1996 Biotechnology Opportunity Guide of Upper Midwest and Mountain States

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I. ABOUT THIS GUIDE

Objectives

The Objective of this Guide is to provide Canadians with a resource guide for biotechnology research and commercial activity in the Upper Midwest and Mountain states of the United States.

Biotechnology Resource Guide

The Guide will direct you to the all organizations engaged in biotechnology research in North Central U.S. The sectors covered include Non-profit organizations - Universities, Clinical Research Hospitals, Federal Laboratories, and Research Institutes; Industries - Pharmaceutical, Diagnostic, Veterinary, Seed, Microbials, Equipment and Specialty Chemicals; and Business Development Organizations.

North Central United States

The Guide addresses biotechnology research and commercial activity in the post region of the Minneapolis-based Canadian Consulate General - the Upper Midwest and Mountain states market. The region includes the following states: Colorado, Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, and Wyoming. For this Guide the region is denoted North Central United States.

How To Use This Guide

The next section of the Guide provide a brief overview of biotechnology and the industries which utilize this technology. The other sections direct you to the organizations in the North Central U.S. that are engaged in biotechnology research and commercial activities. The regulatory environment in the United States is reviewed. with special emphasis given to the North Central U.S.

The specific resource organizations and resource materials mentioned throughout the Guide are cataloged in the appendices of the Guide for your convenience. You are encouraged to contact these organizations to receive more detailed information.

II. BIOTECHNOLOGY OVERVIEW

INTRODUCTION

The term, biotechnology, was coined in 1917 by a Hungarian engineer, Karl Ercky, to describe the large-scale production of pigs using sugar beets as the pig's food source. According to this engineer, biotechnology was " all lines of work by which products are produced from raw materials with the aid of living things." Under this definition, biotechnology has existed since mankind began domesticating microorganisms, plants and animals.

Microorganisms. As far back as eight thousand years ago, our ancestors knew that certain foods and drinks changed during storage, sometimes in tasty ways. Fruit juice would become alcoholic to produce wine; dough would rise and produce pleasing aromas and tasty bread when baked; and milk would sour and curdle to produce cheese. Long before this fermentation process had a name, ancient people learned to control the process by controlling ingredients, temperature and time.

Plants. Stone age farmers began by planting seeds of wild plants. Later they selected the most productive of their domesticated plants to provide the next year's seed stock. Over thousands of years, this process gave rise to most of today's crops.

Animals. Man's symbiotic relationships with animals date to the beginning of recorded history as well. Virtually every society depended to some degree on food-producing animals, beasts of burden and pets. Today, we still rely on animals for much of our food, fiber and companionship.

In the early 1960's, biotechnology was defined as the study of the industrial production of goods and services by processes using microorganisms. Throughout the 1960's and early 1970's, biotechnologists were primarily concern with maximizing the production of industrial quantities of chemicals from microorganisms. Biotechnology research at this time depended on expertise in microbiology, biochemistry, and chemical engineering.

However, this all changed with the development of recombinant DNA technology and monoclonal antibody technology in the early 1970's. Now, biotechnology was no longer limited to microorganisms. With recombinant DNA techniques, any living organism could be directly altered to produce valuable chemicals. This technology provided the means of identifying genes which produce highly valuable proteins and enzymes, and of transferring these genes to any organism. Now, plants and animals, in addition to microorganisms, could be the bioreactors producing valuable gene products.

Today, biotechnology encompasses a diversity of companies, technologies and markets. Karl Ercky's definition of biotechnology, " all lines of work by which products are produced from raw materials with the aid of living thing"' has never been more appropriate. Biotechnology is is no longer the sole activity of entrepreneurial start-up companies; it can be found in the vast majority of the bioscience-based industries from pharmaceutical to food processing companies The following section gives a brief overview of modern biotechnology and the industries which are using this technology. For printed resources with detailed discussions on the science and business of biotechnology, refer to Appendix H.

MODERN BIOTECHNOLOGY

Modern biotechnology was initiated with the development of recombinant DNA technology (ie., genetic engineering) and monoclonal antibody technology.

GENETIC ENGINEERING. Genetic engineering became possible as biologists deepened their understanding of deoxyribonucleic acid, or DNA, the molecule that codes the instructions for growth, maintenance, and reproduction of all living things. Each instruction is called a gene. Many genes - 100,000 to 300,000 - make up an organism's genome, its entire instruction manual. Each gene is a blueprint for a single protein. Proteins are natural substances that give living things their structure and control their functions. Enzymes, antibodies, and some hormones are proteins.

Genetic engineering is a process by which biologists combine the gene(s) of one organism (the donor) with the genome of another organism (the recipient). The resulting transgenic organism is genetically altered to produce a new gene product, be it human insulin, antisense RNA, or an industrial enzyme. Moreover, the transgenic organism can pass this alteration onto to its offspring, thus insuring a endless supply of transgenic organisms.

MONOCLONAL ANTIBODIES. This technology involves the commercial production of identical antibodies from individual clones (ie., monoclonal) of hybridoma cells. A hybridoma cell is created by fusing a lymphocyte with a myeloma cell. The hybridoma inherits its ability to produce antibodies from the lymphocyte and its ability to divide indefinitely from the myeloma cell. Monoclonal antibodies have a high affinity for a discrete region of the antigen, be it a drug, hormone, tumor marker, or infectious disease.

Monoclonal antibody technology is the basis of immunodiagnostics Immunodiagnostic test kits allow for the rapid and accurate detection of a disease or physiological state. Clinical laboratories use immunodiagnostic test kits to detect sexually transmitted diseases, hepatitis B, AIDS, cancer types, and infectious agents. Monoclonal antibodies are also being developed as therapeutic drugs to combat infectious agents and autoimmune diseases. Upon binding to the target cell the therapeutic monoclonal elicits an immune response which leads to the death of the cell.

COMMERCIAL BIOTECHNOLOGY

Biotechnology is not a science, nor is it an industry; it is a technology comprised of many scientific disciplines (eg microbiology, biochemistry, genetics, molecular biology, chemical engineering) that are applied to the production of commercial products by living organisms. Biotechnology is utilized by a diverse group of companies with the shared mission of using biological processes to develop products to meet human needs. The following sections reviews biotechnology applications in medicine, agriculture, and the environment.

MEDICAL. Biotechnology has completely revolutionized medicine. Researchers are discovering the genetic and molecular basis of diseases that have stymied the medical community for generations, such as multiple sclerosis, cystic fibrosis, and breast cancer. With this information, new medicines and therapies can be developed which use proteins, enzymes, antibodies, and other substances naturally produced in the human body to fight infections and diseases, as well as to correct genetic disorders. Human genes are the blueprints for the biotherapeutic drugs; plant and animal cells, bacteria and yeasts are the manufacturing plants, or bioreactors.

The traditional method for cloning human genes centered on purifying the therapeutic

protein (e.g. insulin, factor VII, or erthryopoietin), sequencing the protein, synthesizing DNA probes based on the proteins amino acid sequence, and isolating the target gene from human DNA libraries. This laborious process is limited to genes whose protein products are known. For many clinical abnormalities, the molecular basis is unknown or the protein is not present in sufficient quantities to be purified. The genes for many of these diseases have been cloned via positional cloning, in which the DNA of patients with known clinical abnormalities are compared to normals. Areas in which differences in the chromosomal maps occur are then sequenced to identify the normal and abnormal genes. The success of positional cloning stems from the international effort to map the human genome. Over 3500 genes have been located to specific human chromosomes.

The largest commercial activity of the biotechnology industry is medical products, with approximately 70% of the biotech companies in this sector. In 1995, over $10 billion dollars of medical biotechnology products were sold worldwide. There are four primary areas in medicine in which biotechnology is being employed: biotherapeutics, vaccines, gene therapy, and diagnostics. A brief review of these market sectors follows.

Biotherapeutics. Prior to the development of recombinant DNA technology, most human protein pharmaceuticals (biotherapeutics) were available in limited quantities, they were costly to produce, and often their biological mode of action was not well characterized. Recombinant DNA technology made it possible to produce human biotherapeutics is sufficient quantities for both safety and efficacy testing, and eventual human use. Today, human genes for over 300 different proteins that are potential biotherapeutic agents have been cloned. The U.S. Food and Drug Administration has approved several biotherapeutics, including erythropoietin, Factor VII, Factor IX, granuloctye colony stimulating factor, human growth hormone, interferons, insulin, and tissue plasminogen activator. Biotherapeutic medicines are being used to treat anemia, cystic fibrosis, growth deficency, hemophilia, leukemia, hepatitis, genital warts, transplant rejection and many forms of cancer. Over 100 biotherapeutics are in clinical trials in the U.S. (*Genetic Engineering News*, Vol. 15, 1995)

Monoclonal antibodies are being developed as therapeutic agents to fight infectious agents and human physiologic states as well. This method centers on the monoclonal antibodies eliciting an immune response after it specifically binds to the target cell. To avoid eliciting an immunological response to the mouse monoclonal antibody itself, the mouse monoclonal is "humanized". This is accomplished by cloning the epitope-binding region of the mouse monoclonal into a human antibody gene. This human-mouse antibody gene is then cloned into a mammalian cell, the bioreactor, from which large quantities of therapeutic antibodies are purified. Biotherapeutic monoclonals are under development for infectious agents (bacteria and viruses) inflammatory diseases, and cancer. Over 65 monoclonal therapeutics are in clinical trials in the U.S. (*Genetic Engineering News*, Vol. 15, 1995).

Vaccines. Traditionally, vaccines are either inactivated or attenuated infectious agents (bacteria or viruses) that are injected into a person to elicit the production antibodies and thereby confer immunity to the infectious agent. This method has drawbacks - many infectious agents cannot be grown in sufficient quantities to make a vaccine; handling large volumes of pathogens poses safety problems; attenuated strains may revert to an infectious state; and inactivation may be incomplete. Biotechnology can be used to overcome these shortcomings. Immunological active, avirulent strains can be developed by removing the virulence gene(s). The gene encoding the antigenic protein can be cloned into a passive virus,

thereby creating a noninfectious, immunogenic agent. The antigenic proteins also can be cloned into bioreactors which will produce large quantities of the protein. These proteins are termed subunit vaccines. The hepatitis B vaccine, Recombivax®, is a subunit vaccine that is produced by genetically engineered yeast. There are over 40 biotech vaccines in clinical trials in the U.S. (*Genetic Engineering News*, Vol. 15, 1995).

Gene Therapy. Today, most therapies for genetic disorders involve medications, diets and blood transfusions. Individuals with Gaucher diseases can receive the missing protein through injections, while other individuals with sickle cell anemia may receive blood transfusions or bone marrow transplants. An alternative approach would be to provide the afflicted patient with "corrected" somatic cells which contain a normal, functioning copy of the defective gene. With these normal cells, the patient would be able to produce the missing protein or enzyme, or possibly produce a new therapeutic protein or enzyme. This strategy is termed somatic cell gene therapy and it is in a preliminary stage of development.

Various strategies for implementing gene therapy are under study. Ex vivo gene therapy involves collecting cells from the infected individual, transferring a functional gene into these cells, growing these transgenic cells, and infusing or transplanting the transgenic cells back into the patient. In vivo gene therapy entails the direct delivery of a remedial gene into cells of the prospective patient via a benign vector, typically a virus. By contrast to ex vivo and in vivo therapies, antisense therapy is designed to prevent or lower the expression of a specific gene. In some types of human genetic diseases and cancers, genes are overexpressed. Antisense genes produce RNA that bind to the RNA of the overexpressed gene, thereby effectively "shutting down" the overexpressed gene. Today, there are over 40 diseases being considered for treatment with somatic cell gene therapy (Culver, 1994).

Diagnostics Modern medicine depends on the rapid detection and correct diagnosis of a disease. Molecular diagnostic procedures using either immunologic or DNA detection methods have revolutionized clinical diagnosis. Diagnostic monoclonal antibodies have been commercially developed for polypeptide hormones, tumor markers, cytokines, drugs, infectious disease, and a host of other targets. Immunologic detection systems are sensitive, specific, rapid, and simple. They are used for a wide variety of applications on a daily basis.

Nucleic acid based diagnostics also are powerful tools. DNA probes have been developed for most human, animal and plant pathogens. The PCR procedure allows for the amplification of target DNA sequences which are present in minute amounts. DNA analysis procedures also are routinely used for diagnosing genetic disorders. They can be used for early diagnosis before the onset of symptoms, for prenatal diagnosis, or for identifying carriers of rare genetic diseases. DNA typing methods are also employed by law enforcement agencies to "DNA fingerprint" biological samples (hair, blood, skin, etc.) left at crime scenes; by agricultural companies to patent their proprietary germplasm (seeds, animals, etc); and by naturalists to determine the genetic relatedness of individuals in endangered species populations.

Biotech diagnostics have a wide range of uses. There are over 320 biotech diagnostic companies worldwide competing for this growing market, with $15 billion dollars in worldwide sales in 1995. Over 650 immunodiagnostic and DNA diagnostic products have been approved for clinical use, and an even greater number sold for research purposes (Ernst and Young, 1995).

AGRICULTURAL. Agricultural biotechnology represents a broad collection of technologies and industries.which share a common goal of productively producing safe and healthy food. Veterinary pharmaceutical and biologics companies are utilizing biotechnology to develop new drugs and vaccines. Seed companies are using the technology to insert insect resistance and herbicide resistance genes from microorganisms into traditional crops, such as corn, soybeans, potatoes, sugar beets and canola. Agriculture bioprocessing companies are using "engineered enzymes" to improve the production of specialty chemicals, such as sugars, alcohols, organic acids and amino acids, from grains. Food and feed companies are using biotech diagnostics to monitor product safety and quality.

Biotechnology allows agricultural researchers to identify the molecular basis of "performance", thereby opening the door to developing new treatments and technologies. Virtually every plant and animal grown commercially for food or other application is a product of breeding. Traditional breeding is time consuming and inefficient and subject to limitations. Biotechnology allows animal and plant breeders to identify performance genes that are critical to overall health and productivity. Using rapid genetic identity technologies, these breeders can select the parent stocks which contain the complete set of performance genes, thus eliminating years from development. The following sections briefly review the research and market sectors of agricultural biotechnology.

Animals. Animal research falls into two broad categories - health and performance. Animal health care research addresses the development of medicines, either pharmaceuticals or biologics, for animal diseases caused by infectious agents (bacteria, viruses, parasites, etc.) or stress. According to the United States Department of Agriculture, biologicals are modified live and killed virus vaccines, toxoids and antitoxins; and pharmaceuticals are analgesics, antibiotics, anesthetics, disinfectants, anthelmintics and vitamin supplements. Biotechnology strategies for diagnosing and treating animal diseases follows those incorporated by medical biotechnology firms (see previous section). Most veterinary pharmaceutical and biologics companies have biotechnology R&D programs or employ biotechnology products in their manufacturing quality control procedures.

Obviously, animal performance is greatly enhanced by veterinary medicines. Animal performance can also be improved over generations by selective breeding. Animal breeding has traditionally been a laborious, time-consuming operation that has a "hit-or-miss" aspect. However, today, animal breeders are improving their odds through biotechnology; more specifically, by mapping the genomes of food animals, such as cattle, sheep, swine, poultry, and some fish. These researchers, primarily university and government scientists, use the same rapid and precise mapping techniques being used in the human genome project. They are gaining a fundamental understanding of the genetic basis of many quantitative traits (i.e., controlled by many genes), such as growth rate, liter size, and milk yield. They are developing tools to identify breeding lines with the most favorable set of genes, thus reducing the time for developing superior varieties. Additionally, they open the opportunity for cloning disease resistance genes from nonadaptive populations, and then transferring these genes to superior breeding stock.

A third area of animal biotechnology, transgenic animals, crosses over into medical biotechnology. Transgenic animals contained foreign genes in their genome. These animals are created by a process of taking fertilized eggs, injecting the eggs with donor DNA, and then implanting the eggs into the uterus of receptive females. The offspring are screened for their ability to express the donor DNA. Those that can, generally contain the donor gene in all of their cells, including their germ cells. These transgenic animals can pass the new trait on to their offspring, thereby creating a new animal variety. Transgenic mice engineered to express human genetic disorders, such as Alzheimers, are powerful (and highly valuable) research tools. Several commercial firms have produced transgenic sheep which produce valuable human biotherapeutic proteins in their milk. Sheep have certain advantages over microorganisms and mammalian cells because their milk is produced cheaply, in large quantities and with few contaminating proteins. The use of milk animals as bioreactors is termed pharming.

Plants. As with animals, plant breeding has been revolutionized by biotechnology. Plant breeders are using genomic analysis methodologies to identify individual plants with superior genes. Plant molecular biologists are using these same techniques to identify genes responsible for agronomically valuable traits, such as disease resistance, stress resistance, nutritional quality, and oil composition. Other research areas impacting plant health is biopesticides and seed inoculants, containing genetically engineered microorganisms, such as the nitrogen-fixing bacteria species, *Rhizobium*.

However, the real revolution in plant biotechnology has come about by the invention of gene transfer technologies, of which there are two basic types; biological and mechanical. Some dicots, notably canola and tobacco, can receive DNA into their nuclei by a pathogenic bacterium, *Agrobacterium tumefaciens*. This natural process leads to a cancerous growth, or gall. Removal of the "gall" genes from Agrobacterium maintains the DNA transfer properties of Agrobacterium, without the negative plant growth effects. These disarmed Agrobacterium strains are used as vectors to deliver genes to plants cells. For plant species which are not infected by Agrobacterium, notably all cereals, donor DNA is injected mechanically into nuclei. The preferred method is biolistics which involves "shooting" mircobeads of DNA coated tungsten into plant nuclei with a particle gun. The target tissues are somatic cells which have the ability to regenerate into complete, fertile plants.

Plant transformation is now possible for all the major agricultural and horticultural species. Today, there are numerous commercial transgenic crops, including insect resistant cotton, corn, potato; virus resistant squash; herbicide tolerant soybean; and several flavored-enhanced tomatoes. The type of plants that can be created are only limited by one's imagination!

Biomass Utilization. Biomass is raw biological material, either in unprocessed form (grains, silage, trees) or in processed form (corn steepwater, paper pulp effluent, or whey). Biomass is not only a source of valuable biomolecules (starch, protein, oil, etc.), but is also an excellent feedstock for microorganisms, especially those engineered to produce valuable molecules. Biotechnology allows the development of new strains and processes for the production of novel enzymes with new catalytic properties. Genetically engineered enzymes are being designed to function under extreme conditions and to catalysis chemical transformations, previously possible only by organic catalysts. Engineered enzymes have many advantages over

traditional organic processes, such as specificity, expense, and safety (enzymes are biodegradable).

ENVIRONMENT. For decades, municipalities have used biological methods to treat their sewage and industry has used secondary aerobic treatment to remove harmful materials from their liquid wastes. Today, biotechnology expands the range of treatment choices. Teams of microbiologists, chemical engineers and environmental engineers are working to eliminate pollutants from waste waters, aquifers, soils, industrial effluents and air. These scientists are gaining a fundamental understanding of the mechanisms of aliphatic and aromatic hydrocarbon degradation by living systems. New metabolic pathways are being designed via genetic engineering. Engineers are developing small scale bioreactors to eliminate the pollutant at the point of production (within the factory). These bioreactors are not only more efficient and less expensive, but they also allow for the use of engineered microorganisms in a controlled environment. This technology is termed bioremediation.

III. RESEARCH RESOURCES

INTRODUCTION

The biotechnology industry started in the universities, where basic research on the technology was captured commercially by patenting research and by licensing these patents to industry. In the early days (1976), only the Big Three of university technology transfer - Stanford, University of California, and Massachusetts Institute of Technology - consistently and aggressively sought out university inventions. The explosion of biotechnology companies, 3 in 1976 to 1330 in 1995, has been paralleled by the rise in U.S. patents granted to universities during this same time period; 230 in 1976 to 1800 in 1992 (Terry, 1993) Today, more than 90 percent of the universities are being awarded patents on a annual basis. The rich treasure of potential patents, research collaborators, research facilities, and technically trained personnel available at universities creates the environment for the development and growth of biotechnology companies. Proximity to the founding researchers' academic institution is the key factor in biotechnology company location. The North Central region of the United States is home to world-renown universities, hospitals and federal laboratories, from which are produced leading-edge biotechnology research in medicine and agriculture.

The following section reviews the biotechnology research activities in this region. For further information about a research centers and technology transfer opportunities, refer to Appendices A - D.

MEDICAL RESEARCH. The explosion in medical biotechnology research has revealed that virtually every disease has a genetic basis. That discovery, added to new information provided by the mapping of the human genome, is leading medical science to the threshold of a new era, the era of genetic medicine. Nearly all medical research on diseases utilizes the tools of biotechnology. Scientists and clinicians at the medical schools, research institutes and clinical hospitals in the North Central U.S. (see Table 1) are making major contributions to the field of genetic medicine.

Colorado. The *University of Colorado, Health Sciences Center*, located in Denver, has five separate schools devoted to Medicine, Nursing, Dentistry, Pharmacy and graduate education. Together they serve more than 2,000 students in their basic science and clinical programs in two teaching hospitals, an National Cancer Institute-designated Cancer Center, numerous teaching and research facilities, and affiliated institutions The affiliates include: the Barbara Davis Center for Childhood Diabetes; the Eleanor Roosevelt Institute for Cancer Research; the National Jewish Center for Immunology and Respiratory Medicine, the University Hospital, and the Childrens Hospital. Research conducted at the CU Health Sciences Center campus has given rise to many innovations in areas such as biological growth factors, chromosome analysis, cell cloning, drug delivery systems, and vaccines for infectious diseases. The CU Health Sciences faculty have a long history of federally funded and privately sponsored clinical research.

The Molecular, Cellular and Developmental Biology Department at the *University of Colorado, Boulder* is a top-ranking molecular biology research and training site in the world. With 200 faculty and staff, and Nobel Prize Laureate, Tom Cech, (awarded for Chemistry, 1989 - ribozyme research), the Department produces innovative, breakthrough technology. UC Boulder also is home to the Colorado RNA Center

which supports basic and applies research aimed at developing commercial applications for ribonucleic acids. The Colorado RNA Center is funded by the Colorado Advanced Technology Institute which is located in Fort Collins.

Denver is home to two nonprofit, private medical research organizations: *AMC Cancer Research Center* and *AlloSource/Mile High Transplant Bank*. AMC Cancer Center is an independent research center devoted to cancer research. Their research specialties include early detection diagnostics, new treatment modalities, immunodiagnostics, molecular markers and interferon therapy. Allosource is a network of tissue banks that recover, press, store and distribute human tissue grafts. Sterilization technologies to inactivate viruses in allografts is one of their research specialities.

Table 1. Medical Research Organizations in North Central U.S.

Institution	Location
AMC Cancer Research Center	Denver, Colorado
Creighton University, Medical School	Omaha, Nebraska
Duluth Clinic	Duluth, Minnesota
Human Gene Therapy Research Institute	Des Moines, Iowa
International Diabetes Center	Minneapolis, Minnesota
Mayo Medical Center	Rochester, Minnesota
National Bone Marrow Program	Minneapolis, Minnesota
University of Colorado Boulder	Boulder, Colorado
University of Colorado Health Sciences Center	Denver, Colorado
University of Iowa Academic Health Center	Iowa City, Iowa
University of Minnesota Academic Health Center	Duluth, Minnesota Minneapolis, Minnesota
University of Nebraska Medical Center	Omaha, Nebraska
University of North Dakota Medical School	Grand Forks, North Dakota
University of South Dakota Medical School	Vermillion, South Dakota

Iowa. The *University of Iowa. Academic Health Center*, located in Iowa city, has Colleges of Dentistry, Medicine, Nursing and Pharmacy, a teaching hospital, and other programs in allied health sciences, public health, and hospital and health administration. Numerous research institute and centers are affiliated with UIACH, including: Cancer Center, Clinical Research Center, Diabetes and Endocrinology Center, Digestive Diseases Center, Lipid Research Clinic, Pharmaceutical Services Center, Schizophrenia Research Center, Occupational and Immunological Lung Diseases Center. The 800 faculty scientists in the four UI Health Colleges work in multidisciplinary teams on the cutting edge of medical genetics research, pharmaceutical development, and clinical research.

The *Human Gene Therapy Research Institute* at the Iowa Methodist Medical Center in Des Moines is home to the world renown pioneer in human gene therapy research, Kenneth Culver, M.D.. Dr. Culver and his associates are conducting basic

research in somatic cell gene therapy, with special emphasis on therapies for primary and metastatic brain tumors.

Minnesota. The world renown *Mayo Clinic* in Rochester has more than 1200 doctors and researchers. At Mayo, patient-oriented clinical research and research in the basic sciences are tightly woven into the very fabric of the institution. Basic research is conducted in collaboration with clinical research at the four basic science departments: Physiology and Biophysics; Biochemistry and Molecular Biology; Pharmacology; and Immunology. Clinical research activities at the Mayo Clinic cover a broad range: allergy, cardiovascular disease, endocrinology, gastrointestinal disease, lipid disorders, oncology, pediatrics, pharmacology, renal disease, and surgery.

The *University of Minnesota Academic Health Center* is one of the nation's premier health science centers with Schools of Medicine, Dentistry, Nursing, and Public Health; Colleges of Pharmacy and Veterinary Medicine; and the University Hospital and Clinics. UMACH offers professional and graduate degrees to medical students at campuses in Minneapolis and Duluth. The Minneapolis campus is home to the University Hospital and Clinics, Variety Club's Children Hospital, Masonic Cancer Center, Children's Rehabilitation Center, Biomedical Engineering Center, and the Institute of Human Genetics. UMAHC is recognized as a world leader in organ transplantation, with the world's largest pancreas transplant program, and the second largest bone-marrow transplant program. The faculty bring in $200 million dollars annually in federal funded and private sponsored grants for research in cancer, immunology, cell biology, neurobiology, molecular biology, and gene therapy. The School of Medicine on the Duluth campus is ranked second in the nation in rural medicine training.

Clinical research at UMAHC is often conducted in collaborative one or more affiliated hospitals and medical centers in Minnesota. These institutions include large community, clinical research hospitals such as Abbott Northwestern Hospital, Duluth Clinic, Hennepin County Medical Center, Park Nicolett Medical Center, Ramsey Hospital Foundation, and the Veterans Administration Medical Center Minneapolis is also home to two major private, non-profit medical research centers: *International Diabetes Center* and *National Marrow Donor Program*. The Diabetes center does research directed toward the clinical assessment of new diabetes-related pharmaceuticals and technologies. The National Marrow Donor Program provides bone marrow for a variety of medical uses and conducts research on allotyping and sterilization technologies.

Nebraska. Omaha, Nebraska has two institutions of medical education and research, *Creighton University* and the *University of Nebraska Medical Center.* Creighton University is a private education, research and public service medical school with schools of dentistry, medicine and nursing. The medical school faculty research programs are centered on infectious diseases, allergic diseases, and immunology, The medical school is affiliated with St. Joseph's Hospital, Omaha Veterans Administration Hospital, Children's Hospital of Omaha, and St. Joseph's Center for Mental Health.

The University of Nebraska Medical Center is an education, research and public service academic health center with nine academic and clinical research affiliates. These units are: the Colleges of Medicine, Dentistry, Pharmacy and Nursing; the School of Allied Health Professions; University Hospital and associated services; Eppley Cancer Center; Meyer Rehabilitation Institute; and the Office of Graduate Studies and Research. Biotechnology research at UNMC is supported by the Nebraska Research Initiative (NRI). UNMC investigators have major programs in transplantation, cancer, genetics, virology/AIDS, diabetes, drug delivery systems, and immunology. The Eppley Cancer Research Center is one of the NCI designated research centers. Researchers at the Center for Human Genetics are collaborating in basic and clinical studies with investigators in the fields of cancer, transplantation, cardiovascular diseases and neurosciences.

North Dakota and South Dakota. Each state has a School of Medicine dedicated to education and public service, with special emphasis on primary care and rural medicine education. The schools offer graduate degrees (M.S. and Ph.D.) in biochemistry, microbiology, and molecular biology.

Summary

The North Central U.S. has five centers of excellence in medical genetics and biotechnology. They are: Mayo Medical Center, University of Colorado Health Sciences Center, University of Iowa Academic Health Center, University of Minnesota Academic Health Center, and University of Nebraska Medical Center. Each of these institutions aggressively market to the biotechnology industry by fostering research collaborations, joint ventures, new company startups and other commercial relationships. Appendix A lists the various organizations and individuals within each institution that can assist companies with finding resources to meet their special needs.

AGRICULTURAL BIOTECHNOLOGY. In the North Central U.S. agricultural biotechnology research primarily takes place at the land grant colleges. Under the Federal Morrill Act of 1864, land grant universities have the mission of promoting the commercial development of technology for the improvement of industry, agriculture and public welfare. Historically, agricultural research has been partitioned by scientific disciplines (e.g., agronomy, animal science, food technology, horticulture, plant pathology, veterinary pathobiology, etc.) With the invention of biotechnology, many researchers in these fields found that they shared common research interests and needs. Today, Biotechnology Research Centers/Institutes are being formed in Colleges of Agriculture and Veterinary Schools in order to have core research facilities for academic and industry scientists, to provide public education resources, and to develop commercial relationships with industry.

Colorado. *Colorado State University* in Fort Collins is a land grant college with agricultural biotechnology activities located in various research centers. The units are: College of Veterinary and Biomedical Sciences with Animal Reproduction and Biotechnology Laboratory, Arthopod-Borne Infectious Disease Laboratory, and the Painter Center for Animal Care; and the College of Agriculture, with the Plant Biotechnology Laboratory, and the Mycobacteria Research Laboratory. The *University of Colorado* at Colorado Springs provides technical support and collaborative research with industries in applied microbiology, with particular emphasis on yeasts and brewing technology.

Table 2. Agricultural Biotechnology Research Organizations in North Central U.S.

Institution	Location
Colorado State University	Fort Collins, Colorado
College of Agriculture	
College of Veterinary Medicine	
Iowa State University	Ames, Iowa
Office of Biotechnology	
Montana State University	Bozeman, Montana
College of Agriculture	
North Dakota State University	Fargo, North Dakota
Biotechnology Institute	
South Dakota State University	Billings, South Dakota
College of Agriculture	
University of Colorado	Colorado Springs
The Biotechnology Center	
University of Minnesota	St. Paul, Minnesota
College of Agriculture	
College of Veterinary Medicine	
University of Nebraska	Lincoln Nebraska
The Center for Biotechnology	
University of Wyoming	Laramie, Wyoming
College of Agriculture	
United States Department of Agriculture	Ames, Iowa
Animal Disease Center	
National Veterinary Services Laboratories	

Iowa. The *Office of Biotechnology* at *Iowa State University* in Ames is the focal point for the development and application of agricultural biotechnology in Iowa. The center, located in the modern molecular biology building, has the prime objective of fostering cooperative interactions among scientists, administrators, industry, public officials, and private citizens. ISU are members have three focus areas for research: biomass bioprocessing; plant and animal production efficiency and sustainability; and genetic modifications of plants, animals and microbes to produce a greater diversity of products.

Iowa State University and two federal animal health organizations, *Animal Disease Center* and *National Veterinary Services Laboratories* (both administered by the United States Department of Agriculture) work together to enhance their animal health research and services activities. Together, these institutions have more than 1200 scientists, which gives Ames, Iowa the largest concentration of animal health professionals in the world.

Minnesota. At the University of Minnesota in St. Paul, there are two agriculture biotechnology research centers, *Food Animal Biotechnology Center* (FAB Center) and *Plant Molecular Genetics Institute*, which foster cooperative interactions among faculty at the university. The FAB Center has 34 faculty from the Colleges of Agriculture, Biological Sciences, Natural Resources, and Veterinary Medicine; and the Institute of Human Genetics. The faculty conducts research in the areas of animal health enhancement, diseases resistance, growth and reproduction modulation, and animal gene mapping. The Advanced Genetic Analysis Center provides biotechnology research services for university and industry scientists. The Plant Molecular Genetics Institute, with over 25 faculty, fosters rsearch in molecular biology and genetics of economically important plants.

Nebraska.. The Biotechnology Center at the University of Nebraska in Lincoln recently moved into the 14,000 sq. ft. George W. Beadle Center for Genetics and Biomedical Research. The Beadle Center contains seven core research facilities, a P3 laboratory, and greenhouses. The core research facilities are available to both university and industrial scientists. They consist of Cell Analysis, DNA Sequencing, Fermentation, Mass Spectrometry, Monoclonal/Polyclonal Antibodies, Nuclear Magnetic Resonance Spectroscopy, and Protein Sequencing/Peptide Synthesis. The 180 associated faculty represent 13 department at UNL.

North Dakota. At North Dakota State University in Fargo, the Biotechnology Institute coordinates biotechnology research and education at NDSU. The Biotechnology Institute has 50 scientists from six departments; four research facilities (Biopolymers Services Center, Cell Biology Center, Monoclonal Antibodies Service Center, and Electron Microscope Lab); and the Red River Valley Agricultural Research Center. UDSU is also the home of the Animal Metabolism-Agricultural Chemicals Bioscience Research Laboratory of the USDA.

Montana, South Dakota and Wyoming. Montana State University at Missoula, South Dakota State University at Brookings, and the University of Wyoming at Laramie are land grant colleges were agricultural teaching and research are organized along a traditional College of Agriculture format. Each college offers advanced degrees in the plant and animal sciences. The federal funded and private sponsored research are administered by Research Offices in academic administration.

Summary

Some of the nation's leading research centers in animal health care and performance at located at the land grant universities in the North Central U.S. These same universities support cutting edge research in plant molecular biology and genetics Several universities, most notably, Colorado State University, Iowa State University, North Dakota State University, University of Minnesota, and University of Nebraska, have developed research institutes to facilitate interactions between university and industrial scientist; to educate public officials and citizens about the new technology; and to promote the commercial development of agricultural biotechnology. To learn more abot the research being conducted at these institution, contact the individuals listed in Appendices B and D.

BIOPROCESSING. Bioprocessing research centers and institutes at universities provide critical research and training to the nation's biotechnology industry. These centers foster research and development collaborations with industry by providing the scientific expertise and state-of-the-art equipment and research facilities at a reasonable cost. The industrial clients can determine the optimum conditions for producing valuable biomolecules from their genetically engineered organisms, thus avoiding the costs of expensive equipment. The North Central U.S. has three of the nation's leading bioprocessing centers (see Appendix C for contact individuals). A brief description of each follows.

Biological Processing Technology Institute, University of Minnesota. Located on the St. Paul campus, BPTI's Central Fermentation Research Facility is a 4000 sq. ft. laboratory and pilot plant facility which provides access to state-of-the-art equipment for research and development in fermentation, mass animal and cell culture technology, and large scale separation for biological molecules. There are more than 24 fully instrumented bioreactors ranging in size from 7 to 300 liters. BPTI has an on-line process monitoring, control, and data acquisition with the Rosemount System 3 distributed process control system and a Central Hybridoma Facility for custom hybridoma production (300 L. batches) and large scale antibody purification. There are over 40 collaborating faculty from research facilities and institutes, including: Institute of Human Genetics, Plant Molecular Biology Institute, Center of interfacial Engineering, and the Food Animal Biotechnology Center.

Center for Biocatalysis and Bioprocessing, University of Iowa. More than 30 faculty members - from the University's departments of biochemistry, chemical and biochemical engineering, chemistry, civil and environmental engineering, medicinal and natural products chemistry, and microbiology - have research programs in biocatalysis and bioprocessing. These faculty have a shared commitment to working collaboratively with industry in assessing the technical feasibility of commercially important biotransformations. The Center is located at the Oakdale Research Park in Iowa City. The 13,000 square foot facility has both 3,500 sq. ft. of leasable space for start-up biotechnology companies. Companies can work directly CBB staff in the 7,000 sq. ft. laboratory and fermentation suite. CBB has 22 instrumented fermentors (ranging from 1 -1000L), pilot scale processing center, and analytical research facilities. Fourteen Core Research Facilities at the University of Iowa campus are also available for corporate use.

Colorado Bioprocessing Center at Colorado State University. Colorado Bioprocessing Center provides research and training at its 3,000 sq. ft. facility. the center is equipped with several microbial, insect and mammalian cell reactors ranging in size from 2 -100 liters.; pilot scale chromatography and downstream processing equipment. CBC is a joint program between the Colorado Advanced Technology Institute and Colorado State University.

IV. BUSINESS RESOURCES

INTRODUCTION

Historically, the states that have been the most successful in developing and attracting biotechnology companies have combined aggressive university technology transfer and entrepreneurial development efforts with government support for facilities, financing and general business development. In this section, the business development resources in the North Central United States will be reviewed. Please refer to Appendix E for a listing.

BIOSCIENCE FACILITIES

A typical biotechnology company, faced with meager cash resources and an immediate or near-term expansion, is (or soon will be) looking for "walk-in" wet-laboratory facilities with potential for future expansion. States have addressed this need by the creation of Biotech Incubators and Research Parks The backbone of these facilities is a managerial staff that understands the specialized facility needs of the biotechnology industry, from federal and state laboratory code requirements to cGMP manufacturing requirements. Additionally, these facilities serve as a network for purchasing, waste disposal, and equipment. Bioentrepreneurs wishing to reduce their facility financing burdens are benefited by pre-built facilities, building-related financing, low lease costs, build-out options and favorable state/local incentives. In the North Central U.S., Colorado and Iowa have business incubators dedicated to biotechnology.

The Colorado *Bio*/Medical Venture Center, Inc. (CBVC) is a non-profit, private corporation which manages a 20,000 sq. ft. incubator with 3,500 sq. ft. of wet laboratory space in Lakewood (suburb of Denver). The incubator was built in collaboration with Cadus Pharmaceutical and the AMC Cancer Research Center. It houses six biomedical and biotechnology companies and has graduated two companies into larger facilities. It offers a range of client services (regulatory, accounting, information, clerical, etc) and can provide company development grants. CBVC staff have helped organize the Colorado Medical Device Association and are assisting the formation of the Colorado Biotechnology Association.

In Iowa, both Iowa State University and University of Iowa have research parks dedicated to providing wet laboratory facilities to biotechnology and pharmaceutical companies. The Oakdale Research Park in Iowa city is home to the Biocatalysis and Bioprocessing Center of the University of Iowa and provides access to the only university-owned and FDA-approved pharmaceutical manufacturing facility The Iowa State University Research Park in Ames is surrounded by the world's greatest concentration of animal research centers and scientists. It has housed several companies which have graduated to larger facilities.

RESEARCH FACILITIES

An indirect source of financing that assists biotechnology companies is the availability of research facilities. These core facilities provide state-of-the art equipment and well-trained personnel. Most of the major universities in the North Central region have core research facilities available for contract sponsored research with industrial clients (Please refer to Appendices A - D).

A second critical industry serving the biotechnology industry is the contract research, testing and manufacturing companies. Biotechnology companies will need to expedite move their products through development (ie. clinical trials, animal trials, field trials, etc). Contract research organizations, clinical laboratories, clinical/teaching hospitals, contract manufacturing firms and contract testing companies provide the network of outsourcing partners that cash-poor biotechnology companies require to tightly manage their R&D expenses.

Several contract research organizations are located in Denver and Minneapolis/St. Paul, home to many biotechnology and biomedical device companies (Please refer to Appendix F, under contract research organizations).

BUSINESS ASSOCIATIONS

Business or trade associations provide a means for professionals to network in order to address common business concerns. Historically, trade associations are in the business of providing information with the objective of promoting the growth of their respective industry. The customers are their members, public officials and citizens. Their members meet regularly to discuss the major business development issues, be it workforce training and availability; government regulations; technological breakthroughs, or financing strategies. The association also informs public officials and citizens about their industry, its benefits and special needs. In the North Central region there are biotechnology trade associations in Iowa and Minnesota, with two others under formation in Colorado and South Dakota.

LOCAL/STATE GOVERNMENT INCENTIVES

Local and state programs can support the biotechnology industry in a myriad of ways, such as providing one or all of the following: Research & Development Tax Credits, Deferrals, and Financing Incentives, Seed Capital, and Location Assistance. Colorado, Iowa, Minnesota, and Nebraska have economic development programs designed to assist biotechnology and pharmaceutical companies. Please refer to Appendix E for a list of individuals and organizations that can provide specific details.

V. BIOTECHNOLOGY COMPANIES

INTRODUCTION

As stated previously, biotechnology is a manufacturing process, not an product, market or industry. Nevertheless, the business community will label a business as a "biotech company", if this business is founded upon the technology. The "biotechnology industry" is viewed by many to consist primarily of these development-stage and mid-size firms. However, everyone recognizes that traditional pharmaceutical, veterinary pharmaceutical, seed, and bioprocessing companies are utilizing biotechnology to develop new products. Should these companies be included under the umbrella of the "biotechnology industry" ? Further, there is a large market for scientific instruments, specialty chemicals/reagents, and bioprocessing equipment especially designed for biotechnology research and manufacturing. What about the bioprocessing industry, such as the corn wet millers who use engineered enzymes to produce high fructose corn syrup? For this report, we have defined the biotechnology industry as businesses that develop genetically engineered organisms or use biotechnology research to produce products. We have include businesses that manufacture products specifically for biotechnology research or manufacturing.

OVERVIEW

The North Central U.S. leads the world in the concentration of animal research organizations (federal laboratories and state universities) and food animal production. Therefore, it comes as no surprise that the region also has a high concentration veterinary product companies. Ninety eight percent of the region's 44 veterinary product companies are located in four states - Iowa, Colorado, Nebraska and Minnesota. These companies range in size from development stage companies to multi-national pharmaceutical companies (Table 5 and Appendix F). The region also is home to world-leading seed companies, such as Pioneer, North-rup King and ICI-Garst, and to six development stage microbial companies. Furthermore, several specialty chemical companies have located in the region to utilize the readily available biomass produced by the corn wet milling and meat processing plants located in the region.

Medical technology is another large industry in region. There are 37 biotherapeuticand pharmaceutical companies, and an additional 23 diagnostic companies. This concentration of medical biotechnology companies is served by numerous specialty chemical and euipment companies; and more than 25 contract research organizations (CROs). The medical biotechnology firms are concentrated in Colorado (30 companies) and Minnesota (22 companies). This cluster may be attributable to the large concentration of medical device companies, clinical research hospitals, CROs, and venture capitalist found in these states as well. As documented in previous sections, both Iowa and Nebraska have a strong medical research infrastructure in which to support a medical biotechnology industry.

The greatest concentration of biotechnology companies is located in the four states - Colorado, Iowa, Minnesota and Nebraska - in which are located the largest concentration of publically funded research. The remaining four states - Montana, North Dakota, South Dakota and Wyoming - recognize the economic potential of biotechnology, and have begun to develop programs at their universities to assist biotech entrepreneurs. Montana and North Dakota each have one development stage biotech company. Both companies have immunomodulator drugs in advanced clinical trials. Most of the medical biotechnology companies in the region are development stage companies with products in advanced clinical trials. Some of the diagnostic

companies are mid-size (> 300 employees) companies which are recognized world leaders in immunodianostics (Table 5).

TABLE 4. DISTRIBUTION OF BIOTECHNOLOGY COMMERCIAL ORGANIZATIONS IN NORTH CENTRAL UNITED STATES

PRODUCTS/SERVICES	NUMBER OF COMMERCIAL ORGANIZATIONS NORTH CENTRAL STATES									
	CO	IA	MN	NE	ND	SD	MT	WY	TOTAL	%
BIOTHERAPEUTICS & PHARMACEUTICALS	22	0	11	2	1	0	1	0	37	*21*
MEDICAL DIAGNOSTICS	8	2	11	2	0	0	0	0	23	*13*
VETERINARY PRODUCTS	11	18	4	10	0	1	0	0	44	*24*
TRANSGENIC SEEDS	2	5	3	0	0	0	0	0	10	*6*
MICROBIALS	0	2	4	0	0	0	0	0	6	*3*
EQUIPMENT & SPECIALTY CHEM.	4	10	11	5	0	0	0	0	30	*17*
RESEARCH SERVICES	14	5	9	2	0	0	0	0	30	*17*
TOTAL	61	42	53	21	1	1	1	0	180	
%	*34*	*23*	*29*	*12*	*<1*	*<1*	*<1*	*0*		

TABLE 5. Major Biotechnology Companies in North Central United States

Product/Services	Company	Location
Pharmaceuticals	AMGEN	Boulder, CO
	Bio-Vascular, Inc	St. Paul, MN
	Cadus Pharmaceuticals	Lakewood, CO
	Cortech, Inc.	Denver, CO
	GalaGen, Inc.	Arden Hills, MN
	ImmunoTherapeutics	Fargo, ND
	Lifecore Biomedical	Chaska, MN
	NeXstar Pharmaceuticals	Boulder, CO
	Protein Design Labs	Plymouth, MN
	Ribi Immunochem Research	Hamilton, MT
	Somatogen, Inc.	Boulder, CO
Diagnostics	INCSTAR Corporation	Stillwater, MN
	R&D Systems, Inc.	Minneapolis, MN
	Sanofi Diagnostic Pasteur	Chaska, MN
Veterinary	Diamond Animal Health	Des Moines, IA
	Pfizer Animal Health	Omaha, NE
	Oxford Veterinary Labs	Worthington, MN
	Sandoz Pharmaceuticals	Lincoln, NE
	Sanofi Animal Health	Fort, Dodge, IA
	Solvay Animal Health	Mendota, MN
Plants	Northrup King Company	Golden Valley,MN
	ICI Garst	Ames, IA
	Pioneer Hi-Bred International	Johnston, IA
Bioprocessing	Cargill Incorporated	Several locations
	Genencor International	Cedar Rapids, IA

Overall, the presence of 180 companies engaged in biotech related R&D in the North Central U.S. establishes this region as one of the true biotech centers of the United States. Some of the largest firms are listed in Table 5. The industry is dynamic, with new formations, mergers and relocations. Thus, company listings are always incomplete and outdated. Nevertheless, Appendix F provides a list of biotech companies in the region. To stay abreast with new commercial developments, contact the biotech centers at the major universities, and trade associations; many of these organizations publish newsletters.

VI. REGULATORY ENVIRONMENT

OVERVIEW

The products of biotechnology are regulated on a case-by-case basis under numerous federal and state statutes. The process is applicant driven in that the applicant submits the proposal (permit, notification, petition, request, etc.) and the appropriate federal agency reviews it. Some products may require a decision by three or more government agencies before commercialization. A recent example is corn engineered with the insecticidal crystalline protein gene from *Bacillus thuringiensis*. This Bt corn required regulatory decisions/approvals from three federal agencies before commercial release. Also, one state, Minnesota, has a regulatory process for the release of agriculturally related genetically engineered organisms. This section will briefly review the federal and state regulations covering biotechnology products. The reader is referred to Appendices G and H for a list of resources.

FEDERAL OVERSIGHT

The U. S. Department of Agriculture (**USDA**) broad historic authority to protect plant and animal health is applicable to the regulation of animals, plants and microorganisms developed through biotechnological processes. The USDA has jurisdiction over some animal health care products, like vaccines, under the Federal Virus Serum Toxin Act; and food products from transgenic animals or animals treated with health products or growth proteins made with biotechnology under the Federal Meat Inspection Act & Poultry Products Inspection Act.

The U.S. Environmental Protection Agency (**EPA**) regulates biotechnology products with pesticidal properties under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) and Federal Food, Drug and Cosmetic Act (FFDCA). Under FIFRA, EPA is responsible for regulating the distribution, sale, use and testing of pesticides in order to protect humans and the environment. Under FFDCA, EPA sets tolerances or establishes exemptions from the requirement of a tolerance for pesticidal residues in/on food crops.

The U.S. Food and Drug Administration (**FDA**), under the authority of the Food, Drug and Cosmetics Act, has the authority for pre-market approval of drugs (biotherapeutics, vaccines, and diagnostics), and foods and feeds with new substances, and post-market surveillance of manufacturing, safety and efficacy of these products.

The National Institutes of Health (**NIH**) through its Office of DNA Activities (ORDA) monitors the status of Institutional Biosafety Committees (IBC) at institutions which are engaged in recombinant DNA research and receive NIH funding under federal containment standards. Private companies engaged in recombinant DNA research generally have an IBC group with two or more non-company members, irrespective of NIH funding status.

MEDICAL PRODUCTS

Biotherapeutics and vaccines. These new medicines must undergo a rigorous and expensive review process before receiving commercial approval. Various studies estimate that its takes 12 years and between $200 and $350 million U.S. dollars to get one new biotech drug from the laboratory to the pharmicist's shelf. About one in five of the medicines that begins clinical trials in the United States makes it through the approval process. These medicines are reviewed by FDA's Center for Biologics Evaluation and Research (CBER). Some biotech drugs are reviewed by the Center for Drug Evaluation and Research (CDER). The regulatory approval process for new biotech drugs is as follows:

Preclinical Testing. Laboratory and animal studies are performed to to determine safety and biological activity. Time estimate - 3.5 years.

Investigational New Drug Application (IND). After completion of preclinical studies, the company files an IND, which contains the Preclinical Testing data. The IND details the proposed clinical trials to be conducted on people, the method of manufacturing the biotech drug, and the site at which the studies are to be conducted. The IND must be reviewed and approved by the Institutional review Board where the studies will be held. Time estimate - The IND becomes effective if FDA does not disapprove it within 30 days.

Clinical Trials, Phase I. A small scale study involving 20 to 80 normal, healthy volunteers is conducted to study a drug's safety. The study determines the how a drug is absorbed, distributed, metabolized and exerted, in addition to safe dosage ranges. Time estimate - 1 year.

Clinical Trials, Phase II. Phase II trials are conducted on controlled populations of 100 -300 people. Phase II trials determine whether the biotech drug is effective in treating the targeted disease or medical condition. Time estimate - 2 years.

Clinical Trials, Phase III. An expansion of Phase II Trials involving larger patient populations (1000 - 3000) in clinics and hospitals. Physicians monitor patients closely to determine safety and effectiveness of the treatment. Time estimate - 3 years.

New Drug Application (NDA). Successful completion of phase III trials is followed by filing of a NDA with the FDA. NDA's contain all scientific data from the clinical trials and typical exceed 100,000 pages. Within 45 days of receipt, the FDA may decide to "refuse to file" the NDA if the submission is found to be incomplete. A "complete" NDA must be reviewed by the FDA within six months. However, the average time for review for approved biotherapeutics has been 1.7 years.

Expedited Process. Phase II and Phase III Clinical Trials can be combined for those medicines that show sufficient promise in early testing and are targeted against serious and life-threatening diseases, such as AIDS.

Post-Approval Monitoring. After approval, companies must continue to monitor for any adverse reactions and report these to the FDA. In certain cases, the FDA may require postmarketing Phase IV studies to determine long term effects. Manufacturing facilities are annually inspected by FDA.

User fees. Biotech companies pay user fees to FDA to cover the agency's costs for processing their marketing approval applications.

Gene therapy. Gene therapy clinical trials are reviewed by the Recombinant DNA Advisory Committee (RAC) of the National Institutes of Health (NIH) only after the local institutional Biosafety Committee (IBC) and Institutional Review Board (IRB) of the research hospital has approved the trial. CBER of the FDA has jurisdiction over somatic gene therapy clinical trials (see Federal register, V. 51, p. 23309, 1986.

Diagnostics. Monoclonal and DNA diagnostic test kits which are used to monitor human medical conditions are designated in vitro devices (IVDs) and are reviewed by the Center for Device and Radiological Health (CDRH) for their safety and efficacy. The analyte is the determinative regulatory factor, rather than the biotechnology process used for development and manufacturing.

Cases in which the monoclonal replaces a polyclonal in current use can be favorably reviewed under the 501(k) procedure for Class II devices. Diagnostics designated for laboratory use only come under the Class II designation as well. Class II diagnostics often received regulatory approval within 90 days. Many clinical diagnostics, especially those for tumor markers, fall into the Class III category and require a pre-market approval (PMA).

VETERINARY PRODUCTS

Veterinary products fall into two categories: biologics and pharmaceuticals. Biologicals are modified live and killed virus vaccines, toxoids and antitoxins Pharmaceuticals are analgesics, antibiotics, anesthetics, disinfectants, anthelmintics and vitamin supplements. Biologicals are regulated by Animal and Plant Inspection Service (APHIS) of the United States Department of Agriculture (USDA). Detailed information on the microbiological, molecular biology and biological properties of the vaccine microorganism is required established guidelines. Pharmaceuticals are regulated by the FDA's Center for Veterinary Medicine (CVM) through a clinical trial process.

Transgenic animals destined for human consumption are subject to inspection by the Food Safety and inspection Service (FSIS) of the USDA under the authority given to it by the Federal Meat Inspection Act and the Poultry products inspection Act. The FDA under the authority of FFDCA has expressed an interest in regulating food products produced by or from transgenic animals.

PLANT PRODUCTS

The path of commercializing transgenic plants starts with the United States Department of Agriculture's Animal and Plant Inspection Service (USDA-APHIS). Under the auspices of the Federal Plant Pest Act, APHIS reviews all deliberate releases of genetically engineered organisms. The purposes of the act is to protect U.S. agricultural products from exotic organisms. The USDA must issue a permit before a producer may expose the environment to a potential plant pest. The agency must also issue a permit before the regulated items are moved between states or into the United States. Transgenic plants often fall under the jurisdiction of the Plant Pest Act because they regularly make use of DNA sequences from plant pests, such as *Agrobacterium tumefaciens*, the bacterium that causes crown gall disease. The process is reviewed below.

Laboratory and Greenhouse Studies. The studies provide the genetic stability and gene expression data required by APHIS for field release permits. No permits are required, if the organisms are maintained in a contained facility. However, the biological and physical containment procedures must follow NIH guidelines.

Small-scale field trials. The applicant provides data on donor DNA and its stability and expression. Containment conditions to prevent the establishment of wild populations of transgenic organisms are detailed. For certain plant species with well-characterized transgenes, the applicant need only notify APHIS of their intent with 30 days of release. APHIS will determine whether the notification permit falls within its notification guidelines. If so, the test may proceed; if not, the application is subjected to the formal permit process, which takes up to 90 days to complete. Today, six plant species fall into the notification category: corn, cotton, potato, soybean, tobacco, and tomato.

Transgenic plants with donor genes intended for preventing, destroying, repelling, or mitigating any pest comes under the jurisdiction of the Environmental Protection Agency (EPA) under the auspices of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Early testing towards pesticide registration takes place under Experimental Use Permits on areas larger than 10 acres.

Commercial Release. The applicant petitions the USDA to remove the transgenic plant from the plant pest category by providing data from 2 - 4 years of field trials. Under APHIS jurisdiction, a genetically engineered plant or microorganism may be exempted from regulation if the petitioner has provided experimental data documenting that the organism will not pose either a plant pest risk or a significant impact to the quality of the human environment.

Companies producing transgenic plants with pest resistance properties need to provide EPA with data about the effects of the transgene (both DNA and protein) on non-traget beneficial insects, its fate in the environment and its toxicity. These toxicity studies are laborious, time-consuming and expensive.

The Food and Drug Administration encourages manufacturers of transgenic foods to consult with the agency on specific scientific and regulatory questions before putting transgenic plant products on the market. The agency does not conduct pre-market approval of many new foods, because the Federal Food, Drug and Cosmetic Act (FFDCA) places most of the burden of producing safe food on the manufacturer. In general, the FDA reacts only when the food is found to be unsafe. In the case of food additives, the FDA is required to conduct a formal review if they are not "generally recognized as safe" (GRAS). The agency's position is that transgenic whole food is GRAS if the new food is substantially similar to the non-transgenic food. To date all manufacturers of transgenic foods have voluntarily submitted nutritional data to the FDA for review before commercial release.

Under the FDA's policy, there is no labeling requirement for transgenic foods, unless the transgenic food is significantly different than its normal counterpart in nutritional content or safety. Transgenic plants with genes from allergenic foods (e.g. peanuts) would probably require labelling.

For pest resistant plants, the the EPA has jurisdiction over the human safety issues as well. The applicant petitions the EPA to set tolerances for the pesticidal residues in/on food crops. A tolerance is the amount of pesticide that may legally remain on a crop after harvesting. The EPA conducts a tolerance review of the applicants data in order to address the impacts of human dietary exposure to both the nucleic acid and protein of the donor pesticide genes.

MICROBES

Genetically engineered microbes designed for use in the environment (biopesticides, soil inoculates, etc.) come under the preview of the EPA.

STATE OVERSIGHT

Except for Minnesota, states in the U.S. do not directly regulate the production of genetically engineered organisms and their products. In Minnesota, the deliberate release of agriculturally related, genetically engineered organism requires a permit from the Minnesota Department of Agriculture. The permit process in Minnesota parallels that of USDA-APHIS in that

certain crops can receive approval for small scale field trials under a 30 day notification period. Companies wishing to sell transgenic seed in Minnesota must request a permit exemption. To date, every federally approved transgenic crop has received a permit exemption from Minnesota's Department of Agriculture.

COMMENT

Genetically engineered organisms and the products they produced are heavily regulated by the United States government. The regulations are constantly being revised (both expanded and contracted) by the United States Congress and the federal agencies themselves. Staying abreast of current rules and regulations, proposed revisions, and contentious issues is challenging, to say the least. Appendix G refers you to resources that provide some help.

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University of Minnesota, College of Veterinary Medicine 455 Veterinary Teaching Hospital 1352 Boyd Ave.
Saint Paul, MN 55108
(612) 624-9227 ph (612) 624-8753 fax
David G. Thawley, Ph.D., Dean
Victor Perman, Ph.D., Associated Dean for Research and Graduate education

University of Nebraska-Lincoln, Center for Biotechnology PO Box 880665 Lincoln, NE 68588-0665
(402) 472-2635 ph (402) 472-3139 fax
Donald P. Weeks, Ph.D., Director, Center for Biotechnology

Univeristy of Wyoming, College of Agriculture Office of Research Laramie, WY 82071
(307) 766-5353 ph
William Gern, Ph.D. Vice President, Research

Source: Canadian Consulate General, MN,
1996 Biotechnology Opportunity Guide
in the Midwest & Upper Mountain States.

Appendix C BIOPROCESSING RESEARCH CENTERS

Biological Processing Technology Institute, University of Minnesota 1479 Gortner Ave. Suite 240 St. Paul, MN 55108
(612) 624-1734 ph (612)-1700 fax
Jeffrey Tate, Ph.D., Special Assistant to the Director

Center for Biocatalysis and Bioprocessing, University of Iowa Oakdale Research Park 2501 Crosspark Road, Suite 100C
Iowa City, Iowa 52242-5000
(319) 335-4900 ph (319) 335-4901 fax
John N. Rosazza, Ph.D., Director

Colorado Bioprocessing Center, Colorado State University Ft Collins, CO 80523
(970) 491-6967 ph (970) 491-1001 fax
Brian Batt, Ph.D., Director

Appendix D TECHNOLOGY TRANSFER ORGANIZATIONS

Colorado State University, Office of Academic Research
(970) 491-7194 ph
Ralph E. Smith, Ph.D., Associate Vice President for Research
James E. Brown, Assistant Vice President Research, Patents and Technology Transfer

Iowa State University, Office of Intellectual Property and Technology Transfer 214 Offices and Laboratory Building Ames, IA 50011
(515) 295-3893 ph (515) 294-0778 fax
Mary Kleis, License and Agreements Coordinator

Mayo Medical Ventures 200 First St. SW Rochester, MN 55905
(507) 284-8878 ph (507) 284-5410 fax
Susan Stoddard, Ph.D., Officer

Montana State University Bozeman, MT
(408) 994-2891 ph
Robert J. Swenson, Ph.D., Vice President, Research & Creative Affairs
The Office of Research and Creative Affairs is responsible for all grant and contract sponsored research, creative activities, and technology transfer at Montana State university. The Office represents the research centers, including the Animal Resources Center, the Office of Biomedical Research Programs, and the Center for Economic Renewal .

North Dakota State University, Institute for Business & Industry Development 1300 12th Ave, N. Fargo, North Dakota 58105
(701) 231-8011 ph
Wallace Eide, Director
The Institute for Business and Industry Development is the first point of contact for businesses and industries to acquire access to specialized technical expertise, electronic database information and training needs for developing a product or business.

South Dakota State University, Graduate School-Office of Research Room 130 Administration Building Brookings, SD 57007
(605) 688-4181 ph (605) 688-6167 fax
Christopher P. Sword, Dean, Graduate School and Director of Research

University of Colorado, Office of Intellectual Resources and Technology Transfer Campus Box 51 Boulder, CO 80309
(303) 492 4975 ph (303) 492-5810 fax
Michael G. Gabridge, Ph.D., Director and Assistant Vice President for Academic Affairs and Research
The University of Colorado is the largest educational institution in the state. This system of four campuses (Boulder, Denver, Colorado Springs and the Health Sciences Center in Denver) is dedicated to quality teaching, research and services. The CU faculty produce numerous biotechnology-related inventions, of which the most promising are protected with patents and are available for license by the commercial sector.
Boulder : Stephen O'Neil (303) 492-5647 Denver: Vicki Spencer (303) 556-2771
Health Sciences Center : Stuart Gordon (303) 270-8987 Colorado Sprrings: Lawrence Anderson (719) 538-8227

University of Nebraska-Lincoln, Center for Biotechnology PO Box 880665 Lincoln, NE 68588-0665
(402) 472-2635 ph (402) 472-3139 fax
Donald P. Weeks, Ph.D., Director, Center for Biotechnology
Daniel Helmuth, Ph.D., Associate Vice Chancellor for Research (402) 472-2851 ph
The office of Vice Chancellor of Research is responsible for managing grants and contract sponsored research among the 180 faculty associated with The Center for Biotechnology at the University of Nebraska, Lincoln.

University of Nebraska Medical Center 600 South 42nd St. Box 986810 Omaha, NE 66198-6810
(402) 559-5130 ph (402) 559-7845 fax
William O. Berndt, Ph.D., Vice Chancellor for Academic Affairs and Dean for Graduate Studies and Research

University of North Dakota, Office of Research and Program Development Grand Forks, ND 58202-9037
(701) 777-4278 ph
Thomas E. Norris, Ph.D., Dean for Academic Affairs and Research.

University of South Dakota 414 E. Clark St. Vermillion, SD 57069-2390
(605) 677-5233 ph
J. Stephen Hazlett, Ph.D., Vice President, Academic Affairs

Univeristy of Wyoming, Office of Research Laramie, WY 82071
(307) 766-5353 ph
William Gern, Ph.D. Vice President, Research

National Technology Transfer Center
Access: Call (800) 678-6882
Internet access: Telnet to icon.nttc.edu
NTTC provides access to marketable technologies from federal laboratories including research in progress, technical reports, and new technologies available for commercialization. Records in the NTTC database include short abstracts describing the technology, funding, and the laboratory and contact people working with this technology. Users can access the database via Internet or dial directly and search it by keywords.

Appendix E BUSINESS RESOURCES

COLORADO

Colorado Advanced Technology Institute 1625 Broadway, Suite 700 Denver, CO 80202
(303) 620-4777 x304 ph. (303) 620-4789 fax
Frederick C. Pearson, Ph.D., Director, Biotechnology Programs

Colorado Bio/Medical Venture Center 1610 Pierce Lakewood, CO 80214
(303) 237-3998 ph (303) 237-4010 fax
Lew Kontik, President

Fitzsimons Army Medical Center, Redevelopment Agency Building 500 / Room 1040 PO Box 6027 Aurora, CO
80045-6027
(303) 363-1953 (303) 363-9509 fax
Robert E. Olson, Executive Director
Under contruction

IOWA

Department of Economic Development 200 E. Grand Ave Des Moines, IA 50309
(515) 242-4709 ph (515) 242-4809 fax
Bret Weber, Biotechnology Industry Specialist

Oakdale Research Park 2501 Crosspark Road Iowa City, Iowa 52242-5000
(319) 335-4063 ph
Bruce Wheaton, Director

Iowa Biotechnology Association 100 E. Grand, Suite 160 Des Moines, IA 50309
(515) 246-1452 ph (515) 246-1701 fax
Ms. Myrt Levin, Executive Director

Iowa State University Research Park 2501 North Loop Dr. Ames, IA 50010-1877
(515) 296-7275 ph
Leonard C. Goldman, Director

MINNESOTA

MinnesotaTrade Office 1000 Minnesota World Trade Center 30 E. Seventh St. St. Paul, MN 55101-4902
(612) 297-4649 ph (612) 296-3555 fax
Barbara Mattson, Trade Officer

Minnesota Biotechnology Association P.O. Box 16315 St. Paul, MN 55116
(612) 227-5895 ph (612) 698-0072 fax
James C. Woodman, Ph.D., Executive Director

Minnesota Technology, Inc. 111 Third Avenue South, Suite 400 Minneapolis, MN 55401
(612) 338-7722 ph (612) 339-5214 fax
Karen Arnold, Manufacturing Specialist, Biosciences.

MONTANA

Department of Commerce, Economic Development Division 1424 9th Ave. Helena, MT 59620-0501
(406) 444- 4214 ph (406) 444-2903 fax
Jan Clack, Administration Officer

NEBRASKA

Center for Biotechnology, University of Nebraska-Lincoln PO Box 880665 Lincoln, NE 68588-0665
(402) 472-2635 ph (402) 472-3139 fax
Donald P. Weeks, Ph.D., Director, Center for Biotechnology

Department of Economic Development, Research Division PO Box 94666 Lincoln, NE 68509
(402) 471-3770 ph (402) 472-3139 fax
Thomas Doring, Trade Officer

NORTH DAKOTA

Department of Economic Development & Finance 1833 Bismarck Expressway Bismarck, ND 58504
(701) 238-5300 ph (701) 238-5320 fax
Warren Enyart, CEO, Tech Transfer, Inc.

North Dakota State University, Institute for Business & Industry Development 1300 12th Ave, N. Fargo, North Dakota 58105
(701) 231-8011 ph
Wallace Eide, Director

SOUTH DAKOTA

Economic Development and Tourism Office, Export, Trade and Marketing Division 711 Wells Ave. Pierre, SD
57501-3369
(605) 773-5032 ph (605) 773-3256 fax
Tim Oviatt

South Dakota Biotechnology Association c/o Lake Area Technical Institute
(605) 882-5284, ext 32 ph
Allison Albertson

WYOMING

Department of Commerce, Division of Economic and Community Development 2301 Central Ave. Cheyenne, WY 82002
(307) 777-7284 ph (307) 777-5840 fax

Vivian Watkins, Director

APPENDIX F BIOTECHNOLOGY COMPANIES

MEDICAL

American Laboratories Inc. 4410 S. 102nd St. Omaha, NE 68127-1094
(402) 339-2494 ph
J.E. Jackson, President
Pharmaceutical and biological products from animal by-products.

AMGEN Boulder, Inc. 2045 32nd St. Boulder, CO 80301
(303) 442-7951 ph (303) 442-1290 fax
Michael Bevilacqua, Vice President of inflammation
Amgen, Inc develops, manufactures and markets biotherapeutics to meet human health care needs.

AMRION, Inc. 6565 Odell Place Boulder, CO 80301
(303) 530-2525
Mark Crossen, President & CEO
Nutraceuticals, dietary supplements, and vitamin/mineral supplements.

Atrix Laboratories 2579 Midpoint Drive Fort Collins, CO 80525-4417
(970) 482-5868 ph (970) 482-9735 fax
Lee Southard, Ph.D., President
Atrix is developing innovative drug delivery technologies.

Bioenergy, Inc. 1400 Energy Park Drive, Suite 22 St. Paul, MN 55108
(612) 647-9370 ph (612) 647-9685 fax
Toby Kimball, CEO & President
Bioenergy, Inc. is commercializing the use of ribose in medical and nutritional applications. It produces ribose from corn starch via fermentation.

Biomedical Frontiers, Inc. 1095 10th Ave. S.E. Minneapolis, MN 55414
(612) 378-0228 ph (612) 378-3601 fax
Bo Hedlund President and CEO
Pharmaceutical company focused on two areas: iron-containing polymeric compounds to be used diagnostically in magnetic resonance imaging, and iron chelators as therapeutic products in resuscitation from burns and other trauma.

Bio-Vascular, Inc. 2575 University Ave. St. Paul, MN 55114-1024
Phone: (612) 603-3700
John T. Karcanes, President & CEO
Bio-Vascular, Inc. develops, manufactures and markets tissue and biosynthetic medical products used in cardiac
and vascular surgery.

Cadus Pharmaceutical Corporation 1610 Pierce Street, Suite 110 Lakewood, CO 80214
(303) 202-1200 ph (303) 202-1210 fax
John Cambier, Ph..D., President
A developmental stage company engaged in the discovery, manufacturing and marketing of biotherapeutics.

Ceres UCHCS 4200 E. 9th Ave. Denver, CO 80262
(303) 270-3303 ph (303) 270-8825 fax
Richard Duke, Ph.D.
Vaccine delivery technologies.

Chemical Specialty Products 7031 N 16th St. Omaha, NE 68112
(402) 453-6970 ph
Richard Wood, President
Pharmaceuticals for human and animals.

CIMA Labs 10000 Valley View Road Eden Prairie, MN 55344
(612) 947-8700 ph (612) 947-8770 fax
John Siebert, M.D., President & CEO
CIMA Labs develops, manufactures and markets drug delivery systems for ethical pharmaceutical and OTC pharmaceutical markets.

Cortech Inc. 7000 N. Broadway Suite 300 Denver, CO 80221
(303) 650-1200 ph (303) 650-5023 fax
Kenneth R. Lynn, CEO
Development stage human biotherapeutic company focused on focused on novel therapies for inflammatory and immunologic disorders.

Epigen 1610 Pierce St, Suite 120 Lakewood, CO 80214
(303) 274-8789 ph
Development stage company which is developing
added-value medical and industrial products from plants.

GalaGen Incorporated 4001 Lexington Avenue North Arden Hills, MN 55126
612) 481-2193 ph (612) 481-2380 fax
Robert Hoerr, M.D., Ph.D., President
A biopharmaceutical company focusing on the development of orally delivered products that prevent and treat certain human gastrointestinal diseases.

Geneva Pharmaceuticals, Inc. 2555 W, Midway Blvd. Broomfield, CO 80038-0446
(303) 438-4300 ph
Charles T. Lay, President
Generic pharmaceuticals for human health care market.

Golden Pharmaceuticals 1313 Washington Ave. Golden, CO 80401
(303) 279-9375 ph (303) 279-4390 fax
Charles R. Drummond, CEO
Manufactures sodium iodide *I-123* capsules used for diagnostics purposes for thyroid gland diseases.

Hauser Chemical Research, Inc. 5555 Airport Boulevard Boulder, CO 80301
(303) 443-4662 ph (303) 441-5800 fax
Randy Daughenbaugh, Ph.D., President
Health care products, natural food ingredients and secondary forest products.

Humanetics, Inc. 1107 Hazeltine Boulevard, P.O. Box 53 Chaska, MN 55318
(612) 448-8881 ph (612) 448-8892 fax
Ron Zenk, President
Research, development and commercialization of proprietary "nutraceutical" and pharmaceutical products.

Immunonc, Inc. 4200 E. 9th Ave. Denver, CO 80262
(303) 270-8987 ph
Stuart Gordon, Ph.D., President
Development stage company focusing on cancer diagnostic tests and novel cancer therapies.

Innovative Therapeutics, Inc. 4860 N. Broadway Denver, CO 80216-6344
(303) 298-9625 ph (303) 298-9640 fax
Charles H. Kirkpatrick, M.D., CEO
Development stage company focusing on novel, proprietary immunomodulator proteins.

ImmunoTherapeutics, Inc. 3233 15th Street South Fargo, North Dakota
(701) 232-9575 ph (701) 237-9275 fax
Gerald Voslka, M.D., Chairman and President
Adevelopment stage company involved in the research, development and clinical evaluation of immunotherapeutic drugs for the prevention and treatment of cancer and infectious diseases.

Lifecore Biomedical, Inc. 3515 Lyman Boulevard Chaska, MN 55318-3051
(612) 368-4300 ph (612) 368-3411 fax
James W. Bracke, Ph.D., President & CEO
Lifecore Biomedical develops, manufactures and markets sterile medical products for dental, drug delivery, opthalmic, orthopedic, veterinary, and wound healing applications.

MGI Pharma, Inc. 9900 Bren Road East Suite 300E Opus Center Minnetonka, MN 55343-9667
(612) 935-7335 ph (612) 935-0468 fax
Charles Muscoplat, Ph.D., Executive Vice.President.
Acquires, develops and markets therapeutics for niche areas of medicine.

Myco Tox, Inc. 420 E. 9th St. Box b111 Denver, CO 80262
(303) 270-8647 ph (303) 270-4729 fax
Claude Selitrennikoff, President
Engaged in research and development of anti-fungal compounds.

NaPro Biotherapeutics, Inc. 4725 Walnut St. Suite 100 Boulder, CO 80301
(303) 444-9406 ph
Timothy Prout, Ph.D., CEO
Biotherapuetics for human health care markets.

New Vistas, Inc. 5260 E. 39th Ave. Denver, CO 80207
(303) 33-9269 ph (303) 355-4155 fax
Phil Ballard, Production Manager
Homeopathic pharmaceuticals.

NeXstar Pharmaceuticals, Inc. 2860 Wilderness Place Boulder, CO 80301
(303) 444-5893 ph (303) 444-0672 fax
Patrick Mahaffy, President & CEO
Discovery and development of novel nucleic acid- based pharmaceuticals.

OnGard Systems, Inc. 2323 Delaney St. Denver, CO 80216
(303) 293-2090 ph (303) 293-2095 fax
Mark Weis, President
Manufactures and markets complete line of cGMP and clinical sterilizers and washers.

Orphan Medical 13911 Ridgedale Drive, Suite 250 Minnetonka, MN 55305
(612) 541-1868 ph (612) 541-9209 fax
Bert Spilker, M.D., Ph.D., M.D., President
Develops and markets therapeutics for rare diseases and therapeutics and products for underserved populations.

Pharma Chemie, Inc. 1877 Midland Sreet Syracuse, NE 68446
(402) 269-3195 ph
Mark J. Pieloch, President
Pharmaceutical development and manufacturing for humans and animals

Protein Design Labs 3955 Annapolis Lane Plymouth, MN 55447
(612) 551-1778 ph (612) 551-1780 fax
Mark Young, Ph.D., VP, Technical Operations
Developes computer-designed antibodies that combine the binding site of a mouse monoclonal antibody with 90% of a human antibody.

Ribozyme Pharmaceuticals, Inc. 2950 Wilderness Place Boulder, CO 80301
(303) 449-6500 ph (303) 449-6995 fax
Ralph E. Christoffersen, Ph.D., CEO
Commercializes its ribozyme technology in the fields of human therapeutics and diagnostics, agriculture, and animal health.

Ribi Immunochem Research, Inc. 553 Old Corvallis Road Hamilton, MT 59840
(406) 362-6214 ph (406) 363-6129 fax
Robert E. Ivy, CEO, President and Chairman
Research and development of immunostimulants for use in preventing and treating human diseases.

Rosemount Pharmaceuticals 301 South Cherokee Street Denver, CO 80223-2114
(303) 733-7207 ph (303) 698-1005 fax
Win Mens, President
Manufactures and markets generic pharmaceuticals.

Solvay Pharmaceuticals, Inc. 210 Main Street W. Baudette, MN 56623
(218) 634-1866 ph (218) 634-3540 fax
David M. Hiller, Director of Manufacturing
Solvay Pharmaceuticals' manufacturing plant in Northern Minnesota produces quality therapeutic products for obstretrics, gynecology and gastroenterology.

Somatogen, Inc. 2545 Central Ave. Boulder, CO 80301
(303) 440-9988 ph (303) 444-3013 fax
Andre de Bruin, CEO
Research and commercial development of recombinant hemoglobin technology.

Syntex Chemicals, Inc., Division of Hoffman LaRoche 2075 N. 55th St. Boulder, CO 80301
(303) 442-1926 ph
(303) 988-6808 fax
Milo Bishop, Manager
Manufactures chemical intermediates of pharmaceuticals.

Supragen Inc. 1670 Pierce St. Lakewood, CO 80214
(303) 237-7120 ph (303) 237-1832 fax
Michael T. Burke, CEO
Develops, manufactures and markets vaccines and biotherapeutics which prevent and treat T-cell mediated disease.

Upsher-Smith Laboratories 14905 23rd Avenue North Minneapolis, MN 55447-4709
(612) 473-4412 ph (612) 476-4026 fax
Kevin Evenstad, Chairman, CEO & President
Upsher-Smith Laboratories manufactures oral forms of cardiovascular and lipid lowering pharmaceuticals, and various suppository pharmaceuticals.

DIAGNOSTIC

5 Prime - 3 Prime, Inc. 5603 Arapahoe Avenue Boulder, CO 80303
(303) 440-3705 ph (303)-440-0835 fax
Robert Morris, President
Contract research and manufacturs of RNA and DNA products.

AnCell Corporation 243 3rd St. N. P.O. Box 87 Bayport, MN 55003
(612) 439-0835 ph (612) 439-1940 fax
John Orf, Ph.D., President
AnCell Corporation performs contract development and production of monoclonal and polyclonal antibodies.

Bio-Nebraska, Inc. 3820 NW 46th St. Lincoln, NE 68504-1637
(402) 470-2100 ph
Fred W. Wagner, President
Test kits for heavy metals, oligonucleotide separation technology, and speciality peptides.

Bio-Research Products, Inc. PRB-13 Technology Center University of Iowa Oakdale, IA 52319
(319) 626-6707 ph
Bryce Cunningham, Ph.D., President
Manufactures specialty enzymes for clinical diagnostic use.

Camas Diagnostic Company 1313 Fifth Street SE Suite 219 Minneapolis, MN 55414
(612) 379-3901 ph
Donald L. Robinson, President
Camas Diagnostics is a development stage company which conducts R&D on microbial immunodiagnostic systems; and diagnostic and therapeutic monoclonal and polyclonal antibodies.

Colorado Serum Company 4950 York St. Denver, CO 80216
(303) 295-7527 ph (303) 295-1923 fax
J.N. Huff, President
Animal sera for diagnostic services and veterinary biologics.

DiMed Corporation 2956 Yorkton Boulevard St. Paul, MN 55117
(612) 490-5350 ph (612) 490-3110 fax
Steven L. Marine, President
DiMed Corporation manufactures and markets diagnostic kits for identifying a wide variety of microorganisms.

EnzAmp 7034 Indian Peaks Trial Boulder, CO 80301
(303) 581-0343 ph
H. Lee Sturgeon, President
Immunodiagnostic products

Genetype, Inc 400 East Horsetooth Road Fort Collins, CO 80525-3189
(970) 223-9339 ph
David Cunningham, President
Basic research on DNA polymorphisms

GENTRA Systems, Inc. 15200 25th Ave. N. Minneapolis, MN 55447
(612) 476-5858 ph 612) 476-5850 fax
Ruth Shuman, Ph.D., President
Gentra Systems, Inc. is a privately held biotechnology company established to commercialize DNA technology-based products and services.

Immunochemistry Technologies LLC 2010 E. Hennepin Ave. Minneapolis, MN 55413
(612) 623-4667 ph (612) 623-4887 fax
Gary Johnson, President
Immunochemistry Technologies is a development stage company that provides services and consultation in the areas of antibody and protein modification, and immunoassay development.

Immunonc, Inc. 4200 E. 9th Ave. Denver, CO 80262
(303) 270-8987 ph
Stuart Gordon, Ph.D., President
Development stage company focusing on cancer diagnostic tests and novel cancer therapies.

INCSTAR Corporation 1990 Industrial Boulevard P.O. Box 285 Stillwater, MN 55082
(612) 439-9710 ph(612) 779-0221 fax
John J. Booth, President & CEO
INCSTAR manufactures and markets more than 140 immunodiagnostic testing and research products used by hospitals, clinical reference laboratories and medical researchers worldwide.

LMD AgriVet LLC 1400 Energy Park Dr., Suite 20 St. Paul, MN 55108
(612) 659-9093 ph (612) 659-0651 fax
Paul Hansen, President
LMD AgriVet LLC develops, manufactures and markets the SafePath line of rapid immunoassay test kits for the detection of parasites and microorganisms in food, animals and water.

Midland BioProducts Corporation 800 Snedden Drive PO Box 309 Boone, IA 50036-0309
(515) 432-5516 ph
Richard Jorgenson, Ph.D., President
Bulk manufacturer and distributor of antisera; and custom immunization and antisera production.

Quantech, Ltd 1419 Energy Park Dr. St. Paul, MN 55108
(612) 647-6370 ph (612) 647-6369 fax
Robert McKiel, Ph.D., Executive Vice President
Quantech, Ltd. is a development stage company which designs immunodiagnostic systems for monitoring cardiac conditions.

Raven Biological Laboratories, Inc. PO Box 6408 Omaha, NE 68106
(402) 556-6690 ph
Robert V. Dwyer, President
Biological indicators for sterilization procedures.

Research and Diagnostic Systems Inc. 614 McKinley Place NE Minneapolis, MN 55413
(612) 379-2956 ph (612) 379-6580 fax
Thomas E. Oland, Ph.D., President
R&D Systems discovers, designs, manufactures, and markets cytokine products for research and clinical laboratories..

REAADS Medical Products, Inc 12001 Tejon St., Suite 120 Westminister, CO 80234
(303) 457-4345 ph (303) 457-4519 fax
Luis R. Lopez, CEO
Develops, manufactures and markets diagnostic test kits for autoimmune and vascular diseases.

Sanofi Diagnostics Pasteur, Inc. 1000 Lake Hazeltine Drive
(612) 448-4848 ph (612) 368-1280 fax
Terrence J. Bieker, President
Immunodiagnostic products, equipment and instruments to hospital and clinical laboratories.

Trend Scientific Inc. P.O. Box 120266 New Brighton, MN 55112-3501
(612) 633-0925 ph (612) 633-6073 fax
David A Taus, President & CEO
Trend Scientific Inc manufactures and markets immunodiagnostic test kits, stains, reagents and quality control products for medical, veterinary and research laboratories.

Vitro Diagnostics 8100 S. Parkway, Bldg B-1 Littleton, CO 80120
(303) 794-2000
Roger Hurst, President
Purified antigens.

VETERINARY

Ambico, Inc.
902 Sugargrove Ave., Box 522 Dallas Center, IA 50063
(515) 992-3842 ph
C. Joseph Welter, Ph.D., President
Vaccines for veterinary use.

American Laboratories Inc. 4410 S. 102nd St. Omaha, NE 68127-1094
(402) 339-2494 ph
J.E. Jackson, President
Pharmaceutical and biological products from animal by-products.

American Veterinary Products 1413 Duff Dr. Fort Collins, CO 80524
(970) 484-6100 ph (970) 484-5106 fax
John R. Toedtman, CEO
Veterinary pharmaceuticals

Arko Labs Highway 69 N., Box 400 Jewell, IA 50130
(515) 827-5491 ph (515) 827-5112 fax
Larry Koehnk, President
Vaccines for veterinary use.

Biocor, Inc. PO Box 34325 Omaha, NE 68134
(800) 441-7480 ph (402) 393-4712 fax
F.J. Shade, Director Biological Operations
Vaccines for veterinary use.

Chemical Specialty Products 7031 N 16th St. Omaha, NE 68112
(402) 453-6970 ph
Richard Wood, President
Pharmaceuticals for human and animals.

Chem Tech, Ltd. 4515 Fleur Dr., Suite 303 Des Moines, IA 50321
(515) 287-6778 ph
Jim Melton, President
Manufactures animal health care products and insecticides.

Colorado Serum Company 4950 York St. Denver, CO 80216
(303) 295-7527 ph (303) 295-1923 fax
J.N. Huff, President
Animal sera for diagnostic services and veterinary biologics.

Diamond Animal Health, Inc. 2538 South East 43rd St. Des Moines, IA 50317
(515) 263-8600 ph (515) 263-8661
Lyle Hohnke, Chairman & CEO
Research, develop, manufacture and market animal health care products , pharmaceuticals and biologicals.

Fermenta Animal Health Company 1512 Webster Court Fort Collins, CO 80524-2739
(970) 221-2050 ph (970) 221-5049 fax
Steven Stroh, Ph.D., President
Pharmaceutical R&D testing.

Fort Dodge Laboratories PO Box 518 Fort Dodge, IA 50501
(515) 955-4600 ph (515) 955-9183 fax
W.M. Acree, Executive Vice President
Research, develop, manufacture and market veterinary pharmaceuticals and biologicals

Franklin Labs 800 5th St. NW Fort Dodge, IA 50501
(515) 955-4630 ph
David Sandvig, Vice President, Marketing
Markets veterinary pharmaceuticals and biologicals

Grand Laboratories, Inc. 44130 279th St. Freeman, SD 57029
(605) 926-7611 ph (605) 925-4354 fax
Duane Pankratz, President
Veterinary vaccines, serums and bacterins

Hy-Line International Box 310 Dallas Center, IA 50063
(515) 992-3736
Dennis W. Casey, Ph.D., President
Develops and produces primary breeding stock for poultry industry.

Hy-Vac Laboratory Eggs Co. 1412 Park Gowrie, IA 50543
(515) 352-3871 pf (515) 352-3884 fax
Russ Larson, President
Develops and produces specialty poultry and eggs for pharmaceutical industry.

ID Russell Company Labs 1301 Iowa Ave. Longmont, CO 80501-6354
(303) 678-7112 ph
John P. Russell, Jr., President
Poultry pharmaceuticals and biologicals.

Immuno Dynamics, Inc. 2282 141 Place Perry, IA 50220
(515) 676-2700 ph (515) 676-21116 fax
Richard Cockrum, DVM, President
Manufactures products containing bovine colostrum.

Immunovet, Inc. 11467 West I-70 Frontage Road North Wheat Ridge, CO 80033
(303) 424-6781 ph (303) 431-4863 fax
John A. Connell, President
Veterinary health care products, specializing in immunostimulants and rabies vaccines.

Imu-tek Animal Health, Inc. 3541 E. Vine Dr. Fort Collins, CO 80524
(970) 493-7033 ph
Henry Dyjak, President
Veterinary biologics, specializing in colostrum supplements for newborn calves.

Lloyd Laboratories 604 West Thomas Shenandoah, IA 51601
(712) 246-4000 ph (712) 246-5245 fax
W.E. Lloyd, Chairman
Produces and markets veterinary pharmaceuticals.

LMD AgriVet LLC 1400 Energy Park Dr., Suite 20 St. Paul, MN 55108
(612) 659-9093 ph(612) 659-0651 fax
Paul Hansen, President
LMD AgriVet LLC develops, manufactures and markets the SafePath line of rapid immunoassay test kits for the detection of parasites and microorganisms in food, animals and water.

MacLeod Pharmaceuticals, Inc. 2600 Canton Court Suite C Fort Collins, CO 80525-4421
(970) 482-7254
Michael Pay, President
Veterinary pharmaceuticals and biologicals.

Maplehurst Genetics International Route 1, PO Box 124 Keota, IA 52248
(515) 636-3811 ph (515) 636-3838 fax
R.A. Carmichael, DVM, President
Produces and markets cattle semen and embryos; and veterinary products.

MVP Laboratories, Inc. 5404 Miller Ave. Ralston, NE 68127-3825
(402) 331-5106 ph
Mary Lou Chapek, President
Veterinary pharmaceuticals and biologicals

NOBL Labs, Inc. 1568 N. Main St. Sioux Center, IA 51250
(712) 722-4696 ph (712) 722-0882 fax
G. Michael Daniel, DVM, President
Research, development and manufacturing of animal health products, productivity enhancement products and diagnostic products for swine.

Pharma Chemie, Inc. 1877 Midland sSreet Syracuse, NE 68446
(402) 269-3195 ph
Mark J. Pieloch, President
Pharmaceutical development and manufacturing for humans and animals

Pfizer Animal Health 4444 S. 76th St. Omaha, NE 68127
(402) 339-4900 ph
Ray Williams, Plant Manager
Antibiotics for feed, veterinary and animal health industries.

Pfizer Animal Health PO Box 80809 Lincoln, NE 68521-0809
(402) 475-4541 ph
Donald King, Vice President
Veterinary pharmaceuticals & biologicals

Pisces Molecular 1610 Pierce St., Suite 130 Lakewood, CO 80214
(303) 237-2306 ph (303) 237-4010 fax
John Wood, Ph.D., President
Development stage company engaged in developing diagnostic test and therapeutic treatments for economically important fish diseases.

Oxford Veterinary Laboratories P.O. Box 775 275 Lake Street, Bldg 5 Worthington, MN 56187
(507) 372-7726 ph (507) 372-5052 fax
C.B. Schmidt, DVM, President & General Manager
Oxford Veterinary Laboratories researches, develops, manufactures and markets biologicals and vaccines for swine, poultry, bovine, feline and canine diseases.

Protatek International, Inc. 1491 Energy Park Drive St. Paul, MN 55108
(612) 644-5391 ph (612) 644-6831 fax
Protatek International, Inc. discovers, develops, manufactures and markets vaccines against veterinary hemotopic diseases of food-producing and companion animals utilizing unique, state-of-the-art bioprocess technology.

Ribozyme Pharmaceuticals, Inc. 2950 Wilderness place Boulder, CO 80301
(303) 449-6500 ph (303) 449-6995 fax
Ralph E. Christoffersen, Ph.D., CEO
Commercializes its ribozyme technology in the fields of human therapeutics and diagnostics, agriculture, and animal health.

Sandoz Pharmaceuticals Corporation PO Box 83288 Lincoln, NE 68501
(402) 464-6311 ph
Donna Blake, Manager
Veterinary pharmaceuticals & biologicals

Sanofi Animal Health 2116 8th Ave. South Fort Dodge, IA 50501
(515) 576-4225 ph
John Thomas, director of operations
Develops, manufactures and markets veterinary pharmaceuticals and biologicals.

Schering-Plough Animal Health PO Box 3113 Omaha, NE 68022
(402) 331-3900 ph
Michael Bartkoski, Jr., Director
Veterinary pharmaceuticals & biologicals

Solvay Animal Health, Inc. 1201 Northland Drive Mendota Heights, MN 55120-1139
(612) 681-9555 ph (612) 681-9425 fax
Miles Freitag, President
Solvay Animal Health, Inc. discovers, designs, manufactures and markets vaccines and pharmaceuticals for animal health. It conducts research and development, and manufacturing at its Mendota Heights, MN, facility.

Solvay Animal Health 2000 Rockford Road Charles City, IA 50616
(515) 257-2422 ph (515) 257-3211 fax
Brian H. Pound, Sr., V.P. Operations
Develops, manufactures and markets veterinary pharmaceuticals and biologicals. Manufacturing plant.

Syntex Animal Health 4800 Westown Parkway, Suite 200 West Des Moines, IA 50266
(515) 224-2400 ph
Rich Schuler, General Manager
Develops, manufactures and markets veterinary pharmaceuticals.

Trans-Ova Genetics 2938 3080th Street Sioux Center, IA 51250
(712) 722-3586 ph
Jan Schuiteman, CEO
Embryo transfer in cattle.

Universal Gene Labs, Inc. 30473 260th St. Eldora, IA 50627
(515) 858-9334 ph (515) 858-3691 fax
Steve Kerns, President
DNA typing for stress genes in swine.

Western Instrument Company 4950 York Denver, CO 80216
(303) 295-7528
J.N. Huff, President
Large animal biologics.

Western Laboratories PO Box 594 Omaha, NE 68112
(402) 453-6970 ph
Richard G. Wood, President
Veterinary pharmaceuticals

Wildlife Pharmaceuticals, Inc. 1401 Duff Drive Suite 600 Fort Collins, CO 80524
(970) 484 6267 ph (970) 482-6184 fax
W.R. Lance, PH.D., President & CEO
Veterinary pharmaceuticals and biologics.

Veterinary Biological Systems Analysis RR1, Box 362 Newton, IA 50208
(515) 792-3232 ph
Robert T. Coffey, DVM, President
Diagnostic services for veterinarians and animal health care companies.

PLANT SEEDS

American Crystal Sugar Company 1700 North 11th St. P.O. Box 1227 Moorhead, MN 56561-1227
(218) 236-4766 ph (218) 236-4744 fax
William Doley, Ph.D.
American Crystal Sugar Company is a grower-owned beet sugar cooperative located in the Red River Valley of Minnesota and North Dakota. The Beet Seed Division, headquartered at the Research Center in Moorhead, MN, develops and markets seed of hybridsugar-beet varieties.

Cargill Incorporated Central Research P.O. Box 5699 Minneapolis, MN 55440
(612) 742-6625 ph (612) 742-7235 fax
Steven Anderson, Director SpecialtyPlant Products
Cargill Hybrid Seed uses the latest technologies to produce crops with improved seed and agronomic properties.

DuPont Quality Grains Laboratory DuPont Agricultural Products 10700 Justin Drive Des Moines, IA 50322-3713
(515) 251-3001 ph (515) 251-3040 fax
Daniel Hammes, Ph.D., Research Manager
Develops and markets value-added grains, specializing in high oil corn and low stachyose soybeans.

Holden Foundation Seed Co. Box 839 Williamsburg, IA 52361
(319) 668-1100 ph
Jon Geadelmann, Ph.D., Research Director
Develops proprietary corn inbreds for licensing to hybrid corn seed companies.

ICI Seeds 6945 Vista Drive West Des Moines, IA 50266
(515) 222-1400 ph (515) 222-4758 fax
Ted Crosbie, Ph.D., CEO
Develops, produces and markets seed corn, sorghum, alfalfa and soybeans.

Imperial Holly Corporation Research and Development Center 5320 Mark Dabling Blvd. Colorado Springs, CO 80918
(719) 471-0123 ph (719) 630-3252 fax
Roger Hill, President & CEO
Beet seed and beet sugar.

MBS PO Box 308 Ames, IA 50010
(515) 296-2688 ph
David Smith, President
Develops, produces and markets proprietary parent seed for commercial seed companies.

Northrup King Company 7500 Olson Memorial Highway Golden Valley, MN 55427
(612) 593-7285 ph (612) 593-7389 fax
Edward Shoonsey, President & CEO
Northrup King Company develops, produces and markets corn, soybean, alfalfa, sorghum and sunflower seed.

Pioneer Hi-Bred International, Inc. 7301 NW 62nd Ave. Johnston, IA 50131
(515) 270-3573 ph (515) 270-4312 fax
Peter Fuller, Ph.D., Director of Technology Development
Develops, produces and markets proprietary seeds of corn, soybeans, sorghum. alfalfa, canola, and sunflowers.

Seedex, Inc. 1350 Kansas Avenue Longmont, CO 80501-6546
(970) 678-7333 ph (970) 678-7337 fax
Akio Suzuki, President
Proprietary sugar beet seed.

MICROBIALS

Advanced Microbial System, Inc. 701 County Road 83 Shakopee, MN 55379
(612) 445-4251 ph (612) 445-7233 fax
Richard Fisher, Ph.D. President
Advanced Microbial Systems offers low-cost biotechnology for solving a host of remediation problems.

B & S Research 4345 Highway 21 Embarrass, MN 55732
(218) 984-3757 ph (218) 984-3212 fax
H.W.Lashmett, CEO
B&S Research produces bioremediation products for the clean-up of soil and water contaminated with hydrocarbons, halogenated hydrocarbons, chlorinated solvents, PCB's, fertilizers or pesticides.

Encore Technologies, Inc. 6482 Carlson Drive Eden Prairie, MN 55346
(612) 975-9014 ph (612) 975-9016 fax
Guy W. Miller, Ph.D., President
Encore Technologies develops, manufactures and markets microbial products for agricultural and horticultural markets.

Lemna Corporation 1408 Northland Drive Suite 310 Mendota Heights, Mn 55120
(612) 688-0836 ph (612) 688-8813 fax
Viet Ngo, President
Lemna Corporation is a development stage company which produces a natural alternative for wastewater treatment.

Medipharm USA 10215 Dennis Drive Des Moines, IAS 50322
(515) 254-1280 ph (515) 254-1356 fax
Mark Richards, Ph.D., Managing Director
Develops, produces and markets bacteria for agricultural and industrial uses.

Soil Technologies RR 4, Box 133 Fairfield, IA 52556
(515) 472-3963 ph
Jim Schaefer, President & CEO
Microbial inoculants.

EQUIPMENT & SPECIALTY CHEMICALS

Ajinomoto USA, Inc. Box 648 Eddyville, IA 52553
(515) 969-4561
Ken Saeki, Vice president
Manufactures monosodium glutamate (MSG)

American Allied Biochemical, Inc. 1350 East Eisenhower Blvd. Loveland, CO 80014
(303) 755-7137 ph (303) 755-7135 fax
Marlin Backwater, President
Discovers, manufactures and markets restriction enzymes.

Barnstead Termodyne, Inc. 2555 Kerper Blvd. Dubuque, IA 52004
(319) 556-2241 ph (319) 556-0695
Shakers, incubators and thermal recyclers.

BSI Corporation 9924 W 74th Street Eden Prairie, MN 55344
(612) 829-2700 ph (612) 829-2743 fax
Dale R. Olseth, President & CEO
BSI provides advanced technologies for surface modification and molecular immobilization to improve the wetability, lubricity, hemocompatibility and microbial resistance of medical, biotechnology and industrial products.

Cargill, Inc. 1 Cargill Drive Eddyville, IA 52553
(515) 969-3745 ph (515) 969-3616 fax
Robert Parmelee, Vice President
Corn wet milling products and citric acid.

Cellex Biosciences and LSL Biolafitte, Inc. 8500 Evergreen Boulevard Minneapolis, MN 55433
(612) 786-0302 ph (612) 786-0915 fax
Richard E. Sakowicz, President
Cellex Biosciences idesigns, manufactures and markets cell culture and fermentation systems and services to pharmaceutical, veterinary and bioprocessing companies

Celox Corporation 856 South Fifth Street Hopkins, MN 55343
(612) 933-2616 ph (612) 933-0217 fax
Dr. Milo Polovina, President and CEO
Celox Laboratories produces non-serum cell culture products, liquid basal medium, balanced salt solutions, and andrology and embryology products.

Continental Laboratories 912 S. State St., Box 2000 Madrid, IA 50156
(515) 795-2000 ph
David Bequeaith, President
Manufactures animal health products and hydroxy butyl acetate (HBA)

Cytomation Inc. 400 E. Horsetooth Rd Ft. Collins, CO 80525
(970) 226-2200 ph (970) 226-0107 fax
Brian Hall, Vice President
Manufactures and markets high-performance flow cytometers.

DCI
600 N. 54th Ave.
St. Cloud, MN 56303
(612) 252-8200 ph
(612) 252-0866 fax
Gerald T. Howard, President & CEO
DCI is a manufacturer of stainless steel processing and storage tanks for the food, dairy, pharmaceutical, chemical, cosmetic, beverage, and biotechnology industries.

Despatch Industries 63 St. Anthony Parkway P.O. Box 1320 Minneapolis, MN 55440
(612) 781-5414 ph (612) 781-5353 fax
Paul J. Haas, Pharmaceutical Business Unit Manager
Despatch Industries manufactures a complete line of pharmaceutical heat processing equipment, including granulation drying, sterilization and depyrogenation ovens.

Enzyco 191 University Blvd., Suite 305 Denver, CO 80260
(303) 355 0070 ph (303) 355-0075 fax
Millard Cull, President
Custom enzymes

Feed Energy Co. 3121 Dean Ave. Des Moines, IA 50317
(515) 263-0408 ph (515) 265-4163 fax
Robert G. Riley, Jr., President
Fatty acids for animal feeds.

Fermented Products PO Box 1483 Mason City, IA 50402
(515) 423-1460 ph (515) 423-0832 fax
Stan Zinnel, General Manger
Lactic acid and other specialty chemicals.

Fisher-Rosemount, Inc. 12001 Technology Drive Eden Prairie, MN 55344-3695
(612) 828-3667 ph (612) 828-7723 fax
Robert Sirany, Industry Director, Pharmaceuticals
Fisher-Rosemount supplies instrumentation and control systems for the lab and manufacturing processes found in pilot and production scale pharmaceutical and bio-pharmaceutical facilities.

Food Engineering Corporation 2765 Niagara Lane Plymouth, MN 55447
(612) 559-5200 ph (612) 559-4657 fax
Dale Herron, President
Food Engineering Corporation designs, manufactures and markets industrial processing equipment for food, pharmaceutical and chemical industries.

Genencor International, Inc. 1000 41st Avenue Dr. SW Cedar Rapids, IA 52404
(319) 363-9601 ph
Tom Pekich, Vice President - Manufacturing
Manufactures industrial enzymes and specialty chemicals.

Heartland Lysine, Inc. 1 Heartland Dr. Eddyville, IA 52553
(515) 969-4551 ph (515) 969-4717 fax
Sam Tosaka, Vice President
Production of L-lysine via fermentation

Hoffman-LaRoche, inc. 616 Dayton St. Ames, IA 50010
(515) 232-4668 ph (515) 232-4704 fax
Vern Wolgemuth, Plant Manager
Manufactures vitamins for animal feed supplements.

Hosokawa Bepex Corporation 333 Taft Street NE Minneapolis, MN 55413
(612) 331-4370 ph (612) 627-1444 fax
Gordon Ettie, President
Hosokawa Bepex Corporation designs and manufactures process equipment for the food, pharmaceutical, chemical, polymer, and mineral industries.

ISCO, Inc. - Separation Instrument Division PO Box 5347 Lincoln, NE 68504
(402) 464-0231 ph
Robert Allington, President
Chromatography equipment for biotechnology research.

Li-Cor, Inc. PO Box 4000 Lincoln, NE 68504-5000
(402) 467-0700 ph
Scientific instruments, DNA sequencers.

Megabase Research Products 2820 N. 48th St., Suite 110 Lincoln, NE 68504
(402) 467-6499 ph
Mike Nelson, President
Megabase Research Products makes proprietary, specialty restriction enzymes.

Metabolic Technologies 2501 North Loop Drive, Suite 612 Ames, IA 50010
(515) 296-9916 ph (515) 296-9910 fax
Steven Nissen, Ph.D., CEO
Research and development of hydroxy methyl butyrate (HMB).

Nova-Tech, Inc. 1982 E. Citation Way Grand Island, NE 68801
(308) 381-8841 ph
Gloria Thesenvitz, President
Processed blood sera and media for cell cultures.

Nu Aire, Inc. 2100 Fernbrook Lane North Minneapolis, MN 55447
612) 553-1270 ph (612) 553-0459 fax
Max D. Peters, President
Nu Aire, Inc., designs, manufactures and markets laboratory equipment, including laminar flow cabinets and mammalian cell culture incubation chambers.

OnGard Systems, Inc. 2323 Delaney St. Denver, CO 80216
(303) 293-2090 ph (303) 293-2095 fax
Mark Weis, President
Manufactures and markets complete line of cGMP and clinical sterilizers and washers.

Percival Scientific, Inc. 1805 Mamie Eisenhower Boone, IA 50036
(515) 432-6501 ph (515) 432-6503
Gary Wheelock, President
Manufactures environmental chambers, biological incubators and plant tissue culture chambers.

QMI 245 E. Sixth St. St. Paul, MN 55101
(612) 228-0474 ph
Darrell Bigalki, President
QMI (Food and Dairy Quality Management) manufactures and markets aseptic, inoculation and transfer products to the pharmaceutical, bioprocessing, brewing distillery, food processing, and dairy processing industries.

Strek Laboratories PO Box 37625 Lillard Station Omaha, NE 68144
(402) 333-1982 ph
Dr. Wayne Ryan, President
Lab equipment: hematology reference controls.

TL Systems Corporation 8700 Wyoming Ave. N. Brooklyn Park, MN 55455-1836
(612) 493-6770 ph (612) 493-6776 fax
Allan B. Larson, CEO
TL Systems Corporation designs, manufactures and markets pharmaceutical processing equipment, specializing in sterile liquid filling of injectable drugs into serum vials.

CONTRACT RESEARCH ORGANIZATIONS

Advanced Genetic Analysis Center, Food Animal Biotechnology Center, University of Minnesota
1988 Fitch Ave. 295 ASVM St. Paul, MN 55108
(612) 624-7279 ph (612) 624-7284 fax
Michael Murtaugh, Ph.D., Director
AGAC is designed to provide genetic analysis services to investigators in biomedical sciences and agriculture.

Analytical Development Corporation 4405 North Chestnut St. Colorado Springs, CO 80907
(719) 260-1711 ph (719) 260-0695 fax
Virgil Gary Tye, President
Contract analytical services to the pharmaceutical industry.

Analytical Genetic Testing Center 7808 Cherry Creek South Drive, Suite 201 Denver, CO 80231
(303) 750 2023 ph (303) 750-2171 fax
Moses Schonfield, President
Criminal forensic and parentage services, DNA testing and other molecular biology services.

ATG Laboratories, Inc. 10300 Valley View Rd, Suite 107 Eden Prairie, MN 55344
(612) 829-7699 ph (612) 829-7693 fax
Julie A. Kirihara, Ph.D. , President
ATG Laboratories is a development stage company that performs contract and custom molecular biology services and research. They specialize in gene cloning and high level recombinant protein production systems.

BioDesigns 238 Lois Circle Louisville, CO 80027
(303) 666-1993
Garrett Crawford, President
Molecular screening for ALS.

Biological Processing Technology Institute, University of Minnesota 1479 Gortner Ave. Suite 240 St. Paul, MN 55108
(612) 624-1734 ph (612)-1700 fax
Jeffrey Tate, Ph.D., Special Assistant to the Director
BPTI's Central Fermentation research Facility is a 4000 sq. ft. laboratory and pilot plant facility which provides access to state-of-the-art equipment for research and development in fermentation, mass animal and cell culture technology, and large scale separation for biological molecules. University of Minnesota researchers and corporate clients have access to BPTI's facilities.

BioTest Laboratories, Inc. 8990 Springbrook Drive, Suite 100 Minneapolis, MN 55433
(612-) 785-2414 ph (612) 785-9054 fax
Gregg A. Mosley, M.S., President
BioTest Laboratories provides microbiological and chemical testing of medical products, contract packaging and assembly, and clean room testing and certification.

Cellex Biosciences and LSL Biolafitte, Inc. 8500 Evergreen Boulevard Minneapolis, MN 55433
(612) 786-0302 ph (612) 786-0915 fax
Richard E. Sakowicz, President
Cellex Biosciences designs, manufactures and markets cell culture and fermentation systems and services to pharmaceutical, veterinary and bioprocessing companies

Center for Advanced Drug Development, University of Iowa 100 Oakdale Campus #18 Physiological Research Lab Iowa City, IA 52242-5000
(319) 335-3271 ph (319) 335-1956 fax
Rose Rennenkamp, Director, Research Marketing
The Center provides a wide range of analytical and clinical trial studies for pharmaceutical and biotechnology companies.

Center for Biocatalysis and Bioprocessing, University of Iowa Oakdale Research Park 2501 Crosspark Road, Suite 100C
Iowa City, Iowa 52242-5000
(319) 335-4900 ph (319) 335-4901 fax
John N. Rosazza, Ph.D., Director
A 13,000 sq ft Fermentation and Scale-Up Facility for the conduct of multidisciplinary industry/academic research in biocatalysis and bioprocessing; and exploratory research and development work in collaboration with industry.

Center for Biotechnology, University of Nebraska-Lincoln PO Box 880665 Lincoln, NE 68588-0665
(402) 472-2635 ph (402) 472-3139 fax
Donald P. Weeks, Ph.D., Director, Center for Biotechnology
Established in 1987 to provide a focal point for the development and application of biotechnology which will benefit UNL research and industrial research clients. Biotechnology Research Facilities include: Cell Analysis, DNA Sequencing, Fermentation, Mass Spectrometry, Monoclonal /Polyclonal Antibody, Nuclear Magnetic Resonance (NMR) Spectroscopy, Protein Sequencing/Peptide Synthesis.

Colorado Bioprocessing Center, Colorado State University Ft Collins, CO 80523
(970) 491-6967 ph (970) 491-1001 fax
Brian Batt, Ph.D., Director
A contract research laboratory dedicated to developing production-worthy bioprocesses to assist clients in commercializing their products.

Colorado Quality Research, Inc. 1401 Duff Drive, Suite 700 Fort Collins, CO 80524
(970) 484-0747 ph (970) 484-8414 fax
Carey L. Quarles, Ph.D., Director of Research
Contract animal research, specializing in poultry research.

Elantec Med Inc. 85 S. Union Blvd. Lakewood, CO 80228-2207
(303) 278-7672 ph (303) 278-4968 fax
Larry Allen, Ph.D. Director of Operations
Regulatory and R&D services for pharmaceutical companies.

Elutions, Inc. 3139 South Emerson St. Englewood, CO 80110
(303) 270-4782 ph (3030 270-6730 fax
Diane Kozwich, President
A full service, independent research organization which provides contract scientific services to academia, biotechnology and pharmaceutical companies

Infinity Laboratories Inc. 7800 S. Elati, Suite 100 Littleton, CO 80120
(303) 730-7330 ph (303) 798-4639 fax
Larry Eidlen, President
A microbiology laboratory which provides testing services to biotechnology and pharmaceutical companies.

Integrated DNA Technologies, Inc. 1710 Commercial Park Coralville, IA 52241
(319) 645-2746 ph (319) 645-2921 fax
Joseph Walder, M.D., Ph.D., President & CEO
Custom synthesis and production of DNA and RNA.

Integrated Systems Physiology, Inc. 2648 S. Malon Court Aurora, CO 80401
(303) 279-6116 ph (303) 270-4852 fax
Thomas Burke, Ph.D., President
Contract research organization providing safety evaluations of pharmaceuticals through animal testing.

Iowa State University, Office of Biotechnology 1210 Molecular Biology Building Ames, Iowa 50011-3260
(515) 294-9818 ph (515) 294-4629 fax
Walt Fehr, Ph.D., Director
Contract research services provided for industrial clients through Protein facility; DNA Sequencing and Synthesis Facility; and Cell & Hybridoma facility.

Kimball Genetics 101 University Boulevard, Suite 330 Denver, CO 80206
(303) 321-4809 ph (303) 388-9220 fax
Annette Taylor, President
A certified laboratory that performs clinical research and DNA typing of human genetic disorders for physicians, clinical laboratories, hospitals, and research institutes.

Laboratory Animal Resources, Colorado State University Painter Center Ft. Collins, CO 80523-2007
(970) 491-7364 ph (970) 491-2496 fax
Donald H. Maul, Director
Provides research animal support to the University as well as contract studies with biotechnology, biomedical and pharmaceutical companies.

Minn Vitro-Plant Tissue Culture Laboratories 15 West 36th St. Minneapolis, MN 55408
(612) 825-8862 ph (612) 825-8862 fax
Kathryn Louis, Ph.D. Research Director
Minn Vitro provides contract plant tissue culture services to nurseries, seed companies, and other organizations.

National Biosciences Inc. 3650 Annapolis Lane North, Suite 140 Plymouth, MN 55447-5434
(612) 550-2012 ph (612) 550-9625)
John D. Offerman, President
NBI is a leading developer and supplier of software and research services for the biotechnology industry.

Pharmatech, Inc. 700 Broadway Street, Suite 800 Denver, CO 80203
(800) 383-6610 ph (303) 832-0909 fax
Sarah Carr, Director of Business Development
A clinical research organization which conducts clinical trials, selects investigators, generates biostatistics and performs other clinical management functions for pharmaceutical, biotechnology and medical device companies.

Rocky Mountain Instrumental Laboratories Inc. 456 S. Link Lane Ft Collins, CO 80524
(970) 221-3116 ph (303) 530-1169 fax
Robert K. Lantz, Ph.D., Director
Provides cGLP analytical services to the pharmaceutical and biotechnology industry. Services include peptide sequencing, LC/MS/MS, HPLC, FT/IR, GC/MS and other analytical techniques.

University of Nebraska Medical Center (UMNC) 600 South 42nd St. Box 986810 Omaha, NE 66198-6810
(402) 559-5130 ph (402) 559-7845 fax
William O. Berndt, Ph.D., Vice Chancellor for Academic Affairs and Dean for Graduate Studies and Research
UNMC has core facilities which are available to UNMC faculty and private and industrial scientists. The core facilities are as follows: Cell Analysis Facility; Molecular Biology Core Laboratory; Monoclonal Antibody Facility; and Protein Structure Core Facility; Support facilities include a molecular modeling, image analysis, NMR spectroscopy,mammalian cell production, microbial fermentation, transgenic animal nursery, and P3 containment laboratories.

University of Iowa, Division of Pharmaceutical Services 118 Pharmacy Building Iowa City, IA 52242-1112
(319) 335-8674 ph (319) 335-9418 fax
Rolland Poust, Ph.D., Director
The largest university-affiliated drug manufacturing facility registered with the FDA. The facility and staff work with industrial clients to produce virtually every type of pharmaceutical dosage form All projects are executed with complete confidentiality and in compliance with client-specific needs and cGMP procedures.

Valley Tissue Culture Inc. RR1, Box 261 Halstad, MN 56548
(218) 456-2161 ph (218) 456-2161 fax
Sandi Aarestad, President
Valley Tissue Culture provides contract potato tissue culture services for producing seed potatoes.

ViroMED Laboratories, Inc. 6101 Blue Circle Drive Minneapolis, MN 55343
(612) 931-0077 ph (612) 931-4215 fax
Bonita Baskin, Ph.D., President
ViroMed Laboratories, Inc provides innovative, high quality cell products and testing services to the pharmaceutical, biotech, medical device and healthcare industries.

Xenomatrix Inc. 2860 Wilderness Place Boulder, CO 80301
(303) 447-1773 ph (303) 447-1758 fax
John H. Wheeler, Vice President, Marketing
Research and development organization specializing in in-vitro diagnostic assays to provide molecular toxicology, mutagenicity and carcinogenic information on chemical compounds.

APPENDIX G FEDERAL & STATE REGULATORY AGENCIES

FEDERAL

Department of Health and Human Services, Food and Drug Administration
Office of Communication
1401 Rockville Pike Rockville, MD 20855
(301) 827-0377 ph
Mark Elengold, Director
World-wide home page: http://www.FDA.gov

Biotherapeutics & Gene Therapy
Center for Biologics Evaluation and Research
Kathryn Zoon, Ph.D., Director

Medical Diagnostics
Center for Devices and Radiological Health
Janet Woodcock, M.D., Director

Veterinary Pharmaceuticals
Center for Veterinary Medicine
Stephen F. Sundloff, Ph.D., Director

Food
Center for Food Safety and Applied Nutrition
James Maryanski, Ph.D., Biotechnology Coordinator

Environmental Protection Agency, Office of Pesticide Programs
Communications Branch
(703) 305-5017 ph (703) 305-5558 fax
Darlene Dinkins, Director

Department of Agriculture
Biotechnology Information Center, National Agricultural Library
10301 Baltimore Blvd., 4th Floor Beltsville, MD 20705-2351
(301) 504-5340 ph (301) 504-7098 fax
Internet: biotech@nalusda,gov

Transgenic Plants
Animal and Plant Health Inspection Service
Lonnie King, Administrator

Transgenic Animals
Food Safety and inspection Service
Patrick Basu, Ph.D., Director

Veterinary Biologics
Animal and Plant Health Inspection Service
John H. Payne, Ph.D., Acting Director,
Biotechnology Biologics and Environmental Protection

STATE

Minnesota Department of Agriculture, Plant Protection Division
90 W. Plato Blvd. St. Paul, MN 55107
(612) 296-7509 ph (612) 296-7386 fax
Web page: http://www.mda.state.mn.us
Cheryl Fox, Ph.D. Biotechnologist

APPENDIX H INFORMATION RESOURCES

PUBLIC POLICY

Biotechnology Industry Organization 1625 K Street N.W., Suite 1100 Washington D.C. 20006-1604
(202) 857-0244 (202) 857-0237
Web page: http://www.bio.com

Council for Agricultural Science and Technology 4420 West Lincoln Way Ames, IA 50014-3447
(515) 292-2125 ph (515) 292-4512 fax

Department of Health and Human Services Food and Drug Administration Office of Communication
1401 Rockville Pike Rockville, MD 20855
(301) 827-0377 ph
Mark Elengold, Director
World-wide home page: http://www.FDA.gov

Department of Agriculture Biotechnology Information Center National Agricultural Library
10301 Baltimore Blvd., 4th Floor Beltsville, MD 20705-2351
(301) 504-5340 ph (301) 504-7098 fax
Internet: biotech@nalusda,gov

Environmental Protection Agency Office of Pesticide Programs Communications Branch
(703) 305-5017 ph (703) 305-5558 fax
Darlene Dinkins, Director

DIRECTORIES

Colorado Bio/Medical Venture Center 1610 Pierce Lakewood, CO 80214
(303) 237-3998 ph (303) 237-4010 fax
Lew Kontik, President

Iowa Biotechnology Association 100 E. Grand, Suite 160 Des Moines, IA 50309
(515) 246-1452 ph (515) 246-1701 fax
Ms. Myrt Levin, Executive Director

Minnesota Biotechnology Association P.O. Box 16315 St. Paul, MN 55116
(612) 227-5895 ph (612) 698-0072 fax
James C. Woodman, Ph.D., Executive Director

NEWSLETTERS

Colorado Advanced Technology Institute 1625 Broadway, Suite 700 Denver, CO 80202
(303) 620-4777 x304 ph. (303) 620-4789 fax
Frederick C. Pearson, Ph.D.,Director

Minnesota Biotechnology Association P.O. Box 16315 St. Paul, MN 55116
(612) 227-5895 ph (612) 698-0072 fax
James C. Woodman, Ph.D., Executive Director

Wisconsin BioIssues, University of Wisconsin Biotechnology Center 1710 University Avenue Madison, WI 53705
Tom Zinnen, Ph.D.
Biotechnology Education Specialits
(608) 265-2420
An excellent biannual newsletter on biotech issues publications, and electronic information resources.

MAGAZINES

Applied Clinical Trials
(218) 723-9437 fax
A monthly magazine on the lastest clinical trials issues worldwide. Free for medical professionals

Biotech Reporter
(800) 959-3276
A subscription monthly newsletter on the latest commercial developments in agricultural biotechnology.

BioVenture View
(415) 578-6615
A monthly publication offering in-depth analysis of biotechnology companies, products and events.

BioWorld Today
(800) 879-8790
Daily, faxed intelligence service containing information on latest financial developments within industry.

Genetic Engineering News
(914) 834-3100 ph
An inexpensive but "must-have" trade magazine with latest developments in industry.

Human Genome News
(615) 576-6669
Published by NIH, it contains latest information on Human Genome Project.