate the 1990 average annual salary for Massachusetts biotechnology production jobs not usually requiring a college degree was $22,235. The annual average salary for all production occupations in manufacturing industries in Massachusetts in 1990 was estimated to be $24,106. Thus, on average, non-degreed biotechnology production workers earned $1,871 less than production workers in all Massachusetts manufacturing industries. If we had included the highly skilled production jobs in our estimate of biotechnology production, the average salary would have been $37,227.

We can also compare the Massachusetts biotechnology hourly wage to the national hourly wage for all biotechnology firms (see table 6.2). The U.S. Department of Commerce estimates that the hourly wage for biotechnology therapeutic firms (SIC 2836) was $9.25 in 1990, while it was $11.70 in diagnostics (SIC 2835). We can take the average of SIC 2835 and 2836, which is $10.48 and compare it to Massachusetts biotechnology, which is $10.51. The average Massachusetts biotechnology wage appears to be close to the national average (when we combine 2835 and 2836), but is considerably lower than the national average for pharmaceutical preparations (SIC 2834, $13.58), medicinals and botanicals (SIC 2833, $16.82), and all drugs (SIC 283, $12.95).

One explanation for the difference between biotechnology firms and other drug industries may be that biotechnology firms are young and still largely unprofitable. Feinstein reports that only 44% of the companies in Massachusetts showed a profit, and another 10% had reached break-even (1990: p.29). Once companies become profitable, salaries may begin to rise. The same phenomenon probably explains why diagnostics pay more on average, because more diagnostics are profitable than therapeutics.

While we see that there are differences between degreed and non-degreed salaries in biotechnology production, likewise

there is a substantial difference in salaries within non-degreed. On average, a person with semi-skill training in biotechnology in 1990 could expect to earn $5,605 more than a person in a low-skill position (see table 7.1). The average salary for all semi-skilled labor in biotechnology was $24,300 in 1990, compared to $18,695 for all low-skilled labor. According to a private industry survey, the bottom salary for a low-skilled, entry-level job, such as a tech I or assembler, was $13,500 (or $6.50/hour), and the high was $24,232 ($11.45/hour) -nearly twice the low!

Advancement

In the skills section, we saw that education attainment (more than work experience) delineates job levels in biotechnology production. The implication is that a worker must gain further education before advancing in the company. In traditional industries, an ambitious employee might rise from the shop floor to become a manager. Experience and competence, more than education, were the tickets to advancement. The same cannot be said for biotechnology firms. The reality for low- and semi-skilled labor is that they will have to return to school for a degree in order to advance, or face being stuck in one or two positions within the firm, or look for work in another industry. The implication for employers is that they may have to devise ways to prevent employees from stagnating and becoming frustrated enough to leave.

There are two types of advancement in biotechnology, as in most industries. One path is to move upward, and the other is to move across from one area of production to another. At the time of this research, most firms did not have highly developed personnel plans delineating horizontal or vertical promotions for employees. This difference is due to the fact that these firms are less heavily regulated than therapeutic firms giving them more flexibility to promote their employees. The most common advancement model pertains to therapeutic firms.

Vertical and Horizontal Advancement

The most common advancement model pertains to therapeutic firms and vertical advancement. The generic employment structure for the production area of a therapeutic firm includes five levels—from operators, on the bottom, to the vice-resident at the top (see table 7.2). Levels 4 and 5 repeat themselves for each process area: cell culture and fermentation, purification and aseptic fill, and quality control. Generally, a high school diploma is the minimum requirement for levels 4 and 5, but a BS is required for the top three.

Of the three largest therapeutic firms in the case studies, personnel executives from two of them said there were possi-

bilities for someone with a high school diploma to advance to a supervisory level (level 2) without additional education, but not much beyond.

From the very bottom level, the operator, can move up to become a supervisor, which is the next tier. Someone with only a high school diploma is probably not going to work his/her way up the corporate ladder to become the VP of manufacturing—no matter how good he/she is—because he/she won't have the theoretical base.

Only one major executive of a therapeutic company confidently said than an entry-level person could rise higher to become the head of supervisors. He offered the possibility that someone with a high school diploma, and/or some specialized training, if ambitious and patient, might even rise to management levels within production.

Biotechnology is not unlike other emerging industries. People with a high school diploma can come in and work their way up to a management position—even beyond the first level supervisory position. That's going to happen over a span of time. People can progress through various levels of responsibility and, eventually, having demonstrated management and supervisory ability, can become supervisors in a management position. From there, it's just a question of how good they are. They can potentially move horizontally over to some other position in the company. People coming and making a career in manufacturing tend to stay in those kinds of jobs.
After supervisory level, you tend to see people with bachelor's degrees.

The plant manager of this same company agreed with this assessment. He mentioned several high school graduates he has working in the plant now, who have been training and are picking up semi-skilled jobs quickly. Their plant manager in Europe is a high school graduate with 30 years of experience, and "he knows that plant inside and out."

The second type of advancement involves moving horizontally, from one process area to another. For example, a person working on the assembly line might be asked to move across to aseptic fill, cell culture/fermentation, or quality control, all of which require different skills than assembly. Lateral movement occurs frequently in one of the diagnostic firms. People can move from assembly to cell culture and then to quality control. While similar moves are possible in therapeutic companies, most companies in the study did not describe them as common occurrences.

Worker Stagnation

The danger in not having mobility is that people begin to feel that they are stagnating. Without opportunities to learn new skills and advance, employees begin to get discouraged, and their productivity may decrease or they may choose to leave. Employers would rather not have to pay the costs associated with having a high turn-over rate. Production needs to have stability and continuity, say plant managers. Worker retention is one of their primary goals.

"We should be concerned about the lack of mobility for folks within the production area to really move up. It's difficult to look to moving up in production when you know that the boss has a degree that you don't have. We have a tuition reimbursement program, and we really try to sell it to people in production."

Safety

Biotechnology has attracted as much attention for its potentially harmful environmental and health effects, as for its beneficial effects. Since the beginning, microbiologists have taken unprecedented steps to organize themselves to prevent any harmful effects of their research using recombinant technologies starting with the Asilomar conference in the late 1960s. They wanted to avoid repeating the history of atomic physicists in the 1940s, whose scientific research was carried out in secret and was eventually put to destructive uses.

Today, the commercial biotechnology industry has a strong safety record due in part to efforts by scientists, working through the National Institutes of Health, to develop and promulgate safety guidelines for recombinant DNA research. However, a recent study of occupational safety in biotechnology remarked that although the "informal overlapping web of mostly voluntary safety procedures... is hardly a 'safety net,' yet major exposures and flagrant practices are hardly the norm in biotechnology" (Ducatman et al, 1991, preface).

Since there is self-policing in addition to federal monitoring, employees working in the labs and plants take safety precautions seriously. There are strict standards regarding facility design and management of the production process. As the level of risk increases, requirements for containment and safety increase. Fortunately, the kinds of host organisms used in biotechnology are such that there is a very small chance that they would survive outside the lab. However, workers are still in danger of being exposed to a number of hazards.

The major categories of biohazards are (for a detailed list, see table 7.3):

1. Biological Hazards: workers may be exposed to pathogenic organisms, viruses, and carcinogenic mamma-

lian cells. Besides danger of infection, workers may experience allergic and immuno-responses.

2. Production Hazards: workers will likely handle raw materials used in production, including radioactive materials (i.e. radioisotopes). The risk of over exposure is real.

3. Process hazards: workers are in contact with corrosive chemicals and flammable solvents, which pose risks. In addition, work conditions may cause injury or stress, due to excessive noise, temperature extremes, slippery surfaces, and mechanical problems (i.e. projectiles).

Production workers in the fermentation and purification areas "encounter risks similar to those of workers in pharmaceutical and chemical industries, that is, exposure to the final physiologically active products." (Goldman, see Ducatman, et al. 1991, p. 215). But there are two important differences between pharmaceutical products and biotechnology products. The first is that fewer workers are likely to be exposed, because biotechnology products are more capital intensive. It takes fewer people to produce a product. The second difference is that biotechnology products are purer and more concentrated, and therefore, more dangerous. So, workers are at risk of being exposed to more dangerous products.

Other workplace hazards include animal handling, which may lead to bites or scratches, and subsequent infection by transmittable diseases. The latter may include HIV virus. Finally, there are physical stresses resulting from repetitive motions and heavy lifting due to inadequately designed work spaces and work routines.

Genetics Institute, Inc., located in Cambridge and one of the nations largest DBF, participated in a study of workplace injuries between 1984-89. More than 80% of the accidents were reported due to lacerations, punctures, strains, and burns. Most of the job-loss time was due to back injuries and strains (see table 7.4).

Industry hazards can be controlled through a variety of strategies. The first is to substitute non- or less- hazardous materials for the hazardous materials. The second is to engineer solutions that reduce or eliminate the hazards. Third, hazards may be controlled through proper facility and personnel safety procedures. Medical surveillance of employees based on a plan that accounts for the specific types of hazards for each work activity is strongly recommended (Goldman, see Ducatman, et al. 1991, p. 209).

"Most commercial and academic laboratories are making efforts at containment, and most use safety professionals routinely. It is reasonable to hope that the biotechnology revolution will have markedly fewer victims than past technological revolutions" (Ducatman, et al, 1991, preface).

Conclusion

The major findings about job quality are that:

1. Average annual Massachusetts biotechnology manufacturing salary is the same as the national average for all biotechnology (SIC 2835 & 2836), but is lower than the annual average for all manufacturing in Massachusetts. Most of the new biotechnology companies are not yet profitable. However, many firms also offer company equity at reduced prices as a form of salary compensation.

2. There is considerable variation in salaries between low- and semi-skill, as well as within semi-skill areas. This latter variation is probably due to the mix of degreed and non-degreed labor working in similar job categories.

3. Opportunities for advancement exist, but are quite limited for non-skilled labor. However, there is a difference of opinion about how limiting a high school diploma is for someone in manufacturing operations who is talented and ambitious.

4. While injuries in commercial biotechnology appear relatively uncommon, the potential for harm must be

Table 7.1

AVERAGE ANNUAL SALARIES
for Biotech Production Jobs
Boston (1990)

All Biotech Production (degreed & non-degreed)	$37,227
All Semi-skill (1-3 years college)	$24,300
All Low-skill (high school)	$18,695
All non-degreed (semi + low skill)	$22,235
All Manufacturing/Mass. (1990) *	$24,106

SOURCE: Private Industry Survey, 1990
* Massachusetts Department of Employment and Training, includes production jobs only.

Table 7.1a

U.S. TRENDS AND FORECASTS IN BIOTECH AND
OTHER HIGH TECH INDUSTRIES
Average Hourly Earning in Production (dollars)

EARNINGS	1987	1988	1989	1990	1991	Percent Change 1987-88	1988-89	1989-90	1990-91
Average hourly earnings ($)	12.22	12.73	12.82	12.95	—	4.2%	0.7%	1.0%	—
2833 Medicinals & botanicals	15.32	16.09	16.37	16,82	—	5.0%	1.7%	2.7%	—
2834 Pharmaceutical preps	12.42	12.98	13.25	13.58	—	4.5%	2.1%	2.5%	—
2835 Diagnostic substances	10.74	10.99	11.25	11.7	—	2.3%	2.4%	4.0%	—
2836 Bio prod ex diagnostic	8.87	9.02	9.16	9.25	—	1.7%	1.6%	1.0%	—
3571, -2, -5, -7 Computers and Peripherals	10.47	10.75	11.16	11.45	—	2.7%	3.8%	2.65	—
367 Electronic Components (including semiconductors)	9.32	9.99	—	—	—	7.2%	—	—	—

SOURCE: U.S. Department of Commerce: Bureau of the Census; International Trade Administration (ITA). Estimates and Forecasts by ITA
1988 Advance data from the 1988 Annual Survey of Manufacturers
1989 Estimate
1990 Estimate
1991 Forecast
Trade Administration (ITA). Estimates and Forecasts by ITA

Table 7.2

VERTICAL ADVANCEMENT IN TYPICAL THERAPEUTIC FIRMS
By Level and Degree Required

level 1 (BS, MS preferred) Vice President

The top of the production pyramid is the vice president of Manufacturing/Operations, who directs planning and determines budgets, hiring policies, and programs.

level 2 (BS) Manager or Director

This person oversees the section supervisor, directs manufacturing operations, and manages facilities and work schedules.

level 3 (BS) Head Supervisor

All supervisors in level 4 report to the head supervisor, who coordinates each process area and its staff.

level 4 (HS + experience) Supervisors

Each 'supervisor' manages a small team of operators for one of several process areas (fermentation, separation, purification, aseptic fill, and assembly.

level 5 (HS) Operators or technicians

The bottom of the employment ladder is the 'operator' — or manufacturing assistant— whois usually part of a small team of operators. This person assists manufacturing, including weighing raw materials, preparing media, operating machinery, taking measurements, maintaining GMP records, testing batches, and packaging final products.

Table 7.3

POTENTIAL HAZARDS IN THE WORKPLACE:
Biomedical/Biotechnology

TYPES OF HAZARD	EXAMPLES	POTENTIAL HEALTH EFFECTS
Biological Materials	Blood, viruses, and bacteria genetically engineered organisms	Laboratory-acquired infections such as: tuberculosis
Mutagens and carcinogens	Alkylating agents, ehtidiun bromide	Increased risk of cancer, reproductive system toxicity
Solvents/reagents	Phenol, chloroform methanol, zylenexylene	Headache, dizziness, skin rash, mucous membrane irritation
Acids and bases	Sulfuric acid, hydrochloric acid, Sodium Hydroxide	Skin and eye burns
Gels	Acrylamide monomer	Neurotoxicity
Allergens	Piperizine, hydrazine	Nasal congestion, skin rash, asthma
Chemicals used in special experiments	Cyanide and phosgene	Cyanide poisoning, pulmonary edema
Radiation	Radioisotopes	Increased risk of cancer, reproductive system toxicity
Lifting	Materials handling	Acute muscle strain chronic back pain
Repetitive Motion	Twisting caps	Tendonitis
Electrical	High voltage experiments	Electric shock

SOURCE: The Occupational & Environmental Health Center at the Cambridge, MA Hospital, 1988

Table 7.4

BIOTECH WORKPLACE INJURY RECORD

By Type of Injury, and Percentage of Days Lost
from Genetics Institute, Inc., Cambridge, MA
(1984-89)

Type of Injury

Lacerations punctures	Strains	Back Injury	Thermal Chemical Burns		Other Burns
41.0%	18.0%	14.0%	11.0%	60.0%	10.0%

Type of Injury

Back Injury	Strains	Other
93.0%	60.0%	10.0%

SOURCE: "The Biotechnology Industry - Occupational Medicine" by Ducatman, et al. 1991.

SECTION VIII: WOMEN *and* OTHER MINORITIES

(The term minorities includes both women and other minorities.)

Introduction (and Findings)

The composition of the American workforce is changing. Women and other minorities represent the fastest growing segments of the workforce (see table 8.1). This trend is expected to continue. It underscores the need to design employment policies that are sensitive to demographic changes.

Since wage and employment differences between men and women, and between Caucasians and other minorities persist, access to jobs for women and other minorities must remain a goal of public policy. While minorities are increasing their share of the labor force, they may not be prepared to find skilled work in the biotechnology industry.

One implication of these findings is that commercial biotechnology companies are missing a large segment of the potential workforce that could serve the biotechnology industry well. It is also unfair to minority groups if they cannot have access to an important, growing segment of the region's economy.

In this section, we see that:

1. There are differences among firms in the female and racial/ethnic workforce compositions. This suggests that some firms are more successful in recruiting from an increasingly diverse workforce. Private and public policy can make the difference in tapping the minority workforce.

2. Opportunities for minorities in biotechnology will be enhanced if more minorities are recruited for training programs and if companies adopt goals for hiring.

3. Commercial biotechnology is a promising field for women with science backgrounds, as women earn a high percentage of degrees in the life sciences. Women occupy nearly half of the science positions in biotechnology firms in Massachusetts.

Results

The following analysis is based on information gathered from four Massachusetts' biotechnology firms. While the case study approach limits generalization about all biotechnology firms in the state, the results are still instructive. The case studies probably inflate the presence of minorities in the labor force, because they include the largest biotechnology companies in Massachusetts.

Larger firms tend to have more employment in production activities than small firms. Production jobs require a lower level of education than research jobs, and as a result, the mix of workers available for these jobs becomes more diverse. It would be misleading to evaluate the younger companies whose main activity is research and not manufacturing. All of the firms included in the case studies were founded before 1982, placing them in the older generation of biotechnology firms.

Women in the Biotechnology Labor Force

Women have been employed in biotechnology laboratories in larger numbers than in most science-based, private industries. Women occupy nearly half of the science positions in biotechnology firms in Massachusetts. The percentage of women in the workforce for each company in the case studies ranged from a low of 41.5% to a high of 60.9% (see table 8.2).

Women's participation in biotechnology reflects particular educational degrees granted in the U.S. in the life sciences. After examining the information about who earns life science degrees nationally, it is not surprising to see a high percentage of women in biotechnology. Women earned slightly fewer than half of all advanced degrees in the life sciences, including biology, during the 1986-87 school year.

Biology stands in stark contrast to engineering, where women earned only 13.2% of degrees during the same period. Likewise, of all electrical engineers in U.S. firms, only 7.9% were women (BLS, 1989, Bulletin 23240, p. 90).

At junior colleges during the 1986-87 school year, women earned 55% of the degrees awarded in life sciences nationwide. This past spring (1991) in Massachusetts, junior colleges awarded certificates in biotechnology for the first time. The three participating colleges have reported their enrollments to the Bay State Skills Corporation, which provided seed funds for the Biotechnology Programs. Women represented almost 60% of the enrolled students. If this year's graduating class is typical of

future classes, then women will likely enter the production workforce in greater numbers in the future than at present.

While women have gained access to the labs, they represent a smaller percentage of executive and managerial occupations in biotechnology than in all industries nationwide. Affirmative action goals might help companies address this imbalance.

One scientist, from a local firm, observed that:

"I think you're going to see a lot of women in the labs. I think there's still all the barriers and all the old boy networks being formed when you start going up the ladder (out of the lab and into upper levels of administration)...I would guess that the more academic organizations are much less tolerant of women."

Other Minorities in the Biotechnology Industry

U.S. employment in the entire drug industry, which includes biotechnology, was 8.5% black and 5.5% Hispanic in 1988. This is one-fifth and one-fourth lower, respectively, than the 10.8% and 7.4% of the nation's overall labor force that is black and Hispanic. The three metro-Boston Biotechnology firms surveyed, each with more than 100 employees, averaged 3.5% black and 0.8% Hispanic workers within their firms. Black participation was just one-tenth below the 3.9% of metro-Boston labor force that is black, although Hispanic participation was only one-fourth of the 3.3% of metro labor force that is Hispanic (see table 8.4).

While the low participation of Hispanics is noteworthy, these three firms are hardly an adequate sample by which to measure industry behavior. Case examination does reveal some valuable insights into the figures on black employment.

Of the three case firms, the highest level of minority and women participation is found in the company (a diagnostic) located farthest from minority populations. The oldest and largest firm (a therapeutic) employed the lowest proportions of both women and other minorities. The other therapeutic products firm employs high proportions of women and other minorities even though it is the least involved in product marketing. The results seen in the three case studies cannot be explained by conventional wisdom about market factors; the results run counter to the directions we might expect.

The factor that is consistent with workforce composition for each of the case firms is company policy. The company with the least diverse workforce has no policy or goals for hiring or advancing other minorities or women. The company with the most diverse workforce has targeted other minorities and women for hiring, although most of these are in low-skill positions. The company with an affirmative action policy not only has a workforce comparable to the metro population in composition, but also has most of its minorities in higher skill positions. These findings suggest that growth and maturity do not guarantee hiring and promotional policies that will diversify a company's workforce. Company hiring goals and practices make a difference.

Data on minorities earning advanced degrees in biology were not available, but the Federal Bureau of Labor Statistics reports that the percentage of blacks and Hispanics who worked professionally as biological or life scientists in the U.S. in 1988 was 1.0% and 2.4% respectively (BLS, 1989 bulletin 2340). During the 1986-87 school year, minorities earned 26.8% of the associate's degrees in life sciences in the U.S. which was higher than the rate of all associate's degrees earned by minorities. In Massachusetts' junior colleges, 10.5% of the students enrolled in biotechnology certificate programs were minorities, which is very close to the statewide population of minorities, estimated to be between 10.2% and 12.2% (Mass. Institute for Social and Economic Research, U. MASS, 1991).

Conclusion

In answering the original questions about who gets biotechnology jobs, the following summary of the Massachusetts biotechnology industry presented several major implications for women and other minorities.

1. Commercial biotechnology is a promising field for women with science backgrounds. Women have accessed biotechnology laboratories in larger numbers than most science-based, private industries. This pattern reflects educational degrees granted in the life sciences. As long as the number of women earning biology degrees continues to remain high, their presence in science professions in biotechnology firms should continue.

2. While women have gained access to the labs, they represent a smaller percentage of executive and managerial occupations in biotechnology.

3. Opportunities for women and other minorities to access biotechnology jobs will probably increase as public and private awareness increases.

4. One of the major obstacles facing minorities is education requirements, access to training programs, and absence of minority hiring goals in some biotechnology firms.

5. Given that a small percent of advanced life science degrees go to other minorities, the greatest opportunities for expanding other minority presence will result from a combination of public and private policy actions, directed at increasing the number of other minorities in the certificate programs at the junior college and vocational-technical levels.

6. Other than efforts in Worcester and at Boston University, training programs do not exist in many key urban areas. The development and expansion of training programs near urban areas utilizing the community college and the vocational-technical school structure should be strongly supported by the Commonwealth of Massachusetts.

Table 8.1

CIVILIAN LABOR FORCES IN THE U.S.
Projection to the Year 2000
Numbers in Millions

	1976	1988	2000	1976	1988	2000	1976-88	1988-2000
TOTAL	96,158	121,669	141,134	100.0	100.0	100.0	26.5	16.0
Men	57,174	66,927	74,324	59.5	55.0	52.7	17.1	11.1
Women	38,983	54,742	66,810	40.5	45.0	47.3	40.4	22.0
White	84,768	104,756	118,981	88.2	86.1	84.3	23.6	13.6
Black	9,549	13,205	16,465	9.9	10.9	11.7	38.3	24.7
Hispanic*	4,279	8,980	14,321	4.4	7.4	10.1	109.9	59.5
Asian	1,827	3,708	5,688	1.9	3.0	4.0	103.0	53.4

Notes: Labor Force = age 16+

*Persons of Hispanic Origin can be of any race

SOURCE: U.S. Department of Labor, "Monthly Labor Review" Nov. 1989

Table 8.2

MASSACHUSETTS BIOTECH WORKFORCE
Race, Ethnicity & Gender
Sample of 4 Firms, 1991

Area of Activity	Diag 1	Therap 1	Therap 2	Therap 3	All Firms 4
R&D (% of Total Emp.)	30.4	38.6	31.3	53.0	38.6
Women (% of R&D)	54.3	50.5	61.9	28.6	46.6
	2.0	2.2	4.8	7.1	4.2
PRODUCTION (% of Total Emp.)	69.6	36.9	33.6	15.2	37.6
Women (% of Prod.)	63.7	28.7	51.1	45.0	46.6
Minorities (% of Prod)	40.0	2.3	6.7	10.0	16.8
ADMIN (% of Total Emp.)		24.6	22.4	30.3	20.7
Women (% of Admin)	*	46.6	60.0	60.0	53.9
Minorities (% of Admin)		6.9	0.0	0.0	3.1
SALES (% of Total Emp.)			12.7	1.5	3.1
Women (% of Sales)	(see note)		58.8	50.0	57.9
Minorities (% of Sales)			11.8	0.0	10.5
ALL DEPARTMENTS	100	100	100	100	100
Women	60.9	41.5	57.5	48.5	50.1
Minorities	28.7	3.4	6.7	5.3	9.2
Foreign Nationals	—	3.0	1.5	2.3	1.9

SOURCE: Case Study 4 Massachusetts Biotech Firms, 1991.
* included in production
Note: sales are carried out by parent and alliance partners respectively

Table 8.3

MINORITIES IN BIOTECHNOLOGY WORKFORCE,
By Occupation
(% of total)

	Minorities				
	Therap. Firm 1	Therap. Firm 2	Therap. Firm 3	Therap. Firm 4	4 Firm Average
Exec., manager, supervisory	0.0%	0.0%	5.5%	6.3%	2.9%
Scientist (biology)	0.0%	4.8%	2.2%	0.0%	1.7%
Biological technician	22.2%	0.0%	22.2%	12.5%	14.2%
Administrative support, including clerical	0.0%	0.0%	0.0%	25.0%	6.3%
Assemblers	0.0%	0.0%	0.0%	8.8%	2.2%
Prod. inspectors, testers samplers & weighers	0.0%	0.0%	0.0%	20.0%	5.0%

SOURCE: Massachusetts Biotechnology sample, 1991.
Minorities = both Black and Hispanic.
Asians excluded because BLS does not offer comparison data.

Table 8.4

EMPLOYMENT BY GENDER/RACE/ETHNICITY
1991 Case Study of Three Metro-Boston Biotechnology Firms

(Percent of total workforce)	Company A (Therapeutic)	Company B (Therapeutic)	Company C (Diagnostic)
Women	41.5	48.5	60.9
Black	3.5	2.3	5.2
Hispanic	0	1.6	1.7
Asian	0	1.6	21.7
in Production	36.9	15.2	69.6

Note: All companies founded before 1981, and employ more than 100 people.

Percent Black, Hispanic, and Asian calculated excluding foreign nationals.

SECTION IX: INDUSTRY PARTNERSHIP PLACEMENTS

Vocational-Technical Level

"School/business partnerships are enjoying a period of unprecedented popularity and growth. A 1991 study, conducted by the National Center for Partnerships in Education (NCPE) for the U.S. Department of Education, revealed that more than 65 percent of the total student population attended schools in districts with partnerships. These educators already involved in successful partnerships have learned that such partnerships are built on a single important principle: Both partners need to benefit. (Technology and Learning, February 1992, Volume 5.)"

A discussion of the industrial placement options in the biotechnology field must begin with a brief listing of important terms and their respective definitions.

Cooperative Education *- cooperative vocational technical work experience which provides supervised equal employment opportunities and learning experiences, on a paid basis, for vocational credit.*

Work-Study *- a split day combination of academic study and work experience. Students are released at a specific time during the school day in order to work at paid placements for vocational credit.*

Internship *- a paid or unpaid work experience directly related to an integrated training/academic program. Student participation in an internship program normally earns full vocational credit.*

Practicum *- an unpaid work experience that completes a student's course of study or training in a specific field of endeavor.*

The cooperative placement option is specifically related to high school students, and per Massachusetts guidelines, must:

- *Meet requirements of state and federal laws relative to the employment of minors engaged in Cooperative Education.*

- *Contain a written agreement between the school and the employer which ensures that students-in-training shall be afforded a variety of opportunities to extend compatible competencies and competencies through actual job performance as paid employees. Cooperative employers must assure in writing that they are affirmative action/equal opportunity employers.*

•Select appropriate work sites and meet health/safety standards which ensure maximum employee protection. Participating students should be made aware of the regulations of the Occupational Safety and Health Act governing work sites.

•Assess and evaluate student progress and/or performance which is reported regularly by the employer in a manner or format that is convertible to the school's grading and crediting system.

•Require that the school's Cooperative Education Coordinator or designee conduct regular supervisory activities at the work site to ensure that the agreement is being followed and that students are progressing satisfactorily.

•Allow participation of only those students who have completed at least 2 (two) years, no earlier than the second semester of their junior year, provided that they have completed the approved secondary vocational technical/educational program in the cooperative area of employment.

•Students participating in Cooperative Education shall devote 50% of their school time to the study of academic subject matter during the school year at the school which provided said programs. School authorities shall ensure that a student participating in a cooperative work experience is supervised at the site by a school staff member. It is the responsibility of local school authorities to ensure that the work experience is well suited to the physical, emotional, and intellectual capabilities of the student involved.

Prospective employers have listed, (not in any specific order) age, schedule restrictions, maturity, task assignment restrictions (biohazardous areas), employee acceptance, and attained skill levels, as major areas of concern when considering the employment of high school students. Realistically, the cooperative placement option would be restricted to a very few, highly motivated students who must not only qualify by state guidelines but must also meet individual school requirements and prospective employer expectations.

The work-study option is also focused on the high school age student and is governed by numerous restrictions, although this program could be viable for post graduate high school students depending upon the type of training program involved. The concerns of prospective employers remain the same as those mentioned above if high school students were to be involved with a work-study program. A post-graduate

work-study situation would be much more flexible in terms of scheduling and task assignment, in addition to the fact that restrictions applying to high school students would be removed.

The remaining two placement categories; internships, or practicums, are the most viable options for students, particularly post graduate students, involved with a biotechnology technician program. As previously mentioned, internships can be paid or unpaid. Compensation would have to be negotiated between the sending program and the prospective employer. An internship allows for an intense, focused, hands-on work experience at some point during the student's education.

The point at which a student leaves the classroom and begins his/her internship period may either be prearranged as part of an overall program, (Example: a trimester program with the third semester being the internship) or may be dictated by teacher recommendation, based upon the level of skill attained by a particular student. Obviously, the latter allows for greater flexibility in placing a student when he/she is indeed ready to begin a "real" work experience. Internships also eliminate the potential scheduling restrictions involved with the first two options, as the student is not required to attend school during this period of time. The internship is, in fact, the schooling.

An internship is an extremely positive situation in numerous ways.

- It allows an employer to make a judgment on the abilities of a prospective employee without committing to hire.
- It provides the student with the culminating work experience related to that which he/she may have learned theoretically or through limited hands-on classroom training.
- It allows the student to gain an edge on competing for available jobs within the company for which he/she is working.
- It gives a student resume experience should he/she not work for the interning company after graduation.
- In a paid situation, it allows the student to begin to earn money prior to formal graduation from the program.

However, in order to maintain a positive internship arrangement, student evaluations must be regularly performed by the employer. In addition, consistent communication concerning student progress must be maintained between the employer and sending school or training program.

The words internship and practicum are almost interchangeable in that both situations refer to on-the-job work experiences. The first major difference between the two lies in the fact that practicums normally complete the education and/or training of a student while internships may not necessarily complete a student's study or training. The second major difference between the two is that practicums are normally short term, unpaid experiences while internships normally run for a longer period of time in a paid situation. However, the tasks and duties assigned may be very similar in nature and the positive benefits of an internship are certainly applicable in a practicum circumstance. As with internships, the key variables involved with a positive practicum experience are student evaluation and employer-school communication.

The process of developing these interim placement options, as well as the full-time placement of students, is a process that begins prior to a program's inception and continues for the duration of the program. This process can be summarized into the following components:

1. Assess program needs for placement (interim and full-time).

2. Appoint a program placement coordinator or assign placement responsibilities to a specific individual.

3. Identify prospective employers who have need for manufacturing technicians presently or in the near future.

4. Identify and develop a contact person list for each of the prospective employers.

5. Initiate contact with each of these key people by letter, telephone, or by individual or group meetings in order to make known to them the existence of the program, the curriculum, and its placement objectives.

6. Identify prospective employers with whom personal contact has not been established and pursue individual meetings in order to discuss the program and its placement objectives.

7. Develop an advisory group made up of representatives from the industry and plan regular informational and discussion meetings in order to confer on placement and placement opportunities

8. Inform prospective employers approximately six weeks prior to commencement that the program will soon have a graduating class. Responses and inquiries should be directed to the placement coordinator.

9. Establish a job opportunity listing and match student competencies and abilities to available job offerings.

10. Follow up initial placements with progress inquiries related to the graduate's skill level, performance, attitude, and progress in the company.

As the biotechnology industry moves more rapidly into the manufacturing phase of its development, the need for manufacturing technicians will rise at an equally rapid pace.

In many ways the biotechnology industry and the vocational-technical environment share a common goal: the desire for a better educated "world class" technician. Business and education may view the agenda for achieving this goal from different vantage points, but it is clear that the two sectors are becoming increasingly interdependent. Effective partnering is a way for them to address this important goal together.

SECTION X: TASK FORCE RECOMMENDATIONS

The previous sections of this study and other clear realities lead to some basic conclusions. The conclusions rest in the assumptions that state leaders and educators are interested in both supporting and making use of the economic potential of biotechnology.

State Initiatives

1. Massachusetts has already attracted numerous companies involved in the research stage of biotechnology. Now many firms are ready to move into the manufacturing stage. Our state and individual communities should provide tax, land, loan, and regulation incentives to encourage biotechnology firms to locate their manufacturing operations in this state. The goal should be to make it attractive for firms already in the state to expand their manufacturing here rather than exporting that activity. While this strategy will not lead to the level of job creation experienced by the computer industry in the past, it could significantly expand the job market for semi-skilled workers within the Biotechnology industry. In addition, the Massachusetts Centers of Excellence Corporation can make specific recommendations on other business incentives.

2. Communities interested in competing for the economic benefits of biotechnology development should install a model before a specific proposal exists. Credibility is established by accomplishments rather than promise in economic competition.

3. Tax credits are critical to the expansion of biotechnology manufacturing in Massachusetts. The Governor has already made proposals of this type. These proposals deserve bipartisan support from leaders who understand the nature of interstate competition for new manufacturing facilities. If incentives and early planning are implemented, biotechnology companies can then concentrate on

site selection related to such factors as proximity to their research and development, water and transportation needs, and the availability of skilled workers.

Job Training Initiatives

There is a serious shortage of skilled and semi-skilled workers for technology-based manufacturing. Massachusetts should greatly improve the strategic orientation and coordination of its employment training operations to correct its shortage of skilled workers. It has become increasingly apparent that in order to develop and implement industry responsive programs, there must be a greater amount of flexible monies available to those entities who respond to industry training needs. It is recommended that:

1. Specific attention be given to changing policies, both federal and state, that are inherently obstructive to the development of an industry responsive educational system.

2. Department of Employment and Training (DET) and Department of Education leaders should promote legislative proposals to establish improved funding of vocational-technical programs in two ways:

   First - A minimum level of 35% funding be provided for the operation of vocational-technical programs. This has been recommended by the Mass. Business Alliance for Education and would implement Chapter 731 of the Acts of 1988.

   Second - Improved adult access to relevant vocational-technical training including biotechnology. The special resources of DET and the cooperating vocational-technical schools should be utilized to assist and promote adult access. Unless positive action is taken, Massachusetts will simply fail to invest adequately in the development of a skilled workforce.

3. The Commonwealth of Massachusetts must increase its support to training organizations such as the Bay State Skills Corporation. The private sector 50/50 match that is required by its training programs is key to the successful training of the future workforce of the Commonwealth.

4. Political leaders, Department of Employment and Training officials, and Department of Education officials must develop and implement positive

steps to use education in general, and vocational-technical schools in particular, to develop a skilled workforce. Special attention must be given to providing stable funding for both standard and adult students in vocational-technical schools. The educational reform legislation now under consideration provides an ideal opportunity to provide the right educational support for a blossoming biotechnology industry in Massachusetts.

5. Monies for training programs must be directed towards those programs dealing with the manufacturing aspect of Biotechnology. Manufacturing will create many more jobs than R&D in the next 10 years.

Educational Initiatives

1. It is recommended that three permanent vocational-technical programs be developed in Massachusetts utilizing the Regional Vocational Technical school structure. This will provide an important part of the needed training for future biomanufacturing/biotechnology personnel. These program centers should be in Boston, Lexington where the current program exists, and Worcester. The choice of these locations is predicated on the geographic areas where the biotechnology industry is currently evolving in Massachusetts.
These educational centers would normally train approximately100-150 candidates per year including students in grades 9-12 and non-traditional students. It is envisioned that these centers would be staffed with 2 to 3 full time biomanufacturing/ biotechnology faculty.

   The need to maximize facility utilization is also cost driven. The cost of developing a high quality center to teach biomanufacturing, which would include an electromechanical laboratory, a clean room, and a biotechnology laboratory with appropriate support equipment is estimated to be between $350,000 -$500,000. Such high costs strongly suggest that the number of such facilities must be limited.

2. Our state's teacher training institutions must provide pre-service and in-service programs, on the biotechnology materials outlined in Section VI of this report. Districts should be expected to inte-

grate biotechnology concepts and applications into revised K-12 science programs with student performances evaluated in an updated state assessment program.

3. Special emphasis must be placed on attracting women and other minority students to consider career opportunities in the biotechnology/biomanufacturing industry.

4. The model biotechnology program developed at Minuteman Tech as well as similar programs now being developed at Middlesex Community College and Boston University should be replicated in at least two other urban locations. Worcester and Boston would be suggested locations.

5. The Department of Education should fund the development of competency based curriculum projects in Biotechnology/Biomanufacturing. These projects would serve the following populations:
   a. The Vocational-Technical Student and Post Graduate.
   b. The Comprehensive High School Student (9-12).
   c. The Middle and Junior High Student (6-8).
   d. The Elementary Student (K-5).

6. The K-12 public educational system needs to more strongly focus on teaching the use of academic skills as they apply both to the world of work and to continued study. The SCANS report from the U.S. Department of Labor defines the focus for this need. The SCANS report should form the basis for both revising curriculum and evaluating school performance.

7. Without spending a major amount of money, the state should mandate informed and open guidance practices (K-8) on learning styles while requiring balanced information programs on high school options for students. Local school districts should be specifically evaluated by the State Department of Education on their effective use of the vocational-technical school option. Evaluation should also focus on increasing the applied component of their academic courses. This can be achieved by coordinating with a vocational-technical high school. Local districts should use the vocational-technical high school structure to offer technical literacy and career exploration programs to elementary and middle school students.

8. The Department of Education should encourage and subsequently evaluate partnership experiments at each new biotechnology education and training site. Such experimentation might involve:
   a. Student learning internships no restricted to the standard format of "cooperative education."
   b. Strategies using afternoon and evening classes, summer programs, on site education and training at industry facilities.

9. The establishment of mini-grants (public and private) of not less than $25,000 for schools and teachers. These mini grants will provide individual teachers and schools seed money necessary to begin to integrate aspects of biotechnology into their present curriculum structure.

10. Continue and expand funding sources (public and private) for projects that address education and training in Biotechnology.

11. Private biotechnology companies must be identified as partners to assist in the funding, evaluation, and development of educational training programs.

12. A resource center for teachers must be established. This center will provide technical assistance on curriculum materials, industry and educational specialists, and other resources necessary for those interested in developing or expanding a present or future Biotechnology program.

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