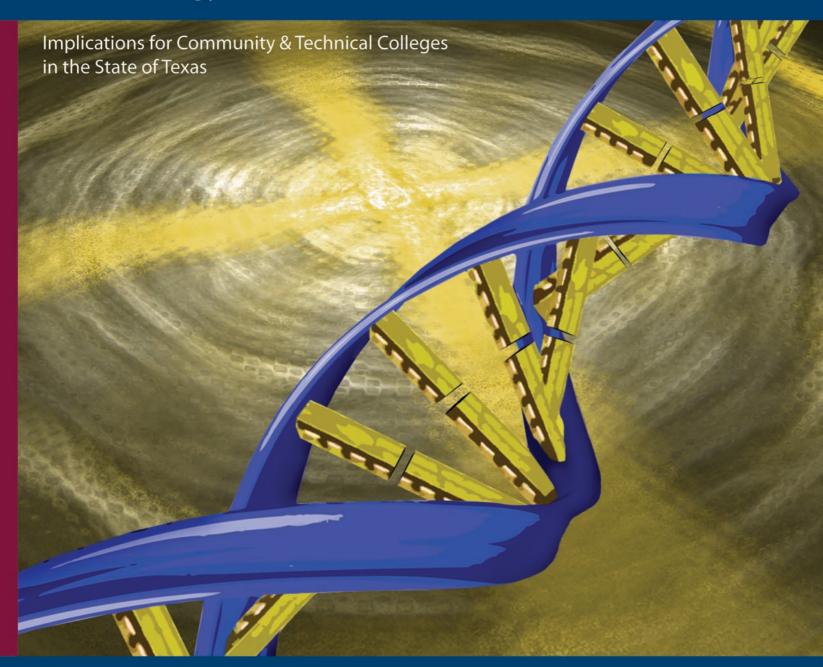
Biotechnology

A Technology Forecast



TECHNOLOGY FUTURES INC.

Authored by: John Vanston, Ph.D. & Henry Elliott, M.S.M.E.

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In February 2005, the Texas State Technical College System (TSTC) contracted with Technology Futures, Inc. (TFI) to conduct an analysis of the role of Texas community and technical colleges in the development of a strong, vibrant biotechnology industry in the state. The primary objectives of this project were to:

- Provide conclusions and recommendations for use by the Texas State
 Leadership Consortium for Curriculum Development (CCD), the Texas
 Higher Education Coordinating Board (THECB), and community and
 technical college (CTC) curriculum decision makers throughout the state
 when making strategic and informed decisions regarding developing new
 and/or updating existing educational programs related to the workforce
 needs of the Texas biotechnology industry.
- Provide assessments and technology forecasts, new and emerging workforce implications, and related curricula implications for four selected biotechnology topic areas.

This report presents the results of this analysis.

Report Organization

Chapter One is a list of recommendations for various organizations in the state offered by the authors. Chapter Two presents an overview of the biotechnology (biotech) field. Chapter Three will discuss the current status of Texas CTC biotech programs, including projections of employment opportunities in the state. Chapter Four discusses the four special biotech programs selected for analysis, i.e., DNA and human health, biotechnology systems instrumentation, bioinformatics, and bioagriculture. Chapter Five presents some general observations on the biotech industry in Texas, and Chapter Six presents a summary of the report, together with a group of general conclusions by the authors.

It will be noted that this report makes extensive use of appendices, both to provide additional related information and to expand some of information presented in various chapters.

Scope

The term *biotechnology* can have a wide range of meanings. In the broadest sense, it includes all technologies involved in human health care including drug and vaccine discovery and development, diagnostic procedures, and medical devices. It can also include technologies involved in animal and crop improvement, as well as technologies related to industrial production of pharmaceuticals, environmental protection and remediation, and associated research. For this analysis,

however, the following definition, utilized by the congressional Office of Technology Assessment is used, i.e., biotechnology includes "any technique that uses living organisms, or substances from these organisms, to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses." This definition is understood to include the development, testing, and production of pharmaceuticals and biotech products, but not medical equipment, such as x-ray or dialysis machines, nor nursing care.

In a similar manner, the term *technician* can be interpreted in many different ways. In this analysis, it is used to indicate those individuals who are charged with and have the capability of performing skilled tasks requiring special training and/or workplace experience. In biotech environments, these special skills include tasks such as installing, calibrating, maintaining, and repairing biotech equipment; conducting, analyzing, and recording experiments using knowledge and techniques developed from scientific research, including gene splicing and recombinant DNA; assuring product and process quality; and the general support of laboratory and manufacturing activities in biotech environments. Although the academic background of these technicians is varied, normally at least two years of post-high school training or equivalent job experience is required for employment success.

In this analysis, the term *biotech industry* is used to indicate all of the organizations that might employ biotech technicians, e.g., small startup companies, manufacturers of biotech products, research institutions, and university research laboratories. It will not include medical facilities, medical device manufacturers, doctor's office workers, or general support workers such as office staff, janitorial services, or administrative personnel.

Supporting Input

The information, assessments, and recommendations included in this report are based on five types of supporting inputs: searches of relevant literature references, a specially designed survey of Texas biotech organizations, a series of personal interviews, a structured meeting of experts in the biotech field, and prior experience of TFI in conducting related biotech analyses.

In conducting the literature search, dozens of reports, professional journals, news reports, and curricula descriptions were gathered and reviewed. The special survey was designed to primarily target Texas biotech industry representatives. The survey included 25 questions involving employment projections, required knowledge, skills and abilities, industry structure, and the utilization of state government support to promote biotech industry growth. Thirty-eight organizations participated in this survey. (A discussion of the conduct of this survey and a list of survey participants is presented as Appendix A.)

In this analysis, more than 30 formal interviews were conducted, in addition to a number of informal discussions. The people interviewed included the directors of all current Texas CTC programs, as well as a broad range of industry and institution

representatives, state officials, subject matter experts, and the director of an out-of-state community biotech program. (A list of interview subjects is presented in Appendix B.)

An important activity in this analysis was the conduct of a Biotech Experts Meeting in Austin on August 11, 2005. This meeting involved 11 participants with expertise in a variety of biotech areas, e.g., research, manufacturing, investment, law, and education, as well as two interested observers. (A discussion of this meeting, a list of meeting participants and observers, and the results of the meeting are presented in Appendix C.)

In conducting this analysis, the TFI team was also able to call upon its own experience in similar studies in the biotech industry, including analyses conducted for the Johns Hopkins Medical Center, the Central Indiana Life Sciences Initiative, the Greater Austin-San Antonio Corridor Council NanoBioTech Summit, and the National Security Agency.



Executive Summary

Overview

- In the world today, there is no field of technology that is more exciting, more dynamic, or more promising than biotechnology (biotech). Continuing advances in biotech have the potential to dramatically improve human health and wellness, provide more efficient food production processes, contribute to a cleaner environment, enhance homeland security, and support human identification techniques.
- As biotech research, development, and application has expanded, the biotech industry has become an increasingly important element of the nation's and, indeed, the world's economy.
- The development, government approval, and commercialization of new pharmaceuticals is a long, costly process, and the percentage of promising candidates that survive to commercialization is very small.
- Even the most successful startup biotech companies go through a series of funding arrangements. Typically, these arrangements involve the following chronological sequence of events: federal funding for basic research at academic and research institutions, funding from angel investors or Small Business Innovation Research grants to demonstrate the commercial potential of the transferred research, early and late stage venture capital funding for FDA clinical trails, a joint development partnership with a large pharmaceutical company, and product launch.
- The goal of modern biotechnology is to understand the precise function of certain cells and molecules, and exploit their properties in a way that can be targeted to solve specific problems while at the same time generating less harmful side effects and unintended consequences. The modern definition of biotechnology is not so much concerned with the principle of using organisms to accomplish certain tasks, as it is with the specific techniques for doing so, including DNA sequencing, molecular biology and chemistry; gene and molecular cloning; cell and tissue culture techniques; polymerase chain reaction; etc.
- In a technical area as broad, far-reaching, and rapidly changing as biotechnology, projecting the future is risky and uncertain. However, by examining the fundamental trends driving advances in biotech, a review of current and planned research projects, and discussions with qualified experts, the following projections appear to be valid:
 - For the foreseeable future, the biotech field will grow rapidly in terms of technical innovation, practical applications, and business opportunities.

- The use of automation and robotics will be of increasing importance in the biotech field, permitting improvements in efficiency, timeliness, and accuracy.
- Biotech will continue to converge with other developing technologies, such as health care, information technologies, and nanotechnology.
- Employment opportunities in the biotech field will grow rapidly over the next several years.

Texas CTC Biotech Programs

- Employment opportunities for graduates of Texas community and technical
 college biotech programs are generally good in terms of initial pay, interesting
 work, high probability for advancement, and long-term employment. Moreover,
 the market for CTC biotech graduates will grow steadily over the next few
 years, and there is a distinct possibility that the market could grow rapidly if
 efforts to expand the state's biotech industries are successful.
- There are at least three reasons to believe that employment opportunities for CTC biotech will become increasingly bright in the future: strong indications that the biotech industry (including research and development institutions) will grow appreciably in the near future; a growing awareness of the capabilities of CTC biotech graduates; and the fact that, as biotech activities move from research to development to commercialization, the percentage of technicians in the organization tends to grow.
- Employment opportunities vary with location. Because the Galveston/Houston
 area has the greatest number of biotech companies, as well as a number of major
 medical and research institutes, employment opportunities are greater there
 than in other areas of the state. Employment opportunities in the Central Texas
 corridor, i.e., the Austin/San Antonio/College Station/Temple area, may grow in
 the relatively near future.
- Starting salaries vary according to specialty area, geographical location, and ancillary training and experience. Depending on these factors, starting salaries vary from the high teens to \$50,000 or higher. Salaries typically increase significantly with experience on the job.
- Successful employment in the biotech industry and biotech research facilities
 requires a variety of skills, knowledge, and abilities. Basic science, mathematical
 and technical knowledge, manual dexterity, and mechanical ability are all
 important attributes for biotech technicians. Typically, employers prefer
 employees who are familiar with and competent in laboratory skills, who
 understand record-keeping requirements, and who are familiar with quality
 control and quality assurance procedures. Employers also place great
 importance on writing and verbal communication skills, the ability to work in
 teams, a problem-solving competency, and a strong work ethic.
- Students in biotech programs tend to have somewhat different backgrounds than those in most other programs. The average age, work experience, and

educational backgrounds of these students tend to be higher than normal. Many of these students are preparing for significant career shifts and bachelor and higher degrees are not uncommon. CTC biotech programs must be adjusted to meet these special needs, as well as those of students entering the programs directly from high school.

- Biotech programs are currently being offered at only a small number of CTCs in Texas, and the number of graduates from these programs each year is currently small. However, there are a number of CTCs that have initiated programs or are considering initiation. The programs at Montgomery College, Austin Community College, and Houston Community College-Northeast Branch are mature and well regarded and can serve as models for other CTCs initiating or expanding biotech programs. Many CTCs that do not currently offer biotech programs do offer programs that include many courses similar to those included in biotech curricula. These courses can, in many cases, provide a foundation for the initiation of a biotech program.
- The biotech education capabilities in the state are scattered throughout a variety of four-year colleges and universities, CTCs, and private education groups such as DeVry University. Coordination and sharing between the various educational institutions will not only strengthen the individual programs, but also the biotech industries of the state. Such sharing might include part-time use of special equipment, remote broadcast of lectures by specially qualified instructors, and short term "learning camps."
- In large measure, the employment prospects for CTC biotech graduates will be
 determined by the growth of the biotech industry in Texas. It is highly desirable
 that a trained workforce be available. Biotech companies and research
 institutions can contribute significantly to the effectiveness of CTC biotech
 programs through the use of such activities as providing equipment and
 supplies, making lab space available, offering internships to selected faculty
 members, and providing instructors for some classes.
- To meet the growing demand for graduates of CTC biotech programs, it will be incumbent on the CTCs both to increase the number of local programs and to increase the capacity of current programs.
- Although current CTC biotech programs indicate that their entry level students
 typically have extensive education and/or work experience, often in other fields,
 the directors agree that, in the longer run, the success of their programs will
 depend on greater direct input from high schools.
- There are a number of reasons why the development of a basic statewide core biotech curriculum for CTCs in Texas would be desirable.

Special Biotech Programs

Although it can be reasonably assumed that students successfully completing
any of the current or planned CTC biotech programs will have the KSAs
necessary for successful employment in the biotech industry, there is increasing
interest in the biotech field in a number of areas of specialization, including

bioinstrumentation, bioinformatics, DNA and human health, and bioagriculture. There is evidence that technicians trained in some of these specialty areas will be awarded by higher salaries, greater recognition, and greater opportunities for promotion.

- A tremendous amount of sophisticated equipment is employed to conduct research and product development in biotech environments. This equipment, which includes tools for automation (robots) and analytical instrumentation, is used to prepare samples and to conduct and analyze the results of experiments.
- Bioinformatics is the field of study that encompasses the creation and development of computational tools and information technologies that can solve problems in molecular biology (National Bioinformatics Institute, 2001). Bioinformatics allows researchers to store, retrieve, and sift through large biological data sets containing information about gene sequences and expression (genomics), protein production (proteomics), and biological structures and interactions. The ultimate goal of this work is to give scientists models they can use to predict the behavior of complex cell processes and their effect on macrolevel biological events such as diseases and drug reactions.
- Using their knowledge of DNA and its relationship to the other basic building blocks of life, scientists have developed a number of tools that manipulate genetic material at the molecular level. These tools, known collectively as biotechnology, employ biological materials and their components to produce a wide variety of products and services. Among these products and services are a number that can be used to ameliorate various health problems including antibiotics, insulin, pharmaceuticals, DNA-based vaccines, and genetic tests that can uniquely identify individuals and diseases.
- Because agricultural products are an important component of the Texas
 economy, Texas agricultural producers are constantly developing new
 production practices and techniques to maintain and extend their competitive
 advantage. The use of biotechnology to facilitate agricultural production
 (bioagriculture) is one of the tools that producers that are using to facilitate
 this goal.

Status of Biotech in Texas

- Although Texas has a number of very strong research institutions and a long history of biotech discoveries, the commercial biotech industry in Texas lags well behind the industries in Massachusetts, New York, North Carolina, and, particularly, California. The primary cause of this lag is the lack of a strong biotech commercialization infrastructure in the state, namely the small number of venture capitalists knowledgeable in biotech investment, and a shortage of experienced executives in biotech. However, there is considerable awakening interest in biotech in Texas, and the state could become a major biotech player in the relatively near future.
- A major problem for Texas biotech businesses is the difficulty of obtaining capital, particularly when the product they are developing is approaching or in Phase I clinical trials. The Governor's Emerging Technology Fund, which was

signed into law in June of 2005, will help overcome this problem. The Fund has allocated \$200 million for the commercialization of technologies developed in Texas. The first ever grant from the fund, worth \$2 million, was awarded to Texas Tech to create the Center of Excellence for Agricultural Genomics and Biotechnology. The Center will assist in the commercialization of bioagricultural products developed by commercial and academic entities in the region.

- The growth of a strong biotech industry in Texas would be greatly facilitated if the various academic, research, and capital providers selected a particular area for concentration and formed cooperative agreements.
- There is currently a significant amount of biotech activity going on in Texas, and this activity promises to be significantly expanded in the relatively near future. Many regions across the state are developing organizations to foster the growth of biotech activities in their region. Although the Houston/Gulf Coast region (Houston Medical Center, Woodlands Research Park, and Galveston) is clearly the leader in biotech research and commercialization, biotech activities in other regions of the state are beginning to emerge. These regions include Central Texas (Austin, San Antonio, and Waco), Dallas-Fort Worth, and West Texas (Lubbock).
- Although Texas research institutions generate a significant number of new patents and discoveries, the number of these that are translated into successful businesses in Texas is small.
- One major trend that might offer a very significant opportunity for Texas is the growing convergence of a number of the most important emerging technologies, i.e., biotechnology, nanotechnology, medical technology, and information technology. Texas has strong positions in each of these fields, and, if it can develop a structure for effectively integrating these technologies, it can establish itself as a leader in the convergence area.



Chapter One: Recommendations

The recommendations presented in this section are based on the following convictions:

- Biotechnology (biotech) will continue to grow rapidly in terms of importance, impact, and business opportunity.
- It is possible for Texas to play a major role in the growth and expansion of the biotech field.
- Texas must have a highly-trained workforce consisting of people with Ph.D.,
 Master, bachelor, and associate degrees in biotech related disciplines in order to successfully compete in the biotech industry.
- The community and technical colleges (CTCs) of the state can play a significant role in providing an important portion of this trained workforce.

Although the primary focus of this project was on the roles of the state CTCs in the emerging biotech field, those roles will be closely tied to overall development of biotech in the state. This development will be defined by the combined actions of biotech companies, advocacy groups, academic and research institutions, and state and local governments. As a consequence, recommendations are presented for these groups, as well as for CTC decision makers and those groups affecting CTC decisions.

Recommendations for Community and Technical Colleges

Today's CTC biotech programs can be logically grouped into three categories: those with mature programs; those with emerging programs; and those with no current programs. The situation in each of these groups is different and, therefore, recommendations to the groups are also different.

Recommendations to CTCs with Mature Biotech Programs

There are a number of mature biotech programs in the state. These programs have long-standing relationships (over five years) with biotech employers in their regions, and have graduated a number of students who have found successful employment in these organizations. The directors of these programs have indicated that there is a strong demand for graduates of their programs, and they expect this demand to grow in the future as biotech activities in the state continue to grow. These programs have developed a number of activities, including biotech outreach and awareness programs to local high school students that are excellent models for new and emerging biotech programs.

1. Offer both degree granting programs and specialized certificate programs to accommodate both full-time and part-time students.

In a field as rapidly changing as biotech, it is essential that technicians have the knowledge, skills, and abilities (KSAs) necessary to deal effectively with advances in technology. In addition, many graduates will desire to upgrade their skills to move up their career lattices. Both of these goals can be well served by courses designed to meet these special needs. The courses will be of value, not only to CTC program graduates, but also to other interested students.

Nicholas Cram, Coordinator, Biotechnology Systems Instrumentation Program, TSTC Waco

Retraining should be an important part of CTC biotech programs. A reasonable mix would be one half of the students involved in degree-granting programs and one-half involved in part-time programs that result in advanced training certificates.

Dr. Larry Loomis-Price, Biotech Program Director, Montgomery College

The job titles of technicians that perform the exact same tasks at different companies often vary. There is a need to standardize job titles and job descriptions. These titles and descriptions should be skill based not degree based.

2. Maintain a liaison with institutions that participate in local advisory committees and other current or potential employers.

Dr. Larry Loomis-Price, Biotech Program Director, Montgomery College

An important factor in building a viable program is the advisory committee. It is extremely important for a biotech program to have local biotech industry involvement. In fact, a program should not be in place until an advisory committee is formed and there is a demonstrated demand for employees. Because biotech lab techniques are constantly changing, it is important that biotech programs regularly probe their advisory boards and seek advice on curriculum changes and updates.

All CTC biotech programs are required to form local advisory committees, and all current mature programs are actively involved with their committees. These advisory committees are composed of representatives from the range of organizations with whom the CTC programs actions have a direct effect. These organizations include private and public entities that will hire program graduates, four-year colleges and universities that have entered into articulation agreements with the CTC, and representatives of local high schools that feed students into the program.

These committees help to ensure that programs remain current and relevant to local industry needs and often provide support in terms of state-of-the-art equipment and lab facilities, part-time instructors, and assistance in placing graduates. CTCs must continue to take full advantage of the support of their local advisory committees.

Dr. Lisa Lock, Biotechnology Coordinator, El Centro Community College (Dallas)

El Centro has the equipment for basic testing—incubators, PCR testing, etc. However, the program doesn't have the more expensive equipment like the big sequencers. To fill this gap, the program will take students on field trips to places like UT Southwestern or other labs. Students will do research on the equipment so that they are at least familiar with its function. In some ways, this is a more effective way of establishing the program because the equipment becomes obsolete very quickly.

3. Plan for expansion of current programs.

Representatives of the biotech industry in Texas have indicated that there will be a marked increase in the demand for the special qualifications of CTC biotech graduates over the next three to five years. Therefore, today's mature programs are making plans to expand the capacity of their programs, and these expansion plans must continue.

Additionally, many CTCs are taking positive steps to ensure that their biotech programs reflect the forefront of advances in the field. This is being accomplished by providing funds for in-service training for faculty members, including internships or fellowships with biotech industries, the use of industry experts to teach courses, and the encouragement of program graduates to return to the college for additional training.

Dr. Larry Loomis-Price, Biotech Program Director, Montgomery College

Adjunct faculty from industry is an important part of biotech programs. They are familiar with the latest techniques and have a lot of credibility with students. ("This is what you need to know to get a job in this industry.")

4. Expand interactions and partnerships with other CTC biotech programs.

The directors of the state's mature CTC biotech programs have maintained close interaction among themselves, both by direct interaction and through the BioLink organization. An example of this cooperative relationship is provided by the fact that the programs at Montgomery College, Austin Community College, TSTC Waco, and a number of other colleges partnered in a joint proposal to the Department of Labor for biotech education funding.

Coordination and cooperation between CTCs is being significantly enhanced by the membership of a number of CTCs in the Life Sciences Technology Consortium, which is led by the University of Houston College of Technology. Mature CTC biotech programs should play a lead role in the sustainment and expansion of such efforts.

5. Support awareness and outreach programs that publicize the attractiveness of a biotechnician career path and the overall importance of biotech to the public.

Although there are strong indications that career employment opportunities for CTC biotech program graduates are very promising and that these opportunities will continue to grow for the foreseeable future, few high school students, faculty members, or career advisors are truly aware of these opportunities. Awareness and outreach programs that promote activities, such as visits to schools, internship programs and conferences for high school science teachers, and the establishment of dual enrollment and Tech Prep programs that allow high-school students to conduct projects or take courses that can result in advanced credit when entering a CTC program are excellent ways of educating students about possibilities in the biotech field. These activities promote the smooth transition of students from high school to CTC biotech programs.

Janet Varela, Production Director, Kelly Scientific

It is important to have outreach to high school programs about biotechnology. Students typically don't think of biotech as a career path. Linnea Fletcher, director of the biotech program at ACC, has one of the best high school outreach programs in the nation. She does targeted recruiting and offers dual credit courses that high school students can use for credit toward both their high school diploma and associate degree.

Linnea Fletcher, Department Chair of Biotechnology, Austin Community College

In time, the introduction to biotech that is being started in high schools will migrate to middle schools and later to primary schools.

In most Texas communities, there is little realization of the positive value of biotech to individuals and the community. Janet Varela, Outreach Director for the Montgomery College Biotechnology Institute (MCBI), visits local high schools and speaks about career opportunities in biotech. To stir students' interest, she encourages them to conduct basic biotech lab procedures. In one such experiment, students actually extracted DNA from a strawberry. According to Varela, the MCBI outreach programs are very successful at feeding students into the Montgomery program.

Dr. Larry Loomis-Price, Biotech Program Director, Montgomery College

It is important for biotech programs to separate the administrative and outreach functions—each of them is a full time position. A mistake a lot of the new biotech programs have made was that their directors tried to fill both functions, which meant that both functions suffered.

Recommendations to CTCs with Emerging Biotech Programs

To meet the growing demand for a biotech technical workforce, a number of new biotech programs have emerged in the state within the past one to three years. These emerging programs have so far produced only a limited number of graduates. Although these programs do not have long-standing relationships with biotech-related organizations in their regions, the directors of these programs strongly believe that the demand for graduates of their programs will grow as biotech activities in the state expand.

6. Tailor your program to meet the needs of your community, including the ability to rapidly expand capacity of programs if needed.

Most emerging biotech programs have established program curricula and tailored their programs to meet local needs. Obviously, students would be ill-served by programs that prepare them for nonexistent jobs. However, because the potential for rapid growth exists, the need for biotech graduates may increase considerably in a small amount of time, and these CTCs will be well advised to structure their programs for expansion if demand increases sharply. This could involve identifying the resources needed for such an expansion and giving early planning to how those resources could be provided.

Lisa Lock, Biotechnology Coordinator, El Centro Community College (Dallas)

In the future, the number of students in the program will be wholly dependent on the needs of the local biotech industry. If that community comes to Dallas Community College and expresses a need for more biotechnicians, then the college will expand to meet that need. The program will not expand unless there are demonstrable opportunities for its graduates.

Jason Moore, Manager of Industry Programs, BioHouston

All of the universities and community colleges in Texas need to begin exploring ways in which they can create biotech programs. It will take awhile to develop such programs, so they need to get started as soon as possible or they will be behind the curve when the industry begins to ramp up.

7. Consider "near biotech" programs.

Many of the KSAs required for biotechnicians are very similar to those of other technology areas, e.g., clinical diagnosis, health care, animal husbandry, or agriculture technology. In situations where there is little current need for biotechnicians, but there are indications that this need may grow over time, CTCs could organize specialized courses that offer students training in various biotech techniques within existing non-biotech programs. Graduates of such programs would have immediate employment in an associated area, but could later become qualified for biotech employment by completing a small number of biotech related courses.

Lisa Lock, Biotechnology Coordinator, Dallas Community College -El Centro

A number of our students enroll in a dual curriculum program that combines elements of medical laboratory training and biotechnology. This pairing has been a great match. These students are able to use molecular biology techniques that they learn in the El Centro program in the traditional clinical laboratory setting which has been very appealing to employers.

Nicholas Cram, Coordinator, Biotechnology Systems Instrumentation Program, TSTC Waco

There are no standardized job descriptions for many of the important biotechnician positions, but the skill sets for many of them are quite similar. The basic skills required for biotechnicians in the various areas include familiarization with validation procedure, quality control assurance, instrumentation, and laboratory techniques. Writing and presentation skills are also of critical importance.

8. Examine the possibility of resource sharing.

Often, emerging CTC biotech programs have limited resources to devote to the program, particularly if the number of students involved is small. In such cases, programs should consider the possibility of sharing resources such as lab space, special equipment, and qualified faculty with other biotech institutions in their communities. For example, students in the Galveston College biotech program complete the lab portion of their courses at the University of Texas Medical Branch Galveston campus. In a similar manner, students in the El Centro program perform basic laboratory procedures, such as cell culture techniques and Polymerase Chain Reaction (PCR) testing on campus. However, they also take field trips to other labs in the Dallas region, such as UT Southwestern, to obtain experience in the use of more expensive equipment, such as DNA sequencers. In some ways, this kind of resource sharing is a more effective way of establishing biotech programs because laboratory equipment is expensive and often becomes obsolete very quickly.

Recommendations for CTCs with No Current Biotech Programs

The majority of CTCs in the state do not have biotech programs. However, biotech related activities are expected to have a major impact across the entire state, even in those regions where direct biotech employment is not significant. Therefore, CTCs should be aware that, while the demand for biotech programs may not currently exist at their institution, this situation could quickly change.

CTCs without current programs should be very cautious about initiating such programs.

The demand for biotechnicians varies greatly between geographic areas in Texas. Moreover, the cost of initiating such a program can be very large. Therefore, CTCs without current programs should very carefully consider the costs and benefits of starting a new program. If there is not a reasonable prospect of biotech companies or research institutions being established in the area or other indications that there will be a number of interested students, it may be better not to make the investment.

Dr. Larry Loomis-Price, Biotech Program Director, Montgomery College

Entry costs of establishing new biotech programs are quite high. A qualified faculty is expensive and difficult to find. Equipment and supplies are also expensive.

Recommendations for the Texas Leadership Consortium for Curriculum Development (CCD)

Based on the results of this project, detailed recommendations, along with the rationale supporting them, were submitted to the CCD. In the following paragraphs, these recommendations are summarized. More detailed information involved in the recommendations is presented in Appendix D.

10. Fund the establishment of a formal CTC Biotech Consortium.

This Consortium would provide the following functions:

- Develop a standard, approved basic biotech curriculum. (See next recommendation)
- Form statewide partnerships that include representatives from the biotech industry, the biotech research community, state and local economic development officials, educational institutions, and the Texas Workforce Commission.
- Work jointly to better leverage combined assets to increase the likelihood of award in federal and state grant and funding activities.
- Take positive actions to assure that CTC biotech programs keep abreast of changes in the biotech environment.
- Establish a framework for continuing education for CTC graduates and other technicians requiring additional training.
- Attract out-of-state biotech companies and research institutions to move to Texas and motivate Texas companies to stay in the state by promoting Texas as an emerging biotech center.
- Create a plan for rapidly increasing the number and size of CTC biotech programs in Texas to enhance the attractiveness of the state to out-of-state biotech companies and research institutes.

11. Fund a curriculum development project that defines a statewide core curriculum in biotechnology.

Although the actual subject matter taught in each individual course would continue to be shaped by the needs and expertise of local industry, development of a core curriculum would serve several functions:

 Define the knowledge, skills, and abilities needed for entry-level positions in various biotech job areas. The KSAs will include those already defined in the widely-accepted "Biotechnology and Biomedical Skill Standards" document published by the Washington State Board for Community and Technical Colleges.

- Facilitate the seamless transition of students from high school to CTC biotech programs.
- Make it easier to construct One–Plus-One articulation agreements between CTCs.
- Facilitate the seamless transition of graduates of CTC biotech programs to four-year colleges and universities through the establishment of Two-Plus-Two articulation agreements.

12. Fund the development of a series of new bioinstrumentation courses that may be easily replicated at various CTCs in the state.

There appears to be considerable interest among Texas biotech organizations for bioinstrumentation technicians. The development of syllabi, learning plans, and assessment plans for the following courses (as outlined by the CCD) would greatly facilitate the effective training of such technicians.

BITC 2372	Introduction to Bioinformatics & Biostatistics
BITC 1271	Food and Drug Biotechnology
BITC 2373	Functional Genomics, Proteomics, & Metabolomics
BITC 2478	Biotechnology Device Instrumentation I
CETT 1479	Solid State Components & Applications

The development of these courses would be greatly assisted if special funding were provided by the CCD. Several colleges with existing biotech programs have expressed an interest in offering one or more of these same courses, and CCD funding would assist in the replication of these courses.

However, at this time, we do not recommend that complete bioinstrumentation programs be duplicated at other CTCs throughout the state.

13. Fund the development of one or more standardized courses in bioinformatics for the state's CTCs.

Because of the increasing need for gathering, analyzing, storing, and archiving data in biotechnology, the inclusion of one or more courses in bioinformatics would be desirable for most biotech programs. However, because of the uncertain nature of meaningful employment of bioinformatics specialists at this time in Texas, funding for stand-alone bioinformatics programs is not recommended.

14. At this time, do not fund the establishment of new programs in the DNA and human health care area.

There are a number of CTCs that have programs that can provide models for program replication in the DNA and human health-care area; therefore it is not recommended that the CCD fund the establishment of any new programs in this area.

15. At this time, do not fund the establishment of new programs in the field of bioagriculture.

Because of the limited current demand for CTC bioagriculture graduates and the relatively low salaries expected for such graduates, funding the establishment of formal bioagriculture programs is not recommended at this time.

Texas State Government

Governor Rick Perry has enthusiastically committed the resources of the state to supporting programs that bolster the international competitiveness of Texas institutions in emerging fields of technology such as nanotechnology and biotechnology. This assistance includes direct monetary grants to private sector employers who create high-paying, high-tech jobs through programs such as the Texas Enterprise Fund and the Emerging Technology Fund and also tax incentives (abatements). This support also includes the resources of agencies such as the Texas Workforce Commission, the Texas Education Agency, and The Higher Education Coordinating Board, whose activities are essential to helping Texas create a workforce that can support emerging technology industries. The recommendations in this section are directed specifically to state agencies that can play a direct role in bolstering the state's biotech industry.

Dr. Larry Loomis-Price, Biotech Program Director, Montgomery College

Texas has a solid biotech research foundation, but has not done well in the area of commercialization. This is because the region has not done well at the super-organization level. The state has not done a good job of offering the kinds of incentives that would foster the development of a biotech industry. These incentives include items such as tax breaks, lab space, financial incentives, and workforce development at the technician level.

16. Initiate public awareness campaigns that increase public awareness of the attractiveness of careers in biotech.

In many cases, the general public's understanding of biotechnology is based on horror motion pictures and lurid articles in the media about cloning, runaway microbes, and the dangers of genetically modified food. The state should take advantage of opportunities such as news articles, local TV and radio broadcasts, and open houses to provide a realistic picture about the current value and future promise of biotech products and processes. This could be done through public service announcements and similar marketing approaches.

Dr. Linnea Fletcher, Department Chair of Biotechnology, Austin Community College

The state must increase public awareness of the new high-tech blue collar positions that are available through education at state CTCs. The Department of Labor has funded television spots in North Carolina that advertise the existence of careers in biotech.

As a corollary, the Texas Workforce Commission should fund programs designed to educate Texas citizens about the possibilities of careers in biotech. Such a picture will serve as a basis for citizens to make informed decisions about careers in biotech.

For example, Dr. Andy Vestal, Assistant Professor and Extension Specialist in the Department of Agricultural Education for the Texas A&M University System, conducts summer conferences in biotech for high school teachers. The one-day conferences, conducted in conjunction with UT Southwestern and the University of Texas Dallas, are held at the Texas A&M Dallas agricultural campus. The annual conference, first held in 2001, brings scientists to labs and classrooms at the A&M–Dallas campus. The scientists develop materials and lesson plans that are used to educate high school teachers, usually senior biology educators, about various biotech lab techniques and practices. Typically, 100 teachers attend the conference. The subjects taught include bioethics, stem cell research, animal cloning, animal gene knockout technology, plant and crop biotechnology, safety of genetically modified organisms, etc. In turn, these teachers return to their home schools and inform other teachers ("teach the teachers") and students of the opportunities that careers in biotech can present.

17. The Texas Enterprise and Emerging Technology Funds should provide funding for early stage biotech companies, particularly those in the "death valley" between federal funding for basic research and early stage venture capital.

A major obstacle to the growth of the biotech industry in Texas has been the inability of Texas entrepreneurs to obtain the funding, e.g., venture capital, necessary to commercialize biotech research. It is the belief of many observers that Texas probably generates the least commercialization activity for the most world class biotech research of any region in the world. Funding for such ventures has been concentrated on the preclinical period (including pharmacology and toxicology), i.e., the period between the discoveries of a suitable drug target (most commonly basic federal research funding) and Phase I trials (early stage venture funding).

The National Institutes of Health (NIH) Small Business Innovation Research program has supported ventures in the conduct research in this so called "death valley" stage, but companies that win such grants usually receive no more than one million dollars, which is about 1 percent of the amount needed to bring a new drug to the market. State programs, such as the Governor's new Emerging Technology Fund, intended to fund the development of high tech businesses that create high quality jobs, are appropriate vehicles to fund companies in this stage of their development.

Dr. Linnea Fletcher, Department Chair of Biotechnology, Austin Community College

One major problem for Texas is that intellectual capital leaves the state because companies can't get venture capital funding.

Dr. Dennis Stone, Vice President for Technology Development, University of Texas – Southwestern

Availability of venture capital funds is of increasing importance for start-up companies. It is very difficult to attract east and west coast money to Texas venture deals; they expect deals here to be much further along than home deals. They see this strategy as a way of de-risking the investment for themselves since they can't keep a close eye on them. I am aware of a startup spun out of UT Southwestern that had trouble raising \$500,000 in venture funding. The company had to move to Colorado to raise money.

Dr. Mitzi Martinez Montgomery, Vice President of Discovery and Preclinical Development, PharmaFrontiers

The Texas Emerging Technology Fund promises to be a great source of funds for biotech companies.

18. Establish articulation agreements between CTCs and four-year colleges and universities.

In order to gain maximum value from the educational resources of the state, it is highly desirable to have articulation agreements among CTC biotech programs and between CTCs offering biotech programs and four-year colleges and universities. Such agreements will support the smooth transfer of credits between these institutions. Several CTCs have such agreements with specific colleges and universities, but general agreements between all CTCs and appropriate colleges and universities would be highly desirable. The Texas Higher Education Coordinating Board would play an important role in determining the appropriateness of such agreements. Another organization whose input will play an important role in the construction of such programs is the Southern Association of Colleges and Schools (SACS), the accrediting agency for state CTCs. Currently, SACS faculty credential guidelines require that courses designed for transfer to a Bachelors degree granting institution must be taught by faculty with a Masters degree in the discipline being taught or a Masters degree and at least 18 graduate semester hours in the teaching discipline. This requirement may pose a problem in the construction of articulation agreements and is a subject of intense debate.

Nicholas Cram, Coordinator, Biotechnology Systems Instrumentation Program, TSTC Waco

Some 30 to 40 percent of positions now offered in the biotech industries can be well filled by CTC graduates with AAS degrees. Other positions may well require a higher-level degree. Therefore, it is important that the CTCs partner with four-year colleges or universities. The two-year program will provide a solid preparation for a BS degree. This is particularly true for bioinformatics.

Dr. Linnea Fletcher, Department Chair of Biotechnology, Austin Community College

Texas should create mechanisms to mandate articulation between twoyear programs and four-year year colleges. This will make students more comfortable about entering programs.

19. Provide funding and political support for programs designed to increase awareness of the state's biotech advantages.

Although Texas currently does not have a reputation as a strong player in biotech, there are a number of activities—commercial, government, and academic—designed to increase the state's position in this area. It is important that the changing state of biotech in Texas be brought to the attention of companies and other organizations looking for favorable environments in which to locate. The Division of Economic Development and Tourism, within the Governor's Office, currently conducts such activities to promote the tourism, agricultural, and film industries. With regard to the biotech industry, promotional activities might include newspaper, radio, and television public service announcements, and/or mobile laboratory demonstrations that allow students and public to complete hands on biotech lab procedures, e.g., basic sequencing and DNA fingerprinting.

Dr. Larry Loomis-Price, Biotech Program Director, Montgomery College

The rest of the country does not think about Texas when it thinks about the biotech industry. That lack of visibility needs to be changed.

Jason Moore, Manager, Industrial Programs, BioHouston

The growth of a biotech cluster in a region requires three factors: (1) top researchers, (2) early stage funding (3) increased awareness of biotech industry so that senior, seasoned executives feel comfortable moving here. These executives need to be assured that if the company they relocate for goes under; there will be other opportunities for them in the region.

Joint Activities

Collaboration among private and public entities with a stake in the biotech industry is essential to the growth of the industry in Texas. Every region in the nation with a significant biotech cluster has placed a strong emphasis on collaboration. These collaboration organizations support networking and resource sharing among biotech stakeholders and also support training and public outreach to promote an understanding of their region's biotech environment. To a large degree, the ultimate success of the state's biotech industry will rest on how well these collaborative organizations manage the implementation of their various strategic actions. A model of such an organization is SEMATECH, which works with its member organizations to find ways to speed development, reduce costs, share risks, and increase productivity in the semiconductor manufacturing area.

Several areas where the joint actions of a number of interested parties might have impact are discussed in the recommendations below

20. Clarify the biotech investment climate in Texas.

Academia, venture capitalists, and industry must clarify the state's biotech investment climate. Unfortunately, most of the state's venture capital community has experience in the semiconductor, software, and telecommunications industries, but they are not familiar with the unique challenges of biotech investments. These

challenges include great technical risk and long commercialization cycles that can easily consume hundreds of millions of dollars in equity funding.

Fortunately, many in the state have recognized this problem and are exploring ways to address it. For example, BioHouston was formed to address the concern that large amounts of important biotech-related research generated in the Gulf Coast region was being commercialized elsewhere. BioHouston's goal is to reverse that trend by bringing together representatives from the offices of technology transfer and commercialization at academic institutions, service providers (accountants and attorneys), and investors to shed light in biotech investment opportunities in the region. Similar organizations in other parts of the state could prove quite valuable.

Donald Hicks, Professor, Political Economy and Public Policy, University of Texas at Dallas

Texas' biggest chokepoint is that the Texas venture capital community is not familiar with biotech investments, e.g., risk factors, huge amount of resources, long commercialization cycles. They are familiar mostly with semiconductors, software, and telecommunications, and they don't understand how to invest in the biotech industry. That is starting to change: Startech in Dallas has put money into a small handful of biotech startups including Reata and also ODC Technology which was launched out of Baylor Research Center.

21. Facilitate resource sharing among biotech companies.

In order for Texas to successfully develop its biotech industry, there must be a feeder layer of growing companies capable of providing a wide range of specialized technical support services and, correspondingly, a variety of employment experiences for biotech technicians. According to many knowledgeable observers, Texas is lacking in this aspect, and collaborative organizations composed of a variety of biotech stakeholders could help close this gap. Such organizations could assist biotech companies in the development and use of tools and services that each individually might find too expensive to support. These organizations would also be well positioned to identify skill gaps in the biotech workforce and to suggest training programs to fill them.

An example of such a group is the still evolving Center for Life Science Technology based at the University of Houston's College of Technology. The goal of the Center, which was started in 2005, is to create technicians and technologists or scientists that support high-end research and science for an M.D. or Ph.D. investigator or biotech entrepreneur. The Center is interested in using similar workforce training centers in Maryland, Wisconsin, and California as models. These centers are actually profit centers that perform services such as recombinant DNA production. The ultimate goal of the center is to create mock facilities that train technicians in various biomanufacturing tasks, including quality systems management, current good manufacturing practices (CGMP), current good clinical practice (CGCP), and current good laboratory practices (CGLP). The creation of such facilities would facilitate statewide training for biotechnicians that individual CTCs might be unable to support because the equipment is too expensive or qualified trainers are too hard to find.

Lee Rivenbark, Director of Cotton Operations for Region Americas, Bayer Crop Science

It is imperative that the biotech industry and the academic community work together more closely. Useful actions could include business internships for students and professors, business professionals serving as adjunct professors, and academics and business personnel working together to develop effective curricula.

Christopher Baca, Director of Center for Life Sciences Technology, University of Houston, College of Technology

The University of Houston, College of Technology, has stepped forward to facilitate the creation of the Center for Life Sciences Technology. The goal of the Center is to create regional training programs for creating a technician workforce for the biotech community. The Center is working with a broad range of entities in the region that have an interest in facilitating the development of a vibrant biotech sector. This includes representatives of all the community colleges that have biotech programs, regional universities with biotech programs from Texas A&M in College Station to University of Texas Medical Branch in Galveston, research universities with biotech research programs (Baylor College of Medicine, MD Anderson Cancer Center, Texas A&M , UTHSC Houston, UTMB Galveston, UH, and Rice), biotech companies, and regional economic development agencies, and nonprofits (BioHouston, Houston Technology Center).

22. Support increased coordination among biotech entities to better leverage state and federal funding.

Federal and state funding of biotech activities has been central to the development of the biotech industry in the United States. It is widely accepted that, in order for biotech to become an important driver for economic growth in the state, Texas biotech institutions must participate in collaborative activities that allow them to more effectively compete for and utilize such funds.

This includes joint grant applications to federal organizations interested in fostering the development of the biotech industry, such as the National Science Foundation, the Departments of Labor and Agriculture, and the National Institutes of Health. Examples of such collaborations exist throughout the United States, including the nonprofit San Diego Multiuse Biotechnology Center, which allows all tiers of academic institutions within the San Diego area to collaborate on workforce training initiatives (Panetta, 2005).

In 2003, then California Governor Gray Davis signed into law a bill that allows various state and local entities in the region, including the San Diego Community College District, California State University, University of California, Employment Development Department, Employment Training Panel, California Health and Human Services Agency, California Workforce Investment Board, and the San Diego Workforce Partnership, to cooperate through the San Diego Multiuse Biotechnology Training Center and apply for state, federal and private funds to finance the center. The goal of the center is to help the San Diego region maintain its status as the leading region for biotech commercialization in the world.

Dr. David G. Gorenstein, Associate Dean for Research, University of Texas Medical Branch at Galveston

Since the 9/11 disaster, the funding for infectious diseases has gone from essentially zero dollars to six billion dollars a year. NIH has also funded two National Biocontainment Labs, one of which is to be located at UTMB-Galveston. The lab is a \$160 million facility, and it is estimated that it will create thousands of jobs. Educated, highly-qualified technicians will be essential to developing this laboratory. UTMB-Galveston believes that community colleges will be an essential provider of such techs.

23. Establish an organization to promote convergence of emerging technologies.

One of the most important current technology trends is the growing convergence of a number of emerging technologies, i.e., biotechnology, nanotechnology, medical technology, and information technology. Because Texas has strong positions in each of these fields, it is quite possible that the state could establish itself as a top player. To accomplish this objective, a state-wide structure must be established for to effectively integrate these technologies. This structure can be based on the expansion of the scope of a current organization, such as BioHouston or the Gulf Coast Consortia in the Texas Medical Center.

A different and possibly more effective approach might be the establishment of new state-wide private organization or association dedicated from the outset to promoting convergence programs. The NanoBiotech Summit and Digital Convergence Initiative, which are sponsored by the San Antonio Corridor Council, serve as useful examples of such organizations.

Overview

Although the recommendations offered in this section are listed for different state entities, it is obvious that the development of a strong biotech environment in Texas will depend on a coordinated effort by the groups involved. As a consequence, many of the recommendations overlap. For example, the importance of enhancing biotech awareness in the State is indicated in each of the group recommendations. It is important that each of involved entities be alert to and supportive of the actions of each of the other groups.



Chapter Two: Biotechnology Overview

In the world today, there is no field of technology that is more exciting, more dynamic, or more promising than biotechnology (biotech). Continuing advances in biotech have the potential to dramatically improve human health and wellness, provide more efficient food production processes, contribute to a cleaner environment, enhance homeland security, and support human identification techniques.

For at least 5,000 years, humans have made advantageous use of biological components and processes. The biological properties of yeast, a microorganism, have been used for thousands of years to make bread and cheese and ferment alcohols such as wine. Furthermore, people have selectively bred animals and plants to develop offspring with certain desirable characteristics. However, the nature of biotechnology changed radically with the discovery and identification of the structure of DNA as the foundation of genetic material by James Watson and Francis Crick in 1953. Using their knowledge of DNA and its relationship to the other basic building blocks of life, scientists have developed a number of tools that manipulate genetic material at the molecular level. These tools, known collectively as biotechnology, employ biological materials and their components to produce a wide variety of products and services including antibiotics, insulin, interferon, genetically modified crops that repel pests naturally, microbes useful for remediation of environmentally harmful substances, and genetic tests that can uniquely identify individuals and diseases (Friedman, 2005).

Since the Watson and Crick discovery, scientists have been working to understand the roles of genes, RNA, proteins, and metabolites in human and other animal biological systems. Understanding gene expression at the global level of the genome, proteome, transcritpome, and metabolome will provide unprecedented opportunities to help explain the unknowns of biological processes. Scientists will be able to complete comparisons of the different functions of various cell types, tissues, and entire organisms (National Centre for Plant & Microbial Metabolomics, 2005).

As scientists are gaining increased understanding of biological processes, new approaches to drug discovery are being developed. Currently, drug development involves an elaborate series of activities, i.e., identifying an attaching molecule, identifying drug targets, determining the targets that are important to successful treatment, finding molecules that are capable of attaching to the appropriate targets, identifying promising compounds, and testing for safety and efficacy. This process can take a number of years and is very costly. In some cases, pharmaceutical companies (pharmas) have been able to design new hit compounds using "rational drug design," i.e., design based on knowing the structure and function of target molecules. As understanding of biological processes continues to grow, use of rational drug design processes will undoubtedly grow in importance. This understanding will also promote the ability to target design for specific population groups and even individuals. This will not only reduce the cost of drug development and testing, but will also enhance treatment efficacy (Golan, 2005).

Bill Gates, New York Times (June 18, 1996)

Sometimes people ask me what field I'd be in if not computers. I think I'd be working in biotechnology. I expect to see breathtaking advances in medicine over the next two decades, and biotechnology researchers and companies will be at the center of that progress.

Biotech Industry

As biotech research, development, and application have expanded, the biotech industry has become an increasingly important element to the nation's and, indeed, the world's economy. A recent study by Ernst & Young found that the revenues of the world's biotech companies reached an all time high of over \$63.1 billion dollars in 2005, an increase of over 18% from the previous year. The same study found that the global biotech industry raised \$19.7 billion dollars in capital funding in 2005 (Ernst & Young, 2006).

The impact of biotech on the nation's economy is further reflected by a recent publication by the Biotechnology Industry Organization (BIO, 2006) that provides the following facts:

- There are more than 300 biotech drug products and vaccines currently in clinical trials, targeting more than 200 diseases, including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS, and arthritis. Thirty-two biotechnology, biotech related, and small molecule products were approved by the FDA in 2005.
- Biotechnology is responsible for hundreds of medical diagnostic tests that keep the blood supply safe from the AIDS virus and detect other conditions early enough to be successfully treated. Home pregnancy tests are also biotechnology diagnostic products.
- Consumers are already enjoying biotechnology foods such as papaya, soybeans, and corn. Biopesticides and other agricultural products also are being used to improve our food supply and to reduce our dependence on conventional chemical pesticides.
- Environmental biotechnology products make it possible to clean up hazardous waste more efficiently by harnessing pollution-eating microbes without the use of caustic chemicals.
- Industrial biotechnology applications have led to cleaner processes that produce less waste and use less energy and water in such industrial sectors as chemicals, pulp and paper, textiles, food, energy, and metals and minerals. For example, most laundry detergents produced in the United States contain biotechnology-based enzymes.
- DNA fingerprinting has dramatically improved criminal investigation and forensic medicine, as well as afforded significant advances in anthropology and wildlife management.

- As of December 31, 2005, there were 1,415 biotechnology companies in the United States, of which 329 were publicly held.
- At the end of 2005, the market capitalization of publicly traded biotech companies (U.S.) at market prices, was \$410 billion. The market capitalization of two companies, Genentech and Amgen, accounted for nearly half of the \$410 billion.
- The U.S. biotechnology industry employed 198,300 people as of December 31, 2003.
- Biotechnology is one of the most research-intensive industries in the world. Publicly traded U.S. biotech companies spent \$16 billion on research and development in 2005.
- The top five biotech companies spent an average of \$101,200 per employee on R&D in 2002.
- The biotech industry is regulated by the U.S. Food & Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture (USDA).

Biotech Funding Realities

Commercialization of New Pharmaceuticals

The development, government approval, and commercialization of new pharmaceuticals is a long, costly process, and the percentage of promising candidates that survive to commercialization is very small. Thus, investment in biotech companies tends to be quite risky, although the rewards of success can be very large. Recent advances in rational drug design, i.e., designing new pharmaceutical candidates on the known structure or function of the target molecule, promise to reduce the time, costs, and risk associated with new drug development. Some pharmaceutical companies are also targeting more limited markets for new drugs, rather than emphasizing "blockbuster" drugs. This also promises to reduce the time and costs associated with FDA approval.

Glenda Overbeck, Vice President of Investment Activities, BCM Technologies, Inc.

The time between discovery and commercialization is extremely long in the biotech industry, and investors that put their money into biotech companies need to understand this. BCM primarily works with venture capital investors as opposed to smaller angel investors because they understand the long timeframes needed to commercialize biotech products. Additionally, experienced VCs with biotech expertise bring value to the companies they invest in through their industry contacts.

Large pharmas will not normally form partnerships with small biotech companies before their products have reached Phase III clinical trials and been approved. As such, partnerships with the pharmas do not supplant venture capital sources. However, pharmas will sometimes work with small biotech companies in the early stages, if a tool or screening device of interest is being developed.

Justin Gillis, "Biotech Revenues Thrive," Washington Post

Biotechnology firms still spend considerably less than on research than rivals in the traditional pharmaceutical industry – about US \$20 billion a year against more than US\$60 billion for the established drug giants. But biotech firms get more results for their money, surpassing pharmaceutical companies for the first time in 2003 in getting novel types of medicines approved by the US Food and Drug Administration.

A prime example is Exubera, the inhaled insulin for which Pfizer, the largest drug firm in the United States, recently won FDA approval. Hailed as a milestone in the lives of diabetics, Exubera is the first new way to get insulin into the body since that hormone was discovered in 1921. But it was not invented at Pfizer. Exubera was devised by Nektar Therapeutics, a small biotech company in California that stands to benefit handsomely if it succeeds in the marketplace.

Dennis Stone, Vice President for Technology Development, University of Texas Southwest

A good bit of partnering is now going on between major pharmas and biotech companies. Major pharmas need to fill their patent pipelines. They tend to outsource the research part more and more, so these partnerships are a very good vehicle for them. It is also good for the biotech companies because they have a partner with experience in the FDA approval process. Within the last year, pharmas are beginning to enter these partnerships earlier and earlier. In the past, they waited until the biotech company's products had reached Phase II or Phase III of the clinical trial process. However, they were finding that, if they waited that long, most of the best prospects had been locked up. Pharmas are now beginning to form partnerships in the pre-clinical stage. The biotech companies don't get the valuation they would get if they were in the clinical stage, but they get more than would have gotten at the same stage of development a year ago.

Biotech Company Funding

Even the most successful startup biotech companies go through a series of funding arrangements. Almost all startup biotech companies are founded around technologies developed in federally funded research labs, typically located at universities, of world class researchers. Typically, these researchers become convinced of the commercial viability of an aspect of their research and form a startup company to develop the technology. In order to legally use the technology, the startup must apply for approval from the sponsoring institution. This typically involves a licensing agreement that gives the startup the right to commercialize the technology in exchange for monetary compensation equal to some percentage of the revenues that the technology generates.

Typically, initial funding for the startup companies is very hard to find. This is the period of a company's development when it attempts to discover the targets, and the corresponding therapeutic molecules, that govern and control certain disease processes. Funding during this stage of a company's development is typically provided by government grants, such as Small Business Innovation Research (SBIR) grants or "angel" investors, often people with personal interest in the development of a particular type of drug. The Governor's Emerging Technology Fund, which was approved in the 2005 legislative session, is another source of funding for companies at this stage of development.

Emerging Technology Fund Created

During the 2005 Legislative Session, the Texas Legislature passed and approved \$200 million in funding for the Governor's Emerging Technology Fund. The legislation (H.B. No. 1765) outlines several emerging technology industries eligible for funding under these programs, including biotechnology, life sciences, medicine, and nanotechnology.

The primary goals of the fund are to attract, create, or expand private sector entities whose commercialization activities generate a substantial number of high quality jobs and to increase the research capabilities of the state's Tier I research universities.

The \$200 million fund, which spreads funding over two fiscal years, provides \$100 million in regional commercialization and innovation grants to entities that are commercializing technologies, which are expected to generate significant economic growth and jobs\$50 million in acquisition of research superiority grants to the state's Tier I research universities that can be use to attract world-class researchers whose work is expected to generate or contribute to significant economic growth. \$50 million in matching grants to entities that have already received federally vetted funding (SBIR, NIH, NSF, etc.) for research activities with significant commercialization potential is also possible.

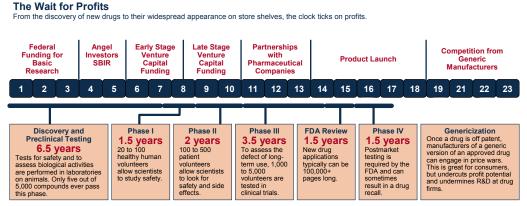
Robert Elder, "State Funds Help Fill a Void on Startup Investing," Austin American Statesman

Unfortunately, biotech companies in Texas have historically found it difficult to raise venture funding. For example, only four early stage biotech and life science companies in the State received venture funding in 2005. The total amount of equity these four companies raised, \$17.6 million dollars, represented less than one-half a percent of the total amount invested in U.S. life science companies last year. To address this problem, the University of Texas Investment Management Company (UTIMCO), which controls over \$19 billion dollars in university endowments and funds, has committed \$50 million dollars to PTV Sciences LP, a Houston based venture capital firm, that invests exclusively in life sciences companies, including startups.

Once the development of a product has reached the point where commercial potential is demonstrated, venture funding can often be found. As the probability of commercial success increases, funding can be obtained from pharmaceutical companies (pharmas), potential partners, and potential consumers. Historically, pharmas have not invested in companies developing new drugs until deep into FDA approval process. However, many pharmas faced with dwindling supplies of new drugs have begun to invest in companies early in Phase II testing, or even near the end of Phase I testing, i.e., demonstration of safety and dosage in healthy clinical trial volunteers.

In reality, the goal of a large fraction of startup biotech companies is to be taken over by a larger company, rather than recourse to initial public offerings.

Figure 1. Biotech Company Funding Stages



Source: Pharmaceutical Research and Manufacturers of America & Technology Futures, Inc

Biotech Basics

The goal of modern biotechnology is to understand the precise function of certain cells and molecules and exploit their properties in a way that can be targeted to solve specific problems while, at the same time, generating less harmful side effects and unintended consequences. The modern definition of biotechnology is not so much concerned with the principle of using organisms to accomplish certain tasks as it is with the specific techniques for doing so, including DNA sequencing, molecular biology and chemistry, gene and molecular cloning, cell and tissue culture techniques, polymerase chain reaction, etc. (Nagda, 2005).

In the following paragraphs, a number of basic facts about biotech are presented. A more detailed discussion of biotech as related to human health is presented in the *DNA and Human Health* section of Chapter Four.

DNA

To understand biological processes, one must start with DNA. The molecular structure of DNA, the famous double helix, can be thought of as a zipper with interlocking teeth represented by the four letters (A, C, G, and T) (Betsch, 2004). These nucleotides A (adenine), C (cytosine), G (guanine), and T (thymine) are the building blocks of DNA. The interlocking teeth come in one of two complimentary base pairs: A-T or C-G. A diagram of a DNA molecule is presented in Figure 2.

The information in DNA that governs most life functions is determined mostly by the sequence of letters along the helix.

No matter how simple or complex an organism is, each and every one of its cells contains the exact same set of DNA. In human beings, every cell carries two sets of 23 chromosomes composed of DNA. This DNA includes genes that govern important life processes and other DNA material for which scientists have yet to determine a purpose. Genes compose about 3% of the total DNA material, and the other 97% is "leftover" DNA that many scientists speculate humans came to no longer need as they evolved (Kahn, 2005). The human genome, or the total genetic material in a human being, consists of about three billion base pairs. The goal of the Human Genome project, which was concluded in spring 2003 (rough draft in 2000), was to generate a genome and complete DNA sequence of human beings. Genomics, decoding the meaning of these sequences to important life functions, is now the goal.

The genetic information contained in a cell is carried on DNA that is composed of several thousand genes. These genes carry the "code" that a cell uses to construct protein molecules that carry out important cell functions and act as building blocks for structural body parts such as muscle and bone. Proteins regulate and drive processes that take place in a cell.

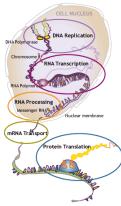
Since genes contain the information for manufacturing proteins, understanding the function of proteins means understanding the function of genes. A diagram of DNA translation is presented as Figure 3.

Figure 2. A DNA Molecule

T: Thymine
G: Guanine

T: A T: Thymine
G: Guanine

Figure 3. Protein Translation



Source: Iowa Public Television

Source: Nobel Foundation

Before a cell can replicate (copy) itself, a copy of its DNA is generated for the new cell. When the cell must generate proteins, the corresponding genes are transcribed into RNA (transcription). After processing, the RNA is transported outside of the nucleus where proteins are constructed according to the code in the RNA (translation).

Recombinant DNA Technology

Modern biotechnology laboratory techniques allow scientists to artificially transfer DNA from one organism to another. In some instances, the organisms are from similar species; in others, they are not.

Molecular cloning involves inserting a new piece of DNA into a cell using a cloning vector, which is a DNA molecule that transports the DNA fragment into the new cell and protects it from DNA degrading enzymes (BIO, 2005). The new DNA, part of a recombinant (combined) DNA molecule, is replicated (copied) every time the cell divides. As the cell divides, the DNA multiplies or amplifies. These DNA copies give scientists access to an unlimited amount of DNA that they can use for various studies. Molecular cloning is an essential biotechnology research tool and has allowed scientists to identify, localize, and characterize genes, create genetic maps and sequence entire genomes, and associate genes with traits (BIO, 2005).

Stem Cells

All the cells in our bodies are derived from a single fertilized egg. The progression from a single undifferentiated cell to a multicell organism involves cell proliferation (division) and cell differentiation, where cells differentiate to perform specific tasks (e.g., nerve cells, bone cells, blood cells, etc.) (BIO, 2005). When animal cells differentiate into tissues and organs, they maintain a supply of undifferentiated cells that can be used to replace damaged cells and replenish certain *specific* cells such as red and white blood cells (National Institutes of Health, 2005).

These undifferentiated cells are called adult stem cells (ASCs). When they are needed, ASCs can divide—one cell remains undifferentiated and the other becomes the needed cell type (somatic). Unfortunately, many cells, most notably nerve cells, are not maintained in an undifferentiated form and cannot be replenished if they are damaged or destroyed. However, embryonic stem cells (ESCs) are much more flexible than ASCs because they can divide and become *any* type of cell. Unlike differentiated cells, they are easily grown in large volumes *in vitro* (culture). This is precisely why there is so much research interest in ESCs.

Bioprocessing

Cell culture techniques involve the growth of cells outside a living organism. Bioprocessing involves the use of such techniques to produce products. Plant, insect, and mammalian cells have been grown in this manner to provide a wide variety of products. An example of a bioprocessing apparatus is presented as Figure 4.

Figure 4. Bioprocessing Apparatus



Source: Life Technologies—Ruhr

The catalytic properties of proteins, such as enzymes, have been altered to develop environmentally-friendly biocatalysts for industrial processes. These biocatalysts are better than manmade chemicals because they dissolve in water and can function at relatively low temperatures (BIO, 2005).

Laboratory Grown Organs

In April 2006, researchers at the Wake Forest University Institute for Regenerative Medicine announced that for the first time ever, human recipients had received laboratory grown organs. The recipients, who were children and teenagers born with a birth defect that caused poor bladder function, received engineered bladders grown from their own intestinal cells. The technology involved growing the intestinal cells in a culture environment until there were enough cells to grown them in a special biodegradable mold (scaffold) shaped like a bladder. Scientists hope that

the technology, which has been in clinical trials since 1999, can eventually be used to grown more complex organs such as hearts and kidneys for transplant candidates. Since the organs are grown with a patients own cells, there is no risk of rejection (Wake Forest University, 2006).

The Future of Biotechnology

In a technical area as broad, far-reaching, and rapidly changing as biotechnology, projecting the future is risky and uncertain. For planning and analysis purposes, biotech forecasts can be considered in three general categories: fundamental trends that can best be determined by examination of current literature and discussions with qualified experts; longer-term projections that can best be determined by examination of current and planned research activities; and shorter-term projections, for which reliance on the information and insights of experts in various areas of the biotech field will be most valuable.

Fundamental Trends

Convergence

As the scope of biotech continues to broaden, it is increasingly involved in a conversion of a number of different areas of technology, such as human health, information technology, materials science, and nanotechnology. These technologies offer symbiotic relationships that will contribute to advances in each of these technology fields. However, the true value of this integration will be development of products, processes, and applications that are superior to what could be achieved by any single one. In reality, it will be increasingly difficult to determine where one technology ends and another begins.

Biotech convergence with health care is discussed in the *DNA* and *Human Health* section of Chapter Four and the convergence with information technology in the *Bioinformatics* section of that chapter. Convergence with nanotechnology is discussed in the following paragraphs.

Nanobiotechnology

Substances and structures with dimensions on the order of nanometers (10-9m) exhibit optical, electrical, and mechanical properties that are unique compared with their bulk or macroscopic forms. The field of nanotechnology encompasses a large and diverse set of technologies that seeks to exploit these unique properties for commercial and social use. The convergence of nanotechnology and biotechnology promises to yield advancements in a number of areas, including drug delivery, clinical diagnosis and screening, and sensors with environmental and homeland security implications. Interesting examples of potential applications are described below.

Drug Delivery

Dr. Naomi Hallas and Dr. Jennifer West of Rice University are developing a nanoparticle-based drug delivery system that uses monoclonal antibodies to deliver targeted cancer treatments. Their system, which is being developed by a Houston-based company called Nanospectra, uses particles called nanoshells. The nanoshells are attached to monoclonal antibodies that attach exclusively to cancer cells. When the nanoshells are excited with infrared light, which is harmless to the body tissue it passes through, their temperature rises. The heated nanoshells destroy cancer cells. Additionally, Dr. Joseph DiSimone, a chemistry and chemical engineering professor at the University of North Carolina and North Carolina State University, has developed a "nanomolding" process that can create cancer fighting nanoparticles from existing cancer drugs. The new synthesis method uses lithographic technology to create molds that can be used to fabricate nanoparticles of nearly any size and shape from organic materials. These nanoparticles, which are composed of cancer fighting drugs, can be attached to monoclonal antibodies for targeted delivery to specific cancer cells. Interest in the technique is high because research has demonstrated that the size and shape of cancer fighting drugs can have a profound effect on their efficacy. For example, smaller drugs, with elongated shapes, have been found to more easily traverse the walls of blood vessels and reach tumors where they are able to deliver greater dosages of drugs directly to diseased cells (Bullis, 2006).

Clinical Diagnosis

Quantum dots are tiny nanoparticles that fluoresce at different wavelengths (read colors) based on their size. They can be attached to monoclonal antibodies and used to detect the presence of specific kinds of cellular structures like cancer (Vanston & Elliott, 2003). Traditional techniques using organic fluorescent dyes fluoresce at only one wavelength, which necessitates the use of multiple tests at different wavelengths to identify multiple structures. With quantum dots, different monoclonal antibodies can be attached to quantum dots of varying sizes. Because the dots fluoresce at different colors when they are exposed to light at a given wavelength, the presence of multiple biological structures can be detected at once.

Automation and Robotics

Automation and robotics are of increasing importance to biotech research and production. Their increasing use in biotech research laboratories is enhancing productivity because it frees researchers from repetitive mundane tasks and decreases the amount of time (read cost) it takes to set up and analyze large-scale experiments (Gwynne & Heebner, 2005). Automation and robotics are having an especially dramatic effect in increasing productivity and reducing the costs to firms engaged in drug discovery and clinical diagnostics work (Gwynne & Heebner, 2005). An example of an automatic system is presented in Figure 5.

Figure 5. Flexible Lab Automatic System/Handler



Source: SSI Robotics

Similarly, firms engaged in DNA sequencing and genomics research have an intensive need for automation because they work with DNA microarrays whose preparation requires a large number of repetitive steps on a large number of samples (DNA microarrays).

An important trend affecting the design of automation systems is related to the use of increasingly small sample volumes for experiments (microliter and even nanoliter volumes). Researchers want to use smaller volumes to conduct their experiments because it means lower reagent and waste disposal costs.

Bio Micro-electromechanical Systems

Micro-electromechanical systems are miniaturized, self contained devices (dimensions on the order of microns [μ m] or 10^{-6} m to 10^{-4} m) that integrate electrical and mechanical functionality to sense, process, and act upon information in their environments. The goal of bioMEMS technology is to decrease the cost and increase the functionality of devices used in medical diagnosis and treatment (Vanston & Elliott, 2004). BioMEMS devices are being explored for use in a wide variety of applications including biosensors (see below), microneedles for noninvasive drug delivery, pacemakers, and DNA purification and sequencing (microarrays).

Biosensors

Biosensors incorporate biological material, e.g., a cell, enzyme, or monoclonal antibody, linked to a physiochemical transducer. The physiochemical transducer reacts to optical, electrochemical, thermometric, piezoelectric, or magnetic interactions between substances it encounters and the biological material that it is linked to (BIO, 2005). It transmits an electrical signal to a second system (microprocessor), which processes that information and develops a diagnosis (e.g., presence or concentration of a certain pathogen or chemical). Biosensors

rely on the specificity of molecular substances such as monoclonal antibodies to identify the presence of substances of interest. Biosensors might be used not only for sensing but also to provide therapies and treatments. Other applications for biosensors include weapons of mass destruction detection, drug delivery at the cell level, pumps for clogged heart arteries, and dialysis for kidney failure patients.

Biosensors might be used not only for sensing but also to provide therapies and treatments. For example, a miniaturized integrated sensor/pump device could be implanted into a patient with diabetes to continuously measure and regulate their blood sugar levels. Such a device could monitor the blood sugar levels of patients and deliver continuous minute doses of insulin into the bloodstream, thereby helping the patient avoid dramatic fluctuations in blood sugar (Elliott & Vanston, 2004). The use of biosensors for this purpose is illustrated in Figure 6.

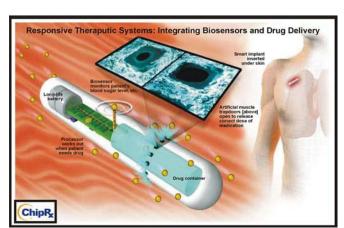


Figure 6. Biosensor and Drug Delivery

Source: Chip Rx

Current and Planned Research Activities

(Much of the information in this section is paraphrased from an article by Dr. Robert Elde, Dean of the College of Biological Sciences at the University of Minnesota in a 2005 paper entitled "Big Research for the first half of the 21st Century.")

Biotech research can be divided into two general categories: basic research and transitional research. Basic research involves efforts "to understand how molecules, cells, and systems work in order to set the stage for discoveries that ultimately find a place in cures for diseases, solutions to environmental problems, and creation of new products that improve the quality of life." This category includes microbial genomics and ecology, global ecosystem changes, and biodiversity; developmental biology; systems biology; and the human brain. Transitional research involves "research that provides a bridge between basic research and the marketplace." This category includes molecular and cellular engineering; renewable energy and biomaterials; and genomic-based approaches for predicting, preventing, and treating human diseases (Elde, 2005).

Basic Research

Microbial Genetics and Ecology

Although we know relatively little about microorganisms, there are more species of this biological species than all other types combined. Through the use of genomics, we can learn how they survive extreme environments, about the chemicals they produce to ward off predators, and about the evolutionary mechanisms that allow them to adapt so rapidly to changes in their environment.

Global Ecosystem Changes and Biodiversity

More research is needed to analyze how human activities interfere with the services that ecosystems provide to sustain life. Better understanding of the delicate balance within ecosystems, at the molecular and systems level, will show how they can best be managed so that they can continue to support human needs.

Developmental Biology

Biology is moving from a focus on individual genes and molecules to systems biology which involves interactions between genes, cells, tissues, organs, and even whole organisms. It is increasingly understood that networks of these components, not individual genes in isolation, determine function.

The Human Brain

The human brain is the pinnacle of biological complexity. Better understanding of the basic brain functions, such as cognition, memory, emotion, and motor coordination, will lead to improved treatment of neuromuscular diseases, mental health, pain, and addiction.

Transitional Research

Molecular and Cellular Engineering

Genomics is revealing genes and gene networks in microbes and plants that produce valuable chemical compounds that cannot be made by standard chemical methods. Moreover, using "gene shuffling" or directed evolution can be used to produce novel biological compounds for use in drugs, foods, and materials. Stem cell research is an example of this type of activity.

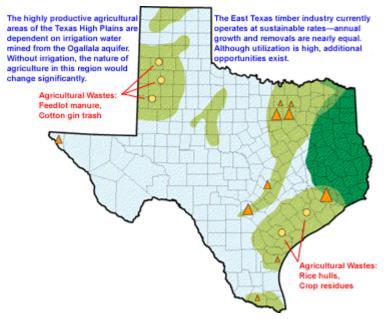
Renewable Energy and Biomaterials

Biocatalysts and other new technologies may make practical the controlled use of biosynthesis to produce biofuels, biodegradable plastics, and other products to replace fossil-based fuels and materials. Additionally, biomass technologies that involve the burning of plant or animal matter to create heat that can be used

in the generation of electricity are being developed. Texas, as one of the nation's leading agricultural and forestry producers, is a major producer of biomass materials that could be used for such purposes. Possible sources of biomass fuel are shown in Figure 7.

Figure 7. Biomass Sources in Texas

TEXAS BIOMASS: GENERAL RESOURCE TYPES				
		<u> </u>		
AGRICULTURE	FORESTS	URBAN BIOMASS		
Harvest Residues	Logging Residues	Municipal Solid		
Process Wastes	Mill Residues	Waste		
Energy Crops	Woody Energy	Sewage		
	Crops	Landfill Gas		
		Used Cooking Oils		



Source: Texas State Energy Conservation Office

Prediction, Prevention, and Intervention in Human Health Problems

Biotech will materially change our approaches to human health and disease. The focus will shift from treatment to prediction and prevention. Treatment of all serious intrinsic diseases will be tailored to individual genomic profiles.

Infectious and zoonotic diseases

A majority of new and emerging infectious human diseases originated in domestic or wild animal species. Determining the processes that result in such emergence will assume increasing importance over time.

Implications

No one knows for sure, of course, where this research will lead, but it can be predicted with considerable certainty that the results of this research will lead to a myriad of practical applications.

Shorter-Term Projections

Throughout this report, statements from various biotech experts about the future of the field are highlighted. To expand the input of biotech experts, a meeting of such experts was conducted as part of this project. In this meeting, the participants were asked to identify what they believed would be the most important developments in biotech in the next five years. A number of their projections are presented below.

Strategic

- Growing globalization of biotech with increased usage and competition throughout the world (Thomas Kowalski).
- Increasing investment capital interest in biotech (Gary Pankonien).
- Movement of more biotech research into the development phase and scaleup for clinical trials (Janet Valera).
- Greater acceptance of biotech by the general public, the investment community, and politicians at the state and local levels (Thomas Kowalski).
- There will be increased attention to the reliable production of biotech products at higher volumes (Dr. Donald Hicks).
- Culturally, biotech manufacturing and application will move from the sensational realm of the media to the mainstream. (Dr. Alan Runge).
- There will be increasing convergence of biotechnology, information technology, and nanotechnology (Jason Moore).

Technical

- Improved crop production through the use of crops that have been genetically modified to have higher stress tolerances, e.g., greater drought and cold resistance (Lee Rivenbark).
- Movement in the consumer market to better medical diagnosis for diseases through development and monitoring capabilities of bio-markers. Lab-ona-chip and monoclonal antibodies will provide home diagnostic kits (Nicholas Cram).
- Significant animal studies will validate the therapeutic potential of siRNA technology. There may also even be early stage clinical trials of the use of siRNA for the treatment of specific diseases (Dr. Margaret Simpson).

- Protein science, e.g., rapid reproduction and manipulation of proteins in free cell systems, will become as important as DNA science (Dr. Larry Loomis-Price).
- Advances in molecular breeding for specific traits, i.e., increasing use of DNA manipulation versus conventional breeding practices (Lee Rivenbark).
- Development of biomarkers for altered physiological states coupled with the ability to monitor those markers (Dr. Linnea Fletcher).
- There will be a better understanding of the cell and immune system functions (Gary Pankonien).
- Significant progress will be made in the area of embryonic stem cell technology with animal studies and, perhaps, early stage clinical trials demonstrating the potential of such cells (Dr. Margaret Simpson).
- There will be a better understanding of metabolic pathways as a way for diagnosing diseases more efficiently (Nicholas Cram).
- Personalized medicine will move from theory to practice through the use of genomics, proteomics, metabolomics, and immunomics. This will lead to better diagnosis and therapeutics (Jason Moore).
- Significant advances will be made in the research and application of immunization and vaccine technology for the treatment of diseases such as HIV, hepatitis C, herpes, MS, cancer, neurodegenerative diseases, and, possible parasites (Dr. Larry Loomis-Price).

Workforce and Education

- There will be a shortage of a qualified workforce to meet the needs of the emerging biotech industry (Janet Varela).
- An increasing percentage of blue color workers will be high-tech workers who are familiar with fairly advanced technology and science, e.g., biotechnicians and nanotechnicians (Dr. Linnea Fletcher).
- The number of life sciences and biotech degrees will overtake the number of chemistry degrees (Alan Runge).

Interestingly, there was one projection that was somewhat counter to the generally optimistic tenor of the other projections.

• There will be little or no commercial development of new biotech products (Dr. Donald Hicks).

Overview

Based on the information and insights discussed in the preceding paragraphs, the following general projections are offered.

- For the foreseeable future, the biotech field will grow rapidly in terms of technical innovation, practical applications, and business opportunities.
- The use of automation and robotics will be of increasing importance in the biotech field, permitting improvements in efficiency, timeliness, and accuracy.
- Biotech will continue to converge with other developing technologies, such as health care, information technologies, and nanotechnology.
- Employment opportunities in the biotech field will grow rapidly over the next several years.



Chapter Three: Status of Texas CTC Biotech Programs

Employment Opportunities

Employment opportunities for graduates of Texas community and technical college biotech programs are generally good in terms of initial pay, interesting work, high probability for advancement, and long-term employment. Moreover, the market for CTC biotech graduates will grow steadily over the next few years, and there is a distinct possibility that the market could grow rapidly if efforts to expand the state's biotech industries are successful.

Nicholas Cram, Associate Professor & Biotechnology Coordinator, TSTC Waco

Critical biotech tasks range from simple diagnostics and repairs to complex diagnostics and calibrations. It will be critical to bottom lines that supporting equipment be online as much as possible, and trained technicians will be required to ensure that this occurs. Genentech [a major biotech company] has found that a graduate of an Associate degree program with the right skill set works perfectly and is most cost-effective as well.

Janet Varela, Kelly Scientific

The most significant development in biotech over the next years will be the lack of a qualified workforce to meet the needs of the emerging technologies.

The U.S. Department of Labor, Bureau of Labor Statistics, and Texas Workforce Commission data do not clearly define a biotechnician. Therefore, it is impossible to determine the exact number of technicians currently employed in Texas. A recent study conducted by Richard Seline for the Texas Health Care and Bioscience Institute estimated that there were approximately 75,000 biotech related jobs in the state. However, this estimate undoubtedly included many types of jobs that would not fall under our definition of biotech.

A September 2004 study for the Gulf Coast Workforce Board conducted by Joel C Wagher, a labor market analyst at WorkSource, identified, and analyzed Department of Labor workforce projections, for a number of Standard Occupation Codes (SOCs) that the Biotechnology Industry Organization considers to be specific to biotech, including biochemists and biophysicists, biological technicians, microbiologists, animal scientists, life scientists, biomedical engineers, and others. However, the problem with this data is that many of the technicians within these SOC codes are not employed in biotech organizations. Regardless, Wagher estimated that the number of technicians employed in these SOC codes in Texas in 2002 was 17,060 and that number would grow to 19,140 in 2010.

The BioHouston organization estimates that there are approximately 4,000 people employed in biotech positions in the Galveston/Houston area, and that approximately

60% of these jobs could be satisfactorily satisfied by graduates of two-year biotech programs.

Currently, all or almost all graduates are able to gain employment immediately upon or even before graduation. This situation promises to continue for the foreseeable future. The projections of new employees taken from the TFI/TSTC survey indicate a steady growth in technician employment over the next five years (see Figures 8 through 10).

Figure 8. New Entrant Employees Over the Last Year

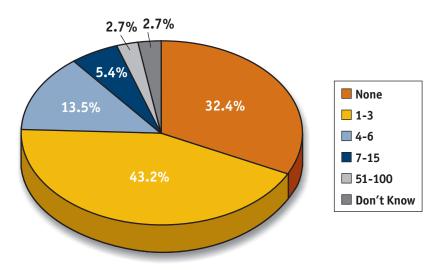
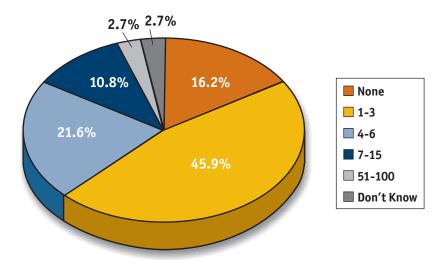


Figure 9. Projected Entrant Employees in Next Year



2.7%
10.8%

10.8%

27.0%

21.6%

13.5%

None
1-3
4-6
7-15
16-25
26-50
More than 100
Don't know

Figure 10. Projected Entrant Employees Between One and Four Years

Personal interviews with Texas biotech industries reflected similar projections of employment growth over the next few years.

Dr. Mary Pat Moyer, President, INCELL Corporation

INCELL currently has 20 employees and expects to hire 50 to 100 new people over the next five to ten years. These new hires will include technicians as well as senior management types. There will be a definite need for biotech technicians; however, it is important to keep in mind that biotech firms are not huge job generators, unless there is biomanufacturing.

Mitzi Martinez Montgomery, Vice President of Discovery and Preclinical Development, PharmaFrontiers

Currently, PharmaFrontiers employs a fair number of technicians with twoyear biotech program backgrounds. In the next couple of years, the company expects the number of techs it hires with that same background to grow.

Dr. David G. Gorenstein, Associate Dean for Research, University of Texas Medical Branch at Galveston

UT Medical Branch is the lead institution for the Western Regional Center for Excellence for Biodefense and Infectious Disease sponsored by National Institutes of Health. Since the 9/11 disaster, the funding for infectious diseases has gone from essentially zero dollars to six billion dollars a year. NIH has also funded two National Biocontainment Labs, one of which is to be located at UTMB-Galveston. The lab is a \$160 million facility, and it is estimated that it will create thousands of jobs. Educated, highly-qualified technicians will be essential to developing this laboratory. UTMB-Galveston believes that community colleges will be an essential provider of such techs.

Reasons for Employment Growth

There are at least three reasons to believe that employment opportunities for CTC biotech will become increasingly bright in the future.

1) There are strong indications that the biotech industry (including research and development institutions) will grow appreciably in the near future.

(see Chapter Five). The establishment of new research facilities (such as the National Biocontainment Laboratory in Galveston, the M.D. Anderson Cancer Genome Center in Houston, and the Scott and White Cancer Research Institute in Temple), the expansion of current facilities, the growing number of biotech companies in the state, and the targeted efforts of communities throughout the state to take advantage of this promising new technology—all indicate a growing need for biotech technicians.

2) There is a growing awareness of the capabilities of CTC biotech graduates. Although there are many technicians employed in Texas biotech industries, few of them are trained in the specific skills required by these industries, and employee turnover is often quite high. However, employers are becoming increasingly aware of the capabilities of CTC biotech graduates, and, as a consequence, demand for these graduates will undoubtedly increase in the future.

Dr. Larry Loomis-Price, Director, Biotechnology Institute, Montgomery College

A reason that employers prefer to hire biotech technicians from community colleges is that many of them have had bad experiences hiring B.S., M.S., or Ph.D. students in the past. Many employees with these backgrounds became bored with entry-level positions, and there was a high turnover rate. Basically, employers end up with employees that are overeducated and under-skilled.

Dr. Dat Dao, Director, Life Sciences and Health Group, Houston Advanced Research Center

People in biotech organizations don't appreciate the capabilities of students graduating from two-year biotech programs. If employers had a better idea of the capabilities of these students, they would be more likely to hire them. Thus, it is very important for biotech program coordinators to inform employers in their regions about the capabilities of these students.

3) Experience has shown that, as biotech activities move from research to development to commercialization, the percentage of technicians in the organization tends to grow. Thus, the transition of many biotech companies in the state from research to development to commercialization will result in a disproportionate growth in technician employment.

Dr. Catherine O'Brien, Dean of Program Development, Institutional and Health Centers, San Jacinto College South

As companies move from R&D to commercialization, the ratio of scientists (Ph.D.s) to technicians becomes much smaller. For example, in a biomanufacturing company, the emphasis moves from the use of aseptic techniques in a lab to the use of aseptic techniques in a manufacturing environment, e.g., using e-coli to produce insulin.

There is one other item to be considered in projecting future employment opportunities for CTC biotech graduates. These graduates have particular advantages in the employment arena because they will be well qualified for a number of employment opportunities outside the biotech area, if jobs in this field

are slow in developing. Examples include health care, environmental monitoring, water quality control, animal husbandry, and greenhouse operations.

Lisa Lock, Biotechnology Coordinator, El Centro Community College (Dallas)

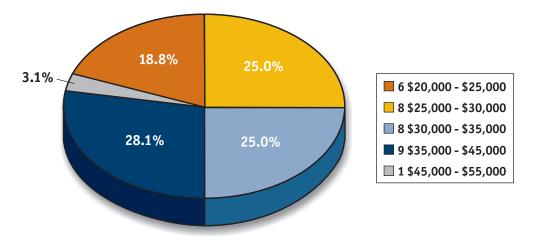
Quite a few students have completed a dual curriculum program that combines elements of medical laboratory techniques and biotechnology. The college came up with the dual curriculum concept because it wanted to ensure that graduates would have employment opportunities regardless of how quickly the biotech industry expanded. The students can still be placed in clinical lab positions. In a clinical laboratory setting, they use some of the molecular biology techniques that they learned in the biotech program. This is a very good match.

Obviously, employment opportunities for Texas CTC biotech graduates vary with geographical location. Regional distribution of biotech employment is discussed in Chapter Five.

Graduate Salaries

Starting salaries vary according to specialty area, geographical location, and ancillary training and experience. Depending on these factors, starting salaries vary from the high teens to \$50,000 or higher. Salaries typically increase significantly with experience on the job. Figures 11 and 12 provide an indication of Texas biotech company salary ranges.

Figure 11. Starting Salaries for Entry Level Biotechnicians



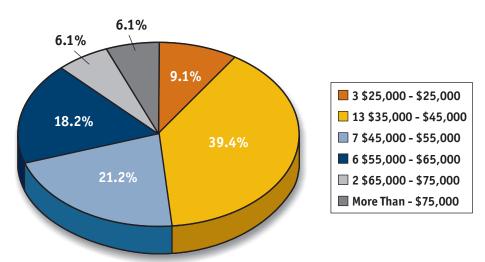


Figure 12. Biotech Salaries after Five Years

It should be noted that more than half of the starting salaries are above \$30,000 per year, and more than half of the salaries are about \$45,000 after five years of experience. These figures correspond well with the information gained from the directors of current biotech programs. For example:

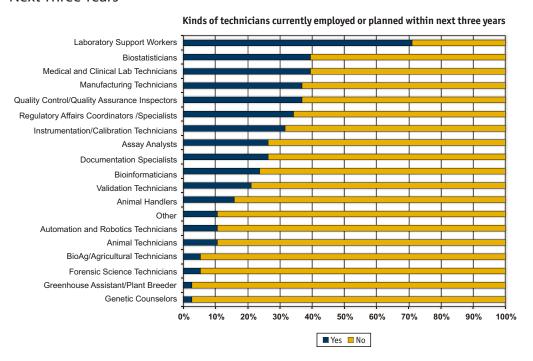
- Dr. Larry Loomis-Price, Director of the Montgomery College Biotechnology Institutes, indicates that graduates of his program typically have beginning salaries in the high twenties. However, starting salaries for some graduates are considerably higher than this, including one recently employed at \$50,000.
- Dr. Linnea Fletcher, Chairman of the Biotechnology Department at Austin Community College, indicates that biotech technicians in her program have entry-level salaries ranging from \$18,000 to \$35,000. Dr. Fletcher also indicated that bioprocess technicians typically earn about \$40,000.
- Lisa Lock, Biotechnology Coordinator, Dallas Community College, El Centro, indicates that graduates of her program have starting salaries that range between the mid teens and low twenties.
- Dr. Bridgette Kirkpatrick, Professor of Biotechnology at Collin Community College in Plano, indicates that typical entry-level salaries for graduates of her program range from the high teens to the low thirties for students who have a previous bachelor degree.
- Dr. Neil McCrary, Biotechnology Coordinator, Northwest Vista College, indicates that entry-level biotechnicians in the San Antonio area range from the high teens to the low thirties, with most falling in the mid-twenties range.
- Nicholas Cram, Director, TSTC-Waco BioTech Instrumentation Program, projects that graduates of the bioinstrumentation program he is initiating will have starting salaries in the range of \$40,000 to \$50,000.

- Lee Rivenbark, Director of Cotton Operations for Region Americas, Bayer Crop Science in Lubbock, Texas, indicates that technicians trained in biotech areas start at \$20,000 to \$24,000. Salaries at about these levels are possible for graduates with special training.
- Dr. Fuller Bazer, Assistant Vice President of Research, Texas A&M University, indicated that biotech technicians working at his university typically earn \$25,000 to \$35,000, but this assumes significant laboratory experience.

In general, there appears to be a hierarchy of salary ranges between different specialty areas. At the top of this hierarchy are those graduates in special skill areas, such as bioinstrumentation, bioinformatics, bioprocessing, and quality control and assurance. Next in the hierarchy are those graduates who bring special skills to the job, including fundamental biotech lab techniques. At the bottom of the hierarchy are the bench level technicians, who have few special skills. Typically, these graduates work at routine jobs in research or academic institutions. However, it should be noted that often these employees are using these positions to support their further academic development.

As indicated in Figure 13, Texas biotech companies employ a wide variety of technicians. Thus, there will be a wide range of career and salary opportunities available to CTC biotech program graduates.

Figure 13. Types of Technicians Currently Employed or Expected to Be Employed in Next Three Years



Required Knowledge, Skills, and Abilities

Successful employment in the biotech industry and biotech research facilities requires a variety of skills, knowledge, and abilities. Basic science, mathematical and technical knowledge, manual dexterity, and mechanical ability are all important attributes for biotech employees, companies, and research facilities. Typically, employers prefer

employees who are familiar with and competent in laboratory skills, who understand record-keeping requirements, and who are familiar with quality control and quality assurance procedures. Employers also place great importance on writing and verbal communication skills, ability to work in teams, problem-solving competency, and a strong work ethic—all attributes stressed by CTCs.

In considering the knowledge, skills, and abilities (KSAs) required for successful employment of technicians in the biotech field, it is important to know the specific technical requirements and general technical requirements. Figures 14 and 15 provide a list of these requirements as indicated by Texas biotech companies.

Figure 14. Required Technician Competencies



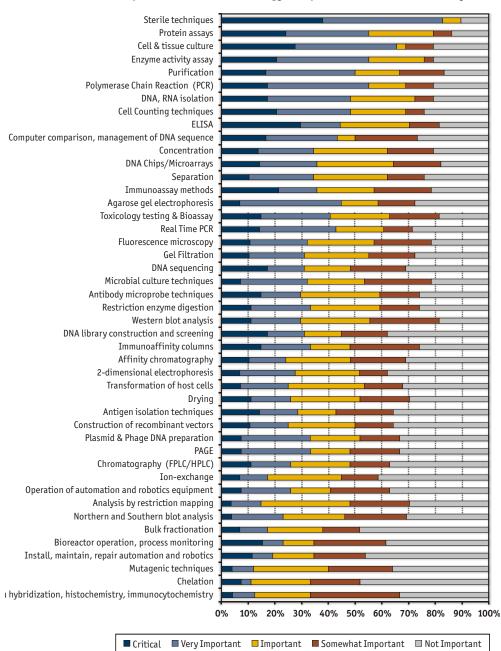
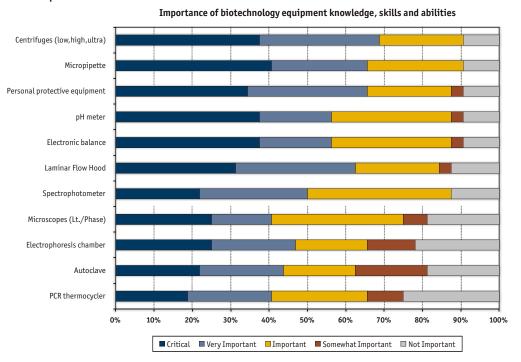
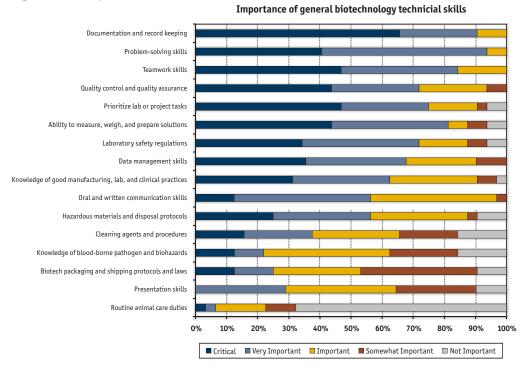


Figure 15. Equipment that Technicians Must Be Able to Use, Calibrate, Maintain, and Repair



Although employers indicated that it was essential for biotech technicians to have appropriate laboratory skills, Figure 16 shows that Texas biotech companies also indicated the great importance of more general skills and qualifications.

Figure 16. Important General Skills and Qualifications



Dr. Linnea Fletcher. Department Chair of Biotechnology, Austin Community College

Writing and communication skills are essential for biotechnicians. In the work environment, biotech technicians most often must work in teams. It is very important for biotech education programs to teach team skills. Good instrumentation and diagnostic skills and manual dexterity are also important.

Dr. Catherine O'Brien, Dean of Program Development, Institutional and Health Centers, San Jacinto College South

Lower-level SCAN skills are important to biotech employers, i.e., communication skills, ability of technicians to follow and record protocol, ability to keep detailed lab notebooks, and understand that those lab notebooks are legal documents. It is important for students who leave the program to understand that their lab notebooks are legal documents that cannot be taken from the lab.

Dr. Celeste Carter, Director of Biotechnology Program, Foothill College (Los Altos Hills, California)

Documentation skills are extremely important for biotech technicians. The Foothill program introduces students to the idea that their lab notebooks are legal documents. The lab notebooks never leave the lab; students are not allowed to take them anywhere. Additionally, the notebook has to be filled out and witnessed just exactly as it would be in an industry situation. A number of students say that the notebooks are a tremendous help. The students are allowed to present the notebooks to potential employers during interviews. Many employers are impressed by the notebooks because they realize that the program's graduates are familiar with the notebook's use as a legal document and the need to document everything they do and see in the lab.

Job Descriptions

Although the application of knowledge, skills, and abilities will vary between various biotech applications, the basic requirements for technicians in most of these fields will be quite similar. The concept of a "biotech industry" encompasses a wide range of fields, including genomics, pharmaceuticals, environmental programs, animal and plant control, proteomics, DNA analysis, bioinformatics, and medical diagnosis, treatment, and supply. In reality, biotech programs concentrating in any one of these fields will be quite similar to programs concentrating in other fields. The differences in programs will be primarily in the subjects covered in the courses, not in the courses themselves.

Nicholas Cram, Associate Professor & Biotechnology Coordinator, TSTC Waco

There are no standardized job descriptions for many of the important biotech technician positions, but the skill sets for many of them are quite similar. The basic skills required for biotech technicians in the various areas include familiarization with validation procedures, quality control, quality assurance, instrumentation, and laboratory techniques. Writing and presentation skills are also of critical importance.

Dr. Larry Loomis-Price, Director, Biotechnology Institute, Montgomery College

The job titles of technicians that perform the exact same tasks at different companies often vary. There is a need to standardize job titles and job descriptions. These titles and descriptions should be skills-based, not degree-based.

Future KSA Requirements

With regard to KSAs, it is interesting to note the requirements projected for five years from now as indicated in Figure 17.

DNA Microarrays 47.4% (DNA Chips) ■ DNA Microarrays - 18 Genomics Genomics - 17 **Automation & Robotics** ■ Automation & Robotics - 15 Proteomics - 15 **Proteomics** ■ Immunomics - 15 **Immunomics** ■ Protein Microarrays - 14 ■ Nanotechnology - 14 **Protein Microarrays** ■ Bioinformatics - 13 Nanotechnology ■ Spectroscopy - 13 ■ Small Molecule Microarrays - 12 **Bioinformatics** ■ Bio Micro-Electromechanical Systems - 10 Spectroscopy (IR, FT-IR, NMR) ■ Metabolomics - 8 ■ Transcriptomics - 8 Small Molecule ■ Other - 2 Bio Micro-Electromechanical Systems Metabolomics 21.1% Transcriptomics **Other** 10 15 20

Figure 17. Required KSAs Five Years from Now

Nicholas Cram, Associate Professor & Biotechnology Coordinator, TSTC Waco

The two areas, biotechnology and biomedical technology, are very separate, but there are tendencies for the two to interrelate, probably for biomedical technology to migrate toward biotechnology, because of new technologies such as lab-on-a-chip.

Dr. Linnea Fletcher, Department Chair of Biotechnology, Austin Community College

Changes in health care are very important to biotech. Advances in bioinformatics will impact all areas of biotech and real-time PCR will materially enhance diagnostics, as well as DNA fingerprinting.

Dr. Celeste Carter , Director of Biotechnology Program, Foothill College (Los Altos Hills, California)

Students with good skills in cell culture (mammalian) techniques will be very employable in stem cell companies. The skills are transferable.

Career Lattices

Students in biotech programs tend to have somewhat different backgrounds than those in most other programs. The average age, work experience, and educational backgrounds of these students tend to be higher than normal. Many of these students are preparing for significant career shifts, and bachelor and higher degrees are not uncommon. CTC biotech programs must be adjusted to meet these special needs, as well as those of students entering the programs directly from high school.

Dr. Larry Loomis-Price, Director, Biotechnology Institute, Montgomery College

The average age of students entering our biotech program is 29 years old, and approximately 70% have at least bachelor degrees or extensive work experience.

Dr. Bridgette Kirkpatrick, Professor of Biotechnology, Collin Community College

A number of students with bachelor degrees are in the Collin Community College biotech program. Plano is located in the telecommunications corridor, and, as a result, the college encounters a lot of retrainees from the computer and telecommunications industries, which collapsed in Dallas around 2001. We also get a lot of biology majors who don't have practical experience in biotech lab techniques. The students with a previous bachelor degrees are the easiest to place.

In the case of the older, more experienced, previously college educated students, programs should be built on taking advantage of these special life experiences. In most cases, these students have strong backgrounds in academic subjects such as mathematics, chemistry, and biology, so emphasis should be placed on providing them with the special lab skills needed for attractive employment.

Mitzi Martinez Montgomery, Vice President of Discovery and Preclinical Development, PharmaFrontiers

The best tech in our company is a woman who was a doctor in East Germany. She completed the Montgomery biotech program and is now employed as a technician. She is the best technician that the company has ever hired.

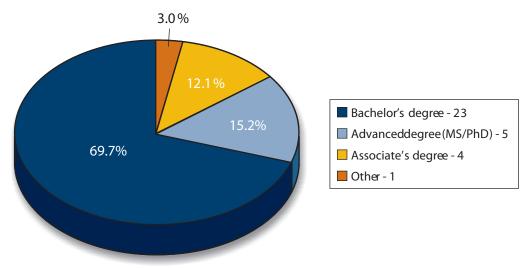
In the case of less qualified students, programs should be designed to provide a basic theory foundation, including personal skills, in addition to laboratory skills.

In both cases, there is often a financial need for the student to seek employment as early as practical. Therefore, emphasis should be placed on employment qualification and certification, rather than degree qualification and certification.

Although many employers have indicated that they are pleased with the special skills and attributes of graduates of CTC biotech programs, most prefer that their technicians have higher academic degrees, if possible. This preference is indicated in Figure 18.

Figure 18. Preference Education Level

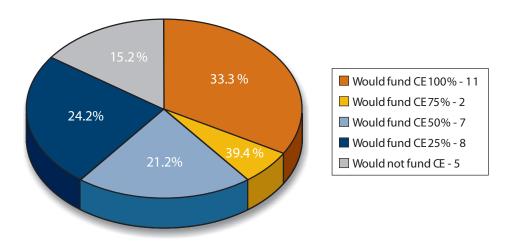
What is the preffered level of education for entry-level biotech technicians that your organization hires?



Because of the dual need for laboratory skills and academic qualifications, more than half of the survey respondents indicated that they would provide fifty percent or more of the expenses for biotech technicians to continue their education on a full or part time basis (Figure 19).

Figure 19. Organization of Support of Continued Education

Would your company find continuing education for employees if such training was significantly related to their job?



The value to both graduates and employers of continuing education for biotech technicians, together with the willingness of employers to support this education argues

for a seamless transition from basic biotech programs to more specialized programs to bachelor and possibly higher degrees in biotech or related fields. The combination of employment certification and degree certification will be beneficial to all concerned.

Nicholas Cram, Associate Professor & Biotechnology Coordinator, TSTC Waco

Retraining should be an important part of CTC biotech programs. A reasonable mix would be one-half of the students involved in degree-granting programs and one-half involved in part-time programs that result in advanced training certificates.

Dr. Celeste Carter, Director of Biotechnology Program, Foothill College (Los Altos Hills, California)

Career lattices are very important to the biotech industry. During the careers of biotechnicians, they will return to school quite often for additional training. The benefits of such an arrangement extend both ways. Students from industry are familiar with the latest techniques. They bring knowledge of these techniques back into the community college program.

A structure for accomplishing such seamless transitions, called "Two-Plus-One-Plus-One," has been recommended by Dr. Larry Loomis-Price of Montgomery College and supported by other CTC biotech directors. Under this structure, students would complete a two-year program composed of general academic and basic biotech subjects and receive an Associate of Applied Science degree. This degree would provide graduates with the necessary KSAs for attractive employment in the biotech area. After completion of the AAS program, graduates could continue, on a full- or part-time basis, with courses in a special area of biotech, such as bioinformatics, bioinstrumentation, bio-quality control, or bioagriculture. These advanced specialized courses and awards would be offered by multiple CTCs based on available faculty expertise and lab equipment. At the end of such a one-year program, graduates would receive an Advanced Technical Certificate (ATC) or Certificate (CERT) in the appropriate specialty area.

Later, graduates could continue study at a four-year college or university to achieve a bachelor or higher degree. The *Two-Plus-One-Plus-One* plan is a flexible, open-ended program designed to ensure the employability of students as biotech technicians if they should choose to pursue post AAS degrees. The success of a *Two-Plus-One-Plus-One* will, obviously, be dependent on appropriate articulation agreements between CTCs and bachelor degree granting institutions, as well as the seamless transition of students between CTCs.

Loomis' plan is very similar to the East Texas Two-Step Project. The Two-Step project allows students to apply up to 48 hours of technical and vocation coursework obtained in completing an Associates degree in specified areas towards a Bachelor of Applied Arts and Sciences degree at Stephen F. Austin State University. Both the proposed Two-Plus-One-Plus-One plan and the East Texas Two-Step project are designed to make students more competent and competitive in the job market.

With regard to continuing education, it is obvious that significant advances in all fields of biotechnology are occurring continually, including DNA microarrays, genomics, proteomics, lab-on-a-chip, automation, and robotics. CTC biotech programs must

be able to accommodate these rapid changes. To begin with, CTC biotech programs must be structured so that graduates have solid foundations in basic subjects such as college algebra and chemistry that are necessary to operate successfully in the changing technology environments. In addition, CTCs should be prepared to offer short courses to periodically update previous graduates. Attendance by graduates currently working in industry will assist CTCs in keeping their curricula relevant and up-to-date.

Current Biotech Programs

Biotech programs are currently being offered at only a small number of CTCs in the state, and the number of graduates from these programs each year is currently small. However, there are a number of CTCs that have initiated programs or are considering initiation. The programs at Montgomery College, Austin Community College, and Houston Community College-Northeast Branch are mature and well regarded and can serve as models for other CTCs initiating or expanding biotech programs. Many CTCs that do not currently offer biotech programs do offer programs that include many courses similar to those included in biotech curricula. These courses can, in many cases, provide a foundation for the initiation of a biotech program.

In the following paragraphs, current CTC biotech programs are briefly described. A listing of current CTC biotech programs is presented in Appendix E, and WECM approved biotech programs and courses in Appendix F.

Montgomery College

Director, Biotechnology Institute: Dr. Larry Loomis-Price

The biotechnology program at Montgomery College (located in The Woodlands) was started in 1989 and is the first CTC biotech program in the state of Texas. The program graduated its first students in the 1993–1994 academic year. The program was founded to serve the workforce needs of the burgeoning biotech industry in The Woodlands area. The ultimate goal of the program is to prepare students for entrylevel positions in a wide range of biotech organizations.

The biotech program has one permanent full-time biotech professor, four faculty members who teach in other departments such as biology, and three adjunct faculty members from industry. All faculty members must hold at least a Master degree. In reality, most faculty members hold Doctorate degrees.

The college offers an Associate of Applied Science (AAS) biotechnology degree, as well as a one-year Advanced Technical Certificate (ATC). Students in the AAS program complete a number of courses that span multiple disciplines including biology, chemistry, molecular biology, biochemistry, genetics, and college algebra, in addition to six WECM approved biotechnology (BITC) courses. Students in the ATC program complete 24 credit hours including most of the BITC courses. Students receive hands-on training in the latest biotech lab techniques, and in their final semester, students in both the AAS and ATC programs must complete an internship in an area biotech company or medical center research lab.

The program currently graduates about 13 to 14 students per year. Its goal is to graduate a minimum of 18 per year. However, Dr. Loomis-Price believes that the program could easily place up to 36 graduates per year since he has more requests for graduates than the program can produce.

Austin Community College

Department Chair of Biotechnology: Dr. Linnea Fletcher

The Austin Community College (ACC) biotechnician training program is housed in the allied health building, but is part of Math/Science Division. The college offers an AAS biotechnology degree, a one-year Certificate in Biotechnology, and for students who already have a four-year degree in the appropriate field, an Advanced Certificate. Students in the AAS program complete a number of courses that span multiple disciplines including biology, chemistry, molecular biology, biochemistry, genetics, and college algebra. In addition, students seeking the AAS degree complete six WECM approved biotechnology courses. The ACC biotechnology program focuses on biotechnology at the lab bench, because this is where the greatest demand for biotechnology technicians currently is in Texas. ACC has more RNA training than most biotech programs because of the demands of local employers.

There are typically 90 people in the ACC program at any one time. About 20 graduate each semester. About 65% of the students in the ACC biotech program have B.S. or higher degrees. Some of the degrees are in biology, but others have degrees or backgrounds in areas such as information technology and business. ACC has a 100% placement rate. Most graduates go into the workforce, although many pursue a B.S. degree on either a full- or part-time basis.

ACC recently acquired a real-time PCR (polymerase chain reaction) machine, which makes it possible to make a huge number of copies of a gene and measure its product while it is being made, unlike regular PCR. This technique is becoming extremely important in both research and in medical diagnostics. This acquisition was particularly important to the program, and will pave the way to an articulation agreement between the Biotech Program and the Medical Laboratory Program (MLT) at ACC.

San Jacinto College South

Dean of Program Development, Institutional Effectiveness and Health Careers: Dr. Catherine O'Brien

Unlike CTCs with biotech programs, San Jacinto (located near Houston) currently offers only academic transfer science courses. The San Jacinto program focuses on foundational courses such as General Biology I, General Biology II, Genetics, Introduction to Microbiology, Chemistry I, Mathematics, Statistics, English, and Technical Writing. San Jacinto plans to begin offering one BITC class in fall 2007. Additionally, the college has revised its genetics course to add a laboratory component, which covers PCR, gel electrophoresis, etc. Students also have the option of taking WECM approved BITC courses at Galveston College, which conducts the laboratory portion of its courses in facilities located on the campus of UTMB Galveston. Graduating students are allowed to transfer their Associate of

Science degree credits to UTMB. At UTMB, students can enter either the Clinical Laboratory Sciences Program (medical route) or the biotechnology program.

The college intends to train technicians who will support bench scientists in the Galveston/Houston area involved in biotech research and development.

Houston Community College, Northeast Campus

Department Chair of Biotechnology, Chemical Lab Technology, Instrumentation Technology and Process Technology: Dr. John K. Galiotos

Houston Community College has a biotech program built on its current courses in biotech and related subjects. The college offers an AAS biotech degree, as well as a one-year biotechnology certificate. Students in the one-year certificate program complete four three- and four-hour courses in biotechnology. Students in the two-year associate program complete eight three- and four-hour courses. The college places its students in various biotechnology institutions throughout the Houston area, as well as numerous Houston- and The Woodlands-based biotechnology companies.

The focus of HCC's program is fourfold—create skilled biotechnicians for the local workforce, develop corporate training programs that develop niche skills for their needs, develop advanced certificate programs in biotech specialties such as biomanufacturing, and help small business incubate some of their ideas for products and services. A key to the training of students at HCC is hands-on training and internships at biotech institutions.

Texas State Technical College Waco

Coordinator Biotechnology Program: Nicholas Cram

Texas State Technical College Waco began offering courses leading to an Associate of Applied Science degree in biotech in fall 2005. This program, approved by the Texas Higher Education Coordinating Board, is the first Biotechnology Systems Instrumentation Specialization program in the nation. In fall 2005, enrollment was nine students, and spring 2006 enrollment was fourteen students. Fall 2006 enrollment is projected to be 19 to 25 students. Core classes will include a combination of traditional biotech, as well as courses in biotech instrumentation, lasers, optics, robotics, three-phase AC power, and solid-state electronics.

TSTC Waco is uniquely suited to offer courses in robotics, chemistry analyzers, and biomedical equipment because it already has longstanding educational infrastructure in these areas. The program has signed an "intent" of articulation agreement with Stephen F. Austin State University.

Dallas County Community College District (El Centro)

Department Chair of Biotechnology (Fall 2005): Dr. Kiren Kaur

The biotech program at Dallas County Community College (El Centro) is only three-and-a-half years old. As a result, only a handful of students have graduated from the program. The college offers an AAS biotechnology degree, as well as a one-

year Level I Certificate. Students in the program complete a number of courses that span multiple disciplines including molecular biology and biochemistry, physics, genetics, and fermentation studies. Skills taught include laboratory management and safety; laboratory operations; planning, recording, and reporting experiments; caring for equipment and living cells; cell and tissue culture; genetics; pipetting; technical writing; and statistical analysis.

A number of El Centro students have completed a dual curriculum program that combines elements of medical laboratory training and biotechnology. This pairing has been a great match, because students are able to use the molecular biology techniques they learn in the El Centro program in traditional clinical laboratory settings.

El Centro has enough lab space to accommodate 20 to 30 students at one time. Because the program lacks certain very expensive equipment, the program takes students on working field trips to biotech labs at institutions such as UT Southwestern or the University of North Texas Health Science Center.

The program enrolled a full class of 10 people for the spring 2006 semester. The program does not plan to expand unless there are demonstrable opportunities for its graduates. Because of limited biotech employment opportunities in the Dallas area, the college has developed the dual curriculum concept in which students are trained for both biotech and clinical lab positions. Students who enter the program that already have a bachelor degree are highly sought after upon graduation.

Initially, the Dallas County Community College district determined that both the El Centro and Mountain View campuses would have biotech programs. However, in practice, Mountain View sends students who are truly interested in biotechnology degrees to El Centro. There is word that Mountain View plans to resurrect their program. However, no official schedule is available at this time.

Collin County Community College Program

Director: Bridgette Kirkpatrick

Collin County Community College (located in Plano) has an AAS Biotechnology degree program, as well as a one-year biotechnician certificate program. These programs are designed to give students practical laboratory experience as well as the theory behind the techniques that they learn. Five to ten students graduate from the program with AAS or certificate degrees each year. The program places a few students at small biotech companies in the Dallas area but, for the most part, graduates take positions at UT-Southwestern. Dr. Kirkpatrick deliberately keeps the program small because of the lack of entry-level biotech positions in the Metroplex region.

A number of students with bachelor degrees are in the program, including many retrainees from the computer and telecommunications industries. There are also a number of biology majors, who do not have practical experience in biotech lab techniques. Students with a previous Bachelor degree who complete the certificate program are the easiest to place because employers are excited about hiring employees with practical biotech lab experience.

Galveston College

Associate Professor and Director Biotechnology Program: Dr. James J. Salazar

Galveston College offers an AAS degree in biotechnology. This two-year, five-semester program is designed to prepare students for entry-level positions in biotech research labs. The program includes courses in general academic subjects, as well as WECM approved BITC courses. The goal of the program is to give students solid "hands-on" training in biotech laboratory techniques. Students who complete the program have to complete two internships at research laboratories. The program is a cooperative effort between Galveston College and UTMB Galveston, and all of the laboratory courses are taught at UTMB Galveston. Two students who entered the program have completed internships and graduated in spring 2006. Dr. Salazar expects twenty to twenty-five students to enroll in the program in fall 2006. The new National Biocontainment Laboratory, which is being built at UTMB Galveston, is expected to be a major employer of graduates.

Alamo Community College District, Northwest Vista

Biotechnology Coordinator: Neil McCrary

The biotechnology program at Northwest Vista (located in San Antonio) is relatively new (started in spring 2002). The college offers an AAS in biotechnology degree. Students in the program complete courses in core academic subjects, as well as five WECM approved BITC courses, in addition to an industry internship. The program is organized to provide hands-on training in biotech lab practices. The program is designed to develop well rounded biotechnicians familiar with a broad range of biotech lab practices and procedures that will allow them to work in a number of different biotech areas.

The first student to complete all of the course requirements for the AAS graduated in spring 2005. Six other students who entered the program have now graduated and completed internships. Of the six graduates, one was hired on at the internship site, and the other five are continuing their education at four year institutions. Eight other students should complete their internships by the beginning of summer 2006. At least three of these eight students have informal, contingent offers to continue working at their internship sites.

As of spring 2006, there were about 30 active biotech students at some point in the program. The program administrators hope to eventually have 40 students in the program, with 10 to 15 graduating each year. Of 30 students in the biotech program, about seven or eight have already earned a bachelor degree. Most of these students are trying to change career paths; many are in their late 30s to early 50s. Most students in the program want to complete further studies and qualify for a bachelor degree in biotechnology.

Temple College

Director of the Health Science Division: Bea Wohleb

In June 2005, the college received a Department of Labor grant of \$920,495 to develop a program for training biotechnology research technicians. As a result, the

College is well on the way to developing a strong biotechnology program which will offer an Associate of Applied Science in biotechnology research technician degree, an Advanced Technical Certificate, and an Enhanced Skills Certificate in Genomics/ Proteomics. Students will work directly in local research laboratories with well-known scientists. There are currently two primary areas of research underway in Temple. These include the Cardiovascular Institute at the Veterans Administration Hospital, and the Cancer Research Institute at the Scott & White Medical Center. The principal investigators in these institutions will provide expertise for developing these new courses and programs.

It is expected that 20 students will enroll in the program in fall 2006. The program will target the following populations: high school students through dual credit classes, students with limited English proficiency, displaced workers, and military personnel and their spouses. Laboratory facilities and classrooms will be located at the Health and Bioscience Research Facility in Temple.

The goal is to create a Bioscience Academic Center that will include dual credit classes for high school students, an Associate of Applied Science Degree from Temple College, the Scott & White Clinical Laboratory Science program, and upper level university classes.

Estimated Capacity of Existing CTC Biotech Programs

The demand for biotech technicians in the state exceeds the number of students that graduate from CTC biotech programs each year. However, in considering the implications of this shortage, it is important to consider that employment opportunities for graduates are dictated largely by the degree of regionial biotech activity and the specific biotech related skills and training they possess.

Table 1. Estimated Capacity of Existing CTC Biotech Programs

стс	Total Number of Students Currently in Program	Graduates Per Year	Projected Capacity w/ o Additional Faculty and Lab Space
Austin Community College	90	20	90
NHMCCDMontgomery College	53	15	75
Houston Community College -Northeast Campus	175	10 ~15	NA
Galveston College	20 ~ 25	5	30
Dallas County Community College District -El Centro College	10	1 ~ 3	Same unless industry indicates increased demand for graduates
Collin County Community College District	15 ~ 20	5 ~ 10	Same unless industry indicates increased demand for graduates
Alamo Community College District -Northwest Vista College	30	3 ~ 5	40
Texas State Technical College Waco	19 ~ 25	New Program	20 ~ 30
Total	412 ~ 428	59 ~ 73	

Academic Coordination

The biotech education capabilities in the state are scattered throughout a variety of four-year colleges and universities, community and technical colleges, and private education groups such as DeVry University. Dual enrollment, Texas TWO-STEPs, "One-plus-One" agreements among CTCs (core curriculum or "career foundations"), articulation agreements with four-year colleges (Two-plus-Two, etc.), and shared facilities are some of the methods Texas K-12 and higher education can coordinate and partner to benefit Texas students and industries, not only biotech.

Articulation Agreements

A major element for the efficient sharing of capabilities would be the establishment of statewide articulation agreements between CTCs, four-year colleges and universities, and among individual CTCs themselves. There are a number of reasons why Texas should pursue and facilitate articulation agreements more aggressively. The employability of CTC biotech graduates depends, in large measure, on employers' recognition of and confidence in the knowledge, skills, and abilities (KSAs) of graduates. Thus, a given CTC's acceptance of courses taught by another CTC (One-plus-One agreements) will depend on its confidence of the quality of that course. Therefore, it is highly desirable that syllabi, learning activities, and assessments be more standardized, and that course quality be assured. This would increase the possibility and attractiveness of articulation agreements among CTCs and four-year colleges and universities. Students could then obtain core foundation skills from one institution, transfer seamlessly to another for specialized skills, and continue on to a four-year, master, or doctorate degree.

A number of CTCs have already established articulation (Two-plus-Two) agreements with individual bachelor degree granting institutions.

Montgomery College has an articulation agreement with the University of Houston–Downtown (UH-Downtown) under which UH-Downtown accepts all biotech credits from Montgomery College and admits graduates of the program as juniors. Moreover, after students enroll at UH-Downtown, they can continue to take biotech courses at Montgomery College for full credit. This special arrangement is the result of consultations between the Academic Dean of UH-Downtown and Dr. Larry Loomis-Price, director of the Montgomery College biotech program.

Austin Community College has articulation agreements with Texas A&M and St. Edward's University.

San Jacinto College has an articulation agreement with UTMB Galveston.

Dallas Community College District (El Centro) has an articulation agreement with the University of Texas at Arlington.

Northwest Vista College has agreements with St. Mary's and Our Lady of the Lakes colleges to accept its biotech courses. The college is seeking to establish an articulation agreement with UT San Antonio.

Alamo Community College District, Northwest Vista is seeking to establish an articulation agreement with the University of Texas at San Antonio.

Texas State Technical College Waco has signed an "intent" of articulation agreement with Stephen F. Austin State University.

Table 2. Current CTC Articulation Agreements with Four-Year Colleges

СТС	Articulation
Montgomery College	University of Houston–Downtown
Austin Community College	Texas A&M University St. Edward's University
San Jacinto College	University of Texas Medical Branch–Galveston
Dallas Community College District	University of Texas–Arlington
Northwest Vista College	St. Mary's University Our Lady of the Lakes University University of Texas–San Antonio (pending)
Texas State Technical College Waco	Stephen F. Austin State University (pending)

Although these agreements are quite valuable to the individual CTCs, each of them is institution specific. Statewide articulation agreements would be much more effective in utilizing the educational resources of the state and significantly reduce time and cost. Again development of a standard core curriculum would materially assist in developing statewide agreements. Moreover, accreditation trends toward student portfolios and competency inventories may drive even more granular transferability in the future.

There is some sentiment among the biotech program directors that the granting of Associate of Science (AS) degrees in biotechnology instead of AAS degrees would aid in the establishment of articulation agreements between CTCs and bachelor degree granting institutions. This is commonly done among CTCs in California. However, some believe that the additional general education courses required for an AS degree would unduly decrease the number of technical courses in a program and possibly undermine placement potential and employer needs.

Nicholas Cram, Associate Professor & Biotechnology Coordinator, TSTC Waco

Some 30% to 40 % of positions now offered in the biotech industries can be well filled by CTC graduates with AAS degrees. Other positions may require a higher-level degree. Therefore, it is important that CTCs partner with four-year colleges or universities. The two-year program will provide a solid preparation for a BS degree. This is particularly true for bioinformatics.

Shared Facilities & Equipment

In many cases, individual institutions have areas of particular strength in terms of faculty, equipment, and industry contacts. For example, Montgomery College has special strength in molecular biology, Austin Community College has special strength in laboratory techniques, and TSTC Waco will have particular strength in bioinstrumentation. Sharing between various institutions strengthens the

individual programs by providing students with more choices and opportunities to succeed. Such sharing might include part-time use of special equipment, using distance learning instructional technologies to share lectures by specially qualified and frequently difficult-to-find instructors, short-term "learning camps" for semester and/or training credits, and shared best practices and outreach programs throughout the state.

Coordination and Partnerships

Institutions offering biotech programs can also partner on state and federal grant applications to leverage institutional and regional assets and increase the likelihood of award. There are several areas of interest, e.g., genomics, microarrays, bioinformatics, bioagriculture, nanotechnology, and bioinformatics, where the state's CTCs would be well served to partner and seek federal funding from agencies that finance new curriculum and program development, i.e., faculty development and equipment grants.

Grant funding sources include the National Science Foundation's Department of Undergraduate Education, especially the Advanced Technology education grants and also the Course, Curriculum, and Laboratory Improvement grants; National Institutes of Health Bridges programs; Department of Agriculture; Department of Labor's High Growth Job Training Initiative; and Department of Education grants. Texas biotech programs have been quite successful in obtaining grants from these sources in the past, e.g., Austin Community College (ACC) Bio-Link (NSF ATE), Temple (DOL High Growth Job Initiative), and Montgomery College (NSF).

In the future, Texas CTCs should partner and coordinate federal and state grant applications to leverage existing strengths across the state rather than compete against one another. The DOL grant in progress now with ACC, Texas State Technical College Waco, and Montgomery College is a great example of how Texas CTCs can partner on competitive bids for the benefit of the state. Additionally, CTCs can partner with employers through grant programs such as the Texas Workforce Commission's Skills Development Fund to design, finance, and implement customized job training programs for the biotech industry.

Initiating New Courses and Programs

To meet the growing demand for graduates of CTC biotech programs, it will be incumbent on the CTCs both to increase the number of local programs and to increase the capacity of current programs.

Jason Moore, Manager, Industrial Programs, BioHouston

All of the universities and community colleges in Texas need to begin exploring ways in which they can create biotech programs. It will take a while to develop such programs, so they need to get started as soon as possible or they will be behind the curve when the industry begins to ramp up.

Initiation of new biotech programs at CTCs will require acquisition of expensive equipment and supplies, recruiting and retention of qualified faculty, and procuring access to adequate laboratory space. Biotech companies may assist in providing some

of these needs, e.g., by providing equipment and supplies, making lab space available, offering internships to selected faculty members, and providing instructors for some classes. Cooperative agreements between CTCs can allow different programs to provide mutual support, such as shared laboratory facilities, acceptance of transferred credit, and joint classes.

Dr. Larry Loomis-Price, Director, Biotechnology Institute, Montgomery College

The entry cost of establishing new biotech programs is quite high. Qualified faculty is expensive and difficult to find. Equipment and supplies are also expensive. Adjunct faculty from industry is an important part of biotech programs. They are familiar with the latest techniques and have lots of credibility with students.

In considering new CTC courses and programs, it should be noted that there are a number of federal government programs designed to support the development of biotech education capabilities. Experience has shown that joint, coordinated proposals are usually more successful at gaining support than smaller competing proposals. Therefore, it is definitely in the interest of CTCs to consider joint proposals to appropriate federal agencies (e.g., Montgomery College, Austin Community College, and TSTC Waco joint proposal to the Department of Labor).

Coordination with Industry

In large measure, the employment prospects for CTC biotech graduates will be determined by the growth of the biotech industry in Texas. Although the availability of a trained technician workforce will not be the most important factor in a company's or research institution's decision to move to Texas, the lack of such a workforce can be a deciding factor against relocating. Therefore, it is highly desirable for industry that such a workforce be available. On the other hand, companies and research institutions can contribute significantly to the effectiveness of CTC biotech programs through such activities as providing equipment and supplies, making lab space available, offering internships to selected faculty members, and providing instructors for some classes.

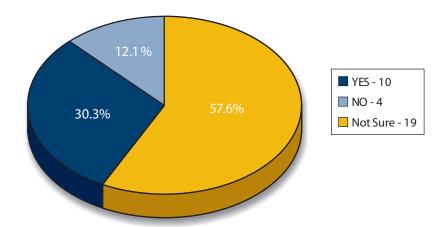
Dr. Celeste Carter, Director of Biotechnology Program, Foothill College (Los Altos Hills, California)

The biotech program at Foothills Community College has been run with no budget from the school for the last 10 years. It is really the biotech industry in the region that supports the program. The local biotech industry has been very good about donating equipment and supplies to the program. Each year, the college receives between \$100,000 and \$200,000 worth of consumables and supplies. Most of this is tissue culture supplies and equipment, which tends to be very expensive. In biotech programs, more than in other programs, there must be a very tight connection between community college biotech programs and the local industry they serve.

Coordination and cooperation among academic entities, commercial organizations, state and federal government agencies, research institutions, and biotech associations will provide symbiotic relationships to the advantage of all. The willingness of many of these organizations to cooperate is indicated in Figure 20.

Figure 20. Willingness of Industry to Cooperate with Academia

Would you be interested in partnering with high schools, technical schools, colleges and/or universities?



It should be noted that, while 30% of the respondents indicated a willingness to partner with academic groups, more than half indicated that they were not sure whether they would or not. This appears to indicate that their willingness to cooperate would depend on the details of such cooperation. CTCs are no stranger to industry partnerships, and it is anticipated that the recently increased Texas Skills Development Funds and new Emerging Technology Fund will result in increased partnerships among Texas higher education and industry. Industry can partner with CTCs in a variety of ways including donations of equipment (often these are tax deductible), sponsoring student scholarships, student internships, accommodating adjunct faculty and guest lecturers, and serving on local advisory committees.

Promotion of Biotech as a Profession

Current CTC biotech programs indicate that entry-level students typically have extensive education and/or work experience, often in other fields. Program directors agree that greater awareness of biotech is needed with high school and perhaps even middle school students to increase enrollment and ensure a long-term capacity of biotech graduates. Therefore, they strongly favor the establishment of projects that will increase the appreciation among high school students, their teachers, their counselors, and their parents of the potential career opportunities for skilled personnel, including technicians, in the biotech field. In general, most people have little or no understanding or appreciation of biotech and its implications for society. Often, some views on biotech are colored by news articles on cloning, stem cell research, and opposition to genetically modified foods with little exposure to the amazing opportunities and advances biotech holds for our collective future.

Tom Kowalski, President, Texas Health Care and Bioscience Institute

It is extremely important that the biotech community enlighten the public of the importance of biotech in their lives and to overcome current fears about biotechnology. In time, the public will be as comfortable with biotechnology as they currently are with computers. Some CTC biotech programs have already established outreach programs to educate high school students, teachers, and counselors of the nature of the biotech field, the promise of biotech to enhance people's quality of life, and employment opportunities for professionals in the field. For example, Montgomery College and Austin Community College have established outreach programs with local high schools. These programs include visits to the school by college instructors, certification for credit for selected high school courses, and integrated learning activities. Similar programs at other CTCs would increase interest in and knowledge about biotech. Again, the establishment of seamless transition schemes from high schools to CTCs would undoubtedly encourage qualified students to enroll in appropriate biotech programs.



Chapter Four: Special Biotech Programs

Although it can be reasonably assumed that students successfully completing any of the current or planned CTC biotech programs will have the KSAs necessary for successful employment in the biotech industry, there is increasing interest in the biotech field in a number of areas of specialization, including bioinstrumentation, bioinformatics, DNA and human health, and bioagriculture. There is evidence that technicians trained in these specialty areas will be rewarded by higher salaries, greater recognition, and greater opportunities for promotion. Because several CTCs are considering initiating new biotech courses or programs or expanding current programs, it would be useful to examine the attractiveness of various areas of biotech application and specialization to various CTCs in terms of basic technology, industry trends, drivers and constraints, employment opportunities, and related current programs. Each of these biotech areas are discussed in this chapter.

Bioinstrumentation

A tremendous amount of sophisticated equipment is employed to conduct research and product development in biotech environments. This equipment, which includes tools for automation (robots) and analytical instrumentation, is used to prepare samples and to conduct and analyze the results of experiments. The use of these tools is dramatically increasing the productivity of biotech research by freeing valuable researchers from nonproductive, repetitive, mundane tasks and decreasing the amount of time (i.e., money) it takes to set up and conduct large-scale experiments (Gwynne & Heebner, 2005). Additionally, the use of such tools removes a significant amount of the "human element" from certain laboratory procedures, which helps assure that large-scale experiments can be conducted in a manner that is reproducible and less prone to errors.

Automation is having an especially dramatic effect on productivity and cost savings for firms engaged in drug discovery and clinical diagnostics work (Gwynne & Heebner, 2005). Pharmaceutical companies use heavily automated, high throughput screening systems to reduce experimental errors and introduce a higher degree of repeatability into test results, which is critical to the success of FDA-monitored clinical trials. Furthermore, the use of automation in clinical laboratories and hospitals offers several advantages—accuracy, convenience, and time to diagnosis—that are critical to favorable patient outcomes. Moreover, large-scale genomic initiatives, such as the Human Genome Project, which sequenced more than three billion DNA sequences, would not be possible without these tools.

DNA Microarrays

The traditional approach to studying gene function one gene at a time is extremely time-consuming and scope-limiting, since most traits and biological processes are governed by interactions among many genes (TrueForce, 2000). Fortunately, microarrays allow researchers to document and study, at one point in time, the expression of a large number of genes on one small substrate. In practice,

DNA microarrays consist of known sequences of DNA deposited on a glass or silicon substrate. The samples, which have micron sized (10-3) dimensions, are deposited on the substrate using high-speed, precision robotics. The deposited DNA sequences, known as probes, are washed with a specially marked sample of partially unknown DNA sequence, referred to as the target, whose identity and/or abundance is being detected. The probe and target DNA sequences will bond with each other according to the complimentary base nature rules (A-T or C-G) (BIO, 2005). The microarray is then scanned with an automated "chip reader" that detects complimentary bonding. These results are quantified and analyzed in conjunction with bioinformatics tools that allow for DNA sequencing of the target. Automated chip creation and detection systems have dramatically increased the pace of "omics" (i.e., genomics, proteomics, transcriptomics, immunomics, and transcriptomics) research (BIO, 2005). An example of a microarray chip is presented as Figure 21.

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Each 20

The Way Ahead*

Each 20

The Way Ahead*

The

Figure 21. Roche Diagnostics AmpliChip CYP450

Source: Roche Diagnostics

Protein Arrays

Genes express themselves through the production of proteins. The presence of not enough or too much of certain proteins can have profound physiological consequences and lead to the development of diseases (BIO, 2005). Therefore, an essential step in understanding biological processes is understanding the function of various proteins, which is where protein microarrays enter the picture. Protein arrays are constructed in the same fashion as DNA microarrays, except that known protein sequences are deposited instead of DNA fragments. Protein microarrays will allow researchers to identify the presence of proteins that indicate the presence of certain diseases, determine the toxicity and efficacy of drugs before expensive clinical trials are conducted, and assess protein expression to identify promising new drug candidates.

Spectroscopy

Spectroscopy is a laboratory technique that measures the change in energy detected from an electromagnetic energy source after it has interacted with a sample substance. The energy source is usually a laser, and the device used to measure the change in electromagnetic energy is called a spectrophotometer (Helmenstine, 2005). Spectroscopy can be used for both quantitative analysis (amount of substance) and qualitative analysis (atomic and molecular energy levels, molecular geometries, chemical bonds, interactions of molecules, and related processes).

There are many different types of spectroscopy including nuclear magnetic resonance, which is probably the most powerful tool that scientists can use to perform detailed structural analysis of complex organic compounds. A 750 MHz nuclear magnetic resonance (NMR) spectrometer in the Pacific Northwest National Laboratory Magnetic Resonance Facility is shown in Figure 22.

Figure 22. NMR Spectrometer



Source: Pacific Northwest National Laboratory

Bioinstrumentation Industry Trends

Market Size

The market for DNA microarrays and LOC/microfluidics will grow rapidly. Key applications include pharmacogenomics and point-of-care diagnostics.

In December 2005, Frost & Sullivan reported that the global market for DNA microarrays totaled approximately \$446.8 million in 2005 and will hit \$532.1 million in 2012 (Frost & Sullivan, 2005). The market for LOC/ microfluidics

devices will grow from \$135 million in 2004 to \$835 million in 2012, a compound annual growth rate of 35.5% (Research & Markets, 2005).

Drivers

Biotechnology is a dynamic and rapidly-evolving field. Various breakthroughs, events, or decisions could materially change the nature, rate, and implications of technical advances and market developments. Factors that might accelerate or constrain the growth of the market for the biotech instrumentation tools include:

- Pharmacogenomics, Genomics and Proteomics. Biotech instrumentation
 (automation, spectroscopy, and microarrays) is essential to DNA sequencing
 and gene expression analysis (genomics and proteomics). The demand for
 these services will be especially acute among firms engaged in drug
 discovery. These firms are interested in using pharmacogenomics to provide
 drug therapies tailored to an individual's genome.
- *Point-of-Care* (*Real-time*) *Clinical Laboratory Diagnosis*. In time, biotech tools, such as LOC, will likely take over biomedical tools such as clinical lab analyzers because these technologies can perform the same critical tasks much more quickly and cheaply. Additionally, many observers of the biotech industry draw analogies between the ever-increasing number of probe sequences that can be placed on DNA chips and sequenced to advancements in the semiconductor industry related to the number of transistors that can be placed on a microchip and processor speeds Moore's Law). Such advances will mean that microarrays will be increasingly used for earlier and more specific detection of disease and identification of the predisposing factors that can influence disease risk, progression, and therapy (TrueForce, 2000). Beckman Coulter, a major manufacturer of clinical lab equipment, is beginning to realize that their company will likely establish a significant presence in this area. The company currently manufactures chemical analyzers for clinical diagnosis and believes that, to a large degree, such systems could ultimately be replaced by biotech solutions such as microarrays, biosensors, and labs-on-a-chip (Cram, 2005).

Constraints

The key barriers to the growth in demand for biotech automation and instrumentation products and services are the same ones for other biotech sectors, including:

- Slow rates of technical progress that lead to slower investment in biotech products and services. The human proteome is extremely complex and there has been a lack of success in identifying and developing appropriate stand alone tests suitable for all proteins (Shaw, 2006).
- Negative publicity concerning biotech products and services that results in widespread rejection by the public.

Bioinstrumentation Employment Opportunities

The demand for technicians to install, calibrate, maintain, and repair bioinstrumentation equipment is great and will continue to increase in the future as the demand for biotech products and services expands. These technicians will be required to be proficient not only in traditional technical areas such as robotics, chromatography, spectroscopy, and electronics, but also possess knowledge of biotech laboratory practices and techniques, including microarrays.

Biotechnology instrumentation specialists will be employed in a wide range of organizations that employ biotech instrumentation. The basic skill sets for these technicians are very similar. In addition to the skills described above, these technicians must know validation, quality control, and quality assurance.

Starting salaries for graduates are estimated to range from the 40s to low 60s, with the upper range available to students with existing degrees. A number of biotech instrument suppliers, including Bruker Optics and Beckman Coulter, both of The Woodlands, have indicated a strong interest in supporting and hiring future graduates of the TSTC Waco program. In fact, Bruker Optics has indicated that they could immediately hire several biotech instrument technicians (Cram, 2005).

Scott Jacpcynski, Production Manager, Bruker Optics

Bruker sees the need for instrumentation technicians at two levels: Our customers have an increasing demand for technicians who have a strong background in instrumentation. This background must include a knowledge of how to manage instrumentation and also the ability to perform first- and maybe even second-level repairs of equipment. Additionally, these firms also want these technicians to have an understanding of the applications they're working on. These people are specialists with a two-year degree with a certificate in an area of specialization. These technicians will work in the research and process areas of the pharmaceutical and petrochemical industries. Our company also needs in-house technicians to build the instruments that the company designs and manufactures. This person will have a background in electronics, information technology, mechanical systems, etc. This person must have a strong foundation in systems engineering because they will be responsible for the final test and calibration of instruments that have been assembled by bench technicians. This type of technician will have to have an understanding of software applications, data systems, and electronics, but also an understanding of our customers end applications through fundamental biotech or physical sciences training.

CTC Bioinstrumentation Programs

The Texas State Technical College Waco has established the first Biotechnology Systems Instrumentation Specialization program in the nation. The program has been approved by The Higher Education Coordinating Board, and courses leading to an Associate of Applied Science (AAS) degree in Biotechnology Systems Instrumentation were begun in fall 2005. Core classes include a combination of traditional biotech subjects such as chemistry, organic chemistry, cell culture techniques, genomics, proteomics, and metabolomics, as well as courses in biotech instrumentation, robotics, three-phase AC power, and solid-state electronics. A Clinical Instrumentation Program emphasizing the repair and maintenance

of clinical laboratory devices such as chemistry analyzers and lab automation equipment is in development. The launch date of this program has not been determined. (The Bioinstrumentation program outline is presented as Table 3.)

Table 3. Biotechnology Systems Instrumentation Program – AAS Degree

First Semester	Course Number	Course Title	Credit
	MATH 1314	College Algebra	3
	CETT 1402	Electricity Principles	3
	BITC 1311	Introduction to Biotechnology	3
	CHEM 1305	Introductory Chemistry	3
	CHEM 1105	Introductory Chemistry Laboratory	1
		Semester Total	13
Second Semester			
	CHEM 1307	Introductory Chemistry II	3
	CHEM 1107	Introductory Chemistry Laboratory II	1
	CETT 1479*	Solid State Components & Applications	4
	LOTT 1343	Geometrical Optics I	3
	BITC 1150	Bioethics	1
	ENGL 1301	Composition I	3
		Semester Total	15
Third Semester			
	LOTT 2336	Wave Optics	3
	RBTC 1305	Robotics Fundamentals	3
	CHEM 2323	Organic Chemistry I	3
	CHEM 2123	Organic Chemistry Laboratory I	1
	PSYC 2301	General Psychology	3
		Semester Total	13
Fourth Semester			
	BITC 2372*	Introduction to Bioinformatics & Biostatistics	3
	ITNW 1325	Fundamentals of Networking	3
	BITC 2301	Molecular Biology Techniques	3
	HUMA 1301	Introduction to the Humanities I	3
	BITC 1271*	Food and Drug Biotechnology	2
		Semester Total	14
Fifth Semester			
	BITC 2331	Cell Culture Techniques	3
	BITC 2478*	Biotechnology Device Instrumentation I	4
	BITC 2286	Biotech Internship	2
	BITC 2373*	Functional Genomics, Proteomics, Metabolomics	3
	ENGL 2311	Technical Writing	3
		Semester Total	15

*Denotes WECM local need course

Courses for the first year of the bioinstrumentation program at TSTC Waco have been developed, and six additional courses will be developed in spring 2006. These are:

BITC 2372	Introduction to Bioinformatics & Biostatistics	
BITC 1271	Food and Drug Biotechnology	
BITC 2373	Functional Genomics, Proteomics, & Metabolomics	
BITC 2478	Biotechnology Device Instrumentation I	
CETT 1479	Solid State Components & Applications	
CTEC 1441	Chemical Technology Instrumentation	

Students who complete an associate program in biotechnology systems instrumentation are suitable for entry-level positions in organizations that manufacture, service, and employ equipment such as microarrays, high-throughput sequencers, spectrophotometers, and laboratory automation equipment (robotics). These students will have a fundamental understanding of biotechnology activities like genomics, but will also be able to perform basic installation, calibration, maintenance, troubleshooting, and repair of biotech instrumentation. Other important skills for these technicians include knowledge of sterile manufacturing techniques, specimen and reagent preparation, and experience in proper hazardous waste handling, transport, and disposal. Students will also have to develop documentation skills that allow them to input, collect, and analyze data, and then present that data succinctly to their employers. Finally, employers will expect these technicians to maintain critical equipment so it is functioning properly—downtime is extremely expensive to biotech companies.

In considering the establishment of bioinstrumentation programs at other CTCs, it is estimated that the initial cost will be somewhere between \$750,000 and \$1,500,000, depending on the amount and type of equipment already available and whether or not private companies are able to provide some of the required equipment. TSTC Waco, unlike most other CTCs in the state, was particularly well suited to offer courses in robotics, lasers, optics, chemistry analyzers, and biomedical equipment because it already had longstanding education infrastructure in these areas. It is estimated that the cost of supplies for the program will be about \$3,000 per student per semester.

In considering the establishment of additional CTC bioinstrumentation programs, it should be realized that it may be difficult to identify and engage faculty qualified to teach the courses included in the program. Because of the costs and difficulties listed, it may not be desirable to establish stand-alone bioinstrumentation programs at other CTCs. However, it might be possible for students to complete core courses at one CTC and then transfer to another CTC for specialized training in bioinstrumentation through One-Plus-One or "Career Foundation" agreements. Some specialized lectures could also be shared among CTCs to take advantage of the special expertise at partner colleges.

Another approach could be for students to complete their basic biotech program at their home college and then specialize in bioinstrumentation or other available specializations at another CTC after graduation. This extra course work would result in the award of an Advanced. Technical Certificate or Certificate. Several colleges,

including Montgomery College, Austin Community College, and El Centro, have expressed an interest in such an arrangement. These colleges have also expressed an interest in offering some of the new courses being developed for the TSTC Waco instrumentation program within their current biotech curricula.

In time, the demand for bioinstrumentation technicians should increase significantly. Additional CTCs could develop full bioinstrumentation programs based on these new courses and existing biotech curriculum. Fully developing the courses outlined above into replicable materials will position Texas to respond quickly to such a future demand.

Bioinformatics

Bioinformatics is the field of study that encompasses the creation and development of computational tools and information technologies that can solve problems in molecular biology (National Bioinformatics Institute, 2001). Bioinformatics allows researchers to store, retrieve, and sift through large biological datasets containing information about gene sequences and expression (genomics), protein production (proteomics), and biological structures and interactions. The ultimate goal of this work is to give scientists models they can use to predict the behavior of complex cell processes and their effect on macro-level biological events such as diseases and drug reactions (Kim, 2004).

The most significant driver for the development of bioinformatics tools has been genome sequencing initiatives such as the Human and Plant Genome Projects. Thanks to more sophisticated lab equipment and advances in molecular biology, scientists are able to rapidly sequence the genomes of a wide variety of organisms.

The abundance of information generated in these projects is very challenging from a data storage, retrieval, and analysis perspective. For example, the Human Genome Project, which was completed in 2003, generated data related to more than three billion DNA sequences. This problem will only grow larger in the years ahead as scientists try to make sense of the avalanche of genomic data being generated. In fact, according to Dr. Richard Casey, Chief Scientific Officer of bioinformatics firm RMC Biosciences, scientists are now able to generate the genome of about one organism per week (Casey, 2005). Decoding the meaning of these sequences to specific gene-related events (e.g., gene expression/protein production) that govern important biological processes is now the goal, and bioinformatics will be central to developing this understanding.

Bioinformatics Technology Overview

A serious challenge facing biotech researchers is the development of computational models and tools that will allow them to sift through the large datasets of biological information being developed by various genomics, proteomics, metabolomics, immunomics, and transcriptomics projects. Bioinformatics, the discipline of biotechnology that attempts to address this problem through the use of advanced information technologies, can be divided into two fields. The first relatively simple one involves gathering, storing, accessing, and visualizing biological information stored in "very large" relational databases. This information includes complete genomes of various organisms including humans, animals, plants, insects, and various microorganisms such as yeast. It also includes protein sequences and three-

dimensional structures, information about metabolic pathways, and embryonic cell line and hybridoma information. As many genome projects involve researchers across many institutions, communication tools like the Internet and peer-to-peer networks are essential to allow researchers to rapidly share their findings across disparate IT platforms and time zones.

Data mining, the second, more difficult challenge, involves recognizing patterns and relationships in the gene and protein sequencing data stored in such databases. These pattern analysis tasks include finding genes in DNA sequences, predicting the structure of newly-discovered proteins and RNA sequences, grouping protein sequences into clusters of related sequences and developing protein models, and aligning proteins that are similar to each other to determine evolutionary relationships (Biomedical Informatics, 2005). It is through data mining (computational biology) that researchers will achieve their ultimate goal, which is to develop models that allow scientists to predict the relationships of complex cell processes, protein production and interaction, and ultimately their effect on macrolevel biological events such as diseases and drug reactions (Kim, 2004).

The wealth of genome sequencing information has required the design of software and the use of computers to process this information. An overview of how computers can be used to process biological information is presented in Figure 23.

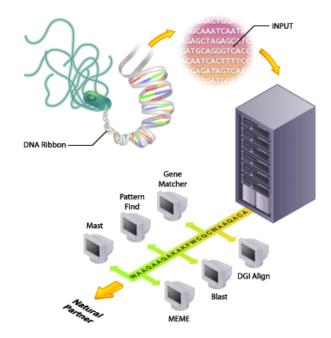


Figure 23. The Use of Computers to Process Biological Information

Source: Artist Jiang Long for University of British Columbia, Bioinformatics Centre

Bioinformatics Industry Trends

The field of bioinformatics is rapidly expanding and evolving to meet new challenges related to efficient organizing and extracting information from the large biological databases that are being developed. Researchers in the field are constantly exploring new ways of exploiting this data more effectively (Carter,

2005). Ultimately, the goal is to develop models so scientists can construct models of biological systems that allow them to test hypotheses before carrying out expensive experiments in the lab. Such models could be used to predict reactions to various drugs and gene therapies much more rapidly and cheaply than available with current tools.

Market Size

According to a 2005 report by BioInformatics, a market research and consulting firm, the global bioinformatics market is estimated to be over \$1.4 billion (Biomedical Informatics, 2005). They expect the market to grow nearly 16% per year, reaching \$3 billion by 2010. Most of this growth will be fueled by the increasing employment of bioinformatics in genomic and pharmacogenomic research. The market for databases that house information related to gene sequences and protein structures and interactions is currently the largest part of the market, at an estimated \$717 million. The market for sophisticated data mining and data analysis tools used to construct computational models from the data for the purposes of drug research is the second largest part of the market, currently, \$445 million (Biomedical Informatics, 2005).

Drivers

- Genomics and Proteomics Studies. In addition to the Human and Plant Genome Projects, there are several other genomic projects at academic institutions around the world dedicated to sequencing the genetic material of various organisms including various insects and bacteria. These projects generate massive amounts of data that must be collected, stored, and analyzed. These projects will be a significant driver for bioinformatics manpower and tools well into the future. The application of bioinformatics to proteomics will also become increasingly important, as scientists target proteins for the development of new drugs.
- *Pharmacogenomics*. Genomics and proteomics projects are increasingly important to drug development and discovery. Many pharmaceutical companies have large bioinformatics research and development divisions that are using bioinformatics to accelerate and cut the cost of drug development. BioInformatics reports that pharmaceutical companies expect bioinformatics to reduce the annual cost of developing drugs by 33% and the time to market by 30% (BioInformatics, 2005).
- Point-of-Contact Medical Diagnostic and Therapeutic Uses. When lab-on-a-chip (LOC) or microarray technology becomes fully realized, the hope is that doctors will be able to perform multiple lab functions (DNA preparation, sequencing, data analysis) on very small devices, in real time. Making sense of this data will require the use of bioinformatics tools that can perform gene expression analysis and also associate protein interactions and structures with various ailments. As such, bioinformatics makes LOCs promising candidates for timely point-of-contact diagnoses, eliminating the need for expensive, time-intensive clinical laboratory diagnosis of diseases (Barry & Ivanov, 2004).

• *Increasing Computer Processing Capabilities*. The accelerating increase in computational power will increase the capabilities and cost effectiveness of bioinformatics applications.

Constraints

Very Complex Computational Problems. In 2004, there were over 826 National
Institutes of Health grants related to bioinformatics (Kim, 2004). This is a
very "hot topic" for research, but the problems of protein sequencing and
structure determination and modeling are computationally difficult and
complex. There is no guarantee that bioinformatics tools can solve all of
these problems and ultimately deliver solutions that business cases can be
developed to support. If so, the demand for bioinformatics could be slowed.

Bioinformatics Employment Opportunities

Bioinformatics is a multi-disciplinary field that draws from discoveries and advancements in a wide range of fields including molecular biology, physics, statistics, biochemistry, and computer science. The need for researchers with expertise in both biotechnology and information technology tools is growing not only at the research and academic level, but also at the level of real-world applications and computational biology. This convergence of interconnected scientific disciplines will continue to grow more important in the future, especially with the field of nanotechnology.

Although it was once widely believed that computational work should be performed by information technology specialists, there is a growing perception that efficient use of biocomputational tools also requires a very good understanding of biological principles. Most likely, bioinformaticians will be employed in research organizations that have genomics programs, such as pharmaceutical companies, that need to store and sift through large amounts of data.

Students who complete an associate program in bioinformatics are suitable for entry-level positions in biotech organizations that collect and analyze biological sequencing data. These students will have a fundamental understanding of genetics, molecular biology, DNA sequencing analysis, protein and molecular modeling, Internet communications and interfacing, BioPerl programming, database retrieval, data integration, and data mining. Obviously, the ideal bioinformatics candidate would have an in-depth understanding of all of these areas, but even a fundamental knowledge of some of the subjects with a hands-on competency in others, makes a candidate that much more valuable.

To be successful in bioinformatics positions, students must be able to access information from the National Center for Biotechnology Information (NCBI) databases and other important molecular modeling programs. NCBI maintains the largest collection of bioinformatics databases and tools for molecular biology research, and it is essential that specialists in bioinformatics know how to retrieve information stored in them efficiently. In fact, knowledge of the databases is the fundamental and most important skill for bioinformaticians (University of Florida, 2005). Table 4 lists some of the most important bioinformatics databases.

Table 4. National Center for Biotechnology Information – Important Bioinformatics Databases

Title	Description
GenBank	GenBank® is the NIH genetic sequence database, an annotated collection of all publicly available DNA sequences.
UniGene	UniGene is an experimental system for automatically partitioning GenBank sequences into a non-redundant set of gene-oriented clusters. Each UniGene cluster contains sequences that represent a unique gene, as well as related information such as the tissue types in which the gene has been expressed and map location.
BLAST	BLAST is a sequence similarity tool that facilitates the analysis of nucleotide databases.
PSI-BLAST	Position Specific-Iterated BLAST for searching protein databases for sequence similarities.

There are a number of institutions in Texas using bioinformatics to collect and make sense of the biological data that they are accumulating. Significant projects include:

- Baylor College of Medicine Human Genome Sequence Center. The Baylor College of
 Medicine was one of only five institutions in the United States responsible for the
 sequencing completed for the Human Genome Project. The college is home to the
 Human Genome Sequence Center (HGSC), which sequenced approximately 10%
 of the genome. The center, which operates 24 hours a day, employs over 200 staff
 members now also completing genomics projects related to organisms such as
 fruit flies and rats (Moore, 2005).
- TexGen. TexGen is a partnership among academic institutions in the Houston Medical Center including the Baylor College of Medicine, the University of Texas Health Sciences Center -Houston, and M.D. Anderson Cancer Center to collecting genetic material from millions of people, and their close relatives, who enter area hospitals. The idea is to establish correlations between individuals' genomes and their general state of health and response to certain drug treatments and other therapies. Storing and making sense of this data will require extremely sophisticated bioinformatics tools.
- M.D. Anderson Cancer Genomics Core. M.D. Anderson established the Cancer Genomics Core to collect and sequence genetic data related to a wide variety of cancers.
- Scott and White Medical Center Cancer Research Institute. Dr. Art Frankel, a world renowned cancer researcher, heads Scott & White's new Cancer Research Institute located in the 500,000 square foot Temple Life Science Research and Technology Center. Dr. Frankel's tenure at the center began in July 2005.

At the university level, a number of institutions have established research groups in bioinformatics. These institutions are listed in Table 5.

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Table 5. University Bioinformatics Research Groups

Rice University	W.M. Keck Center for Computational Biology
Baylor College of Medicine	Department of Computational Biology
Texas A&M University	Bioinformatics Working Group
University of Texas, Austin	Center for Computational Biology and Bioinformatics
University of Texas, El Paso	Bioinformatics Computing Laboratory
University of Texas, Medical Branch/Galveston	Bioinformatics Computing Laboratory
University of Texas, Southwestern	BioHealthBase Bioinformatics Resource Center for Biodefense and Emerging/Re-emerging Infectious Diseases
University of Texas, Southwestern	Immunology Database and Analysis Portal (ImmPort)

Each of these institutions will require technicians trained in bioinformatics. Salaries for entry level technicians specially trained in bioinformatics are estimated to be in the \$35,000 to \$45,000 range.

Although the demand for Texas community college graduates with these skills is not currently significant, demand is expected to grow in the near future as bioinformatics is increasingly employed across the entire range of biotech activities including plant and animal biotechnology, drug and vaccine design, gene therapy, etc.

CTC Bioinformatics Programs

Although no Texas CTC currently offers a bioinformatics program, a small number of community colleges across the nation have already established associate-level programs in the field. Typical core classes include a combination of traditional biotechnology disciplines such as genetics, DNA sequencing, and molecular biology, as well as information technology courses related to multimedia databases, data management systems, data mining tools, and programming languages. In addition, all of the programs include an introductory course in statistics. Most are joint programs between the biotechnology and information technology departments at the college, reflecting the fact that traditional biotechnology and information technology form the foundation of bioinformatics. Existing courses and programs in these areas in various state CTCs indicate that a foundation for bioinformatics courses and programs is already in place. For example, the University of Houston College of Technology is developing a Bachelors degree in general bioinformatics and a specialized healthcare bioinformatics program. San Jacinto College is working towards an articulation agreement, wherein students will take their lowerlevel security, database and systems courses at the community college prior to transferring to the university to complete a specialized bioinformatics curriculum (O'Brien, 2006).

Although it was once widely believed that computational work should be performed by information technology specialists, there is a growing perception that efficient use of biocomputational tools also requires a very good understanding of biological principles. Most likely, bioinformaticians will be employed in research organizations that have genomics programs, such as pharmaceutical companies, that need to store and sift through large amounts of data. CTCs that have existing programs in biotechnology or information technology are well suited for training individuals in the area of bioinformatics.

It is estimated that initiation of a formal bioinformatics program would cost about \$40,000, assuming that a basic biotech program was in operation and that the college had extensive computer capabilities. Although the demand for such graduates is unclear in Texas now, colleges could mitigate the risk in starting such programs by developing a gradual approach. At first, they could offer one or two core bioinformatics courses such as BioPerl and/or Introduction to Bioinformatics databases. As employers in their areas express an increased demand for such employees, colleges could expand these programs into concentrations within their existing biotechnology programs. Ultimately, if the demand for such employees became great enough, the colleges could develop full-scale programs that result in AAS degrees. Before initiating a formal bioinformatics program, college deans and other instructional officers should work closely with biotech companies and academic research institutions in order to make informed decisions about the design, initiation, and conduct of bioinformatics courses and programs at their institutions.

Because of the continuing need for data gathering, analyzing, storing, and archiving, the inclusion of a course in bioinformatics would be desirable for most biotech programs.

A possible model for the initiation of bioinformatics at a Texas CTC is Foothill College in Los Altos Hills, California, which is offering what is believed to be the first formal bioinformation program in the United States. The college offers both an Associate of Science degree and a Career Certificate Requirement in Bioinformatics. The Career Certificate requires students to complete about 54 units in one year. The Associate of Science is essentially equivalent to the Career Certificate, except that it requires students to complete a number of additional general education requirements (a minimum of 90 total units).

The program accepts about 26 students per year, which is about the same number of students that are accepted into the regular biotechnology program. Students who complete the Foothill bioinformatics program have no problem obtaining bioinformatics positions with firms in the Bay Area. Graduates of the Foothill program are being placed at jobs with salaries in the mid-40s to 50s range (Carter, 2005), depending on their level of experience. However, it should be noted that the biotech industry in California is much more mature than it is in Texas. The curriculum for the Foothills College Bioinformatics program is shown in Table 6.

Table 6. Foothills College Bioinstrumentation Curriculum

Biotechnology Core Courses	
BTEC 51A	Cell Biology for Biotechnology (3 units)
BTEC 52A	Molecular Biology for Biotechnology (3 units)
BTEC 65	DNA Electrophoretic Systems (1 unit)
BTEC 68	Polymerase Chain Reaction (1 unit)
BTEC 71	DNA Sequencing & Bioinformatics (1 unit)
BTEC 76	Introduction to Microarray Data Analysis (2 units)
BTEC 64	Protein Electrophoretic Systems (1 unit)
BTEC 66	HPLC (2 units)
Computer Science Core Courses	
CIS 52A	Introduction to Data Management Systems
CIS 52B2	Introduction to Oracle SQL (5 units)
CIS 68A	Introduction to UNIX (5 units)
CIS 68E	Introduction to PERL (5 units)
CIS 68H	Introduction to BioPerl (5 units)
COIN81	Bioinformatics Tools & Databases (5 units)

It is also worth noting that Bellevue Community College in Bellevue, Washington, was selected by the Department of Labor to be one of five National Centers for the Biotechnology Workforce. The college, which received \$775,000 from the Department of Labor, will develop model programs in the area of bioinformatics. Bellevue will create national skill standards in bioinformatics, design curriculum for use in high schools and community colleges, develop faculty training programs, and offer classroom and online training. The College has already initiated its first bioinformatics class, Bioinformatics Essentials, which covers fundamental bioinformatics concepts (Bellevue Community College, 2006).

DNA and Human Health

Using their knowledge of DNA and its relationship to the other basic building blocks of life, scientists have developed a number of tools that manipulate genetic material at the molecular level. These tools, known collectively as biotechnology, employ biological materials and their components to produce a wide variety of products and services. Among these products and services are a number that can be used to ameliorate various health problems including antibiotics, insulin, pharmaceuticals, DNA-based vaccines, and genetic tests that can uniquely identify individuals and diseases.

An understanding of diseases and other health abnormalities at the molecular level is extremely important. It allows scientists to precisely identify the exact genetic components and processes that are at the root of various ailments. By developing therapies targeted toward specific malfunctioning components, scientist can develop interventions much more efficiently and effectively than with traditional "shotgun" medical approaches.

DNA and Human Health Technology Overview

There are a number of areas of biotech that are of major importance to human health and wellness. Some of these are discussed briefly in the following paragraphs.

Human Genome

No matter how simple or complex an organism is, each and every one of its cells contains the exact same set of DNA. In human beings, every cell carries two sets of 23 chromosomes composed of DNA. This DNA includes genes that govern important life processes, and other DNA material that scientists have yet to determine a purpose for. Genes compose about 3% of the total DNA material, and the other 97% is "leftover" DNA that many scientists theorize that humans came to no longer need as they evolved (Kahn, 2005). The human genome, or the total genetic material in a human being, consists of about three billion base pairs. The goal of the Human Genome project, which was concluded in spring 2003 (rough draft in 2000), was to generate a genome and complete DNA sequence of human beings. Genomics, decoding the meaning of these sequences to important life functions, is now the goal.

There are several other genomic projects related to so-called model organisms, whose genetic material has been used as a baseline for other standard genetic analysis. These organisms include the mouse, fruit flies, yeast, plants, and several types of bacteria (Griffiths, 1999). Not only are these projects important to areas such as agriculture and environmental amelioration, they are also important for establishing human analogs for genetic research and early drug tests.

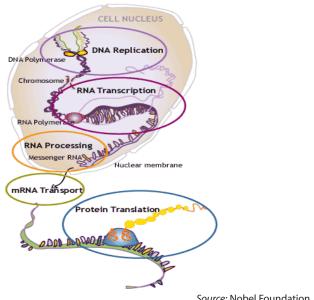
DNA-RNA-Protein Relationship

The genetic information contained in a human cell is carried on DNA that is composed of several thousand genes. These genes carry the "code" that a cell uses to construct protein molecules that carry out important cell functions and act as building blocks for structural body parts such as muscle and bone. The manner in which "information" flows from genes determines protein composition and consequently the functions of the cell (Nobel Foundation, 2004). Proteins regulate and drive processes that take place in a cell.

Since genes contain the information for manufacturing proteins, understanding the function of proteins means understanding the function of genes. A diagram of protein transition is presented as Figure 24.

Before a cell can replicate (copy) itself, a copy of its DNA is generated for the new cell. When the cell must generate proteins, the corresponding genes are transcribed into RNA (transcription). This RNA undergoes processing so that the parts that do not contain information are removed (Nobel Foundation, 2004). After processing, the RNA is transported outside of the nucleus where proteins are constructed according to the code in the RNA (translation).

Figure 24. Protein Translation

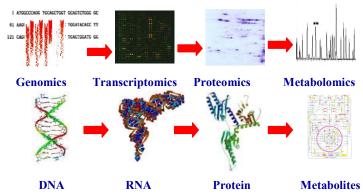


Source: Nobel Foundation

Genomics, Proteomics, Metabolomics, Immunomics and Transcriptomics

A key to developing a complete understanding of biological systems is determining how genes and proteins operate together to influence life processes. The "omics" – genomics, proteomics, metabolomics, immunomics, and transcriptomics—are the tools that scientists are developing and using to assemble findings about distinct individual biological components to generate a complete view of how biological systems work (BIO, 2005). The "omics" rely heavily not only on the tools and processes of biotechnology, but also on information technology tools (bioinformatics) that allow researchers to assemble extremely large datasets and mine them to discover relationships. A diagram of the relationship between the various "omics" is presented as Figure 25.

Figure 25. Relationship between the "Omics"



Source: National Centre for Plant & Microbial Metabolomics

Understanding gene expression at the global level of the genome, proteome, transcritpome, and metabolome will provide unprecedented opportunities to help explain the unknowns of biological processes. Scientists will be able to complete global comparisons of different functions of various cell types, tissues, and entire organisms (National Centre for Plant & Microbial Metabolomics, 2005). Discoveries in this area could provide research services to pharmaceuticals and medical diagnostics companies that allow them to develop new diagnostics and therapeutic agents for human diseases using global and targeted approaches.

Pharmacogenomics

Pharmacogenomics is the field of study that attempts to explain how a person's total genetic makeup affects their response to drugs. The term is an amalgamation of the words pharmacology and genomics and represents an intersection of the two disciplines. Scientists in the field are using information from various genomic, proteomic, transcritpomic, and metabolomic projects to explore the genetic basis for the variance in drug response among individuals. The goal of this work is ultimately to develop custom drug therapies, or "personalized medicine," for specific patient populations or individuals (American Medical Association, 2004). Such an approach would allow doctors to quickly develop effective drug therapies for their patients, while minimizing harmful side effects.

Embryonic Stem Cells – Humans

Researchers believe that, by understanding the complex mix of environmental and genetic factors that turn embryonic stem cells into adult stem cells, they could use embryonic stem cells to develop replacement cells and tissues that could be used to treat a wide variety of ailments, injuries, and diseases (National Institutes of Health, 2005). For example, Type I diabetes is caused by a deficiency of pancreatic cells, called islet cells. If scientists could generate replacement islet cells from a patient's stem cells, they could develop an extremely effective treatment for the disease.

Monoclonal Antibodies

Immune system cells manufacture proteins known as antibodies. These antibodies exhibit specificity, which, in biology, refers to biological molecules that bind to only one type of molecule (BIO, 2005). For example, an antibody that attacks and provides immunity from one strain of flu virus provides absolutely no protection against other strains. Since antibodies bind to specific molecules, they are extremely powerful diagnostic tools that can identify specific molecules such as cancer cells even when they appear in extremely small quantities. Monoclonal antibodies have been used to:

- Identify pollutants in the environment
- Detect the presence of deadly microorganisms in food
- Distinguish healthy cells from cancerous ones

• Quickly diagnose infectious diseases in plants, animals and humans

Monoclonal antibodies can also be used to deliver targeted therapeutic treatments. One disadvantage of traditional chemotherapy is that it kills cancerous and normal cells indiscriminately, which is the cause of the horrible side effects associated with treatment. Chemotherapy attached to specific cancer cell antibodies is a solution to this problem. The antibodies allow the chemotherapy to be delivered directly to cancer cells, while avoiding healthy cells. Researchers are also using monoclonal antibodies to combat specific immune system cells that attack transplanted organs and cause autoimmune diseases (BIO, 2005).

Gene Therapy

Gene therapy involves repairing or replacing defective genes that cause disease. One of several approaches is being explored to accomplish this task (Department of Energy, 2004):

- A normal gene can be swapped with a nonfunctioning gene. This can be accomplished at a non-specific location within the human genome or through a process known as homologous recombination.
- An abnormal gene could be repaired to its original function through a process known as selective reverse mutation.
- The degree to which a damaged gene expresses (turns on and off) itself could be changed.

To date, the Food & Drug Administration has not approved any gene therapy treatments. In fact, as recently as 2004 the Department of Energy reported that, "Current gene therapy is experimental and has not proven very successful in clinical trials. Little progress has been made since the first gene therapy clinical trial began in 1990" (Department of Energy, 2004). However, in April 2006, researchers from Germany, Switzerland, and Britain reported that they had used gene therapy to successfully treat two men who were born with an incurable genetic disorder that suppressed their ability to fight off bacterial and fungal infections (Connor, 2006). The scientists are hopeful that their results will lead to other successful treatment of genetic diseases.

DNA Vaccines – Immunity Stimulants

DNA vaccines, also known as gene vaccines, combine aspects of gene therapy and traditional vaccines to stimulate the body's immune system against disease. Traditional vaccination, which involves infecting the body with a weakened form of a disease to activate the body's immune system response and provide protection against the stronger form of the disease, has been around since the late 1700s when physician Edward Jenner noticed that milkmaids who were exposed to cowpox developed immunity against smallpox, a much more virulent form of the same disease (Griscom, 2002). Highly-effective vaccines have also been developed for diseases such as measles, mumps, and polio.

However, because these vaccines involve the use of living pathogens, they are expensive to manufacture, inconvenient to ship and store, and are dangerous to use against extremely virulent viruses such as AIDS.

Scientists believe that DNA vaccines can overcome some of these problems. Their idea is to inject harmless pieces of DNA from pathogens into a person's body. Once the DNA is injected into the body, it enters the nucleus of cells where it begins the process of manufacturing pathogen proteins (Griscom, 2002). The immune system is "fooled" and begins attacking the foreign proteins even thought the body has not been exposed to the actual disease. According to Jenny Riemenschneider, a scientist at the U.S. Army Infectious Diseases Center at Fort Detrick, "DNA vaccines are incredibly easy to make. You can produce them in days or weeks, whereas the traditional methods often take years" (Griscom, 2002). Clinical trials are being conducted for gene vaccines that combat anthrax, avian flu, Ebola, Alzheimer's, and certain forms of cancer.

DNA Fingerprinting

Although human DNA contains material common to all individuals, there are portions of it that are unique to each person. These unique portions of DNA allow scientists to distinguish individuals from one another with an amazing degree of certainty. The uniqueness of the DNA fingerprint has made it the primary, legally-accepted way of assessing and verifying the identity of criminals who leave DNA evidence (hair, skin, blood, saliva, etc.) at crime scenes.

DNA fingerprinting can also be used to verify the identity of a person's parents (most often the father, but also the mother in cases of adoption), since a child inherits one set of chromosomes from both their mother and father. Such evidence is often used in civil paternity suits. DNA fingerprinting is also useful in determining the likelihood that a couple's offspring will develop diseases with a genetic basis such as cystic fibrosis, sickle cell anemia, and Huntington's disease. Genetic counselors can review prospective parents' DNA sequences, identify traits responsible for certain disorders, and advise parents about the probabilities of their children inheriting the trait from each parent and developing the disorder.

A related application involves the identification of genetic disorders. In such cases, the DNA sequences of a large number of people who have a genetic disorder are compared to the DNA sequences of a large number of people who do not have the disorder. Based on this comparison, the genes responsible for genetic disorders can often be identified (Betsch, 2004). In fact, a number of companies are using data from the Human Genome project to offer "at home" genetic tests that individuals can use to determine their predisposition to certain ailments including cystic fibrosis, blood clotting, and breast cancer. Patients send in a small sample of saliva to the manufacturer of the kit, and a doctor and genetic counselor analyze its DNA content. The tests, which are inexpensive and convenient to administer because they do not require a visit to the doctor, are becoming quite popular. According to the companies that make the kits,

customers can use the results of the tests, which are available online, to make lifestyle choices that control the onset of disease (Elias, 2005).

DNA and Human Health Industry Trends

Market Size

Biopharmaceuticals and Pharmacogenomics. Business Communications Company projects that the worldwide market for pharmacogenomics will rise from \$1.24 billion in 2004 to \$3.7 billion in 2009, an average annual growth rate (AAGR) of 24.5% (Hamilton, 2005). Additionally, according to the Biotechnology Industry Organization there are more than 370 biotech drugs and vaccines in clinical trials related to treating over 200 diseases including Alzheimer's, cancer, pulmonary hypertension, AIDS, and diabetes. In 2005, over 32 biotech related, and small molecule products were approved by the Food & Drug Administration (Ernst & Young, 2006).

DNA Testing. The majority of forensic testing is performed by publicly funded laboratories such as crime labs in major cities (e.g., Houston and Austin) and the Texas Department of Public Safety. Smaller municipalities that cannot afford their own DNA fingerprinting labs rely on DPS for analysis. BCC projects that the market for forensic DNA testing services will rise from \$745.21 million in 2004 to over \$1.75 billion in 2010, an average annual growth rate of 15.9% (Business Communications Company, 2005).

Drivers

- Reduced Medical Costs. Pharmaceutical companies often develop drugs that
 work well in certain populations, but generate harmful side effects in
 others, forcing withdrawal of the drug. Pharmacogenomics could allow
 pharmaceutical companies to avoid this problem by developing drugs
 targeted for specific genetically identifiable populations. Because of their
 potential to be manufactured much more efficiently and at a lower cost than
 traditional vaccines, DNA vaccines could offer material reduction in
 vaccination programs.
- Biodefense/Homeland Security. Since 9/11 and the anthrax attacks of fall 2001, funding for infectious disease research has skyrocketed from essentially zero dollars to \$6 billion a year (Gorenstein, 2005).
- Genetic Counseling/Disease Prevention. "At home" genetic tests may allow
 consumers to determine their genetic predisposition to various ailments
 including breast cancer. The tests are easy to administer and can be done
 without the assistance of nurses or doctors. Moreover, such tests help ensure
 that sensitive information is not recorded in official medical histories.
- Forensics DNA Testing. The Federal Justice for All Act of 2004 requires that DNA testing be made available to anyone convicted of a federal crime that proclaims their innocence. The Act, which provides \$1 billion in funding over five years, offers incentives to states to clear their backlog of untested

DNA evidence related to criminal trials (Business Communication Company, 2005).

Constraints

- Continuous Progress in Biotech R & D is Not Assured. Progress could be slow or nonexistent. Vaccines and gene therapies are in clinical trials that may not be successful. Additionally, the field of pharmacogenomics is still in the very early stages of development; a lot of work remains to be completed in the fields of genomics and proteomics to understand how the interactions between various genes and proteins in our bodies affect drug response and metabolism.
- Negative Publicity. Negative or misleading publicity about the efficacy or danger of biotech products could impede their development. Additionally, a number of biotech startups that received significant funding in the 1980s and 1990s to commercialize gene therapy products have folded, costing investors millions of dollars. As a result, the investor community has become skeptical of funding large-scale gene therapy projects.
- Social Rejection. Concerns about the ethical impact of biotechnology could result in restrictions on certain kinds of research. For example, federal research funding for embryonic stem cell research has been banned since 2001 except under exceptional circumstances.

DNA and Human Health Employment Opportunities

Biotechnicians are employed in a number of institutions that research, commercialize, and use DNA-based products and services for human health care. One area where the demand for technicians with specialized skills is especially acute in Texas is drug discovery. A fundamental understanding of genomics, proteomics, and metabolomics laboratory procedures will be very important to technicians employed in this field. Another need in this area is quality assurance and validation technicians. Because of stringent FDA regulations, quality assurance and validation is a significant requirement for biopharmaceutical companies, even if they are only manufacturing small amounts of drugs for use in clinical trials.

Additionally, traditional health care technicians, such as medical lab technicians, are increasingly using biotech lab techniques in their work. El Centro Community College has created a dual curriculum program that combines training in both traditional medical laboratory and biotechnology techniques. Graduates of this program are able to use molecular biology techniques in traditional clinical laboratory settings, increasing their attractiveness to employers (Lock, 2005).

The salary for entry-level technicians in this area varies widely. They typically range from the low 20s to the low 40s. These salaries are highly regional and specialty dependent. Basic laboratory support technicians with undifferentiated

skills are the lowest paid technicians. Bioprocessing technicians employed in the biopharmaceutical industry tend to command the highest salaries.

Because of the high quality of medical, biochemistry, and molecular biology research in Texas, e.g., UT Southwestern Medical Center in Dallas, the M.D. Anderson Cancer Center in Houston, and Baylor Medical Center in Houston, it is apparent that the potential for employment of CTC biotech graduates in the DNA and health-care area is quite high. Moreover, a number of possible breakthroughs, events, or decisions could materially enhance the employment opportunities of graduates in health-care related applications for biotech. The challenge is to match graduate capabilities with employer needs. A key element is making potential employers aware of and appreciative of the qualifications of these graduates.

CTC DNA and Human Health Programs

Currently, there are a number of Texas CTCs that grant, or are planning to grant, AAS degrees and Certificates in biotechnology. Most of the current Texas CTC biotech programs (described in Chapter Three) are well structured to meet the KSA requirements of employers in the DNA and health-care area. These programs can serve as models for the programs at other CTCs. The development of a statewide core DNA and health-care curriculum would help assure the qualification of graduates and enhancetheir chances for attractive employment. Modification of this core curriculum could be made to serve local needs. Because of rapid developments in the biotech field, existing biotechnology programs must stay abreast of technical, economic, and social developments in the areas of drug discovery, DNA vaccines, gene therapies, DNA fingerprinting, and nanotechnology. Curricula should be modified to reflect the impact these developments will have on the skills they need to teach their students.

CTCs that are interested in establishing DNA and health-care biotechnology programs have a wealth of programs that they can draw from to develop the academic (lecture) component of their programs. BioLink is a National Science Foundation funded Advanced Technological Education (ATE) Center for Biotechnology that was started in 1998. BioLink's mission is to support the development of biotechnology education programs at the community and technical college level "by providing cutting-edge professional development for instructors, by improving curriculum, by making use of technologies and by creating a system that promotes the sharing of information."

It is estimated that initiating such a program will cost about \$50,000. Course supplies are estimated to be about \$1,500 per student per semester. Programs of this type are typically able to support about 20 students.

There are a number of grants for colleges that want to bring in faculty from other community colleges to help develop courses in the early stages of a program's development. Additionally, BioLink provides instructional and curriculum materials that biotechnology programs can utilize as templates for their own materials. It is important to point out, however, that much of the content in such courses, especially the laboratory or "hands-on" courses, must be developed with input from local biotech employers.

CTCs interested in starting programs must establish relationships with employers in their respective areas to ensure that there is actually a demand for graduates that justifies the expense and effort of starting a new program.

Bioagriculture

Agricultural products are an important component of the Texas economy, annually generating \$16 billion in sales and over \$3.4 billion in exports (Texas Department of Agriculture, 2006). These products include forestry and crop products such as pine timber, cotton, rice, and hay, as well as animal products such as livestock and poultry. The markets for such products, from the consumer and producer ends, are becoming increasingly international. As a result, Texas agricultural producers are constantly developing new production practices and techniques to maintain and extend their competitive advantage. The use of biotechnology to facilitate agricultural production (bioagriculture) is one of the tools that producers are using to facilitate this goal.

Scientists are employing biotechnology to create or improve a wide variety of products including more disease-resistant breeds of wheat and rice, biopesticides that are less costly and environmentally harmful than their chemical counterparts, and selective breeding of highly valuable livestock assets. Additionally, in a technique known as biopharming, researchers are exploring ways that proteins and chemicals vital to the production of pharmaceuticals and vaccines can be grown and harvested in crops like corn and soybeans.

Bioagriculture Technology Overview

Although bioagriculture is considered a relatively young scientific discipline, human beings have exploited biological components and processes for their own use for thousands of years. Herders have selectively bred animals and plants to develop offspring with certain desirable characteristics. For example, mules, the cross between a horse and donkey, were bred by farmers to have greater strength and more endurance than horses, while at the same time being less excitable. However, the breeding of mules illustrates a disadvantage of primitive biotech techniques that rely on the use of entire organisms: mules are almost always sterile, and separate lines of horses and donkeys must be maintained for breeding purposes.

Thus, the goal of modern bioagriculture is to understand the precise function of certain cells and molecules, and exploit their properties in ways targeted to solve specific problems while, at the same time, generating less harmful side effects and unintended consequences. Modern bioagriculture is not so much concerned with the principle of using organisms to accomplish certain tasks, as it is with the specific techniques for doing so, including DNA sequencing, molecular biology and chemistry, gene and molecular cloning, cell and tissue culture techniques, polymerase chain reaction, etc. (Nagda, 2005).

The value of bioagriculture techniques to the agriculture industry is discussed in the following paragraphs.

Plant Biotechnology

Genetically Modified (Transgenic) Crops. For centuries, farmers have crossbred plants to produce progeny (hybrids) that combine the most desirable traits of their parents. For example, the commercial wheat varieties used in the production of modern bread are the result of the hybridization of various wild

wheat varieties over the last 9,000 years (Levetin & McMahon, 2003). It is a goal of biotechnology to give modern plant breeders the same capabilities through genetic manipulation. The promise of transgenic crops includes increased yields, increased disease and pest resistance, and the ability to withstand unfavorable environmental conditions such as droughts and extreme cold.

Recombinant DNA technology not only allows plant breeders to selectively transfer and combine desirable traits among plants but, in some cases, from other kinds of organisms. For example, a gene in a bacterium responsible for producing a protein that kills disease causing fungus can be transferred to a crop that does not possess the gene (BIO, 2005). After the gene transfer, the crop also begins to produce the anti-fungal protein. The result is crop protection without the need for environmentally harmful fungicides. Transgenic techniques are more precise than traditional crossbreeding and hybridization, which transfer thousands of genes of unknown function and often require several generations of offspring to produce results.

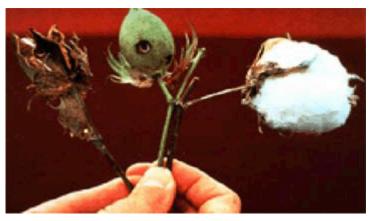
The year 2005 marked the 10th year that genetically modified crops were approved by the Food & Drug Administration and available to farmers in the United States (Council for Biotechnology Information, 2005). The Council found that almost 75% of all the soybean and cotton grown in the United States, and 33% of the corn, was derived from a genetically modified source. Although the demand for such products seems to be steadily increasing, a number of people fear that such products have been rushed to market without adequate study of their long-term effect on ecological systems, as well as on animal and human health.

Herbicide Tolerant Plants. Herbicides are used to destroy weeds that compete with cash crops for nutrients in the soil. Unfortunately, these herbicides are quite expensive, produce undesirable environmental side effects, and ironically, are often harmful to the very crops they are meant to protect. Using transgenic techniques, scientists have developed plants that are tolerant of specific herbicides.

Increased Yields. By manipulating specific genes, scientists can vary cell processes that have a direct effect on crop growth. For example, scientists are using "gene blocking" techniques to manipulate plant metabolism of critical nutrients like nitrogen and to channel certain chemicals from one part of a plant to another. Yields increase as these techniques cause starch to collect in potato tubers as opposed to leaves or when fatty acids collect in the seeds of oil-seed crops such as canola (BIO, 2005). The result is larger potatoes and increased oil yields per acre of planted field.

Biopesticides. The use of microorganisms as biopesticides is being explored. These natural pesticides are harmful to specific targeted pests, but are non-toxic to humans, animals, and desirable insects. They may also be useful against pests that have developed a resistance to conventional chemical pesticides. Bacillus thuringiensis or Bt is such a biopesticide. Bt, which has been used since the 1930s, appears naturally in soil and is toxic to insects like the European corn borer, which costs American farmers over \$1 billion in losses each year (BIO, 2005). An example of the value of biopesticide-treated cotton is presented as Figure 26.

Figure 26. Results of Insect Infestation of Bt (right) and non-Bt (left) Cotton Bolls



Source: Monsanto

Natural Protection for Plants. Scientists have developed chemicals that trigger and amplify a plant's natural defense mechanisms against insects and diseases. These plants are better able to protect themselves against threats.

Bioherbicides. Scientists have developed bioherbicides from natural materials such as fungi that are known to attack and kill specific kinds of weeds without harming nearby crops.

Enhanced Nutritional Value. Scientists are developing genetically engineered crops that have increased nutritional value. Examples include soybean oils with decreased amounts of trans fatty acids, and corn for feeding livestock that contains increased amounts of lysine, an often used amino acid supplement (Pollack, 2006).

Animal Biotechnology

Biotechnology is also being used to enhance the production of animal products such as livestock, fish, and poultry.

Disease Containment. Using biotechnology, breeders can rapidly diagnose diseases that devastate livestock herds and poultry flocks, including hoof-and-mouth disease, brucellosis, and trichinosis. In addition, biopharmaceuticals can be used to treat such diseases, and new vaccines can be employed to protect farm animals from diseases. Scientists will be able to genetically type pathogens to identify the origin and track the movement and spread of diseases through and between herds.

Selective Breeding. Just as in plants, animal biotechnology is being used to guide the development of breeding programs. Producers can test animals for genetically transferred diseases and remove them from breeding programs so that healthier offspring can be produced.

Cloning by Splitting Embryos and In Vitro Fertilization. Animals with desirable traits are selected for breeding. Instead of mating the animals naturally, their sperm and eggs are collected in a Petri dish and allowed to fertilize. Once the

in vitro fertilized egg develops into to a two-day-old embryo, it is implanted into a female of the same species and allowed to grow to term (i.e., an embryo transplant). In other cases, the embryo is divided into several parts, and each cluster is implanted into a female. This procedure, known as cloning by splitting embryos, has been used for decades in livestock herds (Bluhm, 1999). It is essentially the same process that produces identical twins in nature. The problem with this method of cloning is that, even with knowledge of the quality of the parents, the quality of their progeny is still, at best, subject to guesswork. An illustration of splitting embryos is presented as Figure 27.



Figure 27. Splitting Embryos of Highland Cattle

Before Splitting

Source: Mapleview Farms

After Splitting

Biopharming

Biopharming involves the use of genetically engineered crops to produce proteins or chemicals for pharmaceuticals. These proteins and chemicals are extracted and purified after the crops have been harvested for use in pharmaceuticals. Currently, proteins for protein-based drugs are developed in highly-sterile facilities, where stainless steel fermentors are used to manufacture a range of biotech products (Felsot, 2002). These fermentors are very expensive to build and operate.

Advocates of biopharming claim that their techniques can produce pharmaceutical quality proteins and chemicals at a dramatically lower cost than current production methods (Ohrlogge & Chrispeels, 2003). However, there are concerns that the risks associated with such crops are unknown and that they could crossbreed with crops used in the food supply, resulting in devastating consequences (Colorado State University, 2004). Such concerns are not totally unreasonable when one considers that the crops most often used in current field trials include corn, tobacco, and rice. A number of large multinational firms, including Syngenta and DowAgroSciences, have invested significant research monies in biopharming.

Bioagriculture Market Trends

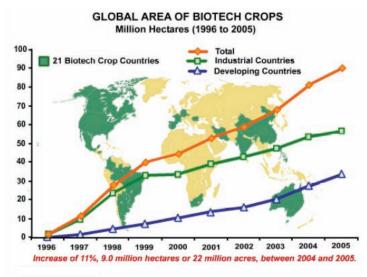
Market Size

Genetically Modified Crops. The amount of land planted with biotech crops in 2005 exceeded 222 million acres in 21 countries (ISAAA, 2005). Almost 55% (117 million acres) of these biotech crops were planted by farmers in the United States. Significant portions of this total included genetically modified corn varieties and herbicide-tolerant soybeans. The market value of biotech crops, which was \$5.25 billion in 2005, is expected to exceed \$5.5 billion in 2006 (ISAAA, 2005). The market is expected to grow steadily as increasing numbers of developing countries, including China and India, expand their use. A diagram of the growth of biotech crops is presented as Figure 28.

Biopharming. Frost & Sullivan projects that the market for biopharm crops will reach \$2.2 billion in 2011(Reuters, 2005).

Animal Biotechnology. Biotechnology-based products and services accounted for over \$4 billion of the total \$21 billion animal health-care market in 2004 (Jain PharmaBiotech, 2005). Jain PharmaBiotech, a firm that provides research and consulting services to the pharmaceutical and biotechnology industries, projects that animal biotechnology products will grow to be a \$5.1 billion market in 2005 and a \$12.5 billion market by the year 2010.

Figure 28. Growth of Biotech Crops



Source: Clive James, 2005.

Drivers

• Less costly, more efficient crop production. Biotechnology allows farmers to develop new crop breeds that can be grown more efficiently than traditional crops. The success of such plants has accelerated the adoption of existing biotech varieties and spurred increased interest in genetically modified crop varieties that are still in development.

- Demand in developing nations. The higher production yields growers in developed nations, such as the United States, enjoy requires expensive infrastructure including irrigation systems, pesticide management programs, and farm equipment. Small-scale farmers in developing nations could overcome these challenges because many of the benefits associated with advanced agriculture infrastructure (e.g., drought mitigation and pest control) are "built" into genetically modified crops.
- Less expensive biopharmaceuticals. It is hoped that the proteins and chemicals used in pharmaceuticals can be grown less expensively in modified crops. Such protein-based pharmaceuticals would be cheaper to produce than existing products that rely on expensive fermentation equipment to produce essential ingredients.
- Environmental benefits. Crops that are genetically modified to be more
 disease and pest resistant and to more efficiently pull nutrients from their
 environment require less chemical fertilizers, herbicides, and pesticides.
 This is essential because these chemical-based products often have a
 deleterious effect on the environment. The increased adoption of genetically
 modified organisms could reduce grower reliance on chemicals and generate
 less environmental pollution.
- More disease-resistant livestock and poultry. Producers lose billions of dollars annually to animal diseases. Biotechnology offers the promise of diagnostic tools, vaccines, and drugs that can be used to more effectively diagnose and treat animal diseases. Additionally, biotech tools can be used to identify genetic disorders for the purpose of improving animal breeding programs. Because these tools save producers money, demand for them is expected to grow as additional products enter the market.

Constraints

- Misinformation. Although the safety of genetically modified organisms must be approved by both the Department of Agriculture and the Food & Drug Administration, the public is often uninformed about their safety. In the minds of many consumers, talk of genetically modified organisms stir images of "Frankenstein" foods with dire long-term health consequences.
- *Bad publicity.* A highly-visible incident that calls into question the safety of genetically modified organisms could lead consumers and the government to call for tighter regulation of the market and dramatically slow the adoption and development of bioagricultural products.
- Technology road bumps. There is still much to learn about the complex relationship between genes and specific traits in organisms, especially animals. Scientists still know relatively little about the specific genes related to increased yield potential, improved stress tolerance, disease progression, and other animal and plant characteristics. Continuous progress in biotech research and development is not assured—progress could be slow or nonexistent.

Bioagriculture Employment Opportunities

The vast majority of animal and plant biotechnology research in the state is conducted at four-year universities. Opportunities for two-year graduates with biotech degrees at these institutions are limited at this time because many of these institutions use undergraduate, Master, and Ph.D. students to perform laboratory tasks. Opportunities for two-year graduates in companies that specialize in animal and plant biotechnology research product and development appear to be limited at this time. However, this demand could begin to grow in the future as technology developed at the state's universities is spun off into startup companies, or as leading bioagriculture companies increase their research presence and demonstrate an increased demand for such workers.

Technicians will be affected by growth in the bioagriculture industry in one of two ways. The first is using technicians involved in the research, development, and commercialization of bioagriculture products and processes. These technicians will be employed by firms that actually develop bioagricultural products and services. These technicians will be laboratory support workers, production technicians, and instrumentation specialists who assist scientists in animal and plant biotechnology laboratories (e.g., Bayer Crop Science, Department of Agriculture Plant Stress Labs) or are employed in facilities that manufacture such products. The second group of technicians will be employees in traditional agricultural firms that employ bioagricultural tools to facilitate the production of plant and animal products. Although these technicians will not develop biotechnology products, they must understand the impact of such tools on their industry.

It must be noted, however, that the directors of the state's current biotechnology programs have indicated that, to date, they have placed few, if any, students within companies with a pure plant and animal biotechnology focus.

It is estimated that salaries for entry-level bioagriculture technicians typically range from \$20,000 to \$24,000 per year. The compensation of public sector employees is generally much lower than that of the private sector.

CTC Programs

Currently, there are no biotechnology community college programs in the state nor, indeed, the nation, with the narrow focus of plant and animal biotechnology. However, many of the skills learned in existing biotech programs are directly applicable to occupations in bioagriculture firms and agriculture-oriented research universities. For example, core biotechnology disciplines such as molecular cloning proteomics, genomics, and bioinformatics are essential to plant and animal biotechnology research and applications.

A number of community colleges have agricultural programs with specializations in a variety of areas related to bioagriculture, including agriculture farm and ranch management, animal science, forestry, etc., whose curricula will be impacted by biotech products and tools. Areas of impact include veterinary science, forestry, horticulture, entomology, agronomy, and wildlife conservation and management. Students will need to know how biotechnology will affect traditional agricultural

practices, such as breeding programs, and the science underlying new strains of crops such as cotton and rice.

As a result, community colleges should stay abreast of the needs of bioagriculture and agricultural industry in their immediate regions. For example, the Lubbock Regional Bioscience Initiative is interested in developing and sponsoring workforce development initiatives with the biagriculture industry in the Lubbock region, specifically Bayer Crop Sciences. The goal of LRBI is to have the region's high schools, community colleges, and four-year universities partner to develop curriculum that ensures a future workforce to meet the needs of the region's bioagriculture industry. Another model for Texas CTCs is the new BioNetwork BioAg Center in North Carolina, which was formed to coordinate education and training activities in agricultural biotechnology. The mission of the program is to develop courses, programs, and curricula to ensure that North Carolina has a well trained agriculture biotechnology workforce.

Colleges that have existing biotechnology programs are well suited for training individuals that can work in plant and animal biotechnology firms. The cost of establishing a formal bioagriculture program built on an existing biotech program is estimated to be about \$40,000.



Chapter Five: Status of Biotech in Texas

Texas Position in Biotech

Although Texas has a number of very strong research institutions and a long history of biotech discoveries, the overall biotech industry in Texas lags well behind the industry in Massachusetts, New York, North Carolina, and, particularly, California, primarily because of the lack of a strong biotech infrastructure, the small number of venture capitalists knowledgeable about biotech investment, and shortage of experienced executives in biotech. However, there is considerable awakening interest in biotech in Texas, and the state could become a major biotech player in the relatively near future. This chapter discusses the reasons that Texas currently lags the nation's leading biotech areas, as well as current and planned biotech activities in the state.

Limited Commercialization

Although Texas research institutions generate a significant number of new patents and discoveries, the number translated into successful businesses in Texas is small. This reality is indicated by the fact that, in 2003, there were 37 biotech companies in Texas compared with 239 in the New England area, 213 in the San Francisco Bay area, 110 in the San Diego area, and 81 in the Los Angeles area. Comparing these figures with cumulative institutional research expenditures during the 1999-2002 period in which Texas expenditures were 40% of those in California, 57% of those in Massachusetts, and 75% of those of New York, indicates the disproportion of research expenditures and successful businesses.

Dr. Warren Huff, CEO, Reata Pharmaceuticals

Texas has quite a number of elite research scientists in the two critical areas for life sciences development: molecular biology and biochemistry. As an example, UT Southwestern has four Nobel Prize winners. Fourteen of its major research labs are run by members of the National Academy of Sciences. UT-Southwestern ranks consistently in the top two or three institutions in the country in molecular biology and biochemistry research. There is also elite research being conducted at labs at M.D. Anderson Cancer Center, Baylor, and UTHSC-Houston and Galveston. There are also several elite labs at Texas A&M. Work at all of these universities will develop a handful of world-class product development opportunities.

There are quite a number of commercially successful biotech products based on ideas conceived in Texas. However, the commercial realization of the products was made in other states. Texas probably has the least industry for the most medical research anywhere in the world. This paradox is very striking.

The failure of Texas to develop a strong biotech industry has been attributed to several factors. First, Boston, San Francisco, San Diego and other leading biotech centers committed to building biotech industries at least two decades ago and have

continually expanded this industries. There are many reasons why new companies tend to locate in areas with existing industries, e.g., available work forces, suppliers, and customers; ability to take part in joint ventures and share ideas; and alternate employment opportunities.

Dr. Dennis Stone, Vice President for Technology Development, University of Texas Southwest

Texas ranks third or fourth in the United States in terms of basic research funding completed at universities. This is an important fact because biotechnology is a relatively immature industry. Unlike semiconductor or telecommunication startups, 99% of biotech startups are built around technologies that originated in university-sponsored research. ScienceWatch, a group that tracks the strength of publications based on how often they are cited and the quality of journals that they appear in, ranks UT Southwestern second in the U.S. in biochemistry and molecular biology, two of the most important fields of investigation for biotech. UT Southwestern spent \$330 million on basic research in 2004.

Other factors working to Texas' disadvantage are the lack of knowledgeable venture capital and experienced senior management. Several industry experts have offered the opinion that two or three success stories might change national perceptions of Texas as a candidate for new biotech investment and lead to enhanced investment in the state. Such a development would, obviously, positively impact the employment situation for CTC graduates in the field. Although the availability of a trained technician workforce will be an important factor in a company choosing to locate in Texas, it will not typically be a deciding factor.

The situation facing Texas companies is illustrated by Figure 29, which shows the importance of various factors to company success. Figure 30 shows the current status of Texas in each of these factors.

Dr. Donald Hicks, Professor, Political Economy and Public Policy, University of Texas at Dallas

A chokepoint to developing a strong biotech industry in Texas is that the typical biotech startup does not aim for an IPO anymore. The liquidity event they are looking for right now is to be bought out by a big pharma company. Pharmas are putting a lot of money into biotech companies; they are trying to buy innovation because their patent pipelines are running dry. They are buying new material to put in their pipeline. Once the pharma purchases the biotech company, there is a tendency to want to move that company to the same region in which the pharma operates. The reason they want to move the biotech company is that Texas does not have the skilled biotech managerial talent to commercialize the products. Texas needs to develop a pipeline of people who know how to manage and run a biotech company that manufactures biotech products.

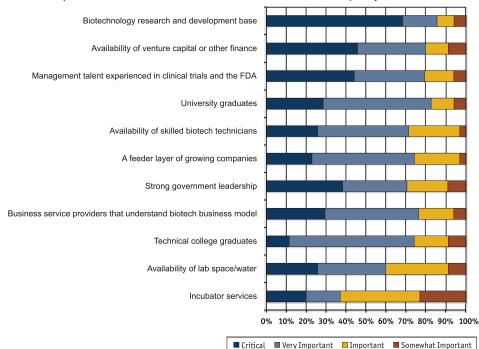
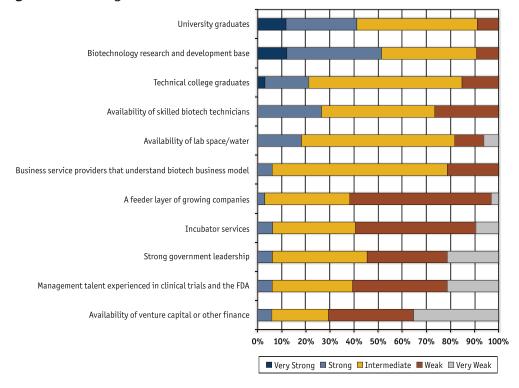


Figure 29. Importance of Various Factors to Biotech Company Success





The responses of survey respondents, illustrated in Figure 29, confirm the observations of the biotech experts. A significant majority, 71% (27 of 38), rated government-sponsored funding of biotech research as a critical or very important factor to the growth of a vibrant biotech sector in the state. Additionally, the

availability of financial resources (71%) and financial incentives (76%) for private biotech enterprise development were rated by respondents as critical or very important factors to the success of the biotech industry in Texas. Of interest to the state's CTCs, 53% rated biotech technician workforce development as a critical or very important activity. Surprisingly, a relatively small percentage (29%) rated embryonic stem cell research as an activity that was critical or very important to the growth of the state's biotech sector.

On the other hand, the need for coordinated action within the state with regard to these issues is illustrated in Figure 30, where very few respondents rated Texas as being very strong or strong in these areas—biotech research and development (42%), availability of venture capital (5%), technical college graduates (18%), availability of skilled biotech technicians (26%), and a feeder layer of growing biotech companies (3%). There is a need for the state's biotech community to address these issues.

Funding Difficulties

As indicated in Figure 30, a major problem for Texas biotech businesses is the difficulty of obtaining capital, particularly before Phase I clinical trials.

Dr. Donald Hicks, Professor, Political Economy and Public Policy, University of Texas at Dallas

Texas biggest chokepoint is that the Texas venture capital community is not familiar with biotech investments, e.g., risk factors, huge amount of resources, long commercialization cycles, and they don't understand how to invest in the biotech industry. That is starting to change. Startech in Dallas has put money into a small handful of biotech startups including Reata and also ODC Technology which was launched out of Baylor Research Center. The potential relationship between the pharmas and the biotech companies does not change the need for VC funding. The pharmas will not buy the biotech companies until the small molecule products they are developing are at least in Stage III and approved. Venture money will get the biotech companies to this point.

Dr. Dennis Stone (Vice President for Technology Development, University of Texas Southwest

The biggest hurdle for Texas is to transfer bench technologies into commercial vehicles, either by licensing agreements or startup companies. There have not been anywhere near the number of companies formed in Texas that the level and quality of research would suggest. The reason for this discrepancy is that most of the biomedical research that goes on within Texas occurs at state institutions—the University of Texas, Texas A&M, etc. It is very difficult for state supported institutions to directly form corporations. Baylor Medical College, a private institution, is the exception. BMC has been able to foster commercialization through its early stage venture capital firm, Baylor College of Medicine Technologies.

Need for Coordination

The growth of a strong biotech industry in Texas would be greatly facilitated if the various academic, research, and capital providers selected a particular area for concentration and formed cooperative agreements. University biotech programs and medical research centers in Texas, including the world-renowned medical facilities

in the Houston area, are providing outstanding research in the biotech arena. These resources could provide a base for a solid biotech industry in Texas. Unfortunately, however, such a robust industry has not yet developed.

A strong biotech industry in the state would be strongly promoted by the success of two or three biotech startups founded around technologies developed at the state's research universities. Concentration of capabilities, funding, and effort would enhance the probability of such successes.

Dr. Warren Huff, CEO, Reata Pharmaceuticals, Inc.

Texas has the main ingredient to have a significant biotech industry presence—world-class research. What Texas is missing is management teams and venture capitalists with world class biotech experience. Texas needs one or two notable successes to be a catalyst for a lot of additional activity. San Diego had early success that spawned several other companies in their wake. The money that was made in these early successes was used to fund the startups.

Dr. Donald Hicks, Professor, Political Economy and Public Policy, University of Texas at Dallas

Biotech clusters tend to take off after one or two companies became very successful. These success stories spawn several other companies. For example, San Diego's first biotech success, Hybritech, spawned a number of leaders who started their own companies, producing a family of companies that includes Gensia Laboratories, Ligand Pharmaceuticals, IDEC, Dura Pharmaceuticals, and Nanogen, as well as several biotech oriented venture-capital companies. Texas is one or two major liquidity events from developing a strong, rapidly-growing biotech industry. Companies such as Reata are strong candidates for taking this leadership position.

Dr. Donald Hicks, Professor, Political Economy and Public Policy, University of Texas at Dallas

Biotech, more than any other industry, is very, very close to university research. The ideas come out of university research for the most part. One of the big problems for this industry, in general, and Texas specifically, is that there is not good tech transfer at the universities. Texas does not commercialize university-sourced research easily. In an analysis of patents granted from the mid-1970s to the early 1990s that led to the emergence of the biotech industry, I found that, in the number of university patents during that time, UT ranked as number two and Texas A&M as number eight or nine. However, because of institutional problems related to tech transfer, and the lack of VCs with a biotech background, those patents were never used as the foundation of a biotech industry in the state.

Given the importance of early and mid-term funding to start up biotech companies, it is interesting to note where Texas companies have received funding as indicated in Figure 31.

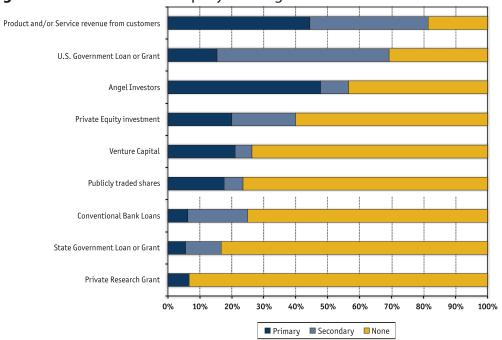


Figure 31. Texas Biotech Company Funding Sources

The largest number of respondents (29%) indicated that the majority of their operating funds were derived from angel investors, which indicates that these companies are very early in their development. Such companies are desperately in need of venture capital and grants from federal and state governments to demonstrate the commercial viability of the technologies they are developing. Thus, it is interesting to note that only 13% of respondents indicated that they had received support from federal or state sources.

Current Biotech Activities in Texas

There is currently a significant amount of biotech activity going on in Texas, and this activity promises to be significantly expanded the relatively near future. Many regions across the state are developing organizations to foster the growth of biotech activities in their region. Although the Houston/Gulf Coast region (Houston Medical Center, The Woodlands Research Park, and Galveston) is clearly the leader in biotechnology research and commercialization, other regions of the state are beginning to emerge. The following is a regional breakdown of significant biotech activities.

Houston/Gulf Coast Area

The region between the University of Texas Medical Branch Galveston, the Texas Medical Center, The Woodland Research Park, and Texas A&M University is widely considered the leader in biotech and bioscience research and commercialization.

Houston

The mission of BioHouston, formed in 2001 by academic institutions with a significant health-care focus in this region, is to foster life sciences industry

growth in the region through workforce development training, public relations initiatives, and lobbying. BioHouston includes representatives from the offices of tech transfer, technology commercialization, and research at member academic institutions. Other members include academic development staff from these institutions and service providers (accountants, attorneys). Institutions involved in BioHouston include Baylor College of Medicine, M.D. Anderson Cancer Center, Rice University, NASA, Texas A&M University, Institute of Biosciences & Technology, University of Houston, University of Texas Health Science Center of Houston, and University of Texas Medical Branch Galveston.

Texas Medical Center

The Texas Medical Center is the largest medical center in the world, hosting more than 40 member academic institutions that conduct over \$1 billion of federally funded research and thousands of clinical trials each year. Despite the Center's prominence in biotech and medical research, the area lags behind the Northern California, San Diego, Boston, and other regions in biotech commercialization. Important biotech activities and institutions in the Center include:

- Baylor College of Medicine Human Genome Sequence Center. The Baylor College of Medicine was one of only five institutions in the United States responsible for the sequencing completed for the Human Genome project. The college is home to the Human Genome Sequence Center (HGSC), which sequenced approximately 10% of the genome. The center, which operates 24 hours a day, employs over 200 staff members who are now also completing genomics projects related to organisms like fruit flies and rats (Moore, 2005). The Center also worked with Texas A&M to sequence the bovine (cattle) genome.
- Texas Institute for Genomic Medicine. The Texas Enterprise Fund has established a grant of \$50 million to create the Texas Institute for Genomic Medicine. The Institute, which is a partnership between Texas A&M and Lexicon Genetics, will create copies of a mouse embryonic stem cell library that is extremely useful in the study of disease diagnosis, treatment, and prevention in humans.
- TexGen. TexGen is a partnership among academic institutions in the Houston Medical Center including the Baylor College of Medicine, the University of Texas Health Sciences Center-Houston, and M.D. Anderson Cancer Center. The goal of the partnership is to collect and sequence genetic material from millions of people who enter area hospitals. The idea is to establish correlations between individuals' genomes and their general state of health and response to certain drug treatments and other therapies.
- M.D. Anderson Cancer Genomics Core. M.D. Anderson established the Cancer Genomics Core to collect and sequence genetic data related to a wide variety of cancers.
- *Rice University.* Rice is a major center of nanotech research in the world. Research is conducted at both the Center for Nanoscale Science and

Technology and the Center for Biological and Environmental Nanotechnology. Several companies in the nanobiotechnology arena have sprung from research developed at the university including Nanospectra and CSixty. Additionally, important work in the area of computational biology and bioinformatics is conducted at the W.M. Keck Center for Computational and Structural Biology.

- Institute of Molecular Medicine for the Prevention of Human Diseases. The University of Texas Health Sciences Center-Houston created the Institute in 1995 to address six key areas of disease research: cardiovascular diseases, cell signaling, human genetics, immunology and autoimmune diseases, protein chemistry, and vascular biology. The Institute is headed Dr. Ferid Murad, winner of the 1998 Nobel Prize in Medicine.
- University of Texas Research Park. The University of Texas Health Sciences
 Center-Houston has created Research Park to allow academics and business
 entities in the Texas Medical Center to collaborate on biotech research and
 commercialization. The Park, which will be operated by UTHSC Houston's
 Office of Biotechnology, will contain over one million square feet of
 laboratory research facilities and office space.
- Texas Heart Institute. The Texas Heart Institute, founded by Dr. Denton Cooley, is developing important cardiovascular drugs and gene therapies in cardiovascular indications.
- University of Houston. The University of Houston has established the Science Engineering Research and Classroom Complex, which will allow researchers in various colleges at the university to collaborate in interdisciplinary research related to biotechnology and nanotechnology research. Additionally, the Center for Life Sciences Technology, which is located in the College of Technology, has received a Wagner Peyser grant from Governor Perry to facilitate biotech workforce development. The Center, which was founded in 2005, is creating a consortium of universities, community and technical colleges, biotech companies, and research institutions to facilitate the training of a biotech workforce that can provide the skill sets necessary to support and accelerate the development of the biotech industry in the region. In pursuit of this goal, the center plans to establish mock manufacturing facilities for "on-the-job-training" (OJT) in several biotech specialization areas.

The Medical Center is home to several companies which are founded around technologies developed at the institutions described above. Companies include:

 Encysive Pharmaceuticals (NASDAQ: ENCY) is a developer of small molecule drugs used to treat cardiovascular and inflammatory diseases. Argatroban, the company's first product to be granted FDA approval, is being marketed by GlaxoSmithKline for the treatment of heparin-induced thrombocytopenia, a disorder related to kidney failure in which there are insufficient platelets in a patient's blood to facilitate clotting. • *Tanox* (NASDAQ: TNOX) is a developer of monoclonal antibodies used to treat autoimmune, infectious, and inflammatory diseases. The company's flagship drug, Xolair, which it developed in conjunction with Genentech and Novartis, can be used to treat allergic asthma and hay fever by blocking allergic reactions. The company was founded by Dr. Nancy Chang.

Baylor College of Medicine Technologies

A significant gap in the Texas biotech industry is the ability to fund the transition of technologies from the laboratory stage to a point of realization that allows investors to feel confident about investing monies for product commercialization. A group that helps biotech startups bridge that gap is the early stage venture capital firm, Baylor College of Medicine Technologies (BCMT), which funds technologies developed within the Baylor College of Medicine. In a typical year, BCMT funds two to four companies. Since 1983, BCMT has started over 35 companies, and they currently have about 17 companies in their active portfolio. These companies are in different stages of development: some are extremely early stage, some are fairly far along. Other venture capital firms with biotech experience: in the region include Cogene, Principals, Essex Woodlands Health Ventures, and Prime Technology Ventures.

The Woodlands Research Park

In the early 1980s, oilman and The Woodlands developer George Mitchell recognized the need to foster the development of high-tech industry in the region and created The Woodlands Research Forest. Mr. Mitchell personally provided financial incentives for biotech companies to move to the region. These incentives included equity investments, lab space, land, and buildings. The Research Forest is now home to more than 19 biotech companies and a total workforce of about 1,100 (*Houston Chronicle*, 2005). Three major biotech employers in the include Lexicon Genetics, Sigma Genosys, and Bruker Optics.

- Lexicon Genetics (NASDAQ: LEXG) is a drug discovery company that employs its patented mice gene "knockout" technology to identify genes that are potential points of therapeutic intervention or pharmaceutical targets. The company is partnering with Texas A&M to create copies of a mouse embryonic stem cell library that will be extremely useful in the study of disease diagnosis, treatment, and prevention in humans. The company was founded by Dr. Arthur Sands on gene knockout technology developed at the Baylor College of Medicine. The company has about 735 employees, 630 of whom are located in Texas (Colbert, 2005).
- *Bruker Optiks* (NASDAQ: BRKR) designs and manufactures spectroscopic (light absorption) instrumentation used in biotech research and development to identify various biological structures (e.g., proteins) of interest.
- *Sigma Genosys* manufactures synthetic DNA and peptides that can be used in biotech research.

A biotech research group in The Woodlands Forest is the Life Sciences & Health

group of the Houston Advanced Research Center. The group's primary research interest is developing biomarkers for cancers, infectious diseases, and environmental toxicology, specifically the toxicity of nanomaterials like single-walled carbon nanotubes, titanium dioxide, and selenium dioxide. In the highly interdisciplinary area of environmental toxicology research, HARC collaborates widely with universities in Texas including UTMB Galveston, UTHSC Houston, and Texas A&M.

Galveston

Galveston, home to the University of Texas Medical Branch Galveston, received a \$167 million grant from the National Institutes of Health to build the National Biocontainment Laboratory, which should be complete within three years. The goal of the laboratory, one of only two planned by NIH, is to develop vaccines and therapeutics that are effective against infectious diseases and threats. The additional faculty and research support to perform the strategic research needed to prepare for these threats is expected to create over one thousand jobs. UTMB Galveston is also the lead institution for the Western Regional Center for Excellence for Biodefense and Infectious Disease sponsored by the National Institute of Allergy and Infectious Disease and the National Institutes of Health. Other participating institutions include UT Austin, UT El Paso, UT Southwestern, UT Health Sciences Center-Houston, Baylor, and Texas A&M.

As a result of this build up, UTMB Galveston is viewed by many scientific leaders and policy makers as one of the federal government's lead institutions in the area of biodefense and emerging infectious diseases. The additional faculty and research support needed to perform this strategic research is expected to create over one thousand jobs. Educated, highly-qualified technicians will be essential to developing this laboratory, and UTMB-Galveston believes that community colleges will be an essential element in providing these workers. In parallel with its research activities, UTMB Galveston is working with economic development agencies and industry groups to plan how the appropriate commercialization vehicles can be put in place to ensure that technologies developed in the new national lab, the only one in Texas, can be developed for the nation's benefit and the common good of Texas. Potential partners currently include GE Healthcare, Isis and Sirna.

Central Texas Corridor

In the Central Texas corridor, i.e., the Austin/San Antonio/Bryan/Temple area, there are currently a number of biotech-related activities. These activities include a number of small companies, outstanding academic research programs, leading medical facilities, and the Greater Austin-San Antonio Corridor Council NanoBioTech Summit, which is creating a unique forum for uniting academic, economic development, government and business leaders throughout the region. If the activities can be properly coordinated, there is a strong possibility of major biotech expansion in this area in the relatively near future.

Austin Region

The University of Texas at Austin is a world-class research institution with first-rate graduate programs in many areas of concentration central to biotech research: molecular biology, computational biology, biochemistry, and molecular genetics.

There are a number of biotech companies in the city including Luminex (NASDAQ: LMNX), a manufacturer of DNA microarrays, Viagen (NASDAQ: BBII), a specialist in livestock cloning, and Ambion, a manufacturer of RNAi kits, which was founded by a former UT Austin professor named Matt Winkler.

Twenty-two miles east of Austin, the city of Bastrop's Economic Development Corporation is offering incentives, such as subsidized land, property tax abatements, and loans, to biotech companies that locate to the region. BioCrest/Stratagene, a supplier of research reagents, has indicated that these incentives, and the opportunity to relocate near world-class research at UT Austin, were the primary reasons they relocated a major manufacturing facility to Bastrop from Northern California.

Other important biotech institutions in the region include the M.D. Anderson Cancer Research Center in Smithville and the University of Texas Science Park, Department of Veterinary Sciences.

Bryan/College Station

Texas A&M is engaged in quite a bit of federally-sponsored research in the area of animal, crop, and plant biotechnology. These projects are funded mostly by the National Institutes of Health, the Department of Agriculture, the National Science Foundation, and private industry. Research is spread across a number of campuses. The College of Veterinary Medicine is a leader in animal biotechnology research, with A&M being the first academic institution in the world to clone six different species of animals (horse, pig, cattle, goat, cat, and a deer) (Lozano, 2005).

The Institute for Plant Genomics and Biotechnology works with faculty, students and scientists from 14 extension units affiliated with Texas A&M, the Texas Agricultural Experiment Station, and the U.S. Department of Agriculture's Agricultural Research Service. Additionally, the Texas Enterprise Fund has established a grant of \$50 million to create the Texas Institute for Genomic Medicine. The Institute, which is a partnership between Texas A&M and Lexicon Genetics, will create copies of a mouse embryonic stem cell library that is extremely useful in the study of disease diagnosis, treatment, and prevention in humans. Announcing the project in July 2005, Governor Perry stated that the Institute will "bring 5,000 new jobs to Texas and lead to the development of lifesaving medical treatments and therapies" (Rieken, 2005).

Furthermore, there are two research centers at Texas A&M that focus on detecting and mitigating threats to the food supply through the use of biotechnology. The first one is the Institute for Countermeasures Against

Agricultural Bioterrorism, which focuses on countermeasures to bioterrorism that are related to agricultural products. The other center is the National Center for Foreign Animal and Zoonotic Disease Defense, which focuses on mitigating the threat from those diseases that are acquired and transmitted through animals but also to humans. The National Center, which also collaborates with researchers from UTMB-Galveston and Texas Tech, is focusing its efforts on three diseases that represent a clear and present threat: foot-and-mouth disease, Rift Valley Fever, and avian influenza.

Plantacor and Inhibitex are biotech companies of note that license technology developed at Texas A&M. Plantacor, headquartered in College Station, is a developer of small molecule drugs for the treatment of cancer. The company is currently conducting preclinical studies at the M.D. Anderson Cancer Center. Inhibitex, which is based in Alpharetta, Georgia, is involved in the discovery of antibody-based products that can be used to treat bacterial and fungal infections, such as streptococcal and staphyloccal, that arise in hospital settings. Another biotech company of note in the region, Prodigene, is moving back to Iowa from College Station. The company encountered some regulatory problems with corn they genetically engineered to produce recombinant proteins for the pharmaceutical industry. Unfortunately, a test field containing that corn contaminated a soybean harvest, which resulted in heavy USDA penalties against the company. However, the company will continue to work with Texas A&M from Iowa.

"BioIndustry South Emerges," Southern Business and Development

A growing number of animal and plant biotech companies in the Research Valley have created a biotech cluster. The Research Valley Partnership, an economic development organization, is supporting Texas A&M"s aggressive new Technology Transfer and Commercialization Center, a vehicle to enhance the cooperation between researchers and the commercial sector. The center provides researchers with avenues of increased funding and outsourcing functions.

San Antonio

A significant amount of biotech and bioscience research is conducted in the San Antonio region. Significant institutions of note include the University of Texas San Antonio Health Sciences Center, the Cancer and Therapy Research Center, and the Southwest Foundation for Biomedical Research. San Antonio is also home to the world's largest genomics bioinformatics cluster. The Texas Research Park was constructed in the early 1980s to spark a biotech boom in San Antonio. Unfortunately, the Park was built on land that was located quite a distance from the UT San Antonio Health Sciences Center, the city's major biotech research center, making it impractical for people who worked at UTHSC to commute back-and-forth from the park. Nevertheless, there are several biotech companies located at the park, including GeneTex, a developer of cancer screening products founded by a University of Texas San Antonio faculty member.

In February 2006, the University of Texas San Antonio opened a new 227,000-square-foot Biotechnology Sciences and Engineering building. The building, which cost \$84 million dollars to build, will house 70 research and instructional

laboratories that will facilitate interdisciplinary biotech research and collaboration between scientists and engineers in various areas of specialization including biotechnology, biology, biomedical engineering, electrical and civil engineering and chemistry.

The San Antonio Austin Life Sciences Association (SALSA), headed by Dr. Mary Pat Moyer, is attempting to combine the unique strengths of San Antonio's biomedical business sector and military medical infrastructure with Austin's information technology strengths and investment capital to create a "biotechnology corridor." In April 2006, SALSA sponsored the 5th annual BioDefense Summit, which explored ways that Texas institutions could develop a leadership position in biodefense preparedness and product development.

Other biotech companies of interest include Dr. Moyer's company INCELL, BioNumerik, BioMedical Development Corporation, OsteoScreen, Genzyme, OsteoBiologics, and BTL Science. All of these companies are fairly small, but they are showing signs of slow growth.

Temple

The City of Temple has several biotech research assets, including the Cardiovascular Institute, and the Scott & White Medical Center, which employs over 10,000 people. The Temple Economic Development Corporation, under the leadership of President Larry Ruggiano, has transformed an abandoned Texas Instruments manufacturing site into the 500,000 square foot Temple Life Science Research and Technology Center. The mission of the center is to provide lab space to research and commercialization organizations in the biotech and life sciences industry. Dr. Art Frankel, a world-renowned cancer researcher, heads Scott & White's new Cancer Research Institute located in the center. In March 2006, the Institute, in conjunction with a Canadian company, Protox Therapeutics, started the first Phase I clinical trial of PRX302, a novel investigational cancer drug designed to retreat recurrent prostate cancer. Protox developed the drug in Temple and has already received clearance from the U.S. Food and Drug Administration (FDA) to start testing. The trial is the first clinical trial ever conducted at the Institute (Scott and White, 2006). Finally, in 2001, Temple College received a Department of Labor grant of \$920,945 to develop highly-skilled technicians for the region's biotech institutions. The biotechnology program at Temple College will begin offering courses in fall 2006.

Metroplex (Dallas – Fort Worth)

The University of Texas Southwestern Medical Center is one of the top biotech research institutions in the nation. The school's faculty includes four active Nobel laureates, twice the number of laureates that serve on the faculty of any other medical school in the world, 15 members of the National Academy of Sciences, and the second largest number of Howard Hughes Investigators in the United States. ScienceWatch, an organization that tracks the strength of publications based on how often they are cited and the quality of journals in which they appear, ranks UT

Southwestern second in the United States in biochemistry and molecular biology, two of the most important fields of investigation for biotech.

In the last several years, five companies have been founded based on research developed at UT Southwestern. Dr. Dennis Stone, UT Southwestern's Vice President for Technology Development, expects three more companies to be spun off in the next 12 months. The university has a very good relationship with STARTech Ventures in Richardson, a business accelerator that provides guidance and financial support to early stage high-tech companies. STARTECH has an equity stake in three companies founded on technologies developed at UT Southwestern.

Reata Pharmaceuticals, founded in 2002, is one of the more successful biotech companies founded on technologies developed at UT Southwestern. Reata develops drugs that treat cancer and neurodegenerative diseases. They currently have seven drugs in development and two in clinical trials. Other companies launched from UT Southwestern research include Myogen, which has partnered with Novartis to conduct heart muscle disease drug discovery, and ODC Therapy, which is developing customized cancer vaccines for individual patient therapy.

Regional stakeholders founded BioDFW to foster regional collaboration and innovation among the region's life sciences entities. The group's objectives include the development of an information clearinghouse of relevant regional biotech resources and the support of regional economic development activities in the life sciences.

The University of North Texas Health Sciences Center offers graduate level biotech training and has built a six-story Biotechnology Center to house its growing research program.

West Texas (Lubbock)

The Lubbock Regional Bioscience Initiative (LRBI), an initiative of the Lubbock Economic Development Alliance (LEDA), has been organized to foster the growth of the life sciences industry in the Lubbock region. In the biotech arena, LRBI believes that the region has a distinct advantage in bioagriculture, specifically in the area of plant genetics. The region has two important assets in this field: the Department of Plant and Soil Sciences at Texas Tech and Bayer Crop Science.

Bayer Crop Science has significant research facilities in the Lubbock region and is interested in expansion. Within its laboratories in Lubbock, Bayer Crop employs about a dozen people. Currently, the company employs about 70 people in Lubbock. Bayer developed FiberMax Cotton, the second leading selling cotton in the United States. Additionally, the company has endowed a professorship at Texas Tech in the Plant and Soil Sciences Department. This recently led to the creation of the Center of Excellence for Agricultural Genomics & Biotechnology at Texas Tech and to the recruitment of Dr. Thea Wilkins, a world renowned plant geneticist who comes to Texas Tech from UC Davis in California. All of this was made possible by a \$2 million research superiority grant from the Texas Emerging Technology Fund. The award represents the first funding anywhere in the state for the Governor's Emerging Technology Fund. Bayer is cooperating with the university on biotech

research related to making cotton more resistant to abiotic drought stresses along with the development of new uses and market opportunities for market applications for fiber. (Abiotic stresses are stresses in the environment that are non-living. This includes excessive rain, heat, cold, drought, etc., but not living pests like insects.) Other major bioagriculture players include Monsanto and Syngenta, which have significant research partnerships with Texas Tech, Texas A&M Lubbock Extension, and the Department of Agriculture's Plant Stress and Research Facility.

According to Dale Gannaway, Director of the LRBI, and Terri Patterson, Director of Workforce Development at LEDA, the organization is interested in developing and sponsoring regional workforce development initiatives for the bioagriculture industry. This initiative would encourage business and industry to partner with educational institutions to offer hands-on bioagriculture training to high school and college students in the Lubbock region. Obviously, Bayer and Texas Tech would be important components of this partnership. The Texas Tech Center for Genomics and Biotechnology offers a Master degree in biotechnology, which is jointly administered by the General Academic Campus and the Health Sciences Center of Texas Tech University. This program could serve as a source of faculty and/or lab space for community college programs (South Plains College and others).

WesTech Ventures, headed by Gary Pankonien, is a venture fund that was formed in 2003 to commercialize university-based biotech research in West Texas. WesTech has acquired an equity stake in biotech companies founded from Texas Tech biotech research activities including ReceptorLogic, which won a three-year, \$2 million award from the Advanced Technology Program (ATP) of the National Institute of Standards & Technology (NIST). The ATP award is funding the development of a cancer profiling and immunotherapy platform targeting breast cancer.

Special Convergence Considerations

Although the Texas biotech industry appears to be growing in importance, size, and potential profitability, it trails, and will probably continue to trail for the foreseeable future, the industries in areas such as Boston, San Diego, San Francisco, and North Carolina. However, there is one major trend that might offer a very significant opportunity for the state. This trend is the growing convergence of a number of important emerging technologies, i.e., biotechnology, nanotechnology, medical technology, and information technology. Texas has strong positions in each of these fields, and, if it can develop a structure for effectively integrating these technologies, it can establish itself as a leader in the convergence area.

If Texas is to take advantage of this opportunity, some group or organization must assume the responsibility for managing the required convergence. Although there are several organizations such as BioHouston, the Gulf Coast Consortia in the Texas Medical Center, and the Texas Health Care and Bioscience Institute, and the Greater Austin-San Antonio Corridor Council involved in coordination activities, no state-wide organization currently exists that is primarily concerned with the promotion of overall convergence.

An organization dedicated to convergence activities in Texas might be established by expansion of the scope of a current organization or by the establishment of a new organization. This organization might be established by the state government as part of an agency such as the Texas Workforce Commission or might involve expansion of the scope of private groups such as the ones listed above.

Two other organizations that are currently actively engaged in coordination work, i.e., the Center for Life Sciences Technology and the Greater Austin-San Antonio Corridor Council, which is responsible for both the NanoBioTech Summit and Digital Convergence Initiative, might also be expanded into an overall convergence activity.

A different, and possibly more effective, approach might be the establishment of anew private organization or association, dedicated from the outset to promoting convergence. In any case, emerging technology convergence presents a very promising opportunity for Texas, its industries and institutions, and its citizens to stake out a position of prominence in this very exciting arena.



Chapter Six: Summary and Conclusions

Dr. Larry Loomis-Price, Director, Biotechnology Institute, Montgomery College

I want to emphasize how important it is to increase the size of our pipeline. Companies already in place can't find enough workers from our programs. We need to find ways to reach into high schools (or junior highs!) and encourage interest in science, math, and specific technologies. We also should be looking at programs to retrain workers rapidly so that they can jump from less rewarding careers (or ones that have downsized) and use their existing work ethics, along with newly learned skills.

The two primary responsibilities of the community and technical colleges of Texas are to ensure that their students are prepared for attractive employment opportunities and to support the state in enhancing the economic well-being of its citizens. In no other area are these two responsibilities more closely intertwined than in the field of biotechnology.

Today, biotech is one of the world's most promising, most exciting, most opportunity-laden technologies. In Texas, the biotech industry has been historically characterized by world-class research with relatively little commercial payoff. However, there are signs that this situation is now changing. Realization of the advantages of the Texas business environment by large biotech companies, commitment to biotech projects by state government, and new and expanded federal government programs—all promise almost unlimited opportunities for Texas businesses, research and development laboratories, and workers.

There are several top quality CTC biotech programs in the state, and a number of other CTCs are either initiating or considering initiation of biotech programs. The experiences of employers who have hired graduates of these programs have been exceedingly positive, and, as the qualifications of these graduates become more widely realized, their value in the labor market will be increasingly recognized.

However, despite these promising factors, there is a serious disconnect. As the size of the Texas biotech industry expands and the qualifications of CTC biotech graduates are more widely recognized, the current CTC biotech structure will not be capable of meeting the rapidly growing needs of the industry. It is, therefore, of extreme importance that the CTCs of the state, together with the Texas Leadership Consortium for Curriculum Development and the Texas Higher Education Coordinating Committee, and the Texas Workforce Commission, develop plans for rapid growth of Texas biotech programs. Otherwise, the Texas biotech industry will not have the technician support it will need, and many citizens of the state will not have the opportunity to take advantage of what promises to be a very attractive employment situation.



Appendix A: Survey

A major source of information for this project was a survey conducted by Technology Futures, in conjunction with the Texas State Technical College System. The 39 survey participants represented a wide range of biotech and biomedical companies and research institutions. This appendix contains a copy of the survey and a list of survey participants.

Survey Questions

Biotechnology: Survey of Trends, Technologies, and Workforce Needs

The purpose of this survey is to assess and highlight important industry, market, and technology trends, as well as determine the workforce and curricula needs of biotechnology industry in the State of Texas. The results of the survey will be reviewed by key decision makers in the state's community and technical college and economic development organizations. Your participation will help ensure that your organization has the skilled workforce required to effectively compete in the global 21st century biotech industry.

I. Information about Your Organization

1) Contact and compa	any information	
First Name		
Last Name		
Email		
Company Name		
Company URL		
Address		
City		
State		
Zip Code		

2) Please check the areas of the biotechnology industry in which your organization plays a role:

	Primary	Secondary	None
Plant/crop biotechnology	0	0	0
Animal biotechnology	0	0	0
Biopharming—use of modified crops to mass produce medicines and industrial products	0	0	0
Biofertilisers, biopesticides, bioherbicides, microbial pest control, and other agrichemicals	0	0	0
Food processing—food products, components, enzymes, yeasts, bacteria culture	0	0	Ο
Gene probes, DNA markers	0	0	0
Therapeutics—vaccines, immune stimulants	0	0	0
Pharmacogenomics	0	0	0
Biopharmaceuticals	0	0	0
Gene therapy	0	0	0
Diagnostic tests/antibodies	0	0	0
DNA testing laboratory—criminal forensics	0	0	0
DNA testing laboratory—civil forensics	0	0	0
Genetic counseling	0	0	0
Genomics/Proteomics/DNA/RNA/protein sequencing and databases for humans, plants, animals, and microorganisms	0	0	0
Cell/tissues/embryo culture manipulation	0	0	0
Extraction/purification/separation	0	0	0
Fermentation/bioprocessing/biotransformation/natural products chemistry	0	0	0
Enzymes/biocatalysts	0	0	0
Microarrays/biochips	0	0	0
Bioinformatics and molecular modeling	0	0	0
Bioremediation/biofiltration/phytoremediation	0	0	0
Consumables and bioreagents for use in biotech research	0	0	0
Specialized biotechnology machinery or equipment	0	0	0

3) W	That is the basic structure of your organization?
Ο	Independent for-profit company
0	Subsidiary of larger company headquartered in Texas
0	Subsidiary of larger company not headquartered in Texas
Ο	Government agency
Ο	Research organization
Ο	Academic Institution
O If y	Other (please specify) rou selected other, please specify:
4) H	fow many employees does your organization currently employ in the biotech area?
0	None
Ο	1-5
0	6-15
Ο	16-40
Ο	100-499
0	More than 500
5) W	That were your company's approximate total revenues in 2004?
O	Startup (negative to \$25,000)
0	\$25,000-\$100,000
0	\$100,000-\$500,000
0	\$500,000-\$2,000,000
Ο	\$2,000,000-\$5,000,000
Ο	\$5,000,000-\$10,000,000
0	More than \$10,000,000

6) What were your organization's primary sources of operating funds in 2004?

	Primary	Secondary	None
Product and/or Service revenue from customers	0	0	Ο
Venture Capital	0	0	Ο
Angel Investors	0	0	0
Publicly traded shares	0	0	Ο
Private Equity investment	0	0	0
Conventional Bank Loans	0	0	0
U.S. Government Loan or Grant	0	0	0
State Government Loan or Grant	0	0	0
Private Research Grant	0	0	0

II. Employment Outlook

- 7) What kinds of technicians does your organization currently employ or plan to employ in the next three years?
 - Medical and Clinical Lab Technicians
 - Laboratory Support Workers
 - O Regulatory Affairs Coordinators/Specialists
 - Forensic Science Technicians
 - O Genetic Counselors
 - Documentation Specialists
 - Animal Handlers
 - O Animal Technicians
 - O Greenhouse Assistant/Plant Breeder
 - BioAg/Agricultural Technicians
 - Assay Analysts
 - Biostatisticians
 - Bioinformaticians
 - O Quality Control/Quality Assurance Inspectors
 - Validation Technicians

Ο	Instrumentation/Calibration Technicians
0	Automation and Robotics Technicians
O If y	Other (please specify) rou selected other, please specify:
	ow many new entry-level biotechnology technicians did your organization hire in e last 12 months?
Ο	0
0	1-3
Ο	4-6
0	7-15
0	16-25
0	26-50
0	51-100
0	More than 100
0	Don't Know
	ow many new entry-level biotechnology technicians does your organization plan to re in the next 12 months?
Ο	0
Ο	1-3
0	4-6
0	7-15
0	16-25
0	26-50
0	51-100
0	More than 100
Ο	Don't Know

 ${\color{red} \bigcirc} \quad Manufacturing \, Technicians$

10) How many new entry-level biotechnology technicians does your organization plan to hire in the period one to four years from now?
0 0
O 1-3
O 4-6
O 7-15
O 16-25
O 26-50
O 51-100
O More than 100
O Don't Know
11) What is the average starting salary of entry-level biotech technicians in your organization? O \$15,000-\$20,000
O \$20,000-\$25,000
O \$25,000-\$30,000
O \$30,000-\$35,000
O \$35,000-\$45,000
O \$45,000-\$55,000
O More than \$55,000
12) What is the average salary of biotech technicians after five years of experience? O \$25,000-\$35,000
O \$35,000-\$45,000
O \$45,000-\$55,000
O \$55,000-\$65,000
O \$65,000-\$75,000
O More than \$75,000

- 13) What is the preferred level of education for entry-level biotech technicians that your organization hires?
 - O High School Diploma/GED No specific formal training
 - O Certificate in biotechnology or related discipline
 - O Associate degree in biotechnology or related discipline
 - O Bachelor degree in biotechnology or related discipline
 - O Advanced degree (MS/PhD) in biotechnology or related discipline
 - O Other (please specify)

If you selected other, please specify:

III. Required Skills

14) How important are the following general skills for technicians in your organization?

	Critical	Very Important	Important	Somewhat Important	Not Important
Knowledge of good manufacturing, lab, and clinical practices	0	0	0	0	Ο
Knowledge of laboratory safety regulations	0	0	0	0	0
Knowledge of hazardous materials and disposal protocols	0	0	0	0	0
Knowledge of packaging and labeling protocols and laws regarding the shipping/receiving of bio and chem. materials	0	0	0	0	Ο
Perform routine animal care duties	0	0	0	0	0
Ability to measure, weigh, and prepare solutions	0	0	0	0	0
Knowledge of basic blood-borne pathogen and biohazards	0	0	0	0	0
Knowledge of cleaning agents and procedures	0	0	0	0	0
Ability to prioritize lab or project tasks	0	0	0	0	0
Documentation and record keeping	0	0	0	0	0
Quality control and quality assurance procedures	0	0	0	0	0
Data management skills	0	0	0	0	0
Presentation skills	0	0	0	0	0
Oral and written communication skills	0	0	0	0	Ο

Teamwork skills	0	0	0	0	0
Problem-solving skills	0	0	0	0	O

Additional comments:	
	1

15) How important is it that technicians be able to use, calibrate, and care for the following equipment?

	Critical	Very Important	Important	Somewhat Important	Not Important
Micropipette	0	0	0	0	0
Electronic balance	0	0	0	0	0
pH meter	0	0	0	0	0
Laminar flow hood	0	0	0	0	Ο
Personal protective equipment	0	0	0	0	Ο
Autoclave	0	0	0	0	0
Electrophoresis chamber	0	0	0	0	Ο
PCR thermocycler	0	0	0	0	Ο
Spectrophotometer	0	0	0	0	Ο
Centrifuges (low, high, ultra)	0	0	0	0	0
Microscopes (lt./phase)	0	0	0	0	0

Additiona	l comments:

16) How important is it that technicians employed in your organization within the next three years be competent in the technologies listed below? (Check all that apply.)

	Critical	Very Important	Important	Somewhat Important	Not Important	Don't Know
Bulk fractionation	0	0	0	0	0	0
lon-exchange	0	0	0	0	0	0
Gel filtration	0	0	0	0	0	0
Affinity chromatography	0	0	0	0	0	0
Chelation	0	0	0	0	0	0
Chromatography (FPLC/HPLC)	0	0	0	0	0	0
Protein assays	0	0	0	0	0	0
Enzyme activity assay	0	0	0	0	0	0
PAGE	0	0	0	0	0	0

2-dimensional elecrophoresis	0	0	0	0	0	0
Western blot analysis	0	0	0	0	0	0
Agarose gel electrophoresis	0	0	0	0	0	0
Polymerase chain reaction (PCR)	0	0	0	0	0	0
Real-time PCR	0	0	0	0	0	0
DNA chips/microarrays	0	0	0	0	0	0
DNA, RNA isolation	0	0	0	0	0	0
Restriction enzyme digestion	0	0	0	0	0	0
Plasmid & phage DNA preparation	0	0	0	0	0	0
Construction of recombinant vectors	0	0	0	0	0	0
Transformation of host cells	0	0	0	0	0	0
Northern and southern blot analysis	0	0	0	0	0	0
DNA sequencing	0	0	0	0	0	0
Analysis by restriction mapping	0	0	0	0	0	0
Mutagenic techniques	0	0	0	0	0	0
Computer comparison and management of DNA sequence	0	0	0	0	0	0
DNA library construction and screening	0	0	0	0	0	0
Sterile techniques	0	0	0	0	0	0
Cell and tissue culture	0	0	0	0	0	0
Cell counting techniques	0	0	0	0	0	0
Toxicology testing and bioassay	0	0	0	0	0	0
Installation, maintenance, and repair of automation and robotics equipment	0	0	0	0	0	0
Operation of automation and robotics equipment	0	0	0	0	0	0
In situ hybridization, histochemistry and immunocytochemistry techniques	0	0	0	0	0	0
Immunoassay methods	0	0	0	0	0	0
Immunoaffinity columns	0	0	0	0	0	0
ELISA	0	0	0	0	0	0
Antibody microprobe techniques	0	0	0	0	0	0
Antigen isolation techniques	0	0	0	0	0	0
Fluorescence mircoscopy	0	0	0	0	0	0
Microbial Culture techniques	0	0	0	0	0	0

Bioreactor operation and process monitoring	0	0	0	0	0	0
Separation	0	0	0	0	0	0
Concentration	0	0	0	0	0	0
Purification	0	0	0	0	0	0
Drying	0	0	0	0	0	0

Additional comments:
If you had an opportunity to hire graduates of a community or technical college biotechnology program with demonstrated competencies in these areas, would you:
17) Be more inclined to hire individuals with this background than non-graduates?
O Yes O No O Not Sure
18) Pay these individuals initially more than non-graduates?
O Yes O No O Not Sure
19) Expect to promote these individuals more quickly than non-graduates?
O Yes O No O Not Sure
20) Which new technologies or skills will your organization be utilizing in the next five years?
O Automation and robotics
O DNA microarrays (DNA chips)
O Protein microarrays
O Small molecule microarrays
O Bio micro-electromechanical systems (microfluidics, biosensors, lab on a chip)
O Spectroscopy (IR, FT-IR, NMR)
O Genomics
O Proteomics
O Metabolomics
O Immunomics
O Transcriptomics
O Bioinformatics
O Nanotechnology
O Other (please specify) If you selected other, please specify:

IV. Success Factors for the Texas Biotechnology Industry

21) Please rate the importance of the following factors to the success and growth of the biotechnology industry in Texas?

	Critical	Very Important	Important	Somewhat Important	Not Important
Biotechnology research and development base	0	0	0	0	0
Business service providers that understand biotech business model	0	0	0	0	0
A feeder layer of growing companies	0	0	0	0	0
A network of management talent with key biotech experience in areas such as the conduct of clinical trials and interaction with the FDA	0	0	0	0	0
Availability of skilled biotech technicians	0	0	0	0	0
Availability of venture capital or other finance	0	0	0	0	0
Strong government leadership	0	0	0	0	0
Availability of lab space/water	0	0	0	0	0
University graduates	0	0	0	0	0
Technical college graduates	0	0	0	0	0
Incubator services	0	0	0	0	0

Additional comments:	

22) How would you rate the strength of Texas in each of these areas?

	Very Strong	Stong	Intermediate	Weak	Very Weak
Biotechnology research and development base	0	0	0	0	0
Business service providers that understand biotech business model	0	0	0	0	0
A feeder layer of growing companies	0	0	0	0	0
A network of management talent with key biotech experience in areas such as the conduct of clinical trials and interaction with the FDA	0	0	0	0	0
Availability of skilled biotech technicians	0	0	0	0	0
Availability of venture capital or other finance	0	0	0	0	0
Strong government leadership	0	0	0	0	0
Availability of lab space/water	0	0	0	0	0
University graduates	0	0	0	0	0

Technical college graduates	0	0	0	0	0
Incubator services	0	0	0	0	0

Additional comments:	
	Ì

23) How important do you believe the following State government policies are to the growth of a vibrant biotech sector in Texas?

	Critical	Very Important	Important	Somewhat Important	Not Important
Biotech research funding	0	0	0	0	0
Financial resources	0	0	0	0	0
Incentives for private enterprises	0	0	0	0	0
Tax credits	0	0	0	0	0
Regulatory environment	0	0	0	0	Ο
Biotech technician workforce development	0	0	0	0	Ο
University intellectual property policies	0	0	0	0	0
Incubators with appropriate lab space	0	0	0	0	0
Embryonic stem cell research	0	0	0	0	0

]			
24) Would you be interested in r	anto anio a rezitla	biab	a ab aala	tochnic

24) Would you be interested in partnering with high schools, technical schools, college	s,
and/or universities on developing curricula that would produce graduates ready to)
work in the biotechnology industry upon graduation?	

O Yes	O No	O Not Sure

Additional comments:

- 25) Would your company fund continuing education for employees if such training was significantly related to their employment as biotech technicians?
 - O Would fund 100% of continuing education
 - O Would fund 75% of continuing education
 - O Would fund 50% of continuing education
 - O Would fund 25% of continuing education
 - O Would not fund continuing education
- 26) I am available for telephone or in-person interviews.

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()	Yes	0	กเก
\cup	162	0	IVO

Texas State Technical College and Technology Futures, Inc. thank you for your participation.

Survey Participants

Organization Location Synthecon, Inc. Houston Lak Technologies, Inc. Houston Seahawk Biosystems Corp. Austin Encysive Pharmaceuticals Houston Texas Heart Institute Houston Quantum Logic Devices Austin Identigene Houston Amarillo Biosciences Inc. Amarillo Applied Maths, Inc. Austin DeWalch Life Technologies Houston JOEPTas Inc Houston VisiGen Biotechnologies Houston University of Texas Health Science Center San Antonio Bethyl Laboratories, Inc. The Woodlands TEF Labs Austin Bio-Medical Services Austin Amplioxus Cell Technologies Houston Tyrell, Inc. Houston Medical Metrics Houston C Sixty Inc Houston Omnimmune Corp. Houston Cumbre Inc. Dallas PharmaFrontiers The Woodlands Fairway Medical Technologies, Inc. Houston </th <th></th> <th>1 0</th>		1 0
Lark Technologies, Inc. Datalign, Inc Seahawk Biosystems Corp. Encysive Pharmaceuticals Encysiv	Organization	Location
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	DelSite Biotechnologies, Inc.	Irving



Appendix B: Biotech Experts Consulted

Probably the most important input to this report was a series of personal and telephone interviews conducted by the authors during the course of this project. The information, opinions, and insights gathered during these interviews had the characteristics of being authoritative, timely, and relevant. The authors conducted a total of 33 formal interviews and a number of informal interviews. The people with whom formal interviews were conducted, together with a brief synopsis of the subjects covered during the interviews, are listed below.

Marc Anderberg—Director of Applied Research, Texas Workforce Commission. Supplied insights about the biotech industry based on the labor market analysis he completed for the 2002 TWC report, The Labor Market Implications of Recent and Anticipated Developments in the field of Biotechnology.

Christopher Baca—Director of Center for Life Sciences Technology, University of Houston, College of Technology. Supplied information about the University of Houston College of Technology's efforts to support the establishment of the Center for Life Sciences Technology, which will facilitate the creation of regional training programs for creating a technician workforce for the biotech community.

Dr. Fuller W. Bazer—Associate Vice President for Research, Texas A&M University. Provided information about the efforts of Texas A&M University, through its Technology Transfer Office, to support the commercialization of biotech research developed in Texas A&M research laboratories.

Barbara Cambron—*Industry Initiatives Manager, Texas Workforce Commission.* Supplied information about the Texas Workforce Commission and its relationship to the Governor's Industry Cluster Initiative, specifically the activities of the Biotechnology and Life Sciences cluster.

Dr. V. Celeste Carter—*Director of Biotechnology Program, Foothill College (California).*Provided information about the biotechnology and bioinformatics programs at Foothill College in California, widely considered a national leader in the development of biotech workforce training programs at the community and technical college level.

Walter "Skip" Colbert—Senior Vice President of Human Resources and Corporate Services, Lexicon Genetics. Provided information about Lexicon Genetics' efforts to establish the Texas Institute for Genomic Medicine with Texas A&M and Lexicon's biotech workforce profile.

Nicholas Cram—Associate Professor & Biotechnology Coordinator, TSTC Waco. Provided valuable information about the workforce needs of the Texas biotech community and how those needs shaped his development of TSTC Waco's Biotech Systems Instrumentation program.

Dr. Dat Dao—Director of Life Sciences & Health Group, Houston Advanced Research Center. Provided information about the Houston Advanced Research Center's Life Sciences & Health group, which is developing biomarkers for cancers, infectious diseases, and environmental toxicology.

Mark Ellison—*Executive Director, Governors Emerging Technology Fund.* Provided valuable information about the Governor's Emerging Technology Fund.

Dr. Linnea Fletcher—*Department Chair of Biotechnology, Austin Community College.* Provided valuable information about the workforce needs of the Austin biotech community, including the University of Texas at Austin. Also provided valuable information about the National Science Foundation's Advanced Technological Education (ATE) Center for Biotechnology called BioLink.

Dale Gannaway—*Director, Lubbock Economic Development Alliance.* Supplied information about the efforts of the Lubbock Economic Development Alliance through the Lubbock Regional Bioscience Initiative (LRBI), to foster the growth of the biotech and life sciences industry in the Lubbock region.

Mike Gilbert—*President, Bayer Crop Science*. Supplied information about Bayer Crop Science's first biotech cotton product called LibertyLink and also the company's cooperative research commercialization activities with Texas Tech University.

Dr. David Gorenstein—Associate Dean for Research, UTMB-Galveston. Supplied information about UTMB Galveston's efforts in the area of biodefense for the federal government, including the \$167 million National Biocontainment Laboratory.

Dr. Donald Hicks—*Professor of Political Economy and Public Policy, UT-Dallas.* Provided valuable insights into the historical development of the biotech industry both nationally and within Texas. Also provided insight into the unique equity funding requirements of biotech companies.

Dr. Warren Huff—*CEO*, *Reata Pharmaceuticals*. Provided insight into the factors necessary to establish and sustain a viable biotech industry in Texas.

Scott Japczynski—*Production Manager, Bruker Optics.* Provided insight into the acute need for biotech systems instrumentation techs in the Houston region.

Dr. Bridgette Kirkpatrick—*Professor of Biotechnology, Collin County Community College.* Provided information about the Collin Community College biotech program and the workforce needs of biotech organizations in the Dallas/Fort Worth region.

Thomas R. Kowalski—*President, Texas Healthcare and Bioscience Institute.* Provided information about the Texas Healthcare & Bioscience Institute's lobbying activities in the 2005 Texas Legislature related to legislation that would impact the biotech industry.

Lisa Lock—*Biotechnology Coordinator, El Centro Community College.* Provided information about the El Centro Community College biotech program and the workforce needs of biotech organizations in the Dallas/Fort Worth region.

Dr. Mitzi Martinez Montgomery—*Vice President of Discovery and Preclinical Development, PharmaFrontiers.* Provided insight about PharmaFrontiers need for entry level technicians, especially in the area of quality assurance and quality control for the manufacture of drugs used in clinical trials.

Dr. Neil McCrary—*Biotechnology Coordinator, Alamo Community College District, Northwest Vista College.* Provided information about Northwest Vista College biotech program and the workforce needs of biotech organizations in the San Antonio region.

Dr. Chandra Mittal—*Professor of Biotechnology, Houston Community College*. Provided valuable information about Houston Community College's biotech program and its relationship to the biotech industry in the Gulf Coast region.

Jason Moore—*Manager of Industry Programs, BioHouston*. Provided information about BioHouston's efforts to support the growth of the biotech industry in the Gulf Coast region.

Dr. Mary Pat Moyer—*President, INCELL Corporation*. Provided insight into the special challenges faced by startup biotech companies, including the challenge of venture funding and the employment of key personnel who are also faculty at major research universities. Also provided information about the efforts of the San Antonio/Austin Life Science Association to support the growth of the biotech industry in the Central Texas region.

Dr. Catherine O'Brien—Dean of Program Development, Institutional Effectiveness and Health Careers, San Jacinto South. Provided information about San Jacinto College's efforts to develop training programs for biotechnicians in the Gulf Coast region.

Glenda Overbeck—*Vice President of Investment Activities, Baylor College of Medicine Technologies, Inc.* Provided information about Baylor College of Medicine Technologies, which is an early stage venture capital firm that funds technologies developed within Baylor College of Medicine that are believed to have commercialization potential.

Terri Patterson—*Director of Workforce Development, Lubbock Economic Development Alliance.* Supplied information about the Lubbock Economic Development Agency's efforts to develop and sponsor bioagriculture workforce development initiatives in the Lubbock region.

Dr. Larry Loomis Price—*Director, Biotechnology Institute at Montgomery College.* Provided valuable information about Montgomery College's biotech program and its relationship to the biotech industry in The Woodlands Research Park and Houston Medical Center.

Steve Spurlock—*Biotechnology Administrative Assistant, Austin Community College.*Provided information about the biotech industry in Central Texas and the organization of the biotech program at Austin Community College.

Dr. Dennis Stone—*Vice President for Technology Development, UT Southwestern.* Provided information about companies founded on technologies developed at UT Southwestern. Also discussed unique funding challenges related to biotech companies and the role of the state's Tier I research universities and their tech transfer offices in fostering the development of the state's biotech industry.

Janet Varela—*Kelly Scientific, also Biotechnology Outreach Coordinator, Montgomery College.* Provided valuable information about Montgomery College's biotech program outreach efforts to high school students and the role of technicians in a startup biotech company.

Dr. Andy Vestal—Associate Professor and Extension Specialist, Department of Agricultural Education Texas Cooperative Extension, Texas A&M University System. Provided information about federally sponsored research at Texas A&M related to animal, crop, and plant biotechnology.

Dr. Bea Wohleb—*Director, Divison of Health Sciences at Temple College.* Provided information about Temple's efforts to establish its biotech program and the relationship of the program to biotech activities conducted in Temple at the Cardiovascular Institute and the Scott & White Medical Center.

Joe Yacono—*Program Specialist- Business Services, Texas Workforce Commission.* Supplied insights about the biotech industry based on his work at the Texas Workforce Commission.



Appendix C: Biotech Experts Meeting

To identify the factors that could materially change the nature, rate, and implications of advances in the field of biotechnology in Texas, the authors conducted a meeting of 12 individuals with expertise in a number of different biotech areas. This group included representatives from universities, biotech companies, CTC biotech program directors, biotech advocacy organizations, a venture capital company, and a law firm with a biotech practice group.

The meeting was held in the Campus Club at the University of Texas at Austin on August 11, 2005 and used a Nominal Group Conference format. Meeting participants were asked to individually record responses to two questions related to the status of the biotech industry in Texas. After these responses had been recorded and discussed, each participant was asked to rate each of the responses in terms of its importance, probability of happening, and the time at which it would most likely occur. These ratings were then combined to produce an overall average rating for each response. In this combination, importance and probability were rated twice as high as timing. Experts taking part in the meeting are listed below; the results of the overall ratings follow.

Nominal Group Meeting Participants

Dr. Linnea Fletcher Department Chair of Biotechnology

Austin Community College

3401 Webberville Rd. Austin, TX 78702

Dr. Donald Hicks Professor of Political Economy and Public Policy

University of Texas Dallas - School of Social Sciences

P.O. Box 830688

Richardson, Texas 75083-0688

Dr. Larry Loomis-Price Director, Biotechnology Institute

Montgomery College 3200 College Park Drive Conroe, TX 77384

Janet Varela Biotechnology Outreach

Montgomery College

Director, Biotechnology Institute

3200 College Park Drive

Conroe, TX 77384

Bruce Leander President

Ambion Corporation 2130 Woodward Austin, TX 78744 Dr. Alan Runge Dean of Academic Affairs

DeVry University 11125 Equity Drive Houston, TX 77041

Jason Moore Manager of Industry Programs

BioHouston 410 Pierce Street Houston, TX 77002

Gary Pankonien Emergent Technologies

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Austin, Texas 78738

Dr. Margaret Sampson Attorney

Vinson & Elkins

The Terrace 7, 2801 Via Fortuna, Suite 100

Austin, TX 78746-7568

Nicholas Cram, MS CBET Coordinator

Biotechnology Systems Instrumentation Program

TSTC

3801 Campus Drive Waco TX 76705

Thomas R. Kowalski President, Texas Healthcare and Bioscience Institute

815 Brazos Street, Suite 310

Austin, TX 78701

Lee Rivenbark Director, Cotton Operations for Region Americas

Bayer Crop Science

3223 S. Loop 289, Suite325 Lubbock, Texas 79423

Observers/Staff

Michael A. Bettersworth Associate Vice Chancellor

Texas State Technical College System Operations Office 3801 Campus Drive

Waco, TX 76705

Henry Elliott Research Analyst

Technology Futures, Inc.

13740 Research Boulevard, Building C

Austin, TX 78750

Carrie Vanston Media Director/Marketing Coordinator

Technology Futures Inc.

13740 Research Boulevard, Building C

Austin, TX 78750

Results of Question One

(1) What will be the most significant development in biotechnology over the next five years?

Criteria:

Importance: If this event occurs within the next five years it:

- 10 Will completely revolutionize the field
- 5 Will have significant impact on the field
- 1 Will have very little impact on the field

Probability: This event:

- Will almost certainly occur within the next five years
- 5 Is as likely to occur as not to occur within the next five years
- 1 Almost certainly will occur in the within the next five years

Timing: Assuming that this event will occur, it:

- Will probably occur within the next two years
- Will probably occur between two and five years from now
- 1 Will probably not occur for at least ten years

Responses

Response	Overall Average
Globalization of biotech - increased usage and competition around the world	7.78
Increasing investment capital interest in biotech sector	7.38
The movement of more biotech research into the development phase and the scale up for regulated clinical trials	7.22
Greater acceptance of biotech by general public, investment community, and politicians at the local and state level	7.02
Improved crop production through the use of crops that have been genetically modified to have higher stress tolerances (e.g. drought, cold tolerance)	7.02

Response	Overall Average
Movement in consumer market to better medical diagnosis for diseases through development and monitoring capabilities of bio-markers. Lab on a chip, monoclonal antibodies provide for home diagnostic kits	6.65
Significant animal studies validating the therapeutic potential of si-RNA technology. Also there may even be early stage clinical trials of the use of siRNA for the treatment of specific diseases	6.50

Increased attention to relaible production of biotech products at higher volumes	6.45
Advancements in molecular breeding for specific traits. Increasing use of DNA manipulation versus conventional breeding practices	6.31
Protein science becomes equal to DNA science. (Rapid reproduction and manipulation of proteins in cell free systems for example.)	6.31
Development of biomarkers for altered physiological states coupled with the ability to monitor those markers	6.15
Shortage of qualified workforce to meet the needs of emerging biotech industry	6.13
Better understanding of cell and immune system function	6.07
Significant progress will be made in the area of embryonic stem cell technology, with animal studies and perhaps early stage clinical trials demonstrating potential of ES cells	5.87
A better understanding of metabolic pathways as a way of diagnosing diseases more efficiently	5.82
Culturally, biotech manufacturing and application will move from sensationalist realm of media to the mainstream	5.67
Personalized medicine moving from theory to practice through the use of genomics, proteomics, metabolomics, immunomics. Better diagnosis and therapeutics	5.65
Increasing percentage of blue collar workforce will be high tech workers who are familiar with fairly advanced technology and science - a biotechnician, a nanotechnology tech	5.64
Significant advances in the research and application of immunology and vaccine trechnology for the treatment of diseases such as HIV, Hepatitis C, herpes, MS, cancer, neurodegenerative diseases, also possibly parasites	5.38
Increasing convergence of biotechnology, information technology, and nanotechnology	5.35
Life sciences and biotech advanced degrees will overtake chemistry degrees in number of graduates	4.76
Very little or perhaps zero commercial development of new biotech products	3.43

Results of Question Two

(2) What actions might be taken by either the Texas state government or some private group, such as industry associations, private companies, research institutions, or colleges and universities, to promote the development of a strong, vibrant biotechnology industry in the state?

Criteria:

Importance: If this action is undertaken, it will:

- Will have a truly dramatic positive impact on the development of a biotech industry in Texas
- Will have a significant impact on the development of a biotech industry in Texas
- 1 Will have little or no impact on the development of a biotech industry in Texas

Probability: This action will:

- 10 Almost certainly be taken within the next five years
- 5 Is as likely to be taken within the next five years as not to be taken
- 1 Almost certainly will not be taken within the next five years

Timing: If this action is taken at all, it:

- Will be taken within the next two years
- 5 Will be taken in about five years
- 1 Will not be taken for at least ten years

Responses

Factor	Overall Average
More joint programs between private industry and state universities for the purpose of biotech research and development and commercialization	7.44
Funding for early stage biotech companies, particularly those in death valley between federal funding for basic research and early stage venture capital	7.31
Increased collaboration between business and educational institutions to develop biotech workforce	7.18
State sponsored PR, awareness campaigns, and expenditure of political capital to support growth of the biotech industry	7.15
More public awareness of biotech careers and the role of educational institutions	7.04
Duplicate BioHouston in other regions of the State - bring together academia, venture capitalists, and industry to clarify biotech investment climate	7.04
Public policy agenda that is supportive of biotechnology (e.g. stem cell research, therapeutic cloning, gene therapy). Public figures must communicate an awareness of biotech to general public	6.96
Greater interaction between private companies, grass root organizations and educational institutions. Less talking and more doing	6.91
Increased investment in biotech activities by the state	6.58
Increased awareness of successful joint operations between biotech companies and educational institutions	6.55

Facilitate seamless transition for biotech students between high schools, two year colleges, and four year colleges	6.47
Demystify controversial biotech activities such as cloning, genetic engineering and embryonic stem cells	6.40
Establish a state biotech academy or curriculum for high school level, similar to Career and Technology Education or National Academy program curriculum	6.27
Horizontal articulation agreements - better one to one articulation agreements between biotech programs at two year schools. Transfer of credit should be automatic between community colleges	6.22
Organization or group that facilitates resource sharing amongst biotech companies -CGMP facilities, contract manufacturing, hybridoma production, etc.	6.20
Increased gap funding for small biotech firms - both SBIR and post SBIR	6.16
Single biotech message from the public and private sectors	6.13
Start a public awareness campaign to educate students (K-12) about the possibilities of biotech	6.00
State grant program, similar to Texas Scholars program, that encourages students to enter biotech workforce in exchange for various incentives such as student loans relief (full and partial)	5.98
Improved transitions to clinical trials for small biotech companies (e.g. lists of doctors interested in participating in clinical trials for specific diseases, etc.)	5.80
Investors must be able to place their money in biotech companies in ways that are less encumbered	5.74
Fund and participate in non-profit organizations whose primary goal is to educate the public and influence policy	5.71
Better coordination amongst various entities (e.g. CTCs and four year universities) to	5.67
Increased funding for biotech academic programs (funds to bring adjunct faculty to universities and colleges from industry, also to send instructors and professors to industry, fellowships, scholarships, etc.)	5.65
Need for Associate of Science (AS) degree instead of Associate of Applied Science (AAS) degree to facilitate articulation agreements between two year and four year schools	5.58
Biotech is a rapidly developing field. Academic institutions must be able to rapidly incorporate these changes into their curriculum. Thus, TAKS model must be rethought	5.46
University professors, administrators, and industry must agree on role of four year colleges in supporting biotech industry	5.38
The Higher Education Coordinating Board should encourage more imaginative interdisciplinary programs between disciplines (e.g. chemistry and information technology) that impact biotech. State should not fund individual companies	4.48



Appendix D: Recommendations to the CCD

In February 2005, the Texas State Technical College (TSTC) System contracted with Technology Futures, Inc. (TFI) to conduct an analysis of the potential role of Texas community and technical colleges (CTCs) in fostering the development of the biotechnology (biotech) industry in the state. One of the objectives of this analysis was to provide recommendations to the Texas Leadership Consortium for Curriculum Development (CCD) regarding developing new and/or updating existing educational programs related to the state's workforce needs in biotech. These recommendations are based on this analysis.

• I. Fund the Establishment of a Formal Community and Technical College (CTC) Biotech Consortium

This Consortium would provide the following functions:

- *Develop a core curriculum,* such as the one described in the second recommendation.
- Form statewide partnerships that include representatives from the biotech industry, the biotech research community, state and local economic development officials, educational institutions, and the Texas Workforce Commission. Such partnerships will be essential to meeting employer demands for a pipeline of workers that allows their organizations to compete in the global biotech industry. Close collaboration among these groups will allow CTCs to identify workforce training gaps before they become critical and construct programs, with employer input, that can close them. For example, a large non-Texas-based harmaceutical company wanted to establish a significant manufacturing presence in the Houston area, but abandoned the idea when it determined that a skilled manufacturing workforce to produce large molecule drugs was not available in either the Houston region or anywhere else in the state. The company needed a workforce skilled in sterile manufacturing techniques and good manufacturing practices (CGMP). These skills, which are extremely important to pharmaceutical companies, can be taught adequately at CTCs. Several CTCs in other states have such programs.
- Work jointly to better leverage combined assets to increase the likelihood of award of federal and state grant and funding activities. There are several areas of interest, e.g., genomics, microarrays, bioinformatics, bioagriculture, nanotechnology, and bioinformatics, where the state's CTCs would be well served to partner and seek federal funding from agencies that finance new curriculum and program development, i.e., faculty development and equipment grants. Grant funding sources include the National Science Foundation's Department of Undergraduate Education, especially the Advanced Technology education grants and also the Course, Curriculum, and Laboratory Improvement grants; National Institutes of Health Bridges

programs; Department of Agriculture; Department of Labor's High Growth Job Training Initiative, and Department of Education grants. Texas biotech programs have been quite successful in obtaining grants from these sources in the past, e.g., Austin Community College (ACC) Bio-Link (NSF ATE), Temple (DOL High Growth Job Initiative), and Montgomery College (NSF). In the future, Texas CTCs should partner and coordinate federal and state grant applications to leverage existing strengths across the state rather than compete against one another. The DOL grant in progress now with ACC, Texas State Technical College Waco, and Montgomery College is a great example of how Texas CTCs can partner on competitive bids for the benefit of the state.

- Take positive actions to assure that CTC biotech programs keep abreast of changes in the biotech environment. Today's biotech environment is characterized by rapid changes in theories, practices, and products. This continuing turbulence means that the skills, knowledge, and abilities required for successful employment in the biotech area are constantly changing, and CTC biotech programs must be prepared to accommodate these changes. One of the ways this can be accomplished is by establishing close relationships with those companies, research laboratories, and other groups that will employ CTC graduates. Such relationships may involve provision of instructors, making laboratory facilities available, and employing students part-time. A biotech consortium could assist in establishing such relationships.
- Establish a framework for continuing education for CTC graduates and other technicians requiring additional training. Because of the rapidly-changing biotech environment, as well as the desire of many CTC graduates to continue their education and training, CTCs must develop the capability for providing continuing education. The exact nature of this training will depend on local factors such as industry needs, number and nature of those seeking further education and training, and the resources available to local CTCs. Approaches that might be considered include evening and weekend classes, subject area "camps," and online and distance learning courses. The use of virtual collaboration and simulation in such activities would provide a modern approach to the learning challenge. A biotech consortium could ensure that CTCs have best-of-practice approaches and techniques available to them.
- Attract out-of-state biotech companies and research institutes to move to Texas and motivate Texas companies to stay in the state by promoting Texas as an emerging biotech center. Relatively few out-of-state biotech investors, managers, or planners are aware of the potential attractiveness of Texas as a biotech center. A biotech consortium could serve as a vehicle for changing these perceptions.
- Create a plan for rapidly increasing the number and size of CTC biotech programs in Texas to enhance the attractiveness of the state to out-of-state biotech companies and research institutes. The existence of such a plan would provide a strong indication that Texas is committed to developing a strong biotech presence.

II. Fund a Curriculum Development Project that Defines a Statewide Core Curriculum in Biotechnology

Although the actual subject matter taught in each individual course would continue to be shaped by the needs and expertise of local CTCs, development of a core curriculum would serve several functions:

- Define the skills, knowledge, and abilities needed for entry-level positions in various biotechnology job areas. This definition would serve to increase the portability of biotech certificates and associate degrees. Graduates could market themselves to employers based on the specific skills achieved and academic subjects covered in degree programs. The qualifications they present to potential employers would be skills-based, not degree-based. Many biotech program coordinators note that it is difficult for students to obtain positions in this field if employers are unfamiliar with the skills taught in the specific biotech program from which they have graduated.
- Facilitate the seamless transition of students from high school to CTC biotech programs. A standardized core curriculum would allow high schools to develop and offer one-year, college-equivalent biotech courses at high schools in the state. ACC has already established such a program with a number of schools in central Texas, using a grant from the National Science Foundation. These courses give students who enter biotech programs directly from high school a head start on completing their degrees.
- Make it easier to construct One–Plus-One articulation agreements between CTCs.
 One-Plus-One agreements would allow students to complete their general education and, possibly, the lecture portion of their lab courses at one CTC and then complete their biotech or lab specific courses at another. These partnering agreements would be important for a number of reasons:
 - 1) The resources, i.e., faculty, equipment, and supplies, needed to start a biotech program are extremely expensive, which may preclude many CTCs from initiating programs.
 - **2)** One-Plus-One articulation agreements would provide students with greater latitude in selecting the specific area of biotech in which they wish to concentrate. Even among CTCs with biotech programs, there will be variations in specific areas of concentration. For example, the focus of the TSTC Waco program is to develop biotech instrumentation technicians, while the Austin Community College (ACC) and Montgomery College (Montgomery) programs focus primarily on developing bench technicians.
- Facilitate the seamless transition of graduates of CTC biotech programs to fouryear colleges and universities through the establishment of Two-Plus-Two articulation agreements. Currently, articulation agreements between CTCs and four-year institutions are developed at each individual CTC. Thus, many of the course credits students earn for their non-general, i.e., academic, or biotech courses can only be transferred for credit toward a degree at a

four-year institution with which the CTC has signed an articulation agreement. A core curriculum developed by a curriculum partnership between CTCs and four-year institutions would serve to increase the range of post-graduation options for biotech program graduates. Students would be able to transfer credits from a greater number of classes, both general and biotech specific, toward a Bachelor degree at any four-year institution that recognized the core curriculum.

III. Fund the Creation of CTC-Sponsored High School Outreach Biotech Programs

Such programs would increase awareness of biotech and its implications among Texas high school students and faculty. The lack of awareness of the nature and promise of biotech among these groups is a major problem in building student interest in this exciting field. The Montgomery College biotech program conducts such an activity through its Biotechnology Institute. They allow students at high schools to complete at least one simple DNA sequencing laboratory or other biotech technique. This program also increases the biotech awareness of the faculty and, in some cases, trains high school teachers to conduct selected biotech courses. ACC has a similar high school outreach program.

IV. Fund Projects that Explore Ways of Increasing the Number of Students Enrolling in Biotech Programs

This can be accomplished by developing curricula that address biotech career ladders and lattices for medical clinical laboratory technicians and biotech/research technicians. Although hospital clinical lab technicians might not be considered biotech technicians in the purest sense, they will increasingly make use of biotech tools. El Centro College has created a dual curriculum program that combines elements of medical laboratory techniques and molecular biotech techniques. Students who graduate from the program obtain jobs in clinical lab settings. However, within those settings, they utilize molecular biology techniques they learned in their biotech programs. Students with such training are considered very valuable by employers. The CCD could fund research that explores the demand for such dual training throughout the state, not only for students in existing biotech programs, but also for clinical lab technicians already working who might need additional training.

V. Fund Special Biotech Courses as Indicated

Bioinstrumentation

It is recommended that the CCD fund the development of a series of new biotech courses listed below so that they may be easily replicated at various CTCs in the state. However, at this time, we do not recommend that complete bioinstrumentation programs be duplicated at other CTCs throughout the state.

Texas State Technical College Waco has established the first Biotechnology Systems Instrumentation Specialization program in the nation. The program, which has been approved by The Higher Education Coordinating Board, will begin offering courses leading to an Associate of Applied Science (AAS) degree in Biotechnology Systems Instrumentation in fall 2005.

Although the courses for the first year of the bioinstrumentation program have been developed, there are five courses that are still under development. These are:

BITC 2372	Introduction to Bioinformatics & Biostatistics	
BITC 1271	BITC 1271 Food and Drug Biotechnology	
BITC 2373	Functional Genomics, Proteomics, & Metabolomics	
BITC 2478	Biotechnology Device Instrumentation I	
CETT1479	Solid State Components & Applications	

Several colleges with existing biotech programs have expressed an interest in offering one or more of these same courses. Therefore, the development of syllabi, learning plans, and assessment plans as outlined by the CCD would greatly facilitate the replication of these courses, and the development of these courses would be greatly assisted if special funding were provided by the Texas State Leadership Consortium for Curriculum Development.

It is estimated that development of each course will require half-time instructor release time, plus limited travel and incidental expenses, together with the part-time services of an editing assistant. The Director of the TSTC Waco bioinstrumentation program projects that there will be from five to ten students in the first year of the program, and that number will grow to from 10 to 20 within two years. He expects to have 20 to 30 students in the program when it reaches maturity. Based on discussions with potential employers, he is confident that all graduates of his program will be employed immediately upon graduation, starting at salaries between \$40,000 and \$50,000.

Scott Jacpcyznski, a production manager for Bruker Optics in The Woodlands, has indicated that there is a strong demand for instrumentation technicians with a fundamental understanding of biotech in the Gulf Coast region. Over the last six or eight months, Mr. Jacpcyznski has hired several technicians with such backgrounds, and expects Bruker, and many of their customers, to hire many more in the future. Bruker is one of the world's foremost providers of advanced instrumentation for the biotech industry.

The initial cost of establishing a new bioinstrumentation program is estimated to be between \$750,000 and \$1,500,000, depending on the amount and type of equipment already available and whether or not private companies are able to provide some of the required equipment. Due to the broad range of technical subjects covered in such programs, CTCs with existing educational infrastructure in the fields of robotics, lasers, optics, chemistry analyzers, and biomedical equipment are particularly well suited to establish such programs.

It is estimated that the cost of supplies for the program will be about \$3,000 per student per semester. Additionally, it should be noted that it will be difficult to identify and engage faculty who are qualified to teach the courses included in the program. Because of the costs and difficulties listed, it does not appear desirable

to establish stand-alone bioinstrumentation programs at other CTCs. However, it might be possible for students to complete core courses at one CTC and then transfer to another CTC for specialized training in bioinstrumentation through One-Plus-One or "Career Foundation" agreements. Some specialized lectures could also be shared among CTCs to take advantage of the special expertise at partner colleges.

Another approach could be for students to complete their basic biotech program at their home college and then specialize in bioinstrumentation at another CTC after graduation. This extra course work would result in the award of an Advanced Technical Certificate or Certificate. Several colleges, including Montgomery College, Austin Community College, and El Centro, have expressed an interest in such an arrangement.

In time, the demand for bioinstrumentation technicians should increase significantly. Additional CTCs could develop full bioinstrumentation programs based on these new courses and existing biotech curriculum. Fully developing the courses outlined above into replicable materials will position Texas to respond quickly to such a future demand.

Bioinformatics

Because of the continuing need for data gathering, analyzing, storing, and archiving in biotechnology, the inclusion of one or more courses in bioinformatics would be desirable for most biotech programs. Therefore, it is recommended that the CCD fund the development of one or more standardized courses in bioinformatics for the state's CTCs. However, because of the uncertain nature of meaningful employment of bioinformatics specialists at this time in Texas, funding for stand-alone bioinformatics programs is not recommended.

Traditional biotechnology and information technology form the foundation of bioinformatics. Although there are no CTC bioinformatics programs in Texas, a small number of community colleges across the nation have established bioinformatics programs. For example, Foothill College in Los Altos Hills, California, offers both an Associate of Science degree and a Career Certificate Requirement in Bioinformatics.

Although it was once widely believed that computational work should be performed by IT specialists, there is a growing perception that efficient use of biocomputational tools also requires a very good understanding of biological principles. Most likely, bioinformaticians will be employed in research organizations that have genomics programs, such as pharmaceutical companies, that need to store and sift through large amounts of data.

Colleges that have existing programs in biotechnology or information technology are well suited for training individuals in the area of bioinformatics. It is estimated that initiation of a formal bioinformatics program would cost about \$40,000, assuming that a basic biotech program was in operation and that the college had extensive computer capabilities.

Although the demand for such graduates is unclear in Texas at this moment, colleges could mitigate the risk in starting such programs by developing a gradual

approach. At first, colleges could offer one or two courses in core bioinformatics courses such as BioPerl and/or Introduction to Bioinformatics Databases. As the demand for bioinformaticians increases, colleges can more easily expand these established courses into concentrations within their existing biotechnology programs. Ultimately, if the demand for such employees becomes great enough, colleges could develop Advanced Technical Certificates, Certificates, and full-scale AAS degree programs. Developing one or two courses in this area will position Texas to respond to future industry demands as these skills become increasingly important in the biotech sector.

DNA and Human Health

Because there are a number of CTCs that have programs that can provide models for program replication in the DNA and human health-care area, it is not recommended that the CCD fund the establishment of any new programs in this area.

Using their knowledge of DNA and its relationship to the other basic building blocks of life, scientists have developed a number of tools that manipulate genetic material at the molecular level. These biotech tools employ biological materials and their components to produce a wide variety of products and services. Among these products and services are a number that ameliorate various health problems including antibiotics, insulin, pharmaceuticals, DNA-based vaccines, and genetic tests that can uniquely identify individuals and diseases.

Various private and public sponsored institutions in the state, most notably in the Gulf Coast region, are researching and commercializing various molecular and gene-based interventions for human health. A number of CTCs in the state have biotechnology programs that grant, or are planning to grant, AAS degrees and Certificates in biotechnology and place their graduates directly into these institutions. Thus, most of the current Texas CTC biotech programs are well structured to meet the KSA requirements of employers in the DNA and health-care area. These programs can serve as models for the development of programs in other CTCs.

It is estimated that initiation of such a program will cost about \$50,000. Course supplies are estimated to be about \$1,500 per student per semester. Programs of this type are typically able to support about 20 students. Graduates of these programs, with experience in fundamental biotech laboratory techniques, can expect starting salaries of \$20,000 to \$25,000, depending on circumstances.

Bioagriculture

Because of the limited current demand for CTC bioagriculture graduates and the relatively low salaries expected for such graduates, funding for the establishment of formal bioagriculture program is not recommended at this time.

Agricultural products are an important component of the Texas economy, annually generating \$14 billion in sales and over \$2.5 billion in exports. As a result, Texas agricultural producers are constantly developing new production practices and techniques to maintain and extend their competitive advantage. The use of

biotechnology to facilitate agricultural production (bioagriculture) is one of the tools that producers are using to facilitate this goal.

Currently, there are no CTC biotechnology programs in the state nor, indeed, the nation, with a narrow focus in plant and animal biotechnology. However, many of the skills learned in existing biotech programs are directly applicable to occupations in bioagriculture firms and agriculture-oriented research universities. CTCs that have existing biotechnology programs are well suited for training individuals that can work in plant and animal biotechnology firms. The cost of establishing a formal bioagriculture program built on as existing biotech program is estimated to be about \$40,000.

A number of CTCs have agricultural programs with specializations in a variety of areas including agriculture farm and ranch management, animal science, forestry, etc., whose curricula will be impacted by biotech products and tools. Areas of impact include veterinary science, forestry, horticulture, entomology, agronomy, and wildlife conservation and management. Students in these areas will need to know how biotechnology will affect traditional agricultural practices such as breeding programs and the science underlying new strains of crops such as cotton and rice. CTCs with such programs might wish to add one or more bioagriculture-oriented courses to their biotech programs based on local industry needs.

It is estimated that salaries for entry-level bioagriculture graduates will be between \$20,000 and \$24,000. However, there appears to be little demand for such graduates at this time.



Appendix E: Current CTC Biotech Programs

Montgomery College

Director, Biotechnology Institute: Dr. Larry Loomis-Price

The biotechnology program at Montgomery College (located in The Woodlands) was started in 1989 and is the oldest biotech program in the state of Texas. The program graduated its first couple of students in the 1993–1994 academic year. The program was founded to serve the workforce needs of the burgeoning biotech industry in The Woodlands area, which was heavily subsidized by George Mitchell, a prominent Houston oilman and developer who personally provided financial incentives to biotech companies that located there. These incentives included equity funding and free lab space and buildings.

Dr. Larry Loomis-Price is the Director of the Biotechnology Institute, while Dr. Nishi Mathew is the Chair of the Biotechnology program. Dr. Mathew is responsible for running the administrative side of the biotech program, which includes budgeting and academics, while Dr. Loomis-Price is responsible for outreach to employers, articulation partners, and secondary schools. He is assisted in the outreach program by Ms. Janet Varela, an employee of PharmaFrontiers with over 20 years of biotech industry experience.

The biotech program has one permanent full-time biotech professor, four faculty members who teach in other departments such as biology, and three adjunct faculty members from industry. All faculty members must hold at least a Master degree. In reality, most faculty members hold Doctorate degrees, because that is the credential needed to conduct biotech research. Dr. Loomis-Price points out that it is important for biotech programs to separate the administrative and outreach functions because each of them is effectively a full-time position. He believes that a lot of the new biotech programs make the mistake of having their directors fill both functions, which means that both functions suffer. "Community colleges tap an administrator, but they neglect the outreach side of running a successful biotech program. Without outreach, you don't have a program. In order to place students, the director of a successful program must have face time with employers. Employers will not hire students from a program unless they have confidence in the person leading the program and understand the lab skills students are learning. Sixty per cent of my job is outreach to employers."

The college offers an AAS biotechnology degree as well as a one-year Advanced Technical Certificate (ATC). Students in AAS program complete a number of courses that span multiple disciplines including biology, chemistry, molecular biology, biochemistry, genetics, and college algebra. In addition, students seeking the AAS degree complete six WECM approved biotechnology (BITC) courses: Introduction to Biotechnology, Biotechnology Lab Instrumentation, Biotechnology Laboratory Methods and Techniques, Cell Culture Techniques, Molecular Biology Techniques, and a Biotechnology internship. Students in the ATC program complete 24 credit hours,

which includes all of the BITC courses, except for the Introduction to Biotechnology course, and a course in genetics.

Key to the training of students at Montgomery College is hands-on training in the latest biotech lab techniques. Additionally, in their final semester, students in both the AAS and ATC programs must complete an internship in an area biotech company or medical center research lab. The ultimate goal of the Montgomery College Biotechnology Institute program is to prepare students for entry-level positions in a wide range of biotech organizations. The program currently graduates about 13 to 14 students per year. Its goal is to graduate a minimum of 18 per year. However, Dr. Loomis-Price believes that the program could easily place up to 36 graduates per year since he has more requests for graduates than the program can produce.

Dr. Loomis Price believes that a strong advisory committee is an essential factor in building a viable biotech program. In fact, he believes that a program should not be in place until an advisory committee is formed, and there is a demonstrated demand from local biotech employers for graduates. Additionally, since biotech lab techniques are constantly changing, it is important that biotech programs regularly probe their advisory boards and seek advice on curriculum changes and updates.

The advisory board of the biotech program at Montgomery is extremely diverse: some members are from companies that will hire students, while other members are a part of the four-year academic institutions that students might enter upon graduation. The membership is composed of a mix of people from both the human resources and research departments of industry partners. The advisory board hires students for internships and donates money to the biotech program. Dr. Loomis Price states, "If a program does not keep up with the demands of industry, employers will not hire its graduates. A successful biotech program must be dynamic."

An interesting structure for continuing biotech training and education is being developed by Dr. Loomis-Price. The program, called Two-Plus-One-Plus-One, would allow students to complete a standard Associate Degree program in biotechnology. The AAS degree would provide students with the credentials they need for immediate employment in the biotech industry. After completing this degree, graduates would be encouraged to enter a one-year program in a biotech specialty, i.e., bioinformatics or biotechnology systems instrumentation. Those students completing this specialist program would be awarded a certificate verifying their competence in the selected field. This certificate should result in increased value to employers and enhanced responsibilities and salary. After completing the Certificate program, students could continue their education on a full- or part-time basis and work toward a Bachelor degree in an appropriate field.

Biotech Courses

CIP	Rubric Number	Course Title
41.0101	BITC 1211	Introduction to Biotechnology
41.0101	BITC 1402	Biotechnology Laboratory Methods and Techniques
41.0101	BITC 2431	Cell Culture Techniques
41.0101	BITC 2486	Internship - Biology Technician/Biotechnology Laboratory Technician
41.0101	BITC 2411	Biotechnology Laboratory Instrumentation
41.0101	BITC 2441	Molecular Biology Techniques

Austin Community College

Department Chair of Biotechnology: Dr. Linnea Fletcher

The Austin Community College (ACC) biotechnician training program is housed in the allied health building, but is part of Math/Science Division.

The college offers an AAS biotechnology degree, a one-year Certificate in Biotechnology, and for the student who already has a four-year degree in the appropriate field, an Advance Certificate. Students in the AAS program complete a number of courses that span multiple disciplines including biology, chemistry, molecular biology, biochemistry, genetics, and college algebra. In addition, students seeking the AAS degree complete six WECM approved biotechnology courses: Introduction to Biotechnology, Biotechnology Lab Methods and Techniques, Cell Culture Techniques, Molecular Biology Techniques, Biotech Instrumentation, and a Biotechnology Internship. Students in the Certificate program complete 29 credit hours, which includes two BITC courses, Biotechnology Lab Methods and Techniques, and the Biotech Internship. Four-year students take the six biotechnology courses and do an internship to obtain the Advance Certificate.

The ACC biotechnology program focuses on biotechnology at the lab bench, because this is where the greatest demand for biotechnology technicians currently is in Texas. ACC has more RNA training than most biotech programs because of the demands of local employers, primarily Ambion (kits) and UT Austin (lots of RNA labs). Other large employers in Austin include Stratagene, Luminex, M.D. Anderson, Abbot Laboratories, and the Department of Public Safety (DNA fingerprinting). UT Austin is not normally considered an attractive employer for graduates because of its low pay.

There are typically 90 people in the ACC program at any one time. About 20 graduate each semester. Some 60% to 70% of the students in the ACC biotech program have B.S. or higher degrees. Some of the degrees are in biology, but others have degrees or backgrounds in areas such as information technology and business.

ACC has a 100% placement rate. Most graduates go into the workforce, although many pursue a B.S. degree on either a full- or part-time basis. Starting salaries for entry-level biotech technicians graduating from the ACC program range from about \$18,000 to \$35,000. Pay varies by region and specialization. Basic lab techs with no specialized skills are the lowest paid technicians. Bioprocess technicians tend to command the highest salaries, with salaries starting at about \$40,000; these jobs are mainly in the

Houston region. Unfortunately, Texas is not very strong in bioprocessing. Presently the majority of bioprocessing jobs are on either coast. For example, in Northern California, Genentech is working closely with community colleges to recruit bioprocessing technicians.

ACC has recently acquired a real-time PCR (polymerase chain reaction) machine, which makes it possible to make a huge number of copies of a gene and measure its product while it is being made, unlike regular PCR. This technique is becoming extremely important in both research and in medical diagnostics. This acquisition was particularly important to the program, and will pave the way to an articulation agreement between the Biotech Program and the Medical Laboratory Program (MLT) at ACC.

Dr. Fletcher tries to include some bioinformatics in each of her classes. She wants students to learn how to use the National Center for Biotechnology Information (NCBI) database and molecular modeling programs. However, she does not believe there are many companies in Texas that specialize in bioinformatics specifically.

ACC has articulation agreements with Texas A&M and Texas State University, but not with UT Austin. UT will not accept ACC courses because it sees them as upper-level courses. UT does not accept upper level courses for transfer credit except from other universities.

Biotech Courses

CIP	Rubric Number	Course Title
41.0101	BITC 1311	Introduction to Biotechnology
41.0101	BITC 1402	Biotechnology Laboratory Methods and Techniques
41.0101	BITC 2411	Biotechnology Laboratory Instrumentation
41.0101	BITC 2431	Cell Culture Techniques
41.0101	BITC 2441	Molecular Biology Techniques
41.0101	BITC 2486 BITC 2487	Internship - Biology Technician/Biotechnology Laboratory Technician

San Jacinto College South

Dean of Program Development, Institutional Effectiveness and Health Careers: Dr. Catherine O'Brien

Unlike CTCs with biotech programs, San Jacinto (located near Houston) offers only one WECM approved BITC course together with academic transfer science courses. The San Jacinto program focuses on foundational courses such as General Biology I, General Biology II, Genetics, Introduction to Microbiology, Chemistry I, Mathematics, Statistics, English, and Technical Writing. San Jacinto does want to begin offering one BITC class in fall 2007. The class is BITC 1311, Introduction to Biotechnology. The College has revised its genetics course to add a laboratory component, which covers PCR, gel electrophoresis, etc. Students also have the option of taking WECM approved BITC courses at Galveston College, which conducts the laboratory portion of its courses in facilities at UTMB Galveston.

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The College has an articulation agreement with UTMB Galveston, which allows students to transfer their Associate of Science degree credits to UTMB. Students can either choose to enter either the Clinical Laboratory Sciences Program (medical route) or the biotechnology track. San Jacinto is also looking to form an articulation agreement with the University of Houston-Downtown that would allow students to finish out a Bachelor degree in biotechnology.

As San Jacinto College develops its biotech program, it intends to focus on developing technicians who will support bench scientists involved in biotech research and development. The college is focusing its program on biotech companies between Houston and Galveston. It will not focus on the development of biomanufacturing/ bioprocessing technicians, because those segments of the biotech industry do not currently exist in Texas to any great extent. There are a few small companies (less than 200 employees) involved in this part of the industry.

According to Dr. O'Brien, bioinformatics technicians, per se, have not necessarily been in high demand in Texas, but that is changing. However, it is a skill set that many Texas-based companies, including the health care industry, need. Perhaps it is not important to have an entire two-year bioinformatics program, but biotechnicicans must be familiar with the computational techniques and software used to mine data from genomics and gene expression studies. The University of Houston College of Technology is developing a Bachelors degree in general bioinformatics and a specialized healthcare bioinformatics program. San Jacinto is working towards an articulation agreement, wherein students will take their lower-level security, database and systems courses at the community college prior to transferring to the university.

San Jacinto, just like other CTCs, is convinced that lower-level SCAN skills are important to biotech employers, e.g., communication skills, ability of technicians to follow and record protocol, ability to keep detailed lab notebooks, and understand that those lab notebooks are legal documents. Dr. O'Brien believes that is important for students who leave the program to understand that their lab notebooks are legal documents.

San Jacinto is targeting a number of area employers who utilize biotech technicians, e.g., UT Medical Center (Houston) and UT Medical Branch (Galveston). Research and development is the foundation of the biotech industry in the Gulf Coast region.

Houston Community College, Northeast Campus

Department Chair of Biotechnology, Chemical Lab Technology, Instrumentation Technology and Process Technology: Dr. John K. Galiotos

Houston Community College has a biotech program built on its current courses in biotech and related subjects. The college offers an AAS biotechnology degree, as well as a one-year biotechnology certificate. Students in the one-year certificate program complete four three- and four-hour courses in biotechnology. Students in the two-year Associate program complete eight three- and four-hour courses. The college places its tudents in various biotechnology institutions throughout the Houston area including the M.D. Anderson Cancer Center, the Baylor College of Medicine, and the University of Texas Health Sciences Center, as well as numerous Houston and Woodlands based biotechnology companies.

Students in the program complete a number of courses that span multiple disciplines including molecular biology and biochemistry, physics, genetics, and fermentation studies. Key to the training of students at HCC is hands-on training and internships at biotech institutions. The focus of HCC's program is fourfold—create skilled biotechnicians for the local workforce, develop corporate training programs that develop niche skills for their needs, develop advanced certificate programs in biotech specialties such as biomanufacturing, and help small business incubate some of their ideas for products and services.

Students who complete the one-year certificate program are typically placed in positions that pay salaries that average between \$17,000 and \$20,000 annually. Students who complete the two-year program are placed in positions that pay between \$25,000 and \$30,000 annually.

Biotech Courses

CIP	Rubric Number	Course Title
41.0101	BITC 1211	Introduction to Biotechnology
41.0101	BITC 1402	Biotechnology Laboratory Methods and Techniques
41.0101	BITC 2441	Biotechnology Laboratory Instrumentation
41.0101	BITC 2431	Cell Culture Techniques
41.0101	BITC 2441	Molecular Biology Techniques
41.0101	BITC 1491	Special Topics in Biological Technology/Technician
41.0101	BITC 2386 BITC 2387	Internship - Biology Technician/Biotechnology Laboratory Technician

Texas State Technical College Waco

Coordinator Biotechnology Program: Nicholas Cram

Texas State Technical College Waco has established the first Biotechnology Systems Instrumentation Specialization program in the nation. The program, which has been approved by The Higher Education Coordinating Board, began offering courses leading to an Associate of Applied Science degree in fall 2005. Core classes include a combination of traditional biotech subjects such as chemistry, organic chemistry, cell culture techniques, genomics, proteomics, and metabolomics, as well as courses in biotech instrumentation, lasers, optics, robotics, three-phase AC power, and solid-state electronics. A Clinical Instrumentation Program emphasizing the repair and maintenance of clinical laboratory devices such as chemistry analyzers and lab automation equipment is in development. The launch date of this program has not been determined. TSTC Waco is uniquely suited to offer courses in robotics, chemistry analyzers, and biomedical equipment because it already has longstanding educational infrastructure in these areas.

Biotech Courses

Current

CIP	Rubric Number	Course Title
41.0101	BITC 1311	Introduction to Biotechnology
41.0101	BITC 2431	Cell Culture Techniques
41.0101	BITC 2286	Internship - Biology Technician/Biotechnology Laboratory Technician
41.0101	BITC 2311	Biotechnology Laboratory Instrumentation
41.0101	BITC 2011	Biotechnology Laboratory Instrumentation
41.0101	BITC 1250	Special Studies and Bioethical Issues of Biotechnology

Under Development

CIP	Rubric Number	Course Title
41.0101	BITC 2372	Introduction to Bioinformatics & Biostatistics
41.0101	BITC 1271	Food and Drug Biotechnology
41.0101	BITC 2373	Functional Genomics, Proteomics, & Metabolomics
41.0101	BITC 2478	Biotechnology Device Instrumentation I

Dallas Community College District (El Centro)

Department Chair of Biotechnology (Fall 2005): Dr. Kiren Kaur

The biotech program at Dallas Community College (El Centro) is only two-and-a-half years old. As a result, only a handful of students have graduated from the program. The college offers an AAS biotechnology degree, as well as a one-year Level I Certificate. Students in the program complete a number of courses that span multiple disciplines including molecular biology and biochemistry, physics, genetics, and fermentation studies. Skills taught include laboratory management and safety, laboratory operations, planning, recording, and reporting experiments, caring for equipment and living cells, cell and tissue culture, genetics, pipetting, technical writing, and statistical analysis.

A number of El Centro students have completed a dual curriculum program that combines elements of medical laboratory training and biotechnology. This pairing has been a great match. These students are able to use the molecular biology techniques they learn in the El Centro program in traditional clinical laboratory settings, which has been very appealing to their employers.

El Centro has enough lab space to accommodate 20 to 30 students at one time. Equipment for biotech programs is very expensive. El Centro has the equipment for basic testing (incubators, PCR testing, etc.). However, the program does not possess more expensive equipment like high throughput sequencers. To fill this gap, the program takes students on working field trips to biotech labs at institutions like UT Southwestern or the University of North Texas Health Science Center.

The program is anticipating a full class of 10 people for the fall. Dr.Kiren Kaur of UT Southwestern will take charge of the program. According to Bridgette Kirkpatrick, "In the future, the number of students in the program will be wholly dependent on the needs of the local biotech industry. If that community comes to the Dallas Community College and expresses a need for more biotechnicians, then the college will expand to meet that need. The program will not expand unless there are demonstrable opportunities for its graduates. The college is very cautious in this regard. This is just the way it is."

In fact, the lack of biotechnician job opportunities in the Dallas area is why the college developed the dual curriculum concept. The college wanted to ensure that graduates of the biotech program would have employment opportunities regardless of how quickly the biotech industry in the region expanded. The students can still be placed in clinical lab positions. There are strong indications that the Stryker Corporation will be moving to the Dallas area (Grand Prairie), which would open up some avenues of potential employment for graduates of the program. According to Lisa, "Quite honestly, we are still trying to figure out where graduates of our program can be placed. Dallas-Fort Worth has not been a very wide open market as far as placement of our biotech graduates."

Students who enter the program that already have a Bachelor degree are highly sought after by UT Southwestern. UT Southwestern seems to require a Bachelor degree for entry-level technicians. Students who complete only the AAS in biotech usually have to pursue further education to expand their job opportunities. The program does have an articulation agreement with UT Arlington. The vast majority of students, however, complete the dual med lab/biotech curriculum. These students are doing quite well.

Initially, the Dallas Community College district determined that both the El Centro and Mountain View campuses would have biotech programs. However, in practice, Mountain View sends students who are truly interested in biotechnology degrees to El Centro. There is word that Mountain View plans to resurrect their program. However, no official schedule is available at this time.

Students who complete the program are typically placed in positions that pay salaries anywhere between \$15,000 and \$23,000.

Biotech Courses

CIP	Rubric Number	Course Title
41.0101	BITC 1302	Biotechnology Laboratory Methods and Techniques
41.0101	BITC 1311	Introduction to Biotechnology
41.0101	BITC 2431	Cell Culture Techniques
41.0101	BITC 1391 BITC 1491	Special Topics in Biological Technology/Technician
41.0101	BITC 2286 BITC 2486	Internship - Biology Technician/Biotechnology Laboratory Technician
41.0101	BITC 2311	Biotechnology Laboratory Instrumentation
41.0101	BITC 2441	Molecular Biology Techniques
41.0101	BITC 1350	Special Studies and Bioethical Issues of Biotechnology

Galveston College

Associate Professor and Director Biotechnology Program: Dr. James J. Salazar

Galveston College offers an Associate of Applied Science Degree in Biotechnology. It is a two-year, five-semester program designed to prepare students for entry-level positions in biotech research labs. The program includes courses in general academic subjects such as biology, chemistry, and microbiology, as well as WECM approved BITC courses: Introduction to Biotechnology, Biotech Lab Methods and Techniques, Molecular Biology Techniques, Special Topics in Biotechnology, and Biotechnology Internship. The goal of the program is to give students solid "hands-on" training in biotech laboratory techniques (pipetting, solution preparation, separation and identification techniques, etc.). Students who complete the program have to complete two internships at research laboratories. The program is a cooperative effort between Galveston College and UTMB Galveston, and all of the laboratory courses are taught at UTMB Galveston.

The program expects to prepare students for entry-level positions in medical research facilities and in the biotechnology industry. The entry-level salary range will depend on a number of factors, including geographic location, educational background, duties of employment, on-the job experience and personal qualities. Experienced and degreed research assistants have access to a higher salary scale. Articulation agreements in place with major universities (e.g. UTMB) will open opportunities to graduates to move into a career ladder to pursue higher degrees such as bachelor, master, and doctoral degrees; available within the Houston-Galveston biotechnology corridor area.

Biotech Courses

CIP	Rubric Number	Course Title
41.0101	BITC 1311	Introduction to Biotechnology
41.0101	BITC 1402	Biotechnology Laboratory Methods and Techniques
41.0101	BITC 2411	Biotechnology Laboratory Instrumentation
41.0101	BITC 2441	Molecular Biology Techniques
41.0101	BITC 1291 BITC 1391	Special Topics in Biological Technology/Technician
41.0101	BITC 2286 BITC 2387	Internship - Biology Technician/Biotechnology Laboratory Technician

Alamo Community College District, Northwest Vista

Biotechnology Coordinator: Neil McCrary

The biotechnology program at Northwest Vista (located in San Antonio) is relatively new (started in spring 2002). The college offers an AAS in Biotechnology degree. Students in the program complete courses in core academic subjects including college algebra, chemistry, biology, microbiology, and English composition. In addition, they complete five WECM approved BITC courses: Introduction to Biotechnology, Molecular Lab Techniques, Cell Culture Techniques, Lab Instrumentation, and Lab Methods, in addition to an industry internship. Like other biotechnology programs, instead of

educating technicians for specific sectors of the biotech industry, e.g., bioagriculture, bioprocessing, etc., the school aims to train well rounded biotechnicians familiar with a broad range of biotech lab practices and procedures. The goal is give students a broadbased education that allows them to work in a number of different biotech areas.

The first student to complete all of the course requirements for the AAS graduated in spring 2005. Six other students in the program have now graduated and completed internships. Of the six graduates, one was hired on at the internship site, and the other five are continuing their education at four year institutions. Eight other students should complete their internships by the beginning of summer 2006. At least three of these eight students have informal, contingent offers to continue working at their internship sites.

Currently, there are about 30 active biotech students at some point in the program, whether it is just starting out, in the middle, or near completion. The hope is to eventually have 40 students in the program, with 10 to 15 graduates a year. Of 30 students in the biotech program, about seven or eight have already earned a Bachelor degree. Most of these students are trying to change career paths; many are in their late 30s to their early 50s. The Northwest Vista program aims to give their students handson training in biotech lab practices, which a Bachelor degree in biology and chemistry often does not provide. Many of the students in the program with Bachelor degrees in the natural sciences have told Neil McCrary, the coordinator of the program, that they completed more laboratory work in his program than they did in their entire four years of undergraduate work.

Most students in the program want to complete further studies and qualify for a Bachelor degree. Private schools in the region (St. Mary's and Our Lady of the Lakes) accept biotech courses offered at Northwest Vista. The college is still in the process of trying to establish an articulation agreement with UT San Antonio.

Neil believes that the demand for biotechnicians in the San Antonio region has been slow in developing. However, he believes that, as time goes on, there will be a higher demand for a program such as his that produces entry-level technicians who are familiar with biotech lab practices and can hit the ground running when they enter biotech firms. Although the sample size is small, there have been good reviews from employers of Northwest Vista interns. However, none of the Northwest Vista graduates has actually taken a position with a biotech firm.

Salaries for entry level biotechnicians in the San Antonio area vary from the high teens to the low thirties with most positions falling in the mid 20s. Poorly funded startups and research/academic labs tend to offer the lowest salaries.

Biotech Courses

CIP	Rubric Number	Course Title
41.0101	BITC 1311	Introduction to Biotechnology
41.0101	BITC 1402	Biotechnology Laboratory Methods and Techniques
41.0101	BITC 2411	Biotechnology Laboratory Instrumentation
41.0101	BITC 2431	Cell Culture Techniques

41.0101	BITC 2441	Molecular Biology Techniques
41.0101	BITC 2486	Internship - Biology Technician/Biotechnology Laboratory Technician

Temple College

Director of the Health Science Division: Bea Wohleb

Temple College first became interested in starting programs in biotechnology about four years ago when the leadership at Scott & White Medical Center expressed a need for biotechnology research technicians. The college realized that it did not have the funds to meet this need. Therefore, the College applied for a Department of Labor grant to develop programs to create a pipeline of research technicians to work in the specialized cardiovascular and cancer research laboratories.

In June 2005, the college received a Department of Labor grant of \$920,495 to develop a program for training biotechnology research technicians. As a result, the College is well on the way to developing a strong biotechnology program. which will offer an Associate of Applied Science in biotechnology research technician degree, an Advanced Technical Certificate, and an Enhanced Skills Certificate in Genomics/Proteomics. Students will work directly in local research laboratories with well-known scientists. There are currently two primary areas of research underway in Temple. These include the Cardiovascular Institute at the Veterans Administration Hospital, and the Cancer Research Institute at the Scott & White Medical Center. The principal investigators in these institutions will provide expertise for developing these new courses and programs.

Plans for the program are being finalized and curriculum is being developed with the expectation that 20 students will be enrolled in fall 2006. The program will target the following populations: high school students through dual credit classes, students with limited English proficiency, displaced workers, and military personnel and their spouses. Laboratory facilities and classrooms will be located at the Health and Bioscience Research Facility in Temple. The goal is to create a Bioscience Academic Center that will include dual credit classes for high school students, an Associate of Applied Science Degree from Temple College, the Scott & White Clinical Laboratory Science program, and upper level university classes.

Collin County Community College

Professor of Biotechnology: Dr. Bridgette L. Kirkpatrick

Collin County Community College (located in Plano) has an AAS Biotechnology degree program, as well as a one-year biotechnician certificate program. These programs are designed to give students practical laboratory experience as well as the theory behind the techniques that they learn. Five to ten students graduate from the program with AAS or certificate degrees. The program has placed a few students at small biotech companies in the Dallas area but, for the most part, graduates take positions at UT Southwestern. Dr. Kirkpatrick is very honest with her students concerning current job prospects in the Dallas region: jobs at UT Southwestern are available but salaries are quite low. She noted that Collin County Community College is in Plano, a fairly affluent

community, and students who graduate from their programs are extremely reluctant to enter positions that pay in the low 20s. Many students in the program will transfer to universities and finish a Bachelors degree.

A number of students with Bachelor degrees are enrolled in the program. Plano is located in the telecommunications corridor. As a result, an interesting number of students who enter the program are retrainees from the computer and telecommunications industry, which collapsed in Dallas around 2001. The program also enrolls a number of biology majors seeking practical biotech laboratory experience. Students with a previous Bachelor degree who complete the certificate program are the easiest to place; employers are excited about hiring students with practical biotech lab experience. They typically make more money than students who earn only an Associate degree. Employers at UT Southwestern are typically more interested in the students who have a Bachelor degree background rather than just an Associates degree.

Typical entry-level salaries for graduates range from the high teens to the low thirties (previously attained Bachelor degree). Pay for interns at UT Southwestern is low (about \$7.50/hour) but students gain invaluable lab experience which counts toward work experience if they are hired.

Biotech Courses

CIP	Rubric Number	Course Title	
41.0101	BITC 1311	Introduction to Biotechnology	
41.0101	BITC 1402	Biotechnology Laboratory Methods and Techniques	
41.0101	BITC 2411	Biotechnology Laboratory Instrumentation	
41.0101	BITC 2431	Cell Culture Techniques	
41.0101	BITC 2441	Molecular Biology Techniques	
41.0101	BITC 1350	Special Topics in Biological Technology/Technician	
41.0101	BITC 2387	Internship - Biology Technician/Biotechnology Laboratory Technician	



Appendix F: Approved Biotech Programs and Courses

Approved Programs

CTC	Program	Award	
Alamo Community College District, Northwest Vista College	Biology Technician/ Biotechnology Laboratory Technician - 41.0101	Biotechnology AAS	
Austin Community College	Biology Technician/ Biotechnology Laboratory Technician - 41.0101	Biotechnology AAS	
Austin Community College	Biology Technician/ Biotechnology Laboratory Technician - 41.0101	Biotechnology Certificate	
Collin County Community College District	Biology Technician/ Biotechnology Laboratory Technician - 41.0101	AAS Biotechnology	
Collin County Community College District	Biology Technician/ Biotechnology Laboratory Technician - 41.0101	Biotechnology Certificate	
Dallas County Community College District El Centro College, Mountain View College	Biology Technician/ Biotechnology Laboratory Technician - 41.0101	Biotechnology AAS	
Dallas County Community College District El Centro College, Mountain View College	Biology Technician/ Biotechnology Laboratory Technician - 41.0101	Biotechnology Certificate	
Galveston College	Biology Technician/ Biotechnology Laboratory Technician - 41.0101	Biotechnology AAS	
Houston Community College System Northeast Campus	Biology Technician/ Biotechnology Laboratory Technician - 41.0101	AAS Biotechnology	
Houston Community College System Northeast Campus	Biology Technician/ Biotechnology Laboratory Technician - 41.0101	Biotechnology Certificate	
NHMCCD Montgomery College	Biology Technician/ Biotechnology Laboratory Technician - 41.0101	AAS Biotechnology	
NHMCCD Montgomery College	Biology Technician/ Biotechnology Laboratory Technician - 41.0101	Laboratory	
Texas State Technical College Waco	Biology Technician/ Biotechnology Laboratory Technician - 41.0101	Biotechnology Systems Instrumentation	

Approved Courses

CIP	Rubric Number	Course Title	
41.0101	BITC 1091 BITC 1191 BITC 1291 BITC 1391 BITC 1491	Special Topics in Biological Technology/Technician	
41.0101	BITC 2041	Molecular Biology Techniques	
41.0101	BITC 1011 BITC 1211 BITC 1311	Introduction to Biotechnology	
41.0101	BITC 1302 BITC 1402	Biotechnology Laboratory Methods and Techniques	
41.0101	BITC 2031 BITC 2431 BITC 2531	Cell Culture Techniques	
41.0101	BITC 2001	Molecular Biology Techniques	
41.0101	BITC 2x86 BITC 2x87	Internship - Biology Technician/Biotechnology Laboratory Technician	
41.0101	BITC 2311 BITC 2411	Biotechnology Laboratory Instrumentation	
41.0101	BITC 2011	Biotechnology Laboratory Instrumentation	
41.0101	BITC 2341 BITC 2441	Molecular Biology Techniques	
41.0101	BITC 1005	Biotechnology Laboratory Methods and Techniques	
41.0101	BITC 1050 BITC 1250 BITC 1350	Special Studies and Bioethical Issues of Biotechnology	

CIP Code: 41.0101 (Biology Technician/Biotechnology Laboratory Technician)



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Biotechnology A Technology Forecast Implications for Community & Technical Colleges in the State of Texas

Continuing advances in biotechnology have the potential to dramatically improve human health and wellness, provide more efficient food production processes, contribute to a cleaner environment, enhance homeland security and support human identification techniques. In this report we examine fundamental trends driving advances in biotechnology, review current and planned research projects, include discussions with leading biotech experts and provide strategic and targeted recommendations to increase the competitiveness of Texas biotechnology companies.

For the foreseeable future, the biotech field will grow rapidly in terms of technical innovation, practical applications and business opportunities. The use of automation and robotics will be of increasing importance in the biotech field, permitting improvements in efficiency, timeliness and accuracy. Biotech will continue to converge with other developing technologies, such as healthcare, information technologies and nanotechnology. Moreover, employment opportunities in the biotech field will grow rapidly over the next several years.

There are at least three reasons to believe that employment opportunities for biotechnicians will become increasingly bright in the future: strong indications that the biotech industry (including research and development institutions) will grow appreciably in the near future; a growing awareness of the capabilities of 2-year biotechnician graduates; and the fact that, as biotech activities move from research to development to commercialization, the percentage of technicians in the organization tends to grow.

TSTC Emerging Technology Programs

TSTC's Emerging Technologies identifies emerging technology trends, evaluates potential workforce implications and recommends new courses and programs for two-year colleges in Texas. The purpose of this program is to ensure Texas employers continue to have the highly skilled workforce necessary to compete in an increasingly global and technologically complex marketplace. Visit www.forecasting.tstc.edu and www.publishing.tstc.edu for more information and to access this and other TSTC publications.

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