Preparing today’s students for the biotechnology workforce of tomorrow

Massachusetts Biotechnology Industry Overview

Life Sciences Career Development Pilot Project
A project of the MassBioEd Foundation and its flagship program, BioTeach

Suzanne Grillo, Program Manager
Metro South/West Regional Employment Board
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What is Biotechnology?

**Bio**—the use of biological (life) processes

**Technology**—solve problems or make useful products
Biotechnology...

a collection of technologies that capitalize on the attributes of cells
Example: their manufacturing capabilities

AND

put biological molecules to work for us
Example: DNA and proteins

*Altering live cells and putting them to work.*
Biotechnology Timeline

- 1953 James Watson and Francis Crick, using crucial evidence gathered by Rosalind Franklin, discover the double-helix structure of DNA.
- 1973 California biochemists Stanley Cohen and Herbert Boyer create the first recombinant DNA organism, work that forms the basis for modern biotechnology.
- 1975 Scientists gathered at the Asilomar Conference recommend the National Institutes of Health provide guidelines for recombinant DNA research.
- 1976-77 The Cambridge City Council holds hearings on the safety of recombinant DNA research and passes the country’s first ordinance regulating the work.
- 1978 Harvard University professor Walter Gilbert, MIT professor Phillip Sharp, and others found the biotechnology company Biogen (now Biogen Idec Inc.).
- 1980 The US Supreme Court rules in Diamond v. Chakrabarty that genetically engineered microorganisms can be patented.
Biotechnology Timeline

- 1980 The Bayh-Dole Act allows universities to hold patents on federally funded research.
- 1981 Genzyme Corp. sets up shop on the 17th floor of a building in Chinatown.
- 1982 The Food and Drug Administration approves the first biotechnology therapy, a human insulin drug made by Genentech.
- 1982 Whitehead Institute is founded in Cambridge. It becomes a leading research center, and provided about one-third of the human genome sequence in 2000.
- 1991 Genzyme’s Ceredase is approved to treat Gaucher’s disease; the recombinant DNA version of the drug was approved three years later and last year posted $1 billion in sales.
Biotechnology Timeline

- 1994 FDA approves the first genetically engineered food, the Flavr Savr tomato. The product never makes it to market.
- 1996 FDA approves Biogen’s Avonex, a recombinant interferon drug used to treat multiple sclerosis that is now a “blockbuster,” with more than $1 billion in sales each year.
- 1996 Dolly the sheep is cloned.
- 1998 Human embryonic stem cell lines are established.
- 2000 “Working draft” of the human genome’s 3.15 billion letters is completed after a decade of research.
- 2003 Broad Institute is founded in Cambridge to give scientists access to the human genome project, and to understand the molecular basis of disease.
- 2006 Craig C. Mello, a University of Massachusetts researcher, shares the Nobel Prize with Andrew Fire of Stanford University
Massachusetts: a biotechnology hub employing nearly 43,000 workers

Source: U.S. Bureau of Labor Statistics and MBC*

* The MBC uses estimated proportions of federal numbers based on the biotech industry's share of certain North American Industry Classification System (NAICS) codes in the state of Massachusetts.
Biotechnology Applications and Industries

- Agriculture
- Consumer Products
- Environmental Applications
- Food Safety
- Healthcare
What Do Biotech Companies Do

- Agricultural Biotechnology
- Bio-Medical Devices
- Bioinformatics Services
- Research Instruments & Reagents
- Contract Manufacturing
- Human Diagnostics
- Contract Research
- Human Therapeutics

- Other
  - Environmental Biotechnology
  - Industrial Biotechnology
  - Marine Biotechnology
  - Platform Technologies
  - Veterinary Diagnostics/Therapeutics
Massachusetts has strong research and product representation in 8 major commercial market sectors within the biotechnology industry.
Agricultural Biotechnology (AKA "AgBio")

Companies that focus on the development of tools, technologies, and products needed to create a greater and safer food supply:

- Increase agricultural yields,
- Enhance the nutritional value of foods
- Provide environmentally-friendly pest control methods
Agricultural Biotechnology
Market Overview

- Hunger and malnutrition are major problems in developing and developed areas of the world.
- Food and Agriculture holds a great deal of promise for the biotechnology industry.
- One of the largest components of U.S. economy.
Agricultural Biotechnology Applications

- Biopesticides
- Diagnostics
- Environment Adaptations
- Genetically modified food

- Natural Fertilizers
- Nutraceuticals
- Transgenics
Massachusetts Agricultural Biotechnology Companies

- **Metabolix, Inc.**
  Cambridge, MA
  *55 employees*

- **Mascoma Corporation**
  Cambridge, MA
  *24 employees*

- **SunEthanol Inc.**
  Cambridge, MA
  *5 employees*
Bio-Medical Devices

Companies use naturally derived materials to make medical appliances, such as those that are used in reconstructive surgery:

- Bone
- Cartilage
- Heart valve replacements
- Skin grafts
Bio-Medical Devices
Applications

- Tissue Regeneration & Engineering
- Skin Grafts/Wound Closures
- Wound Healing Devices

- Drug-Coated Stents
- Microdevices (e.g. embedded drug delivery devices)
- Bone Growth Devices
Massachusetts
Bio-Medical Devices Companies

- **ABIOMED, Inc.**
  Danvers, MA
  320 employees

- **TEI Biosciences, Inc.**
  South Boston, MA
  55 employees

- **Organogenesis, Inc.**
  Canton, MA
  190 employees

- **SeraCare Life Sciences, Inc.**
  West Bridgewater, MA
  80 employees

- **Confluent Surgical**
  Waltham, MA
  62 employees

- **ECI Biotech**
  Worcester, MA
  14 employees
Bioinformatics Services

- Computer-based tools addressing biological questions.
- Important discipline facilitating modern biological research which involves the generation, analysis and storage of massive amounts of data.
Bioinformatics Services
Market Overview

Advent of genomics and proteomics has created an explosion of biological information.

To realize the full potential of this information, researchers need new methods for organizing, storing, and mining massive amounts of data.

*Example:* DNA sequencing and analysis to assist with drug targeting
Massachusetts Bioinformatics Services Companies

- **Compucyte Corporation**
  Cambridge, MA
  20 employees

- **GenomeQuest, Inc.**
  Westborough, MA
  20 employees

- **GulfStream Bioinformatics**
  Lexington, MA
  17 employees

- **Schering-Plough Research Institute - Cambridge**
  Cambridge, MA
  87 employees

- **U.S. Genomics, Inc.**
  Woburn, MA
  85 employees
Contract Manufacturing

Biotechnology companies that lack internal manufacturing capabilities contract with manufacturing companies to make significant supplies of therapeutic products.

Manufacturing companies offer a range of services and volume capabilities:

- Small Amounts
  - Pre-clinical trials and development
- Larger Volumes
  - Clinical trials and commercialization
Biotechnology companies must make enough of their product to have sufficient quantities for testing in clinical trials.

Upon FDA approval, the biotechnology company must decide between building its own large facility to manufacture the product for the marketplace or fully contract that activity to another firm.
Massachusetts Contract Manufacturing Companies

- **Formatech, Inc.**
  Andover, MA
  51 employees

- **GLSynthesis, Inc.**
  Worcester, MA
  23 employees

- **Cell Essentials, Inc.**
  Boston, MA
  10 employees

- **Hyaluron Contract Manufacturing**
  Burlington, MA
  65 employees

- **Dow Biopharmaceutical Contract Manufacturing**
  Danvers, MA
  30 employees
Contract Research

Drug development requires specific skills and precise studies that extend beyond the research capabilities of some biotechnology companies.

To meet these needs, companies may outsource clinical and even pre-clinical research to specialized organizations, called Contract Research Organizations (CRO).
Biotechnology companies have increased the use of Contract Research Organizations (CRO) substantially over the past 5 years.

This reflects increased spending on traditional CRO services of Phase III study monitoring, data management, *pharmacoeconomic analysis* and medical writing.

Increasingly, areas of basic research are being supported by contracts with leading academic and medical institutions that possess focused research areas.
Massachusetts Contract Research Companies

- **BattelleCRO, Inc.**
  Newton, MA
  125 employees

- **Cambridge Biomedical Research Group**
  Allston, MA
  26 employees

- **Charles River Labs**
  Wilmington, MA
  1,000 employees

- **MicroTest Laboratories Inc.**
  Agawam, MA
  50 employees

- **Abt Associates**
  Lexington, MA
  54 employees

- **Accovion Inc.**
  Boston, MA
  3 employees
Research Instruments & Reagents

- Instrumentation & biological reagent companies work to improve the efficiency and efficacy of drug development research and testing done by universities, hospitals, and private companies

Example: Microassay technology improves drug targeting analysis
Research Instruments & Reagents
Market Overview

Research instrumentation technology requires multidisciplinary approaches using powerful tools from applied mathematics, applied physics, chemistry, engineering and computer science to solve biological problems.

These products yielding novel ways to discover potential disease therapies by revealing thousands of new biological targets FASTER.
Research Instruments & Reagents
Applications

- Micro-assay Technology
- Microfluidic Technology
- DNA Diagnostics
- Medical Diagnostic Testing
Massachusetts Research Instruments & Reagents Companies

- **Proteome Systems**
  Woburn, MA
  130 employees

- **SeraCare Life Sciences, Inc.**
  West Bridgewater, MA
  80 employees

- **Caliper Life Sciences**
  Hopkinton, MA
  1000 employees

- **Cell Signaling Technology**
  Danvers, MA
  80 employees

- **Millipore Corporation**
  Billerica, MA
  1,100 employees
Human Diagnostics

Companies in this sector focus on the identification of the presence or absence of specific chemicals, genes, or proteins within the body which may indicate disease or malfunction of human processes.
Diagnostic products have a shorter development cycle and lower development risks and costs than medical therapeutics.
Diagnostic products are not required to go through the arduous process of human clinical trials.

Because early detection is a pillar of cost-effective health care, the market demand for more sensitive, specific and cost-effective diagnostic products and processes is likely to explode in the next few years.
Human Diagnostics Applications

- Biological Imaging
- Biosensors
- DNA Probes
- Monoclonal Antibodies
- Polymerase Chain Reaction (PCR)
Massachusetts
Human Diagnostics Companies

- Athena Diagnostics, Inc.
  Worcester, MA
  300 employees

- Bristol-Myers Squibb Medical Imaging
  Billerica, MA
  500 employees

- AdvanDx
  Woburn, MA
  22 employees

- Exact Sciences Corp.
  Marlborough, MA
  21 employees

- Osmetech
  Rockland, MA
  75 employees

- Predictive Biosciences, Inc.
  Lexington, MA
  10 employees

- Matritech Inc.
  Newton, MA
  84 employees
Human Therapeutics

Development and/or production of new and unique drugs for the treatment of human diseases and disorders such as:

- Cancer
- Alzheimer’s Disease
- Multiple Sclerosis
- AIDS
- Diabetes
- Tuberculosis
- Cystic Fibrosis
- Asthma
What is a clinical trial?

A clinical trial (also clinical research) is a research study in human volunteers to answer specific health questions. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people and ways to improve health.
Drug Development Process

On average, it takes 10-15 years to develop a drug, from basic research through FDA approval.

<table>
<thead>
<tr>
<th>Clinical Phase</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>70%</td>
</tr>
<tr>
<td>Phase II</td>
<td>33%</td>
</tr>
<tr>
<td>Phase III</td>
<td>25-30%</td>
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Drug Development Process

**Discovery**
- Synthesis of Compounds
- Studies in Healthy Volunteers (Phase I)
- Early Safety Studies
- Candidate Formulations Developed
- Extensive Safety Studies
- Candidate Medicine Tested in 300-10,000 Patients (Phase II)
- Clinical Data Analysis
- NDA/MMA

**Exploratory Development**
- Project Team and Plans

**Full Development**
- Studies in 100-300 Patients (Phase II)
- Large Amounts of Candidate Medicine Synthesized

**Registration**
- Extensive Safety Studies
- NDA/MMA
- Studies in 100-10,000 Patients (Phase III)
- Clinical Data Analysis
- Candidate Medicine Tested in 300-10,000 Patients (Phase III)
Human Therapeutics
Market Overview

Risks in gaining approval for a new biological drug are very high.

- Of those drugs that complete Phase III trials and apply for a New Drug Application (NDA), approximately 75% will gain approval.

- Out of 200 drugs that enter pre-clinical tests, only one will gain approval.
Human Therapeutics Applications

- Therapeutics
- Vaccines
- Gene Therapy
- Human Growth and Other Hormones
Massachusetts
Human Therapeutics
Companies

- **ABBOTT Bioresearch Ctr, Inc.**
  Worcester, MA
  70,000 employees

- **Alkermes, Inc.**
  Cambridge, MA
  550 employees

- **Amgen, Inc.**
  Cambridge, MA
  20,000 employees

- **AstraZeneca R&D Boston**
  Waltham, MA
  50,000 employees

- **Biogen Idec, Inc.**
  Cambridge, MA
  2352 employees

- **Pfizer, Inc.**
  Cambridge, MA
  90,000 employees

- **Serono, Inc.**
  Rockland, MA
  4500 employees

- **Sepracor, Inc.**
  Marlboro, MA
  837 employees

- **Vertex Pharmaceuticals, Inc.**
  Cambridge, MA
  1,000 employees

- **Wyeth Biotech & Wyeth Research**
  Cambridge, MA
  52,000 employees
Other Market Sectors

This category includes important biotechnology sectors, such as environmental and veterinary, that currently do not have a large enough share of the market in Massachusetts to warrant a separate category definition.
Other Market Sectors

- Environmental Biotechnology
- Industrial Biotechnology

- Marine Biotechnology
- Platform Technologies
- Veterinary Diagnostics/Therapeutics
Website Resources

Massachusetts Biotechnology Industry Directory
www.massbio.org/directory

Access Excellence at the National Health Museum
www.accessexcellence.org

Biotechnology Industry Organization – www.bio.org

Biotechnology Institute-  www.Biotechinstitute.org

Northeast Biomanufacturing Center – www.biomanufacturing.org
Life Sciences... Key to the Future
The Partners

MASCA

Massachusetts Department of Education

Center for School Counseling

MassBiOEd

Outcome Research

The Metro South/West Regional Employment Board
End Notes

- Biotechnology Applications and Industries, Rosa Tang, from An Introduction to the Biotechnology Industry power point presentation
- **Access Excellence at the National Health Museum** [www.accessexcellence.org](http://www.accessexcellence.org)
- **Biotechnology Industry Organization** – [www.bio.org](http://www.bio.org)
- **Biotechnology Institute**- [www.Biotechinstitute.org](http://www.Biotechinstitute.org)
- **Northeast Biomanufacturing Center** – [www.biomanufacturing.org](http://www.biomanufacturing.org)