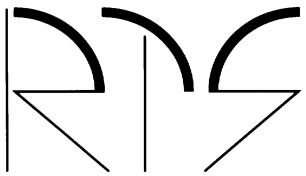
Clusters of Creativity:
Innovation and Growth in Montana

A Report to the Montana Governor's Office of Economic Opportunity on
The Life Sciences Cluster



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Prologue: Industry Clusters in Montana

In the Spring of 2002, the Montana Governor's Office of Economic Opportunity embarked on a bold new direction in pursuing the state's economic development. After meeting with leading national experts and consulting with the Montana business community, the state's economic "stewards" embraced the most innovative and promising new approaches to developing good jobs, prosperous businesses, and a competitive Montana economy for the 21st century. The new approaches work from the simple premise that Montana's existing businesses are the state's most important assets. Their entrepreneurial energy and skills represent the state's most efficient source of economic growth. They have chosen to be in Montana for a reason.

This paper represents a single chapter taken from a report conducted by Regional Technology Strategies, Inc., (RTS) that was delivered to the Montana Governor's Office of Economic Opportunity in May 2003. It examines Montana's existing and nascent industries as a set of "clusters." A cluster is defined, in simplest terms, as a geographic region containing enough companies that have similar or related needs and interests to generate external economies of scale and produce innovation. Ultimately, these innovative businesses are likely to export more goods and services outside of the state, creating jobs and wealth for Montanans. To "supercharge" their potential and the state's economic wellbeing, economic development leaders at the state and local levels can focus on working together to organize the state's services in a way that helps them compete and grow, and help the businesses themselves organize to collaborate in ways that enhance their competitive standing. In tandem with this report, RTS also conducted an assessment of innovation and entrepreneurship support capacity within Montana's regions.

The study therefore focused on the questions: Which industries are the drivers of Montana's economy; where, if anyplace, are they clustered; how does this translate to advantage for the industries; and what further advantages can be developed to accelerate growth? The full report analyzes the state's assets and opportunities and recommends a set of cluster-based policies and strategies designed to strengthen its regional economies. It identifies existing and nascent clusters, assesses their strengths, challenges, and potentials, and recommends actions for building and elevating their respective competitive positions. The report also focuses on small, creative, and innovative businesses that are particularly important to Montana's economic success.

We have chosen to analyze six value-added clusters, which represent important regional economic drivers in some depth. The clusters were selected because (a) they already have a significant scale and therefore are important to Montana's overall economy and (b) they comprise very different kinds of industries in different stages of growth.

- The **creative enterprise cluster**, and the **experience enterprise and tourism cluster** encompass products and services and convert Montana's unique culture, heritage, and natural resources into economic advantages.

- **Wood-based industries** and **food processing** are traditional industries important to the state for many decades.

- **Information technology** and **life sciences**—often grouped under the term "New Economy"—are ascendant clusters that have not yet reached their potential.

Some businesses cross the boundaries of these clusters such as agricultural biotechnology (agriculture and life sciences), or custom furniture design firms (wood and creative enterprises, complicating efforts to say just how much of Montana's economy is involved in these ventures. Nonetheless, a rough estimate is that one-fourth of Montana's business establishments and just under one-fourth of the state's employees are involved in these clusters. Cluster members comprise a larger proportion of the state's highest value-added industry and, we believe, are a significant source of its future growth.

In addition to the industry clusters examined by this report, many other industries employ large numbers of people and produce significant revenue. These include embryonic clusters such as aerospace, environmental technologies, and health care planners, as well as mature clusters such as oil and gas or metalworking. The goal of this report is not to be the "last word" on Montana's industries of importance, but rather, to help Montana begin to build more effective structures and programs to work with the six clusters and empower the state to be a more effective partner to all of the state's industries.

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Relative to the size of its economy, Montana has a substantive, relatively diverse, and growing life sciences cluster. This is true whether one takes a strict, narrowly defined view of industry or a more expansive view that includes biomedical, hospitals, and other life sciences-oriented endeavors. It is interesting to note that the existence of this cluster in Montana runs against the grain of conventional wisdom that holds that the presence of medical schools is a necessary condition for biotech cluster development. In this case, Montana has moved forward in spite of this handicap by developing its own distinctive infrastructure that includes several medical/bioscience research institutes, hospitals with research and clinical trials capacity, and a very strong life sciences and related-engineering presence and interest within its two major universities.

This section will address, first of all, how to define biotechnology and life sciences – terms that often have different meanings in different contexts. Next is a quantitative description of Montana's life sciences cluster, followed by a description of the companies and infrastructure elements that comprise the cluster. The cluster analysis concludes with a profile and assessment section. Finally, we summarize our key findings and, in the final part of this section, offer our recommendations for stimulating the growth and development of the life sciences cluster.

A The Life Sciences Industry: Descriptions and Definitions

Definition Issues

There are a number of terms and definitions commonly used to describe clusters that feature biotechnology and biotechnology-related products, processes, and services as their centerpiece. The terms include *biotechnology, biomedical, biosciences*, and *life sciences*. Some definitions are narrow enough to include only commercial activities associated with DNA and RNA manipulation, while some definitions are more loosely defined to include all drugs and pharmaceutical companies, medical devices and instruments, and even hospitals and clinics.

For the purposes of this cluster development strategy, we have elected to use the more general term, *life sciences*, because it includes both the narrow and loose definitions. The narrow definition is useful because it emphasizes the basic technological platform that is at the heart of this cluster. From a pragmatic standpoint, the loose definition is useful because it includes a number of important sectors, from hospitals to agricultural chemicals to laboratory instruments, all of which can play important support roles in advancing the competitiveness of the cluster. Additionally, as the industry continues to evolve, previously distinct lines are blurring between biotech and pharmaceutical and among therapeutics, diagnostics, and devices. Emerging areas such as systems biology and bioinformatics that require interdisciplinary teams are also causing the boundaries to be redrawn.

Of all the terms, *biotechnology* is the most commonly used, but its applications and definitions are far from uniform. Its narrowest definitions focus exclusively on recent advances in the manipulation and modification of RNA and DNA, while the broadest

include any research or application of "the use of living organisms for human needs." Somewhere in the middle is the official definition of the Biotechnology Industry Organization: "the use of cellular and molecular products to make products." None of these definitions is very helpful in determining which industries are and are not engaged in biotechnological research and production. For this reason, most biotechnology industry studies begin by establishing a definition that is most appropriate for the project at hand—that sheds the most light on the areas of interest.

To bring more specificity to the field, some studies use the term *biomedical* to refer to medical instruments, devices, and other products that are primarily purchased by the medical field, reserving the term *biotechnology* for firms that produce or perform research on biological substances. These two terms are then sometimes combined into the umbrella term *biosciences* or *life sciences*. The more specific terms have not, however, produced much consistency across studies; the 2001 Battelle study *State Government Initiatives in Biotechnology* found that no two states included the same industries in their bioscience or biotechnology definitions.

The problem is not that researchers refuse to be consistent; it is that the terms *biotechnology* and *bioscience* do not really define an industry at all, at least not in the product-centered sense that SIC and NAICS codes define industries. Rather, these terms describe a set of technology-based platforms that are centered around, but not confined to, specific capacities in biological science. These platforms can be used by firms in a range of industries, which vary somewhat among localities. Any attempt at capturing these industries through a codified system such as NAICS thus faces an inescapable tension between comprehensiveness, including all the firms that *may* be engaged in biotechnological activity; and precision, including only those firms that *definitely* are devoted to biotechnological research and production. An overly broad definition can substantially overstate the size of the industry, especially in macro-level studies such as national economic impact analyses. Too narrow a definition, however, could leave out important players; this would particularly distort a micro-level or regional analysis, where the omission of only a few firms could significantly alter the picture of the local industry.

We choose to resolve this tension by choosing both—that is, through a two-step process that uses both a narrow and a broad definition of biotechnology to take two different pictures of the makeup of Montana's biotechnology cluster. First, we will use a fairly narrow definition, based on the one endorsed by the Biotechnology Industry Organization (BIO), to look at what we will call the core biotechnology firms in Montana. This definition includes only a few SIC codes:

2833	Medicinal chemicals and botanical products
2834	Pharmaceutical preparations
2835	In vitro and in vivo diagnostic substances
2836	Biological products, except diagnostic substances
8731	Commercial physical and biological research
8733	Noncommercial physical research

This definition is nearly identical to that created by Ernst and Young for BIO, with one exception: because Ernst and Young were conducting an economic impact analysis, they did not include noncommercial research. Clearly, however, noncommercial research centers such as federal and university labs can make a huge difference in a region's ability to sustain biotech industry activity; therefore we chose to include them.

The reason to conduct one analysis using this narrow definition is that it provides a picture of the core of a region's biotech activity, unadulterated by any fuzziness that could be caused by including firms that may not focus on biotech. The possibility is there, however, that this analysis would miss strong biotech activity taking place in other industries. To capture this, we also conduct a broader count to detect what we are calling *cluster capacity*—these are not industries that have been identified as comprising a biotech cluster, but rather are those that can create the necessary supply and support context for cluster growth. The SICs we use for this broader analysis are:

027, 074	Agricultural services (veterinary specialties)
283	Drugs
286	Agricultural chemicals
287	Industrial organic chemicals
3821	Laboratory apparatus and furniture
3826	Analytical laboratory instruments
3827	Optical instruments and lenses
384	Medical instruments and supplies
806	Hospitals
807	Medical and dental laboratories
8731	Commercial physical and biological research
8733	Noncommercial physical research
8734	Testing laboratories

An Industry Overview

The Life Science industry, which is based on biological knowledge and research, is one of the most technology-intensive industries in the world. The industry is driven by major and continuous investments in research and development, with 2001 R&D investments totaling more than $15 billion.[i] It has experienced substantial growth over the past decade, tripling in sales from $8 billion to $20 billion.[ii] For the purposes of this overview, we are using the narrower definition of life science industries, since we are focusing, not on support and supply industries, but on the market for and production of life science products and research. In addition, we also provide overviews of the pharmaceutical and bio-agriculture industries, the two primary markets for biotechnology products and research. Agricultural biotechnology will, no doubt, play a prominent role in Montana's future biotechnology industry.

A Few Industry Statistics

- Profit margins for biotechnology companies are low, between 15 and 30 percent. This is in part due to the high cost of research and development.[iii]

- Biotechnology firms spent an average of $101,000 per employee on research in 2000.[iv]

- There are currently 1,457 biotechnology companies in the United States, of which 342 are held publicly with a total value of $224 billion.[v]

- Revenues have increased from $8 billion in 1992 to $27.6 billion in 2001.[vi]

- Life science firms currently employ 179,000 people in the United States.

- The FDA has approved more than 130 biotechnology drugs, with another 350 currently in clinical trial.[vii]

- In genetics research, business is highly concentrated among the top five companies who make up one-third of the total revenue.[viii]

The Human Applications Segment: Some Things To Consider

Two of the most up-to-date analyses of the biotechnology industry are offered in the Brookings Institution's *Signs of Life*[ix] and the Massachusetts Biotechnology Council/Boston Consulting Group report *MassBiotech 2010*[x]—both published in 2002. Here are several of the findings that are worth considering for any region seeking to build its capacity to support a biotechnology industry or cluster.

- **The biotechnology industry is highly concentrated.**

  Most biotechnology research and commercialization in the U.S. takes place in nine metropolitan areas: Boston, San Francisco, San Diego, Raleigh-Durham-Chapel Hill, Seattle, New York, Philadelphia, Los Angeles, and Washington, D.C. The gap between the top nine life science regions and the rest of the nation is considerable. Compared to the other 42 largest metropolitan areas in the U.S., these nine cities have eight times as much biotech research activity, ten times as many large and newly established biotech firms, and thirty times more venture capital funding.

- **This is usually an expensive and long-term endeavor – especially for drugs.**

  Drug development can take up to 15 years and $800 million for a single product. The drug development value chain is comprised of four steps.

  - Research: promising compounds, treatments, and approaches are identified by companies and academic researchers

  - Development: testing and refinement in three steps

    - pre-clinical – testing on animals to see if suitable for testing on humans

- clinical – testing on patients to see if it is effective and safe. This is also accomplished in three steps or trial levels (Phase 1, Phase 2 and Phase 3).

- FDA Review – Food and Drug Administration analyzes clinical trial test results to determine if the product is safe and effective for its intended use.

❖ Manufacturing: large quantity production

❖ Commercial: sales and marketing activities

- Risky business: product development

According to the Boston Consulting Group analysis, here are the success probabilities and time-to-market estimates for each of the development phases and the FDA approval process.

	Success Probability	Time to Market
Phase 1	21%	6 yrs.
Phase 2	31%	5 yrs.
Phase 3	59%	3 yrs.
Approval	91%	1 yr.

- **Manufacturing generates the greatest impact.**

  Manufacturing/bio-manufacturing spreads the economic benefits to a much broader segment of the population. This is because a wider range of employment opportunities is involved including manufacturing personnel, lab technicians, and quality control and assurance personnel. Furthermore, these jobs are more stable because the complex FDA approval process also involves the approval of the manufacturing process and the actual site (hence a strong disincentive to move).

- **The biotechnology industry has a strong employment multiplier.**

  It has been estimated that for every direct job created by biotechnology, about two additional indirect jobs are generated in support services such as professional services (legal, accounting, etc.), business supplies, and in related consumer spending.

- **Networking & collaboration = innovation & technological dynamism.**

  Networked firms and firms that collaborate are quicker to generate discoveries and commercialize products than firms who do not network. They also have better access to technical information, capital, and alliance opportunities.

- **The economic impact of biotechnology firms can depend greatly on their connections with pharmaceutical companies.**

  In the exploratory and development phases, biotechnology research requires a great deal of capital. Once the research has yielded a product, it must be manufactured, distributed, and marketed on a large scale if it is to have any real economic impact. Alliances with pharmaceutical companies are often the only way for human-science oriented biotech firms to gain access both to capital and to the necessary production and distribution infrastructure. Many worthwhile biotech products languish for lack of connection to a powerful partner.

- **"No Bucks, No Buck Rogers": The Risk Capital Requirement**

  Significant life sciences cluster development requires copious amounts of patient risk capital. As documented in the Brookings *Signs of Life* report, the country's nine most distinctive biotech concentration areas have, on average, thirty times more venture capital than other metro areas – including areas with significant research capacity.

The above-presented findings are, for the most part, derived from analyses of biotechnology industry segments that focus on human applications. It is important to note that there is also a great deal of biotechnology-related research and product development activity taking place in agriculture, food processing, environmental remediation, as well as other sectors. While several of the above findings may also apply to these sectors, each of these areas have their own separate and distinctive set of scientific, technological, business challenges and ethical issues.

Agriculture

Biotechnology is becoming an increasingly important part of everyday agriculture production. In some ways, agricultural producers have been using biotechnology for over a hundred years, ever since Gregor Mendel crossbred his first pea plants. Today, genetic manipulation and other biotechnological processes are used to create plants that can ward off insects or that are resistant to insecticides and weed-killing chemicals; plants that can tolerate hostile climates and environments such as deserts; plants that can produce a high yield from less acreage; and plants that contain additional necessary nutrients (such as the vitamin A-rich golden rice that is now grown for famine-susceptible countries). All of these applications will become more significant as the world's population continues to grow; the UN estimates that by 2025, half of the world's population will live in cities and need to be fed by the market. Food production will have to double on existing land over the next 30 years to provide for the increasing

population.[xi] The U.S. is a leader in transgenic crops, of which soybeans, cotton, and corn are the leading products; in 2000 the United States had 30.3 million hectares of transgenic crops, which was 20 million more than Argentina, the next closest country, and 69% of the world's total.

Pharmaceuticals

Because the biotechnology industry is so closely connected to the pharmaceutical industry – and in fact in some studies, biotech is considered part of pharmaceuticals – we include an overview of this industry to supplement our description of the biotechnology field. The structure of the pharmaceutical industry is quite different from that of the biotechnology field; where biotech firms tend to be small and volatile, pharmaceutical companies are large – and are getting larger in the recent wave of mergers – and long-lived. And, in contrast to the slight profit margins that make biotechnology research such a risky proposition, pharmaceutical firms see profit margins of around 70 percent – among the highest for any industry. Pharmaceutical firms are the single largest market for biotechnology products and research, and are also one of the most important sources of capital for biotech companies. Many small, cash-starved biotech firms establish partnerships (these may be joint ventures, cross-ownership or licensing agreement, or contracting relationships) with pharmaceutical firms to conduct research.

B Who Are They and Where Are They? Geographic Concentration of Montana's Life Sciences Cluster

Life Sciences Companies in Montana: The Basics

The group of findings presented below is gleaned from a region-by-region quantitative analysis of life-science-related employment and establishment concentrations of four-digit SIC code data. The analysis can be found in the Quantitative Data Companion Volume of this report.

- Montana has above average concentrations of establishments within its economy compared to the rest of the country for the core biotechnology industry definition as well for the broader, life sciences oriented version.

- Montana's core biotechnology cluster is small (616 employees in 2000) with a particular strength in noncommercial research and manufacturing of biological products. Employment in commercial physical research is declining, and some component industries (pharmaceutical preparations, medicinals and botanicals, and diagnostic substances) are not represented.

- The Southwest is the center of Montana's biotechnology industry. Concentrations of core biotechnology companies are also above average in Western Montana and – to a lesser degree – in the South Central region. Biotech employment is insignificant in the North Central and Eastern parts of the state.

- Establishment concentrations in the core biotechnology cluster are above average in Western Montana and almost twice the national average in the Southwest. At the same time, employment concentrations are clearly below average even in these regions, indicating that Montana's biotechnology cluster consists primarily of small companies. This could suggest some promising entrepreneurial activity.

- While all five regions have at least some employment in research organizations, core biotechnology manufacturing is new to the state and still limited to the Southwest and South Central parts of Montana.

- Compared to the national cluster distribution, noncommercial research organizations are over represented in all five regions.

- In the more broadly defined life sciences cluster, Montana's strength is more in research and testing than in manufacturing. Hospital employment accounts for almost 89 percent of the total cluster employment.

- Between 1990 and 2000, employment in the life sciences related chemical industries and in medical instruments and supplies grew by 96 and 67 percent, respectively. Both industries remain relatively small, however. Chemicals are concentrated in the Southwest, while medical instruments are dispersed across large portions of the state.

- Employment and establishment concentrations are particularly high (well above the national average) in smaller component industries that in most cases are of limited potential importance for the development of a life sciences cluster. For example, animal specialties, dental equipment, or fertilizer mixing companies are not key components on which to build a policy strategy for creating a life sciences cluster.

- The Western and Southwestern parts have a fairly diverse and well-developed life sciences cluster with significant employment in a number of component industries.

- Employment and establishment concentrations and distribution in the South Central region suggest the possible existence of a still weak, but potentially emerging cluster.

- Life sciences employment in the North Central and Eastern parts of Montana is concentrated almost exclusively in large hospitals, with very few other component industries represented.

Life Sciences in Montana: Industry Concentrations

As previously mentioned, this strategy employs two different working definitions for what a biotechnology industry cluster might look like. The first is a narrow definition that focuses on the capacity to manipulate and modify DNA and RNA. The second

biotechnology cluster definition is much more expansive in scope and includes biomedicine and bioscience and the use of cellular products. The latter is most consistent with what other states have used in their bioscience and biotechnology definitions. No statistically derived national benchmark exists for a life sciences cluster. At the state level, Montana has above average concentrations of employment and establishments within its economy compared to the rest of the country for the core biotechnology industry definition as well for the broader, life sciences oriented version.

Life Sciences Concentration Narrow Definition

The number of employees under the narrow definition was 616 in 2000, down 12.5 percent from 1990. The number of establishments, on the other hand, increased by 22 percent to 110 in 2000. As shown in Table VI-1, the employment LQs for the narrow cluster definition are below average, while the establishment LQs for most core biotechnology industries and the total cluster are greater than one. Montana has particularly high establishment concentrations in noncommercial research organizations and in biological products except diagnostic. While these two industries experienced significant employment growth between 1990 and 2000, commercial physical research employment declined sharply.

Table VI-1
Biotechnology Cluster (Narrow Definition) – Montana Summary Data

	EMPLOYMENT			ESTABLISHMENTS		
INDUSTRY	1990	2000	LQ 2000	1990	2000	LQ 2000
Medicinals and botanicals	D	D	D	D	D	D
Pharmaceutical preparations	0	D	D	0	D	D
Diagnostic substances	0	0	0.00	0	0	0.00
Biological products exc. diagnostic	0	52	0.84	0	3	1.43
Commercial physical research	407	163	0.25	46	48	1.05
Noncommercial research organizations	262	398	0.92	43	56	1.70
Total	704	616	0.32	90	110	1.20

Source: ES-202 data and RTS, Inc.
"D" indicates disclosure suppression. Statistics based on fewer than three respondents or where on respondent represents 80% of the employment are suppressed. Source: MT Department of Labor and Industry, and RTS, Inc.

Life Sciences Concentration Broad Definition

The more broadly defined life sciences cluster in Montana shows upward trends in employment and number of establishments. Employment increased from 15,701 in 1990 to 19,987 in 2000, or by more than 27 percent. The number of establishments in the cluster totaled 445 in 2000, a five percent increase from the 423 firms in 1990. These numbers illustrate the vast difference in scale between the two biotechnology cluster definitions. The employment levels for the broader definition are much higher than for the narrow one; almost 20,000 jobs compared to 600. As Table VI-2 shows, hospitals are responsible for most of that difference.

Employment and establishment concentrations for the broader cluster definition are above average. The employment LQ for the extended life sciences cluster is much higher than for the narrow biotechnology definition, indicating a specialization in industries that is more related to biomedicine, medicine, and medical devices rather than concentrated in biotechnology in the purest sense. However, agricultural (including veterinary) services and hospitals are the only two areas with above average employment concentrations. Combined, they account for more than 92 percent of the total life sciences employment in Montana. Establishment LQs are greater than 1.0 for agricultural services and research and testing laboratories. It is important to remember that these numbers only indicate high employment or establishment concentrations in industries that often sell products or services to biotechnology companies, or share a common labor pool or other resources. The data indicate a *potential* and not an *actual* relationship. For example, hospitals can play an important role in a life sciences cluster if they perform clinical trials, tests, or research. Many hospitals, however, are exclusively healthcare facilities.

Table VI-2
Life Sciences Cluster (Extended Definition) – Montana Summary Data

	EMPLOYMENT			ESTABLISHMENTS		
INDUSTRY	**1990**	**2000**	**LQ 2000**	**1990**	**2000**	**LQ 2000**
Agricultural services	474	672	1.02	138	142	1.04
Drugs	D	54	0.06	D	6	0.46
Chemicals (agricultural and industrial)	147	289	0.62	22	11	0.95
Medical instruments and supplies	139	233	0.24	20	22	0.69
Hospitals, medical and dental laboratories	13,977	17,745	1.54	113	117	0.99
Research and testing	800	962	0.70	119	145	1.22
Total	15,701	19,987	1.26	423	445	1.04

Source: ES-202 data and RTS, Inc
"D" indicates disclosure suppression. Statistics based on fewer than three respondents or where on respondent represents 80% of the employment are suppressed. Source: MT Department of Labor and Industry, and RTS, Inc.

A complete table with all cluster component industries as well as a more detailed analysis of regional industry concentrations and the distribution of industries within the cluster is included in the quantitative data companion volume. There we present employment and establishment concentrations and growth rates by region and compare the structure of Montana's regional life sciences cluster comparison to the national benchmark cluster.

C Basic Composition Of Montana's Life Sciences Cluster

The prior section presented a statistical summary of employment and establishment concentrations and distribution for a broadly defined life sciences in Montana. This summary is based on published data and intended to deliver a general sense of the life sciences industry-related presence within the state. This section presents a ground level view of the basic composition of Montana's life sciences cluster and as such employs a

cluster perspective that occupies a middle ground between the core and extended definitions used in the statistical description. Three aspects of this perspective should be noted.

It includes firms engaged in developing, marketing and manufacturing biological products and medical/biomedical devices and equipment as well as key suppliers whose products and services are tailored to the industry. The firms were identified from interviews, literature searches, and Internet searches and from input from Montana economic development professionals and life science industry representatives.

It includes some public and non-profit entities that are significant actors within the cluster, on a case-by-case basis. For instance, a hospital may be included if it is an active and recurring participant in research activities or clinical trials – especially with other companies or universities.

This is intended to be a representative but not comprehensive characterization of the cluster. There is no product-centered standard definition for this industry, so there are no directories or formal rosters other than an occasional piece-meal listing that includes small groups of companies that have identified themselves as biotech firms.

Companies

The project team was able to identify more than 50 firms, as well as an important group of public or non-profit laboratories, research institutes and hospitals that were active within this cluster (see Appendix A for a complete listing). As shown in Table VI-3, the group represents a fairly diverse collection of products, services, technology platforms and R&D activities for human, agricultural and environmental applications. Of the firms that have been identified to date, the largest number (19) are pursuing or producing human diagnostics or therapeutic applications. While almost all of these firms are supporting some level of R&D effort, eight of them indicate they have a product or service currently on the market and three indicate they engage in manufacturing.

Eleven firms are operating in the plant or animal applications field and seven are pursuing or producing life science related environmental applications. (Note: the numbers in these applications categories are not discrete – a firm may be represented in more than one category.)

Table VI-3

Commercial Focus Area	Number of Firms with Offerings
Human Applications	
Diagnostics/Therapeutics	19
Devices/Instruments	13
Agricultural Applications	
Plant	6
Animal	5
Environmental Applications	7

In addition, fifteen firms indicated they supplied biological products or life-science-based products or services to the life sciences industry. Their activities ranged from testing services to data mining software. Over half of these companies (nine) offer services while seven sold products to the industry. Six of the companies featured information technology-based products or services (software, data mining/manipulation, communications/reporting) and five of the companies provided some form of support for the FDA approval process or compliance monitoring.

Research Infrastructure

The cluster also features a cadre of public or non-profit institutions that engage in biotech or biomed-related research and/or support clinical trial activity. In addition to the state's two major research universities – *the University of Montana (Missoula) and Montana State University (Bozeman),* this group includes:

Rocky Mountain Laboratories Hamilton
Federal lab
Large laboratory of the National Institute of Allergy and Infectious Diseases

The Center for Biofilm Engineering (CBE) Bozeman
Montana State University
Multidisciplinary research teams find solutions and applications for industrially relevant problems and potentials of microbial bio-film formation

International Heart Institute Missoula
The International Heart Institute of Montana engages physicians and scientists from St. Patrick Hospital and Health Sciences Center and The University of Montana. Performs basic and clinical research on advanced cardiac procedures and the treatment of heart disease.

Montana Neuroscience Institute Foundation (MNIF) Missoula
St. Patrick Hospital and Health Sciences Center
The University of Montana
MNIF promotes the integration of neuroscience research and patient care. Through collaboration fostered by the Foundation, experts in research and clinical medicine develop innovations in patient care to help those afflicted with diseases of the nervous system.

Montana Biotechnology Center Missoula
University of Montana
The Center's mission is to stimulate applied and basic research in biotechnology, to coordinate efforts between public sector investigators and private sector enterprises and to increase collaboration between all parties involved in biotechnology within the state of Montana.

Deaconess Billings Clinic Billings
Deaconess Billings Clinic's Research Division conducts clinical research studies of human disease, new drugs, and medical devices.

McLaughlin Research Institute for Biomedical Sciences Great Falls
Biomedical research and transgenic facility that offers a range of services for the production and preservation of genetically modified mice.

Montana Board of Research, Commercialization & Technology Helena
Under the Governance of the Montana Department of Commerce, the board offers grants and loans for research and commercialization projects that (1) expand and strengthen the state's basic industries and (2) encourage the diversification of the state's economy. The board has authority to grant or loan $4.85 million in fiscal year 2003. The emphasis of the program is on projects that lead to marketable products or processes. Projects must be matched with non-Montana state government funds at an amount equal to at least 25% of the total project cost. Eligible applicants are Montana-based research and commercialization centers. Research and commercialization centers are statutorily defined as the campuses of the University of Montana or Montana State University, tribal colleges, colleges of technology, community colleges, agricultural research centers, or private laboratories or research centers.

Geography

Almost 90 percent of the cluster firms identified to date are located in the western half of the state with twenty-five in the Southwest Region and 20 companies in the Western Region. Two companies were located in the South Central region and in the Eastern Region. No cluster companies have been identified yet in the North Central Region.

The research infrastructure is concentrated in the Western Region (Missoula, Hamilton) with some additional assets associated with MSU in the Southwestern Region. The North Central and South Central Regions each have one strong research infrastructure institution.

Again, it is interesting to note that in spite of the substantive level of biotechnology industry related-activity in the western half of the state, Montana does not have a medical school.

D Cluster Profile and Assessment

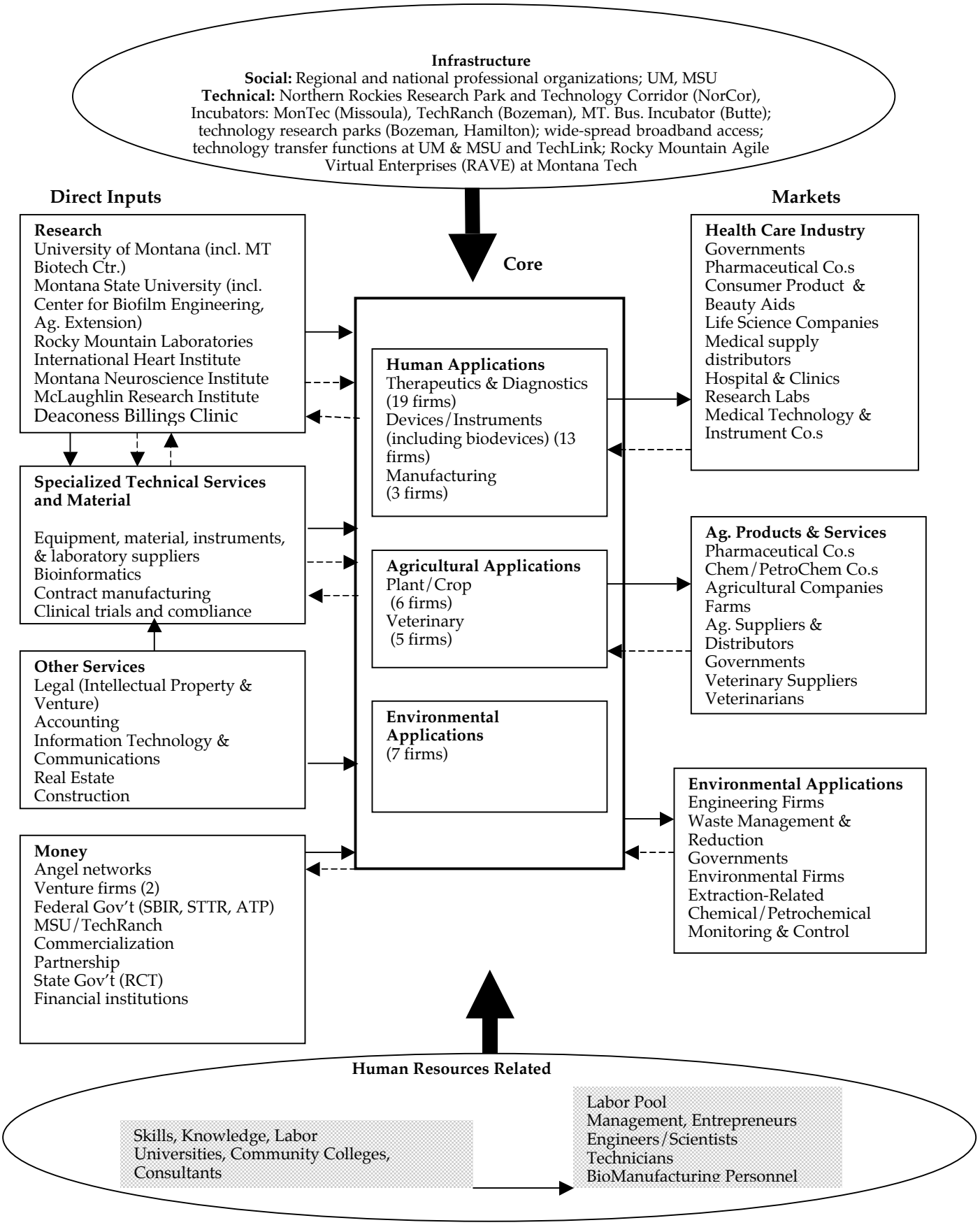
Cluster Map

A visual representation of the Montana Life Sciences cluster is presented in Figure VI-1. The cluster has been divided into five elements: (1) direct inputs (specialized, general services, capital, and research), (2) core firms (human, agriculture/livestock, and environmental), (3) markets/customers for each of the core applications, (4) infrastructure (social and technical) and (5) human resources-related inputs (sources of

skills and knowledge and the actual labor pool). The solid line arrows connecting the various elements indicate transactions. The dotted line arrows indicate information flow.

While the profile presented below addresses all the elements of the life sciences cluster, the basic frame of reference for the analysis is the group of firms that define the cluster's core.

Figure VI : Life Sciences Cluster



Skills and Labor

The core companies generally recruit from the national market for experienced scientists, engineers, and managers with specific skill and knowledge sets. For technicians and manufacturing-related positions, including entry level, they generally require a bachelor's degree. For entry level positions, employers often hired from in-state universities and were pleased with the quality of the graduates. The core firms, as a general rule, also provided specialized training, in most cases without using an outside vendor.

Providing some sense of the annual flow of in-state graduates into the potential life sciences labor pool, Table VI-4 presents a listing of university and college completions by degree and by program for the 2000-2001 academic year. As detailed in Table VI-4, for that year there were 346 degrees granted in programs whose graduates tend to be oriented toward human applications fields (biology, biochemistry, microbiology, medical technology, and biotechnology research.) Of these, 323 were bachelor's degrees while two were associate's, 16 master's and five doctorate. There were 87 degrees granted in programs oriented toward plant, crop, and livestock-related applications (animal sciences, plant sciences, horticulture sciences, plant pathology, soil science, entomology, and range science and management). Of these, 76 were bachelor's degrees while 11 were master's. There were no associate's or doctorate degrees granted. There were 111 degrees granted in programs where graduates tend to be oriented toward environmental applications (environmental sciences, environmental health engineering, and environment control technology). Of these, 58 were bachelor's degrees, while eight were associate's, 43 master's and two doctorate.

Table VI-4 Completions in University/College Programs, 2000-2001					
Program	**School**	**BA/BS**	**Master's**	**PhD**	**Associate's**
Animal Sciences, Gen.	MSU-Bozeman	24	6	-	-
Biochemistry	Carroll College	1	-	-	-
Biochemistry	MSU-Bozeman	-	3	1	-
Biology, General	Carroll College	25	-	-	-
Biology, General	MSU-Billings	13	-	-	-
Biology, General	University of Great Falls	3	-	-	-
Biology, General	Montana Tech	5	-	-	-
Biology, General	MSU-Bozeman	105	6	1	-
Biology, General	University of Montana-Missoula	90	3	3	-
Biology, General	MSU-Northern	4	-	-	-
Biology, General	Rocky Mountain College	8	-	-	-
Biological Tech/Technician	MSU, College of Tech-Great Falls	-	-	-	2
Biotechnology Research	MSU-Bozeman	12	-	-	-
Entomology	MSU-Bozeman	-	4	-	-
Entrepreneurship	MSU, College of Tech-Great Falls	-	-	-	7
Environmental Control Tech, Others	Fort Peck Community College	-	-	-	3
Environmental Hlth Eng.	Montana Tech	24	9	-	-
Environmental Science/Studies	Carroll College	4	-	-	-
Environmental Science/Studies	MSU-Billings	10	-	-	-
Environmental Science/Studies	MSU-Bozeman	3	4	2	-
Environmental Science/Studies	University of Montana-Missoula	5	26	-	-
Environmental Science/Studies	Rocky Mountain College	3	-	-	-
Environmental Science/Studies	Salish Kootenai College	9	-	-	5
Environmental Hlth. Eng.	MSU-Bozeman	-	4	-	-
Horticulture Sciences	Montana State University-Bozeman	37	-	-	-
Medical Technology	University of Montana-Missoula	9	-	-	-
Medical Technology	University of Montana-Missoula	3	-	-	-
Microbiology/ Bacteriology	MSU-Bozeman	26	3	-	-
Microbiology/ Bacteriology	University of Montana-Missoula	18	1	-	-
Molecular Biology	University of Great Falls	1	-	-	-
Plant Pathology	MSU–Bozeman	-	1	-	-
Plant Sciences, General	MSU-Bozeman	5	-	-	-
Range Science& Management	MSU-Bozeman	9	-	-	-
Soil Sciences	MSU-Bozeman	1	-	-	-

Source: Montana University System

Recruitment does not appear to be a substantial problem. The companies indicate that for highly specialized or skilled positions there are an adequate number of potential candidates in the national market who would like to move to Montana. While some

qualified candidates have no interest in moving to Montana, the companies indicate that there is usually a set of candidates who are very eager to relocate to the state for life-style reasons. This is a significant human resource competitive advantage, especially for highly sought technical and management positions. There is also an adequate supply of entry-level candidates because large percentages of recent graduates with life science-related degrees seek to remain in Montana.

Recruiting Savvy: Leveraging Life-Style

Local: TechRanch
TechRanch in Bozeman, Montana provides its technology company clients with incubation space and services, technical assistance, and capital access assistance. Its client base tends to be a mix of life science and information technology-related firms. The organization's Executive Director, John O'Donnell, assists his companies in recruitment efforts to fill highly specialized and competitive positions. O'Donnell indicates that one of his most cost-effective approaches for identifying qualified and interested candidates is to search Montana State University's alumni rolls for individuals with relevant degrees and backgrounds in out-of-state companies. For any particular position, there is often at least one Montana State graduate with the right skills and experience looking to get back to the Bozeman area. O'Donnell also has reservoir of resumes sent to him by out-of-state technology company personnel seeking employment in the area.

Statewide: Montana-Jobs.net
On a larger scale that is both statewide and for all industries, Julie Foster, CEO at Montana-Jobs.net in Billings, Montana uses a similar approach that connects Montana alumni and expatriates in out-of-state senior management and technical specialist positions to Montana companies in need of their skills. At last count, Ms. Foster had over 2,600 resumes on file.

While the cluster's core companies are not experiencing any significant workforce problems, they frequently pointed out that the specialized experience and skills levels for technology-based companies, especially biotech, were in short supply among attorneys, accountants, business consultants, and other professional service providers in their region.

Relationships and Social Capital

Knowledge of peers among the core firms was uneven, with a few firms indicating a pretty good grasp of what other life science firms in the region were doing. For the most part, however, most firms knew very little about the operations of their peers and had little to no contact with them. Most firms had employees who were active in national scientific and/or industry associations (one of the main ways that they keep up to date on scientific and industry developments). However, the firms are unaware of any local, intrastate regional, or statewide biotech or life science associations or networking groups. Some of the core firms were active in local economic development organizations but firm representatives indicated they considered this a civic duty and did not receive any real business benefit from their involvement.

Although life sciences industries tend to be collaborative, there was a low level of collaborative activity among Montana life science cluster firms. Most firms did use collaboration and networks as a business strategy; however, they were networked within their market space rather than the geographic space. They worked with partners and

suppliers within their market segment located out-of-state. One core firm CEO summed it up: "We can't afford to collaborate with each other. No one has any money. Everyone is partnering with firms outside the region with some access to financial resources."

However, the connections did seem to be very strong with the two research universities – Montana State University and the University of Montana. Many of the firms have some kind of relationship with the faculty or a specific center. Both universities seem to function as natural hubs – as common ground among otherwise unconnected firms.

Benchmark Practice: BiotechConnect: The New Orleans Regional Biotech Networking Group was organized by a small group of research universities, medical schools, and biotech companies to begin to make connections among the firms and organizations within the area's emerging biotech cluster. The group as biotech, pharmaceutical and medical device firms, defined the cluster core. About three times a year the group sponsors an event called BiotechConnect. The gatherings are held at a local bar and are regarded by the biotech and economic development communities as extremely successful in a competitive environment where the prudent regard networking, collaborative venture, and strategic alliances as a requirement for success. The meetings are exclusively for networking and are "program free." Here is an excerpt from an email announcement for a recent meeting:

"No lectures, no agenda, just relaxed networking. There will be many people you'll recognize and plenty of new faces: Entrepreneurs, investors, attorneys, scientists, executives, deans/presidents, biotech incubator directors, journalists, consultants, and other professionals. Please feel free to invite your colleagues and friends from biotech, pharma, and medical device-related firms."

Supply Base

The core companies indicated they purchased most of their critical material inputs from out-of-state suppliers or manufactured their own. Some companies did deal with local representatives of national suppliers. There are some life science related technical services and material suppliers present in the cluster population, but their trading relationships with the core companies were at best sporadic. Though the overwhelming tendency was to purchase from out-of-state vendors, smaller and/or early stage companies such as TechRanch that received assistance from the infrastructure organizations had stronger connections to technical material and service providers. The companies also indicated they relied heavily on the Internet.

Markets and Transportation

On the positive side, there were no major concerns expressed about the adequacy of the existing transportation system. Most companies were heavy users of overnight courier services but reported no issues.

Reliable, affordable broadband Internet access was regarded as a "transportation" asset but also a requirement. As one CEO remarked, "We use the Internet for everything."

Commercial isolation was considered a problem. Core company representatives frequently pointed out that it was "great to live in Montana but there is no business

advantage to being located here." For those shipping product or planning to ship product, distance from customers was a significant concern.

Companies focused on developing or delivering drugs that required partnering relationships with larger pharmaceutical firms took it for granted that there would never be a strong pharmaceutical company presence in the state because it "made no sense for them to be in Montana."

Technology and Innovation

Like the rest of the world's emergent life science industry, the small Montana life science cluster is innovation driven. The ability to develop and commercialize new life science-related technologies and the products, processes, and services in which they are embodied will determine the long run viability of this cluster.

On the positive side of the ledger, the core companies and the economic development professionals who work with them reported that there were no chronic problems recruiting highly skilled people (see Skills and Labor assessment above). Because the industry is tightly networked at the national and international level, the companies reported that they had good access to up-to-date information on R&D and business development. Once again, the Internet was frequently mentioned as an information source and development tool.

The two most often cited innovation support assets were the two research universities and the state's aggressive and user-friendly SBIR program. To a great extent, the two research universities are functioning as the technical and social hubs for the nascent cluster and the SBIR program has been functioning as the main life science business seed capital provider in the state. In fact, over the last four years, roughly fifty percent of the awards have been for life science-related applications or have featured life science related technologies.

There are also other innovation infrastructure strengths including the universities' technology transfer operations, assistance and support from TechLink and TechRanch, research hospitals with clinical trials capacity, and strong federal and non-profit laboratories.

Full Service Innovation Support: Growing Your Own on the Ranch

Montana State University's College of Business, the Montana Governor's Office of Economic Opportunity, the federally funded TechLink Center (links NASA and Department of Defense technologies to companies) and the Technology Venture Center (TechRanch) in Bozeman, Montana have partnered to launch a pilot program to pull commercially promising technological opportunities out of the Montana State University System and the federal government, "vet them out" (proof of concept and function, assess commercial potential), and then wrap a startup company around them.

The program, called Grow Your Own, is supported by a $600,000 grant from the National Science Foundation and features a small pre-seed fund to support the innovation effort in its initial stages. In addition to the funding, the partnership supplies space, incubation services, interim management, technical assistance, business formation assistance, and will even recruit permanent management at the appropriate time. The partnership brings all its resources to bear to combine the right mix of talent, technology, know-how, and capital to start technology companies in a rural setting.

The Grow Your Own program, which began in the fall of 2002, has already formed one life science company around an MSU technology. The company, Envirozyme, has developed a yeast fermentation system that allows for more cost-effective production processes that can produce large quantities of enzymes. Envirozyme's initial target is the aquaculture feed industry.

Two distinct negatives loom as major obstacles to the continued development of the cluster. First, for a host of reasons, university medical centers and schools are perhaps the single most important life science research infrastructure element and Montana has none. The mix of research activities, clinical operations, ebb and flow of faculty and student, budding technical entrepreneurs, sponsored research, technology disclosures and intellectual property portfolios, and research centers is an integral part of a productive development milieu.

The second major obstacle is the lack of risk capital for startups or expansion. This will be discussed in the "entrepreneurship profile" element. At present, SBIR funds, and to an extent the Montana Research Commercialization and Technology funds, are the main sources of pre-seed and "feasibility" capital. The role of angel investors on the human applications side is very limited because of the large funding requirements and the long technology gestation period.

Entrepreneurship and Capital

In recent years, Montana's overall business startup rate has hovered slightly above the national average (see Volume II of this report for a separate entrepreneurship and innovation capacity analysis). However, the core companies indicated that in the case of the life sciences cluster, the entrepreneurial environment was well below average. The companies offered two main reasons for the below par startup rate: first was "very limited access to venture capital at all levels"; second, from their perspective, there is a basic lack of understanding of or interest in the biotechnology industry throughout the state. The companies' reasons for starting up in Montana tended to fall into two categories: either they had strong ties to MSU or UM or their founders "just wanted to live in Montana."

While lack of public interest and very limited risk capital access translate into a difficult life science-related business startup environment, there is some progress being made – especially in the western and southwestern regions. In these regions, (as noted in elsewhere in this report) a substantive infrastructure is emerging with capacity to support life science enterprise development and life science-related technological innovation. In addition to the research assets mentioned earlier in this section, it also includes elements such as incubators (TechRanch, Montec), progressive technology transfer operations at the universities, research parks (Bozeman, Hamilton) and technical support providers like the Center for Entrepreneurship for the New West (at MSU) and Montana Business Connections (at UM).

In spite of this progress, there was a strong consensus among the core companies that very limited access to seed and venture capital is the cluster's most acute and persistent problem. In fact, the firms felt any appreciable additional development for the cluster was unlikely unless the capital issue is addressed.

Best Practice: The University of California at San Francisco's Center for BioEntrepreneurship: The University of California at San Francisco (UCSF)'s Center of BioEntrepreneurship supports the UCSF community's effort to launch and grow life sciences companies. The Center does this in four ways:

1. Courses on such subjects as intellectual property for life scientists or how to build value in life sciences companies

2. Access to the UCSF Innovation Accelerator – a network of Bay Area scientists and business professionals who support life science entrepreneurship

3. Symposia and conferences such as the Entrepreneur – Investor Interface or the Biotech-InfoTech Summit

4. Frontiers in Biotechnology lecture series that showcases leading edge research at the university-industry interface.

The data bear this opinion out. An analysis of the PricewaterhouseCoopers MoneyTree Survey for the 1996-2001 time period (see Volume II) shows only two life sciences company fundings – one later stage deal ($500,000 investment) in 1996 and a single "early stage" funding ($180,000 investment) in 2001. The core companies, primarily because of the typical investment size and the long gestation period did not regard Angel networks as a viable funding source. In fact, according to the core companies, the primary early stage risk-financing source for a life science firm in Montana is the federal SBIR program. A quick inventory of SBIR awards from 1999 through 2002 lends credence to this claim. Roughly half of the total awards listed during this time period (see Volume II) were for life science-related human, agricultural, or environmental applications, or featured life science related technology.

To be sure, routine access to venture financing is difficult to manage for most communities. The venture capital industry is concentrated on the West Coast (a San Jose/Palo Alto hub) and the East Coast (Boston and to a lesser extent, New York). There is a strong tendency for fund managers to invest close to home (within two hours travel

time of originating office) in spite of the fact that the "official" geographic scope of the fund might be national or international. Research in the mid-1990s documented the fact that over half of the several billion dollars of venture fund disbursements each year in the U.S. were invested in companies located in California and Massachusetts.

While there is some mobility (money will travel outside of its management's location to find good deals) for larger deals, there is little or none for smaller fundings—especially early stage deals. This means, as a rule, that if you want access to early stage capital, you had better "do it yourself." This recognition has given rise to a host of early stage capital fund inducement efforts at the state and municipal levels throughout the country. Locally owned and managed early stage venture funds are important to regional economies for at least four reasons:

1. The kinds of companies that need and attract these funds are high value-added, high-growth companies capable of raising the standard of living in Montana communities. Life science and biotech companies are a prime example. They generally pay higher wages, require higher knowledge and skills levels of their employees, and tend to operate on higher gross profit margins. When these companies are successful, they retain and reinvest more earnings than other companies. Also, successful high growth, higher value-added firms return more money to owners and investors, leading to reason number two.

2. When venture funds are locally owned and managed, a greater portion of their returns to investors is added to the wealth of the community in which the funds are located.

3. Reason number three is less tangible but just as important. These early stage, locally owned and managed funds make a powerful public contribution by their mere existence. By fueling the birth rates and improving the likelihood of success for high value-added firms, the venture capitalists infuse their communities with a sense that all things are possible and an appreciation for risk-taking, knowledge, and skill. They foster and shape a culture of innovation – this is especially important within younger innovation-driven industries like biotech and life sciences.

4. Well-managed, local, early stage funds can serve as a gateway or link to larger venture firms, providing subsequent rounds of risk financing as the company enters the market and begins to grow.

Circumstances in recent years have rendered the development of smaller local funds even more problematic. Within the industry, more capital has been concentrated in fewer hands. Many institutional investors that invest in venture capital funds want to invest at least $10 million in a fund and represent no more than 10 percent of the fund's capital, thereby limiting their focus to funds of $100 million or more. Smaller institutions also perceive safety in investing in large funds. When a fund has $100 million under management, they need to invest $2 million to $5 million in a company over time. This leads them to favor the later stage deals. Seed and start-up companies are more people-

intensive than capital-intensive. Early stage companies need smaller amounts of capital to hit their early milestones, and they require the active involvement of the investor to help fill the gaps in the initial management team. Therefore, although they are a critical development asset, early stage funds often don't make sense as a strictly private, rate of return-maximizing investment. Larger funds and larger deals offer a better alternative because the investment is more "efficient" and there is much less risk while still realizing an acceptable rate of return.

Equity

This is a small, emerging, and vulnerable cluster with high education and skill level requirements. Areas and people with limited access to educational opportunity will have a difficult time acquiring the skills and knowledge required to become a member of the life sciences cluster labor pool. This circumstance is exacerbated by the fact that the vast majority of the life sciences companies are concentrated in the western and southwestern part of the state, far removed from the largest concentration of disadvantaged people, the Native-American citizens, in the eastern portion of Montana.

Thus, training and education outreach efforts should extend to the eastern portion of the state. In concept, one logical place to begin is skills training for biomanufacturing and life science-related manufacturing; however, it is doubtful there will be enough demand for these kinds of jobs in the near future. As the cluster continues to develop and begins to add manufacturing jobs, training outreach should be carefully considered.

At the university level, special effort should be made to recruit students into life sciences related curriculum and cooperative endeavors with life sciences firms. For instance, the previously described Grow Your Own program, while open to all entrepreneurs, has a goal of starting more female- and Native American-owned companies.

E Key Findings Revisited

The following findings from the national industry overview and the quantitative scan provide additional context for the cluster competitiveness factors analysis and, together with the factor analysis, form the basis for the set of Suggested Actions concluding this section.

Table VI-5: Cluster Competitiveness Factors		
Factor	**Rating**	**Comments**
Skills & labor	8	Montana's attractiveness as a life style choice mitigates its remote location. Companies report no major workforce problems.
Relationships & social capital	5	Very little connectivity among Montana life sciences companies but strong connectivity with the universities.
Suppliers & services	2	No appreciable supplier base and limited of technical and specialized professional services.
Marketing & transportation	5	Adequate transportation system but remote location is a problem. Good broadband access is also an asset.
Technology & innovation	5	Universities exhibit strong innovation impulse, progressive technology transfer operations and willingness to collaborate. Also strong federal lab presence. Lack of university medical center and medical school is a major drawback.
Entrepreneurship	2	Some strong technical entrepreneurship support but very limited risk capital supply and public lack of interest are major obstacles.
Equity & opportunity	5	Individuals with limited access to educational opportunity will find it very hard to participate. Though some outreach efforts underway, cluster scale not large enough to justify major outreach efforts.

From The National Biotech Industry Overview

- ***Patience is a requirement.*** Life sciences-related product and service development is a long term and risky process—especially for human applications.

- ***Concentration is key.*** Compared to the other 42 largest metropolitan areas in the U.S., the top nine biotech clusters areas have eight times as much biotech research activity, and ten times as many large and newly established biotech firms.

- ***Manufacturing generates the greatest impact.*** Manufacturing/bio-manufacturing spreads the economic benefits to a much broader segment of the population. This is because a wider range of employment opportunities is involved, including manufacturing personnel, lab technicians, and quality control and assurance personnel. Furthermore, these jobs are more stable because the complex FDA approval process also involves the approval of the manufacturing process and the actual site (hence a strong disincentive to move).

- ***Networking = innovation*** Firms that network and collaborate are quicker to generate discoveries and commercialize products than firms that do not network. They also have better access to technical information, capital, and alliance opportunities.

- ***Connections to pharmaceutical companies are very important.*** In the exploratory and development phases, biotechnology research requires a great deal of capital. Once the research has yielded a product, it must be manufactured, distributed, and marketed on a large scale if it is to have any real economic impact. Alliances with pharmaceutical companies are often the only way for human-science oriented biotech firms to gain access both to capital and to the necessary production and distribution infrastructure.

- ***No bucks – No Buck Rogers*** Significant life sciences cluster development requires copious amounts of patient risk capital. The country's nine most distinctive biotech concentration areas have, on average, thirty times more venture capital than other metro areas, including areas with significant research capacity.

From the Quantitative Scan

- Even though its core biotechnology cluster is small (616 employees in 2000), Montana has above average concentrations of employment and establishments within its economy compared to the rest of the country for the core biotechnology industry definition as well for the broader, life sciences oriented version.

- Compared to the national cluster distribution, noncommercial research organizations are over-represented in all five regions.

- The Western and Southwestern parts of Montana have a fairly diverse and well-developed life sciences cluster with significant employment in a number of component industries. The Western region contains most of the infrastructure and some of the firms while the Southwestern region contains most of the firms and some of the infrastructure.

- Establishment concentrations in the core biotechnology cluster are above average in Western Montana and almost twice the national average in the Southwest. At the same time, employment concentrations are clearly below average even in these regions, indicating that Montana's biotechnology cluster consists of primarily small companies. This could suggest some promising entrepreneurial activity.

- While all five regions have at least some employment in research organizations, core biotechnology manufacturing is new to the state and still limited to the Southwest and South Central parts of Montana.

- Employment and establishment concentrations and distribution in the South Central region suggest the possible existence of a still weak, but potentially emerging cluster.

- Life sciences employment in the North Central and Eastern parts of Montana is concentrated almost exclusively in large hospitals, with very few other component industries represented.

F Suggested Actions

Recommendation :

The Life Science Cluster Leadership Council

Action: As with the other clusters, the Governor's Office of Economic Opportunity should take the lead in forming and staffing a Life Science Cluster Leadership Council. Within this role, the Governor's Office of Economic Opportunity should represent the interests of the Council to the State and function as the Council's link to the State of Montana's multifaceted web of financial and technical resources, service providers, people, and regulatory entities that can affect the competitiveness of the cluster.

The Council will be comprised of fifteen members of whom at least nine should be from the private sector. Membership should be drawn from life science firms, key technical support providers (such as intellectual property attorneys, risk capital providers, clinical trials support firms including CROs), public and non-profit research organizations and higher education institutions. The private sector membership should represent human, agricultural, and environmental applications companies.

The Governor should appoint the initial group of Council members. Once the Council is convened, it should elect its own officers and develop rules that provide for staggered terms as well as for nomination and election procedures of the private sector members. The non-private sector representatives should continue to serve at the discretion of the Governor.

The Life Science Cluster Leadership Council should:

- communicate industry issues and opportunities to the state support group (capital, workforce, permitting, etc.)

- provide feedback on effectiveness of state-sponsored programs and actions to support the life science cluster

- work with and through the Governor's Office of Economic Opportunity to foster life sciences cluster awareness throughout the state and within the legislature

- form life science or biotechnology regional councils

- transmit information from state government back to the life sciences community
- sponsor networking functions
- link to other clusters through leadership councils – especially the Information Technology cluster.

Recommendation :

Financing Life Science Innovation and Startups

Based on the interviews with core companies as well as with local economic and state economic development professionals, the single most significant and acute issue facing the life science cluster is lack of risk capital. If this cannot be effectively addressed, growth prospects for the cluster are very limited.

On one hand, much greater access to venture capital – especially seed and pre-seed – is a requirement for the continued development of the life science cluster. On the other hand, as previously explained, it is unrealistic to expect institutional type venture capital providers to establish a presence in Montana given the rate, quantity, quality, and investment size of the deal flow and the fact that there are no local providers to lead deals or with whom to co-invest.

To break this deadlock, there are several actions worth considering to induce demand and build supply for the risk capital market. While these suggestions address approaches for developing a more active risk capital market without regard to investment focus, they are being presented in this particular cluster development strategy because life science firms are likely to be one of the main demand-side participants this market and beneficiaries of its machinations.

a Leveraging the SBIR Program

It makes sense to begin by leveraging the state's most productive innovation and business startup financing asset. Montana has an effective SBIR program, highly valued by the private sector. This program has been functioning as the main pre-seed capital provider in the state, and roughly fifty percent of the awards have been for life science-related applications or featured life science related technologies.

The program has several strong elements: awards are highly competitive and based solely on technical and commercial merit; it is considered to be among the most effectively administered federal programs; it is private sector oriented but most often features strong links to university resources; and it targets very early stage capital market gaps. It features three development phases: Phase 1 supports grant awards of up to $100,000 and focuses on initial feasibility assessments; Phase 2 awards grants up to $750,000 and concentrates on R&D activities and commercial viability; and Phase 3 is the commercialization phase and relies on private sector or non-SBIR funding.

Action: SBIR Phase 1 Match with Commercialization Incentives: Establish a dollar for dollar SBIR "bridge match" program for any Montana company that receives an SBIR Phase 1 award. The match should be automatic but the Montana program should feature a strong commercialization incentive that stipulates that no company can receive more than two automatic match awards until it can document that one of its prior match awards has reached Phase 3 (attracted significant private sector funding) or has resulted in a commercial product or service. The company shall be eligible for an additional Phase 1 match award every time a prior award reaches a Phase 3 stage.

It is suggested that the award match program be administered by the Montana Department of Commerce (Board of Research and Commercialization) or the Governor's Office of Economic Opportunity. The state match should be automatically awarded upon proper documentation of receipt of federal Phase 1 award on a "first come, first serve" basis until the match fund budget is depleted. It should be emphasized that any Montana firm receiving a federal SBIR Phase 1 grant has been awarded funding based on an independent assessment of technical and commercial merit in a very active national competition. At the state level, this should be a relatively straightforward and cost-effective program to administer because state personnel will not be tasked with assessing technical and commercial feasibility. The program should be closely coordinated with the activities of the Board of Research and Commercialization if this group does not administer it.

The state's automatic bridge match should:

- Boost life science firms' capacity to demonstrate technical feasibility and increase the likelihood of Phase 2 funding
- Act as a funding bridge to span the gap that often occurs between the end of Phase 1 and the receipt of Phase 2 funds
- Help the firm build links to other capital providers
- Accelerate the entire commercialization process.

b Access to Early Stage Risk Capital

The state should encourage and support efforts to provide Montana companies and entrepreneurs much greater access to early stage risk capital. However, it should not "go into the risk capital business" but instead develop and offer cost-effective incentives for private for-profit and private non-profit, locally managed early stage fund formation.

There are a number of publicly sponsored venture capital-related incentive programs operating throughout the country. In view of the very low activity level in Montana, it probably makes sense to begin by considering more aggressive incentive actions. Here are two risk capital market formation inducement initiatives that fall into this category.

Venture Capital Match Program

The purpose of this initiative is to encourage the formation of local, *professionally managed venture* capital funds. In a market where there is very little activity, this can be a very effective action.

Action: The State or a State-funded intermediary would provide a "set" 2 to 1 or 3 to 1 co-investment match once the prospective fund organizers had reached a specified fund raising level. The match would need to be large enough to boost the fund size to a level that could generate sufficient management fees to attract experienced management.

For instance, for a 2 to 1 co-investment match, once a group had raised $10 million the State would co-invest an additional $5 million. A 3 to 1 match at the $7.5 million threshold would boost capital under management to the $10 million, or $15 million funds raised would produce a $20 million fund size.

Three additional elements should be stressed.

1. This initiative should contain a sunset provision. The purpose is to "prime the market development pump" by encouraging the initial formation a small group of in-state funds. Once this has happened the program should shut down.

2. The match is not a grant or a loan. The program would invest at the same terms and conditions as the fund's other investors and would expect the same return. This means the state would not only need an entity or mechanism to administer the program but also to receive any returns.

3. Accountability is critical. The state or its agent would need to develop and promulgate rules, perform its own due diligence, and "certify" the match recipients.

Certified Capital Companies (CAPCO)

Action: The State should consider establishing a CAPCO program that features tax credits against insurance tax premiums. The enabling legislation should include provisions to set aside a significant portion of the funds go to early stage companies, accelerate investment timetables; require larger shares of funds be dedicated to in-state investments; and establish a ceiling on the dollar amount of credit that can be issued in any one year.

The CAPCO program allocates tax credits to encourage investment in private venture capital firms certified under the legislation. There are a number of versions of Certified Capital Company (CAPCO) programs operating throughout the U.S. The program described below focuses on insurance premium tax credits (as opposed to income tax, etc.). This approach is designed to increase the supply of privately managed venture capital in a state and create a pool of experienced venture capital managers that become part of a state's permanent venture capital infrastructure.

Although individual state legislation varies, typical CAPCO legislation provides a 100% tax credit (over 10 years) to insurance companies in return for investments in capital companies certified by the state. The models also vary, especially concerning requirements for certification, the schedule for making investments, how qualified businesses are defined, and whether or not the state participates in the returns to CAPCO investments. They typically exclude credits on investments in businesses that are primarily engaged in oil and gas exploration and development, gaming, real-estate development, banking, insurance or professional services provided by accountants, lawyers, or physicians.

CAPCO programs have been independently assessed as very productive vehicles for significantly increasing the supply of venture capital in a state. In Louisiana, where the first CAPCO legislation was passed, an independent performance audit report by the State's Legislative Auditor found that the program resulted in $184 million invested in qualified Louisiana businesses and created or retained 3,503 full time jobs and 543 part time jobs. The assessment also reported $205 million of insurance premium tax credits eligible to be claimed by investors.

CAPCO critics point out the expense of the program as well as public accountability issues. CAPCO advocates counter that the accountability issues have been addressed by newer versions of the legislation and point to the program's outcomes relative to the even larger and ever-increasing costs of recruitment incentive packages. For instance, the Mississippi State legislature approved a $295 million incentive package for a Nissan auto facility that projected up to 3,000 jobs. They also argue that the ripple effects associated with the additional jobs and incomes are not taken into account.

Certainly, if not properly structured, CAPCO programs can be very expensive (in terms of tax revenues foregone.) Some of the most recent versions of the program have effectively addressed expense and efficacy issues raised by the earlier versions. New requirements have dramatically improved the potency of the program from a public policy standpoint. They include provisions that: require a significant portion of the funds go to early stage companies, set-aside portions for minority-owned or disadvantaged businesses, accelerate investment timetables, require larger shares of funds be dedicated to in-state investments, and establish a ceiling on the dollar amount of credit that can be issued in any one year.

Other Finance-Related Actions

Two other actions that other states have considered may also be appropriate in Montana. One is a 100% loss carry forward for state income tax purposes. The other is a tax credit against R&D expenses or certain types of R&D or "biotech" jobs. Both the loss carry forward and the credits would need to be re-saleable if they are to be effective.

A capital gains tax credit for angel investors might also be effective, especially for companies that focus on environmental and agricultural applications.

Recommendation : Two Strategic Actions at the State Level

a Targeting Biomanufacturing

Action: The state should identify companies with Phase 2 and Phase 3 clinical trials products and actively service their prospective manufacturing needs. This should include support and technical assistance for permitting, facilities planning, site location, key supplier development, and workforce training.

The state should target biomanufacturing because these facilities have the greatest economic impact. The latest round of industry research suggests that while biomanufacturing facilities would still prefer to locate close to their R&D sources, in fact these establishments are beginning to locate outside the major urban biotech industry centers. The most often cited reason for this is "permitting considerations." Companies are seeking stable and efficient permitting environments and they are also looking for locations with acceptable sites and facilities. It is important to note that once a biomanufacturing facility locates in a particular place it is very difficult for them to move because the FDA must approve their manufacturing process and their site. Availability of qualified workforce and training programs has also surfaced as an important consideration.

b The Montana BioEntrepreneurship Center

Action: The State should consider creating a Montana BioEntrepreneurship Center at Montana State University and the University of Montana to educate and support university faculty and graduate student on business startup issues and business aspects of the life science industry.

The Center(s) should be patterned after one currently operating at the University of California at San Francisco's (UCSF) Center for BioEntrepreneurship. The UCSF center hosts lectures and symposia and develops and delivers educational programs on entrepreneurship and business in life sciences for the "UCSF Community." It is recommended that the MSU Center for BioEntrepreneurship build an active link with the incubator and technical support at TechRanch and that the UM Center do with same with Missoula's MonTec incubator and technology innovation center. The Center could represent a very cost-effective way to create a nexus of life science cluster business activity within each of the communities.

Appendix

Montana Life Sciences Companies

American Eagle Instruments, Inc. Missoula 406-549-7451
Develops and manufactures dental tools an instruments

Androscore Corporation Alzada 307-878-4495
President: Dr. Ronald Ericsson (also President of Gametrics)
Diagnostic devices for male fertility (human & livestock
Products on the market
Employees: 1
www.mcn.net/~gamandro

Bacterin Bozeman 406-556-0272
Develops coatings for antimicrobial uses
(incubator)
www.bacterin.com/cgi-bin/bacterin/index.html

Biologicals Bozeman 406-586-3790
Biotech supply company

Biological Control of Weeds, Inc. Bozeman 406-586-5111
Leading supplier of live insects for non-chemical control of rangeland and pasture weeds

Bio Constructives, Inc. Bozeman 406-582-8571
Biotech and R&D lab – birth control and veterinary applications

BioScience Laboratories, Inc. Bozeman 406-587-5735
Testing lab for antimicrobial properties of products for the health care industry.
Assesses study needs for topical antimicrobials, 510-K submissions to USFDA, virus clinical claims and statistics
www.biosciencelabs.com

BioSciences Consulting 406-994-6374
Contract biological research

Biosurface Technologies Corp. Bozeman 406-585-2812
Drinking water monitoring systems
Provide biofouling and biocorrosion monitors to industry and research
http://cu.imt.net/~mitbst/

Bitterroot Restoration - Corvallis 406-961-4991
Produces seeds for native plants

Cardiopak Billings 406-259-6387
Packaged sterile surgical kits

The Center for Biofilm Engineering (CBE) Bozeman 406-994-4770
Engineering NSF Research Center, MSU
Multidisciplinary research teams find solutions and applications for industrially relevant problems and potentials of microbial biofilm formation

ChelaTech Missoula 406-728-5897
Richard Hammen
Rapid polynucleotide synthesis

Computer Compliance, Inc. Bozeman 406-388-7832
Support service – not a core member
Performs engineering services for manufacturers of medical devices, pharmaceuticals, and biotechnology products which are regulated by the FDA and are required to provide documented evidence that the equipment used to manufacture these regulated products meet FDA specifications.
www.ccionline.com

Corixa Montana Hamilton 406-363-6214
Developer of immunotherapeutics with a commitment to treating and preventing autoimmune disease, cancer and infectious disease by understanding and directing the immune system. Corixa is focused on immunotherapeutic products and has a broad technology platform enabling both fully integrated vaccine design and the use of its separate, proprietary product components on a stand-alone basis. Currently has 16 programs in clinical development and 22 programs in preclinical development, including its most advanced product candidate, BEXXAR®, a monoclonal antibody conjugated to a radioisotope.

Deaconess Billings Clinic Billings
Private biomedical research facility

Deden Technologies Missoula
Develops and manufactures core training exercise and rehabilitation equipment

Emerald Bio Butte 406-782-2386
Emerald BioAgricultural Company (formerly Mycotech)
Manufacturing Division (HQ in Michigan)
Gary Chatriand (Manufacturing VP)
Use of biological and biochemical agents and plant genetics to improve crop yields, enhance quality, combat disease and fight pests

Endobiologics Missoula 406-543-7909
Pharmaceutical development to treat enteric diseases

Envirozyme Bozeman 406-556-0272
Cliff Bradley
Develops products for animal foods - fish, chickens (incubator)

Gametrics Alzeda 307-878-4494
President: Dr. Ronald Ericsson (also President of Androsdore Corp.)
Veterinary products – diagnostics, veterinary and human sex selection, sperm isolation, sperm genetics
Employees: 20
www.mcn.net/~gamandro

Golden Helix Bozeman 406-585-8137
Produces subject specific, data mining software for pharmacogenomics and intelligent, target-specific compound selection. The firm pioneered the creation of advanced pharmacogenomics software that can relate thousands of interacting genes and environmental factors to clinical outcomes. This computational system will empower pharmaceutical companies to create customized drugs, i.e., drugs that render maximum efficacy and minimize side effects based on an individual's genotype. The company's flagship product, **HelixTree**, is being developed in collaboration with **GlaxoSmithKline,** where successful determination of candidate genes has been accomplished.
www.goldenhelix.com

Intermountain Biological Medical Services Kalispell 406-752-8101
Medical testing and repair

International Heart Institute Missoula 406-728-4558
(and related companies)
Researches, develops, and sells stents and heart valves
http://www.saintpatrick.org/ihi/

Kinetic Sports Interactive Missoula 406-829-3318
Develops and markets medical exercise equipment

Ligocyte Pharmaceuticals, Inc. Bozeman 406-585-2733
Uses proprietary technologies to develop flow of therapeutic drugs and vaccines (formerly Montana Immunotech)
www.ligocyte.com

McLaughlin Research Institute for Biomedical Sciences Great Falls 406-452-6208
non-profit
Biomedical research and transgenic facility that offers a range of services for the production and preservation of genetically modified mice
http://www.montana.edu/wwwmri

Medical MultiMedia Group, LLC (MMG) Missoula 866-721-3072
Support service – not a core member
Information tools that make complex medical concepts understandable and effectively deliver that information to patients
http://www.sechrest.com/mmg/

MedIntel Helena 406-449-4741
Mathematical chemistry information systems, combinatorial chemistry for biotechnology applications

MMP (Montana Microbial Products) Missoula
Cliff Bradley
Develops enzyme technologies for agricultural uses

Montana Biotech Corp. Belgrade 406-388-0942
Commercial R&D, analytical laboratory
Specializes in developing commercial products from microorganisms living in extreme environments, such as boiling, acidic, or radioactive water

Montana Medical Research, LLC Missoula 406-549-1124
Clinical Trial Research in a broad spectrum of therapeutic specialties

Montana Microbiological Service Bozeman 406-586-5590
Full service analytical facility – provides analyses and consulting services for public health, mining, petroleum, and environmental based industries

Montec Butte 406-494-5555
Larry Farrar
Bioreactor

MorTan, Inc. Missoula 406-728-2522
Markets eye irrigation devices

MorTech Missoula 406-542-7040
Develops and manufactures plastic medical devices

MPA Bozeman 406-556-0272
Charley Spangler
Develops products to be used in cancer diagnostics and therapy (incubator)

MSE Applications Butte 406-494-7100
Biofilm applications
Business development: Neal Egan, 406-494-7367

Neurogenic Technologies, Inc. Missoula 406-549-4649
Develops, manufactures and markets devices for evaluating muscle tone
http://www.neurogenic.com

Nurture Inc. Missoula 406-728-0260
Biotechnology Research
Developer, manufacturer and marketer of proprietary, high value-added ingredients derived from oats and other cereal grains. Lead product, OatVantage™, is a highly concentrated soluble oat fiber that benefits cardiovascular health, diabetes, and weight management.

Nutritional Laboratories □ Missoula □ 406-273-5493
Pharmaceutical OEM Manufacturing

Omega Biologicals Bozeman 406-586-3790
Manufactures biotechnological and biological products; supplier of antibodies and antigens to medical diagnostic test kit manufacturers
www.omegabiologicals.com

Planet Natural Bozeman 406-587-5891
(formerly Bozeman Bio-Tech) are retailers and wholesalers, supplying a wide range of beneficial insects, organic fertilizers, traps and lures, weed control products, microbial insecticides, etc.

Pyron Technologies □ Missoula □ 406-543-9211
Medical compliance consulting

Quad Five – Materials Bio, Inc. Ryegate 406-568-2911
Located in the heart of Montana rangeland, QUAD FIVE offers quality donor animal blood products. All QUAD FIVE donor animals are carefully selected and maintained under veterinary care and diagnostic protocols.

Purity Systems, Inc. □ Missoula □ 406-532-3237
Resins to remove toxic metals from solutions

Rocky Mountain Laboratories Hamilton □ 406-363-3211
Federal lab
Large laboratory of the National Institute of Allergy and Infectious Diseases

SGM Biotech, Inc. Bozeman 406-585-9535
John Gillis
Manufactures biological indicators for sterilizing companies
http://www.sgmbiotech.com/

Specialty Surgical Products Victor 406-961-0102
Develops and manufactures medical implants

Sunburst Sensors □ Missoula □ 406-243-4118
Self-calibrating chemical sensors

TRI LTD. □ Hamilton 406-363-0571
Medical regulatory compliance consulting

Transgenic Systems Inc Bozeman 406-587-8556

Veridical Research and Design Bozeman 406-522-9045
Specializes in the domain of visual perception and cognition, with emphasis in the areas of visual search, color and texture perception, memory and attention, and the use of eye

movement technology.
http://www.veridicalresearch.com/

Western Plant Breeders Bozeman 406-587-1218
Agricultural Research
Research and development company for cereal grains in the North America. Western Plant Breeders combines a rich tradition of growing experience with leading edge technologies to create and breed cereal grain seed. These licensed varieties are marketed through a network of associate seed companies located throughout the North America.

Endnotes

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[ii] Ibid

[iii] Cortright and Mayer.

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[v] Biotechnology Industry Organization. (2002). *Biotechnology Industry Statistics*. Retrieved from http://www.bio.org/er/statistics.asp

[vi] Ibid.

[vii] Ibid.

[viii] US Business Reporter

[ix] Cortright, Joseph, and Heike Meyer. *Signs of Life: The Growth of Biotechnology Centers in the U.S.* The Brookings Institution Center on Urban and Metropolitan Policy. Washington, DC: June 2002.

[x] Massachusetts Biotechnology Council & The Boston Consulting Group. *MassBiotech 2010: Achieving Global Leadership in the Life-Sciences Economy*. Boston, MA: 2002

[xi] Biotechnology Industry Organization. (2002). *Biotechnology Industry Statistics: Agriculture.* Retrieved from http://www.bio.org/er/agriculture.asp