Welcome

Massachusetts BioReady Community Seminar

MassEcon
Location is everything.

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Massachusetts Biotechnology Council

BRT BUSINESS RESOURCE TEAM

Table of Contents

I. The Background on Biotechnology

a. What is Biotechnology?

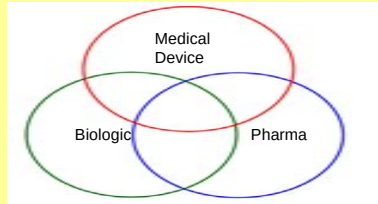
The use of biological processes to solve problems or make useful products.

Biotechnology is a collection of technologies that capitalize on the attributes of cells, such as their manufacturing capabilities, and put biological molecules, such as DNA and proteins, to work for us.

- Biologic-based medicines
- Biologic-assisted medical devices
- Biofuels
- Bio Agriculture
- Bio industrials

I. The Background on Biotechnology

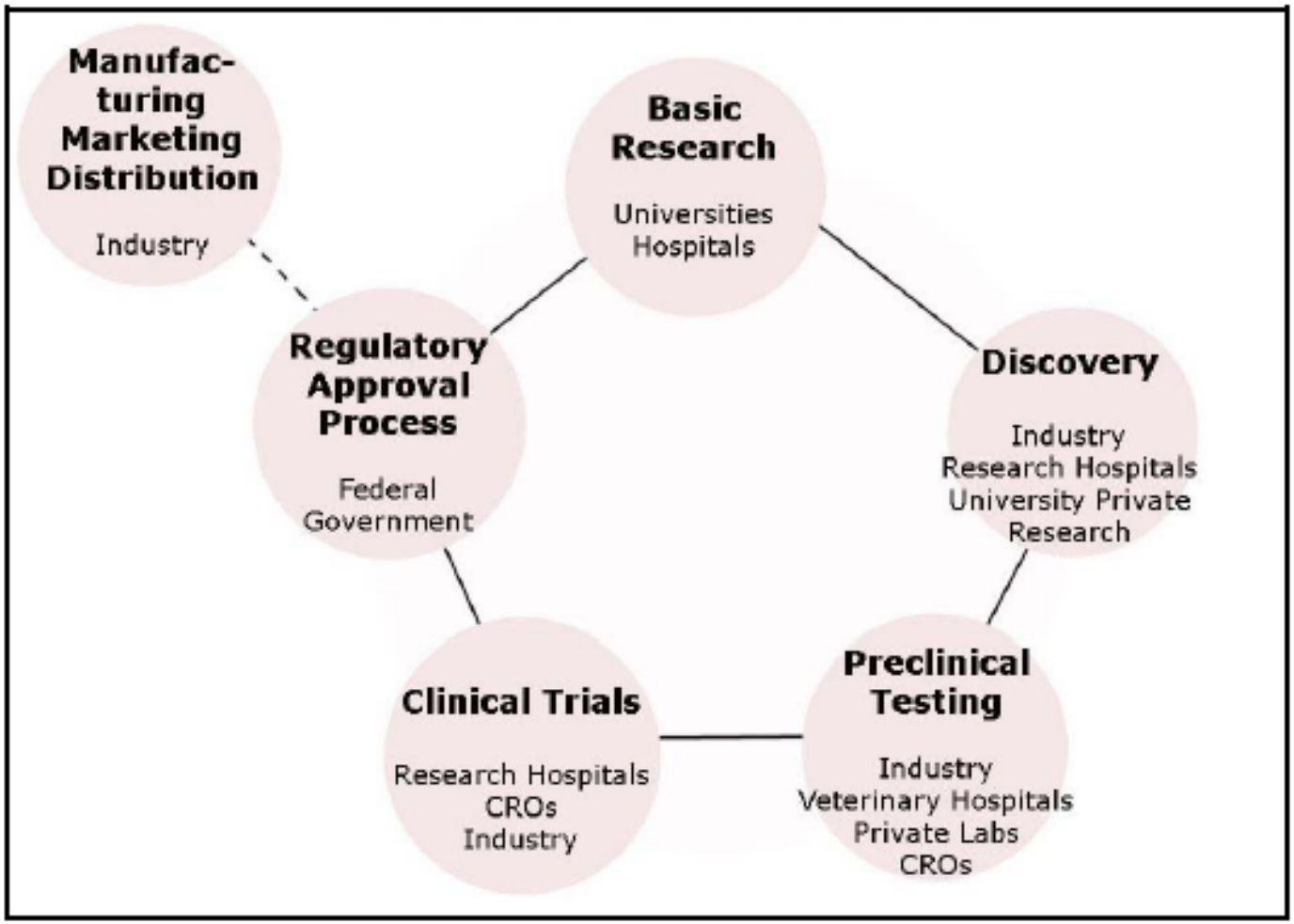
b. BioPharma Products

Pharmaceutical (Small Molecule)	Biologic (Large Molecule)	Combination Product
		
•A therapeutic compound with its source and manufacture being chemical (non-biologic) in nature. •Usually in pill form Examples: Advil (Wyeth Pharmaceuticals)	•A therapeutic product originating from or manufactured within living organisms •Incude: virus, toxin, vaccine, blood components, etc. •High molecular complexity, high sensitivity to manufacturing process •Usually injected Examples: Cerezyme® (Genzyme Corp.) EPOGEN® (EPOETIN ALFA) RECOMBINANT (Amgen Ltd.)	•One product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic •Examples:  (Drug-eluting Stent, Boston Scientific)  (Insulin Detector/Pump, Medtronic)

I. The Background on Biotechnology

c. The Business Model

Figure 1: Bio-pharma Development Lifecycle: Phases and Institutional Players



Source: UMass Donahue Institute, 2006.

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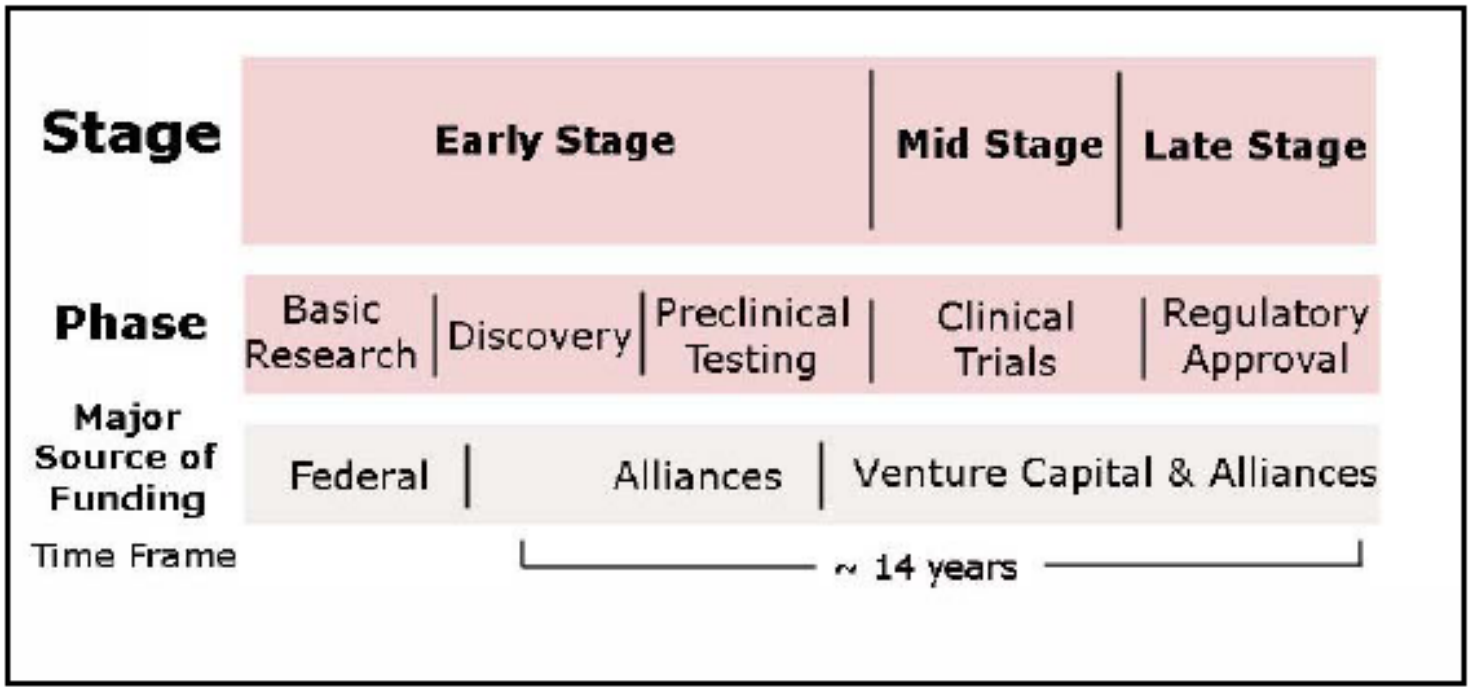
I. The Background on Biotechnology

c. The Business Model

Figure 2: Bio-pharma Discovery Process: Sources of Funding by Stage



Source: UMass Donahue Institute, 2006.

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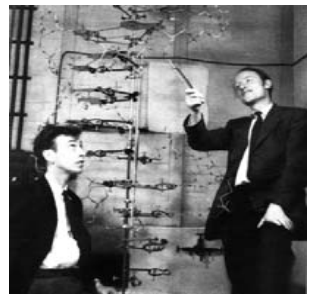
II. Biotech in Massachusetts

II. Biotech in Massachusetts: A Timeline

1953 — Double helix of DNA explained by Watson & Crick



1978 — Biogen founded

1980 — U.S. Supreme Court approves patenting of recombinant life forms

1985 — MBC becomes the 1st biotechnology industry association

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2000 — Map of the human genome is completed

2002 — Novartis locates Global Research HQ in Cambridge, MA

2006 — BMS chooses to build $1b facility in Devens, MA

2007 — Gov. Patrick Announces $1b Life Sciences Initiative

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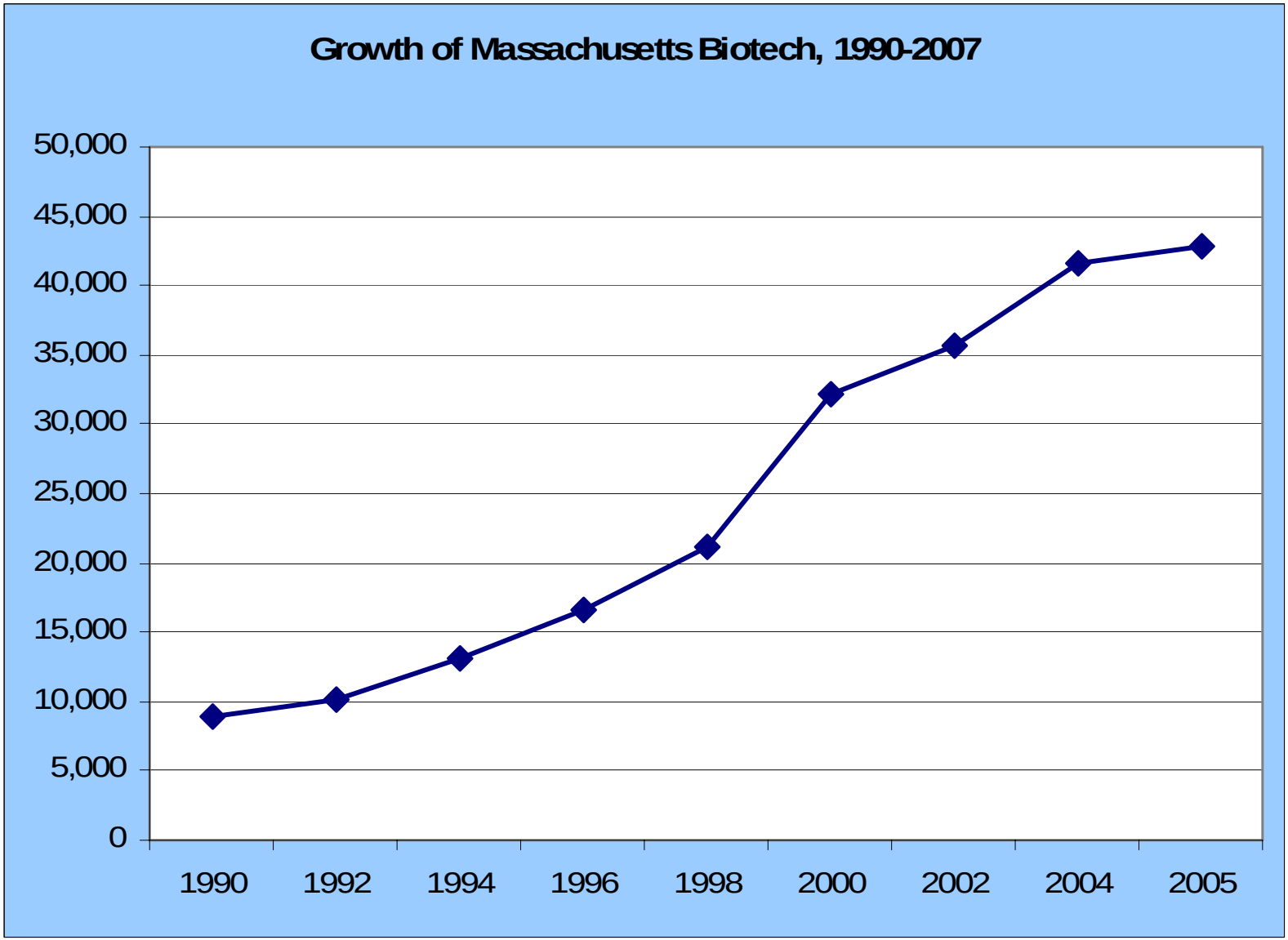
II. Biotech in Massachusetts



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II. Biotech in Massachusetts

Wyeth Biotech, Andover

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II. Biotech in Massachusetts

Millipore Corp., Bioprocess R&D Center, Bedford, MA.

II. Biotech in Massachusetts

Abbott Bioresearch Center, Worcester, MA

II. Biotech in Massachusetts

Caliper Life Sciences, Hopkinton, MA

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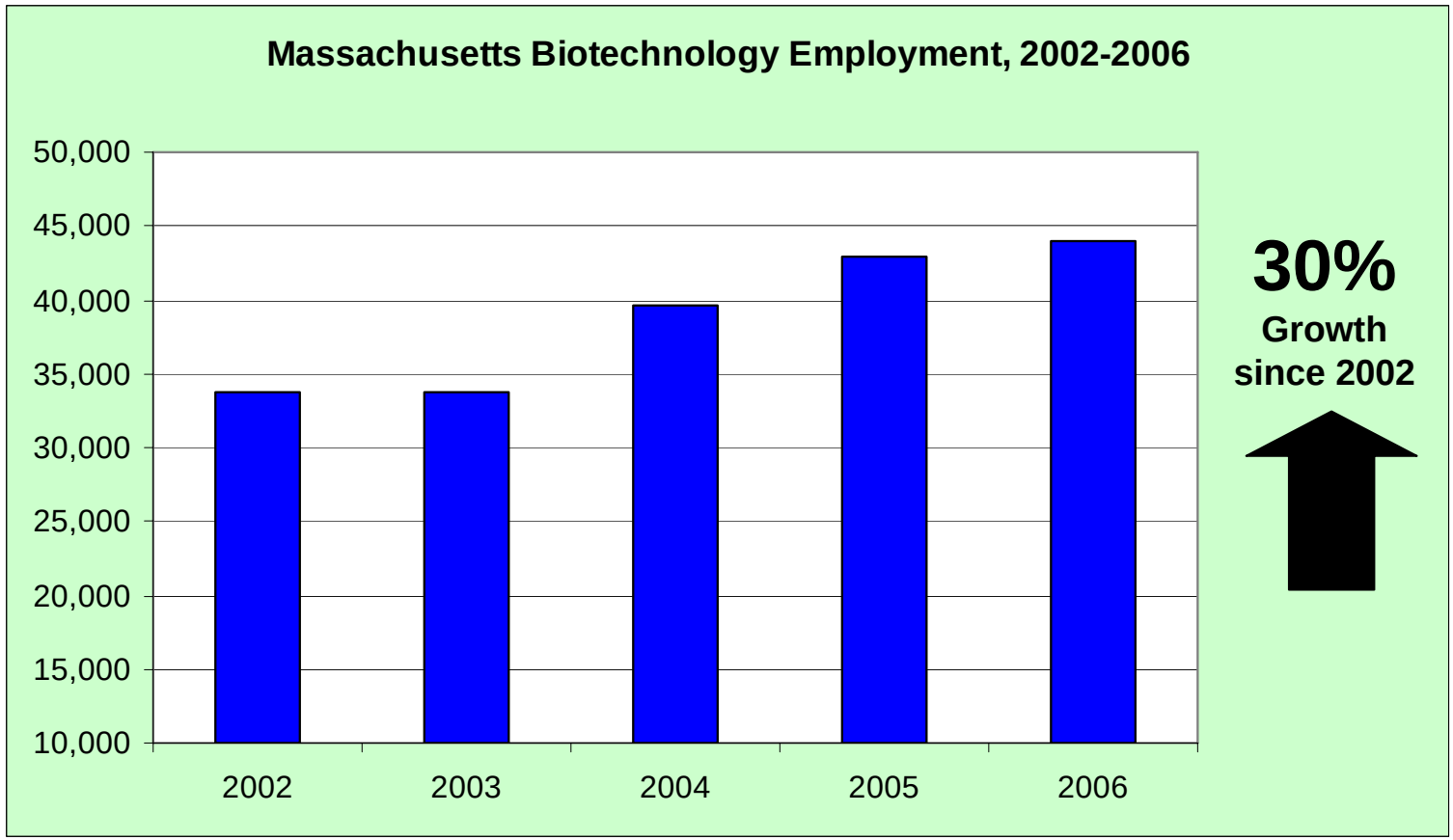
II. Biotech in Massachusetts

AstraZeneca R&D Boston, Waltham, MA

A Growing Industry

420+ Biotechnology Companies
237 Companies in Drug Development



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III. Massachusetts as a Global Biotech Player

Biotech is a U.S. Industry

Global Revenues, 2006:	$73.5 billion
U.S. Revenues, 2006:	$55.5 billion
Europe revenues, 2006:	$11.5 billion
Canada, 2006:	$ 3.2 billion
Asia-Pacific, 2006:	$ 3.2 billion
Global R&D Expenditures:	$27.7 billion
U.S. R&D Expenditures:	$22.8 billion

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III. Massachusetts as a Global Biotech Player

7.27% of the Global Drug Development Pipeline

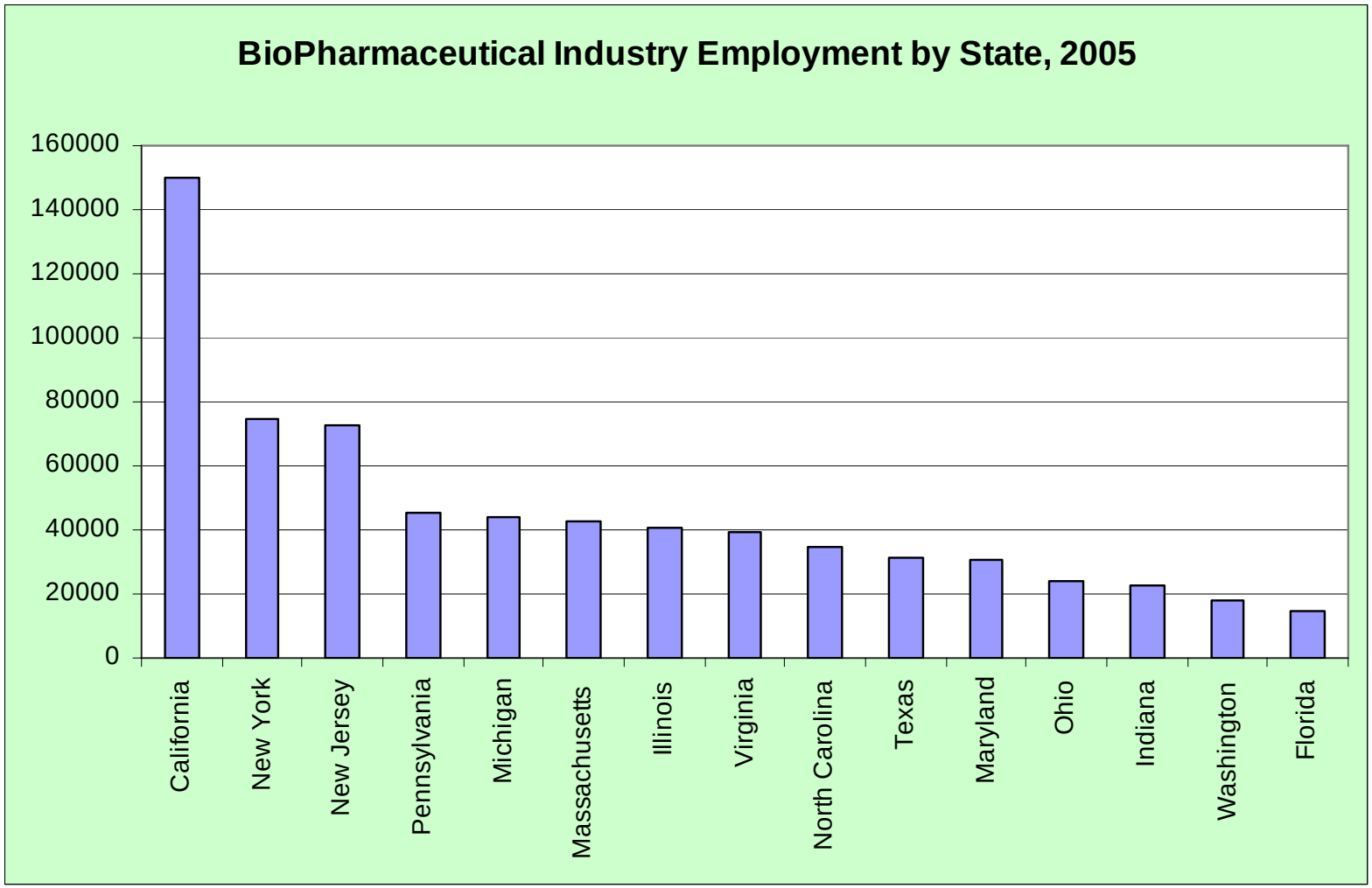
Massachusetts % of N.A. Pipeline		9.88%
Massachusetts % of Global Pipeline		7.27%

*Biopharm Insight Database 2/22/2007

Therapeutic Distribution of Massachusetts Pipeline

Therapeutic Area	Number of Companies	Total # of Investigational Drugs	Percent of MA Pipeline
Cancer		**496**	**28.04%**
Infectious Diseases		**169**	**9.55%**
Central Nervouse System		**149**	**8.42%**
Cardiovascular		**138**	**7.80%**
Immune System		**123**	**6.95%**
Other		**694**	**39.23%**
Hormonal Systems		89	5.03%
Musculoskeletal		83	4.69%
Diagnostic/Imaging Agents/Delivery		71	4.01%
Gastrointestinal		70	3.96%
Hematology		57	3.22%
Respiratory		54	3.05%
Dermatology		49	2.77%
HIV Infections		37	2.09%
Genitourinary		36	2.04%
Pain		33	1.87%
Eye & Ear		17	0.96%
Miscellaneous		98	5.54%
		1,769	100.00%

III. Massachusetts as a Global Biotech Player



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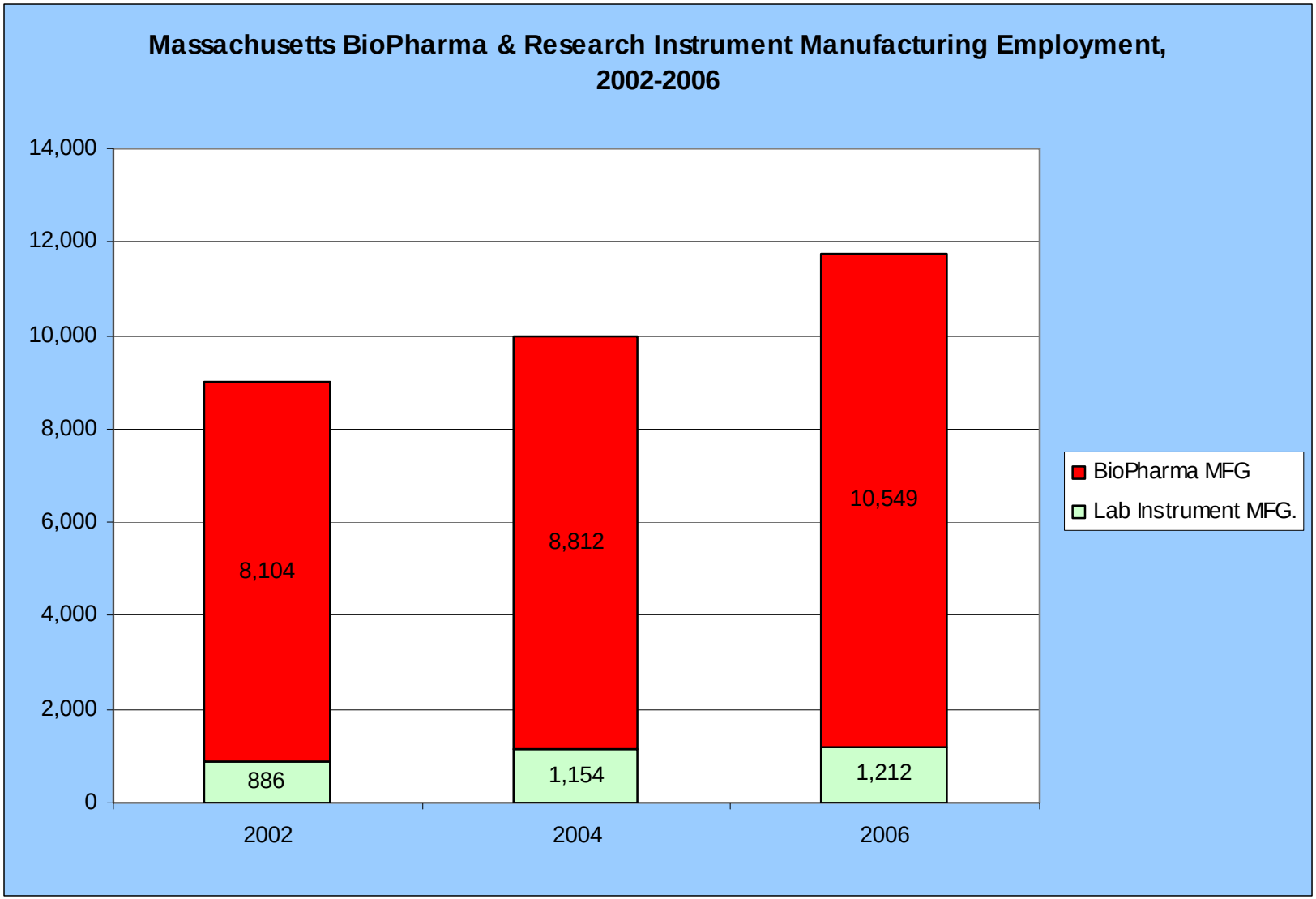
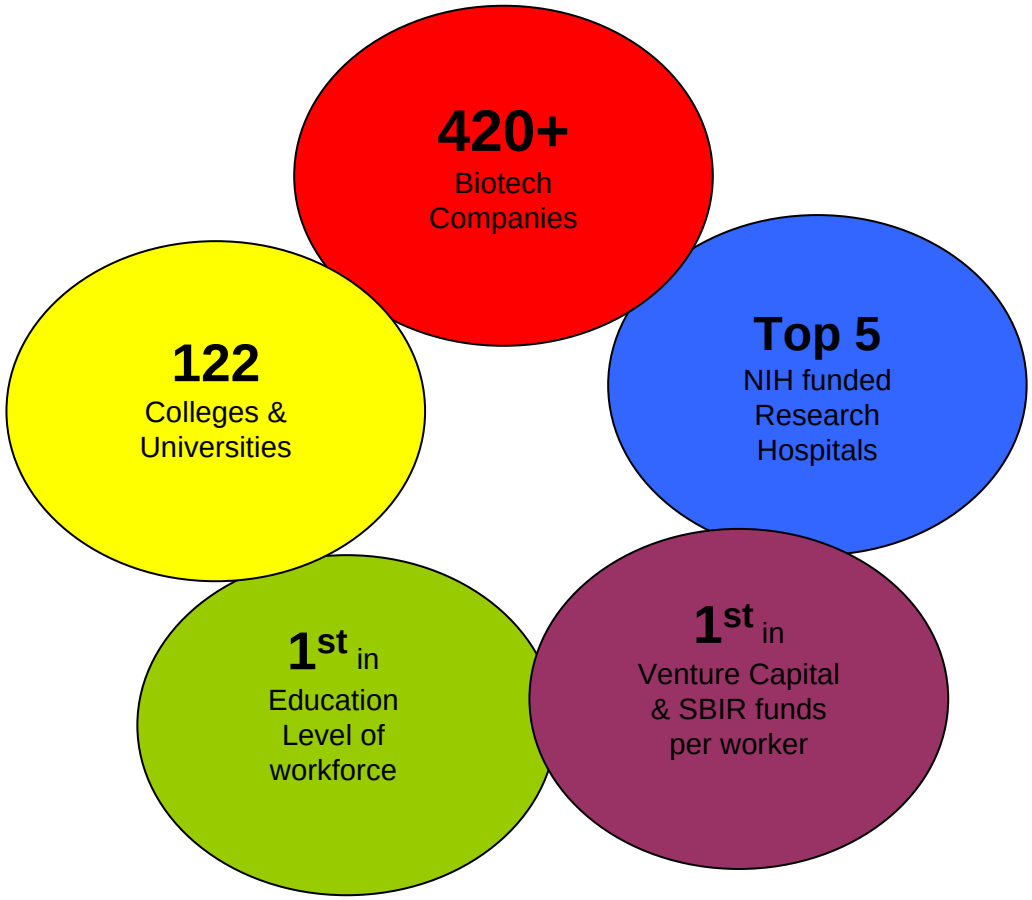
III. Massachusetts as a Global Biotech Player



III. Massachusetts as a Global Biotech Power
Why Massachusetts?

The Massachusetts Biotech Super Cluster



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III. Massachusetts as a Global Biotech Power

Between 2002-2006, biotechnology jobs increased by 30%, or 9,000 jobs.
- Massachusetts Biotechnology Council, 2008

Biotechnology jobs in MA grew at more than double the national rate for the industry.
- MassInc, *Mass Jobs* report, 2007

The Massachusetts share of the national biotech industry grew from 4.5 to 4.9%.
- MassInc, *Mass Jobs* report, 2007

Biotechnology accounts for $4 billion in payroll in Massachusetts.
- Massachusetts Biotechnology Council/Bureau of Labor Statistics, 2005

Life Sciences products account for $6 billion in exports from Massachusetts, or 25% of all Massachusetts exports.
- Mass Export Center, 2006

For each additional job in biopharmaceutical manufacturing in MA, 5 additional jobs in other industries are created.
- Northeastern University, Nov. 2007

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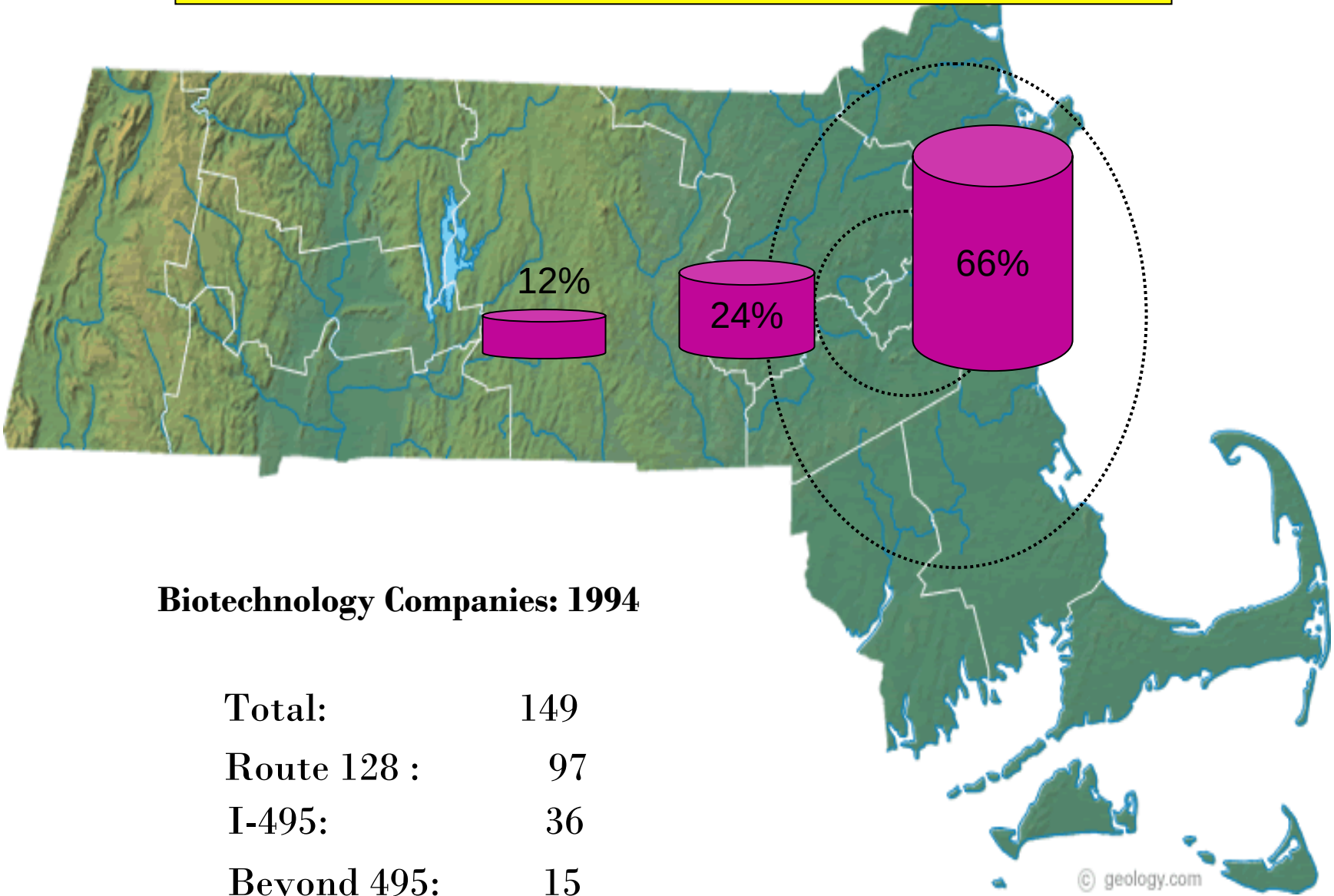
IV. The Geography of Biotech in Massachusetts



Biotechnology Companies: 1994

Total:	149
Route 128 :	97
I-495:	36
Beyond 495:	15

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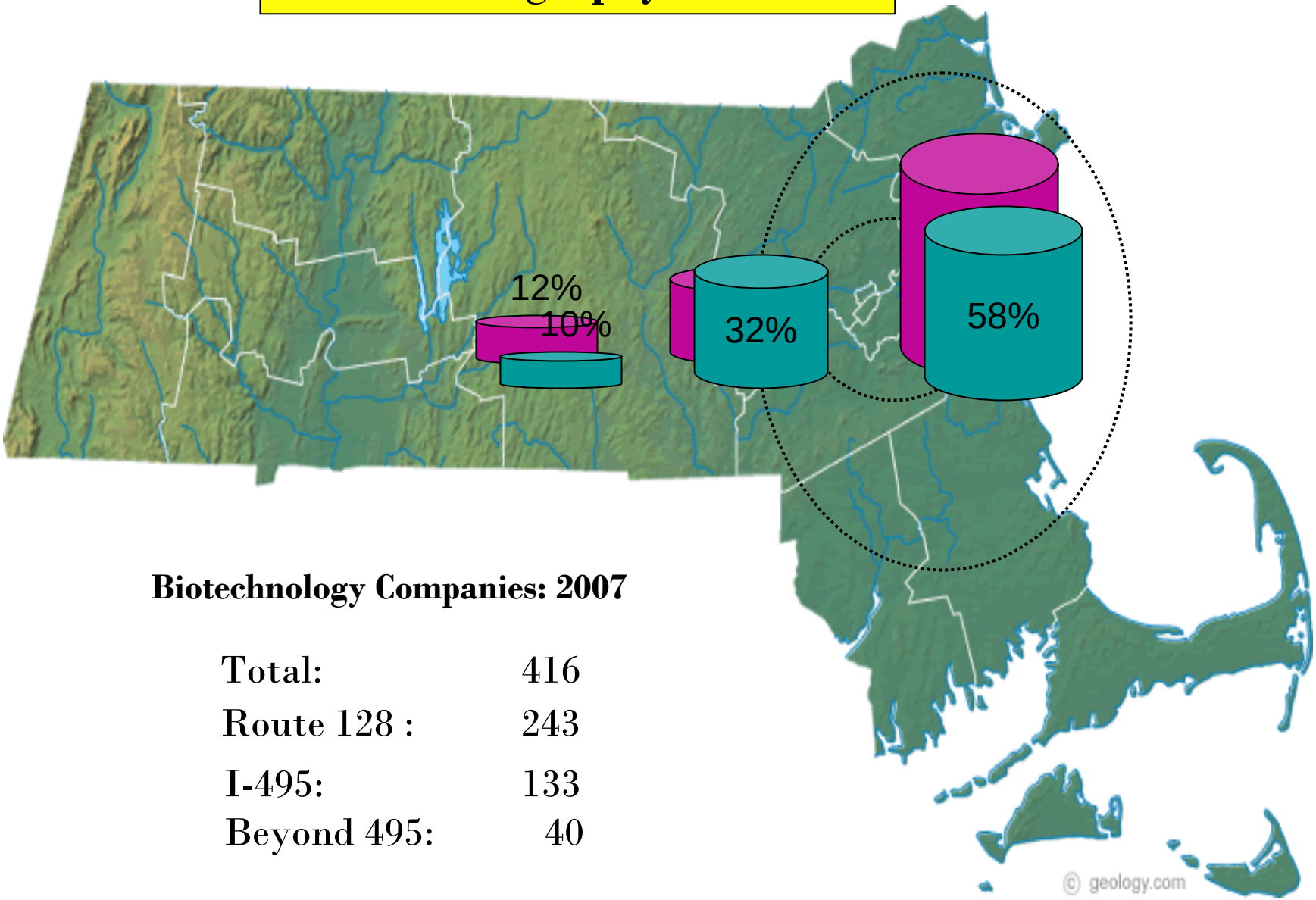
IV. The Geography of Biotech



Biotechnology Companies: 2007

Total:	416
Route 128 :	243
I-495:	133
Beyond 495:	40

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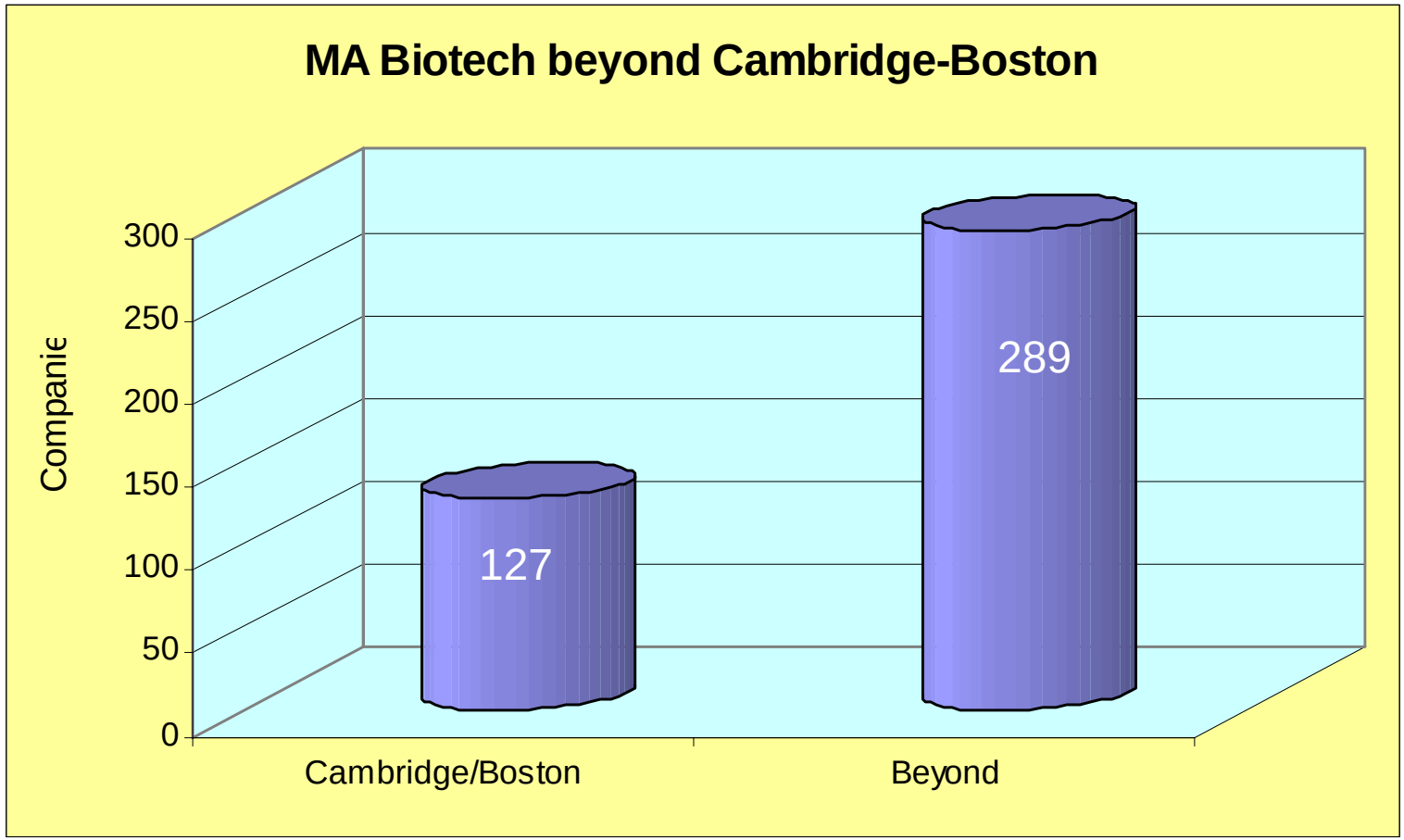
IV. The Geography of Biotech



69.5% of the biotechnology industry is outside of the Cambridge/Boston core

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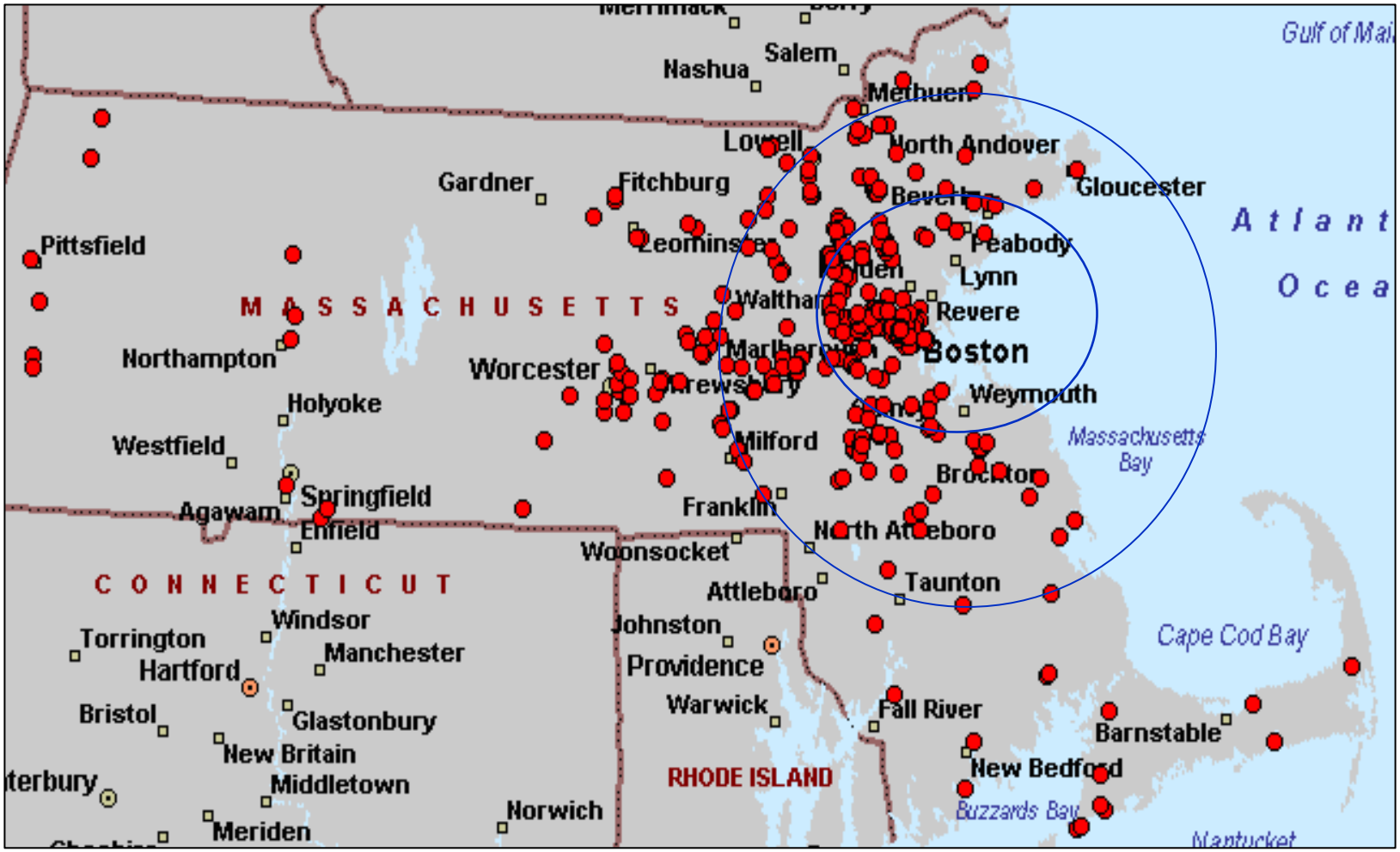
IV. The Geography of Biotech



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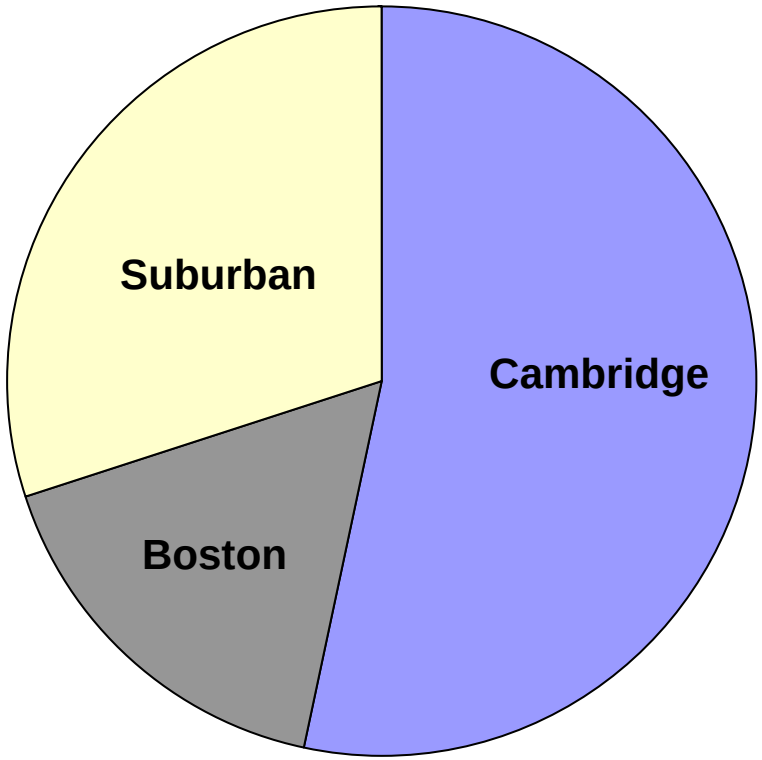
IV. The Geography of Biotech

Eastern Massachusetts Laboratory Space



V. Biotechnology Facilities

V. Biotechnology *Laboratory* Facilities

Biological Safety Cabinets

Chemical Fume Hoods

V. Biotechnology *Laboratory* Facilities

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V. Biotechnology *Manufacturing* Facilities

Clean Rooms

Fermentation Tanks

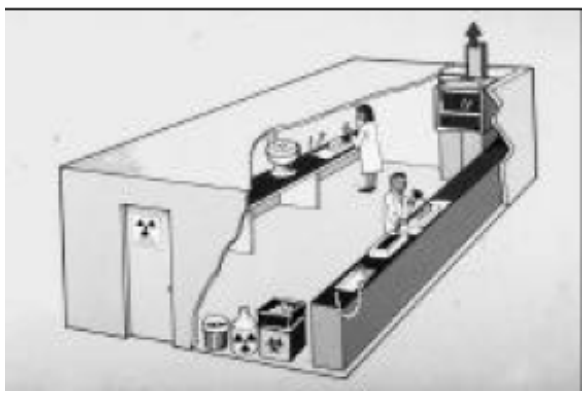
Bioreactor

V. Biotechnology *Manufacturing* Facilities

V. Biotechnology Facility: *Laboratory Safety*

BioSafety Level 1

Suitable for work involving well characterized agents not known to cause disease in healthy adult humans and of minimal potential hazard to laboratory personnel and the environment.

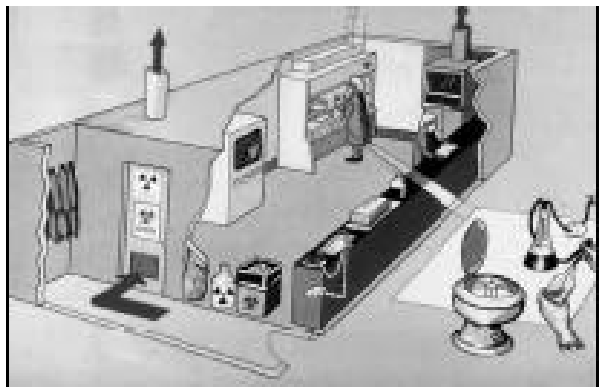


BioSafety Level 2

Suitable for work involving agents of moderate potential hazard to personnel and the environment.

BioSafety Level 3

Suitable for work with infectious agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.



Source: Centers for Disease Control

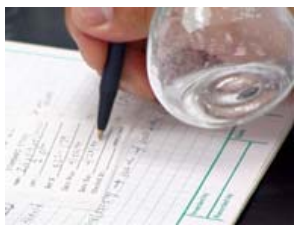
V. Biotechnology Facility: *Manufacturing Safety*

Good Manufacturing Practice regulations (GMPs) are used by pharmaceutical and medical device manufacturers as they produce and test products that people use. In the United States, the U.S. Food and Drug Administration (FDA) has issued these regulations as the minimum requirements.

- Human pharmaceutical products and veterinary products (21 CFR 210-211)
- Biologically derived products (21 CFR 600 and 21 CFR 620)
- Medical devices (21 CFR 820)

The manufacturing or "production" area is where the drug products are actually made with the active pharmaceutical ingredients and other materials such as high-purity water or sugars and other binding/lubricating agents. Depending on the final product, the manufacturing process can be very simple or extremely complicated.

Facilities
Control Room



Labeling in Laboratory

Laboratory Instrumentation

Quality assurance

Quality Control

Validation

Source: Learning Plus, Inc.

V. Biotechnology Facility *Requirements*

Minimum Basic Facility Requirements to be listed on the BioSites Inventory at **MassachusettsSiteFinder.com**

	Lab/R&D	Bio Manufacturing	Land
HVAC	Heating and cooling at 1.5cfm/sf	Heating and cooling at 1.5cfm/sf	
Electrical Capacity	20watts/sf	40watts/sf	
Floor loading	100lbs/sf	100lbs/sf	
Ceiling height – Floor to Floor	12’	20’	
Natural gas	Yes	Yes	Yes
Appropriate zoning	Yes	Yes	Yes
Municipal sewer connection	Yes	Yes	Yes
Municipal water connection	Yes	Yes	Yes

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V. Biotechnology Facility *Requirements*

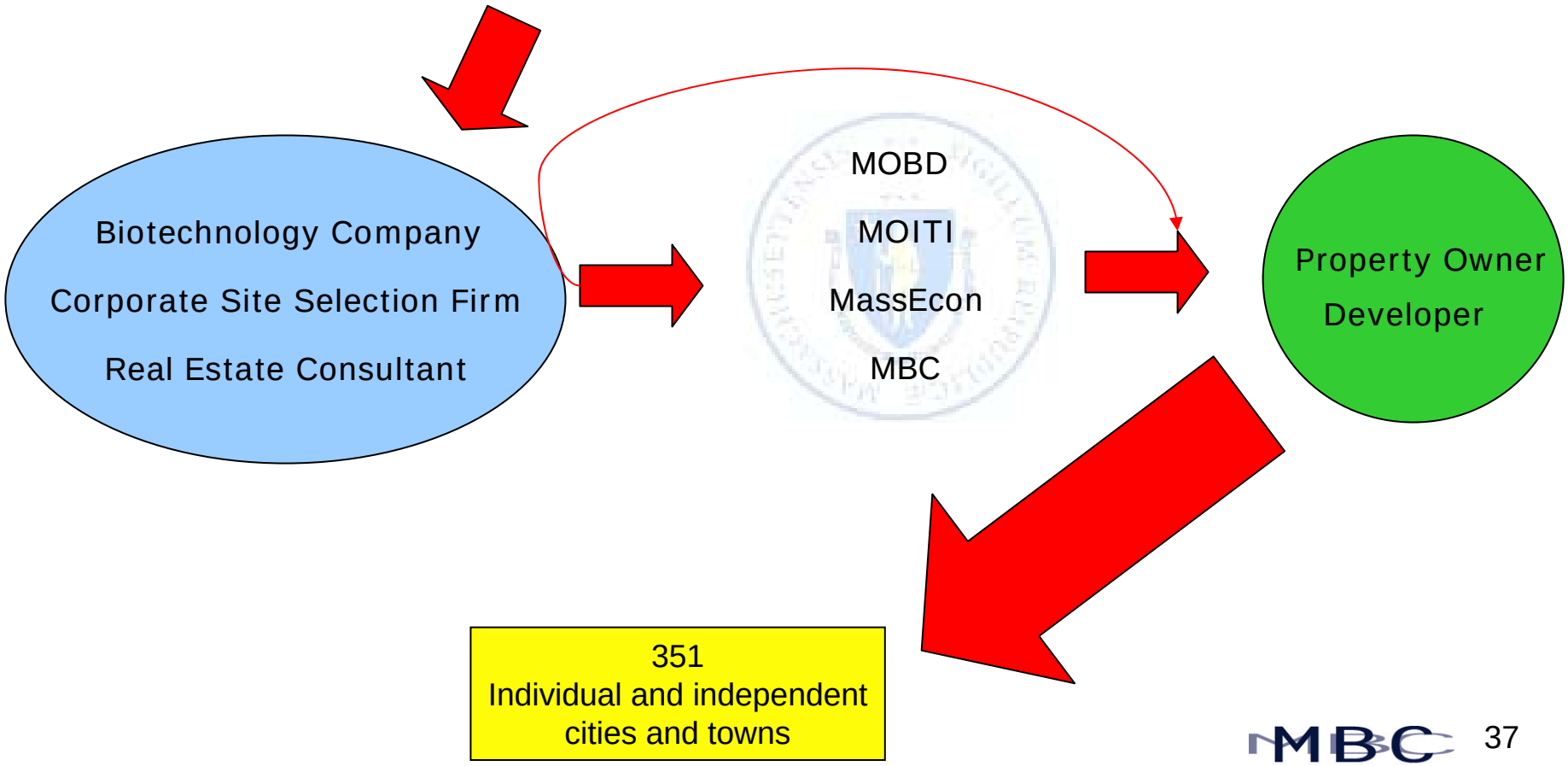
Snapshot of Lab & Plant Physical Requirements

	Hours of Operation	Floor to Floor heights	Electrical	Water	Sewer	Gas
Basic Research Facility	Typical business hours	14-18'	12 KV	8-20,000 GPD	Some pretreatment, use of neutralization tanks	Required
Process Development Facility	Typical business hours	14-18'	12 KV	20,000 GDP	Pretreatment using neutralization tanks	Required
Pilot Manufacturing	24 hours a day, 7 days a week	18-25'	15 KV	2,400 GPH per 1,000 s.f. (approx. 60,000 GPD for 30 K s.f. facility)	Adequate public sewer capacity. Discharges require kill syetems and pH pretreatment	Higher volume than research or process facilities.
Manufacturing	24 hours a day, 7 days a week	20-40'	25 KV with redundant supply	Varies, greater than Pilot facility, redundent supply often required. (1.5 M GPD for 100 k mfg space an example)	Adequate public sewer capacity. Discharges require kill syetems and pH pretreatment	High volume
Fill and Finish Facility	5 days of operation, 24/7 on utilities	25' minimum	12.5 KV	Varies, but significantly less than mfg. facility		Required

VI. Corporate Site Selection Process

Site Selection Criteria

Workforce	Infrastructure
Proximity to Assets	Readiness to Proceed
Business Environment	Costs
Incentives	



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VII. Preparing Municipalities for Biotech Opportunities

Appropriate Zoning

Providing a Clear Path

Identify and Prepare Sites for Biotech

Board of Health Regulations

MassBio Council's BioReady Community Rating System

Bronze

• Municipal water and sewer available in commercial and industrial areas.

• Zoning allows for biotech laboratory and manufacturing uses by *special permit*.

• Identified point of contact in town/city hall to assist biotech projects.

Silver

• **Bronze Criteria** *plus*

• Municipality allows biotech laboratory and manufacturing uses *by right*.
• Has identified buildings and/or land sites for biotechnology uses in municipal plans.

AND

• Municipality convenes site plan review meetings, bringing together all pertinent departments, to provide an overview of the local approvals process for significant commercial and industrial projects.

• Has land sites and/or buildings included in BioSites inventory at www.massachusettssitefinder.com

OR

• Community has identified Priority Development Sites per Chapter 43D
• Municipality has a site designated as a Massachusetts Growth District

Gold

• **Silver Criteria** *plus*

• Municipality has sites or buildings pre-permitted for biotechnology laboratory or manufacturing use, *OR*

• Municipality has existing buildings in which biotech laboratory or manufacturing activities are taking place.

Platinum

• **Gold** Criteria *plus*

• Municipality's Board of Health has adopted the National Institutes of Health guidelines on rDNA activity as part of its regulations.

• Municipality includes a building or buildings that are already permitted for biotech uses and have 20,000 square feet or more of available space for biotech uses.

OR

• Municipality has a shovel-ready pre-permitted land site with completed MEPA review and municipal water and sewer capacity to meet additional demand.

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