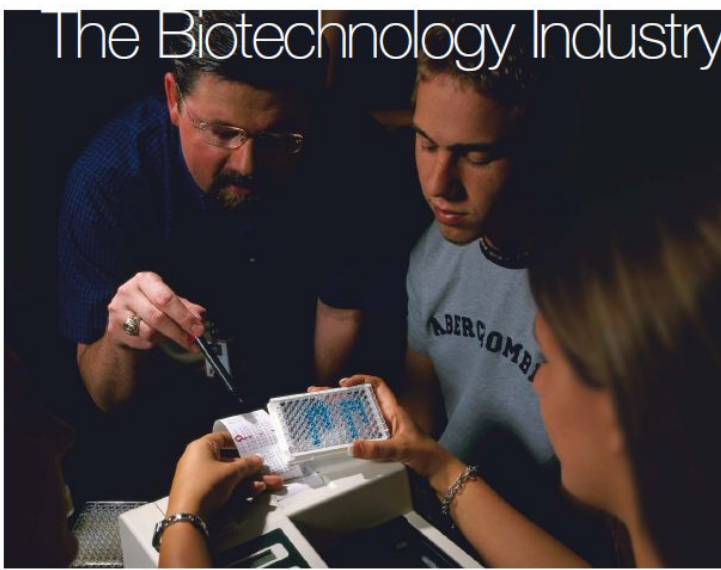


# The Biotechnology Industry



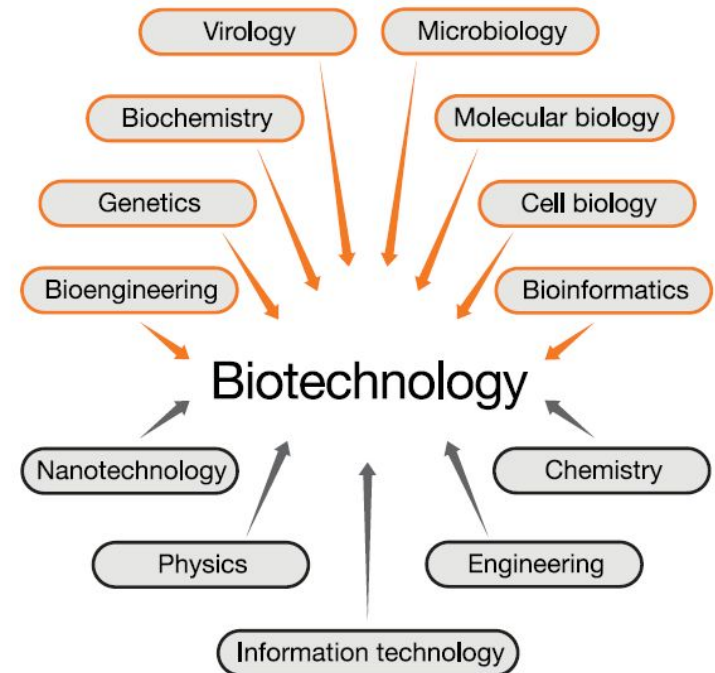
# The Biotechnology Industry

## Chapter 1: Background



# What Is Biotechnology?

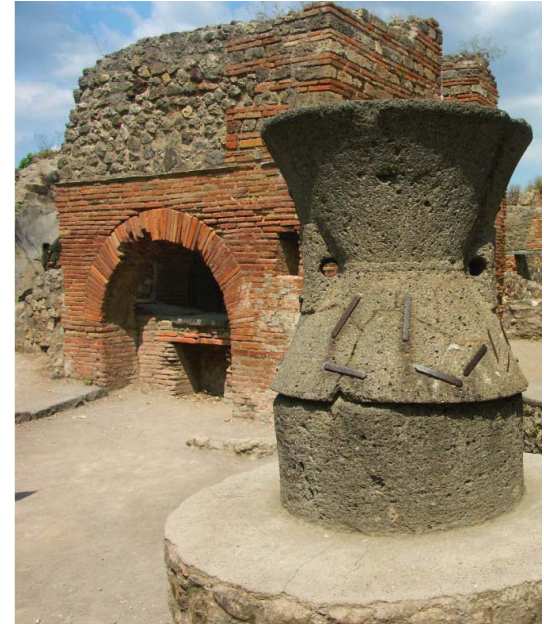
- **Biotechnology = technology based on biology in the broadest definition**
  - Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific uses.
    - United Nations Convention on Biological Diversity (1992, 2003)



Orange boxes are biological sciences and gray boxes are other scientific disciplines.

# Historical Uses of Biotechnology

- 4,000-2,000 BC: Egyptians use yeast to ferment beer and leaven bread
- 500 BC: Chinese use moldy soybeans to treat boils, the first use of antibiotics
- 1914: Bacteria are used to treat sewage for the first time in England
- 1962: Green fluorescent protein (GFP) is isolated by Osamu Shimomura, who won the Nobel Prize in 2008
- 1980: U.S. Supreme Court approves the principle of patenting an organism, allowing Exxon to patent an oil eating bacteria



Ancient bakery in Pompeii

# Historical Uses of Biotechnology

- 1983: Kary Mullis invents the polymerase chain reaction (PCR)
- 1986: first field trials for genetically modified crop (herbicide-resistant tobacco in the U.S. and France)
- 1990: CHY-MAX, an enzyme used in cheese making is the first product of recombinant DNA technology to be used in the U.S. food industry
- 1997: Ian Wilmut creates Dolly the sheep, the first animal cloned from an adult cell
- 2002: first draft of the human genome is released
- 2010: first synthetic cell created by Craig Venter

# Systems Biology and “-omics”

- Systems biology = an approach that shifts from looking at a single gene or protein to exploring how whole cells, organisms, or ecosystems function on the molecular level
  - Omics are disciplines using the systems biology approach
    - Genomics investigates the whole genome
    - Proteomics studies the proteome, or the entire protein complement of a cell or organism
    - Transcriptomics studies the transcriptome or the part of the genome that is transcribed
    - Metabolomics investigates the metabolome or all of the metabolites in a cell or organism. Metabolome are small molecules that are involved in signaling, hormones etc..

- Bioinformatics is the use of information technology for biological applications. This can include:
  - Storing data
  - Sorting and searching data sets
  - Analyzing and comparing data
  - Predicting structures
  - Modeling the interaction of molecules

# Uses of Biotechnology

- Health Care/Pharmaceutical

- Drug discovery

- Utilizes high throughput tools and techniques

- Microarrays are used to screen thousands of drug candidates by binding them on a microscope slide and incubating them with the target protein

- Drug development

- Chemical engineering, cell cultures, and animal models are used to test whether the drug works as expected

- Transgenic animals are often used that have been engineered to express the specific gene or genes and these can be inhibited or deleted if desired
      - Nanotechnology is also used to help deliver drugs to their targets. These are devices and particles that are nanometers in size

# Uses of Biotechnology

- Health Care/Pharmaceutical

- Clinical trials

- Controlled tests to see if the drugs work in humans

- Phase I: a small group of healthy individuals, usually less than 100, are given the drug to test for safety and dosage levels. This is often used to see how long it will remain active in the bloodstream
      - Phase II: the trial is expanded to between 100 and 300 participants to investigate whether the drug helps people suffering from the disease
      - Phase III: is a large trial that expands to serve 1,000 to 5,000 patients. The patients are monitored for effectiveness and side effects
        - » In 2009 there were 587 phase III human trials being conducted in the U.S.



# Uses of Biotechnology

- Health Care/Pharmaceutical
  - Personalized medicine
    - Also referred to as pharmacogenomics. The adjustment of treatment of a patient by determining which drugs or treatments that would best suit the patient's genotype or expressed differences
      - Herceptin is a drug that is prescribed for patients that have breast cancers that are HER2 positive. HER2 is a specific protein that is overexpressed
  - Clinical diagnostics
    - The development of tests for the diagnosis of disease. Some of these tests are done at the molecular level, such as with antibodies.
      - HIV testing, Lyme disease, SARS



Bio-Rad's Genie II  
HIV1/HIV2™  
assay

# Uses of Biotechnology

- Agriculture
  - Genetically modified crops
    - Pest-resistance: Bt corn
    - Herbicide-resistance: Roundup Ready cotton
    - Production of human proteins: SemBioSys conducted phase I and II clinical trials on safflower that produces recombinant insulin. This would reduce costs for insulin production
  - Genetically modified animals
    - Increased milk production: rBST or recombinant bovine somatotropin (cow growth hormone)
    - Pharming: use of farm animals to produce therapeutic drugs
      - Animals are being explored as potential sources for organ transplant

# Uses of Biotechnology

- Food
  - Biotechnology is used to improve the quality and nutritional content of basic food staples. This is a direct link to agricultural biotechnology
    - Golden rice: genetically engineered to express beta-carotene, which helps to prevent vitamin A deficiency which leads to blindness
    - Increased growth rates: AquAdvantage salmon grow at much faster rate for meat production
    - Increased nutritional value: pigs have been developed that express higher levels of omega-3 fatty acids
      - As of 2010, genetically modified animals have not been approved for sale as food



AquAdvantage salmon as compared to a non-transgenic Atlantic salmon. Photo courtesy of AquaBounty Technologies.

# Uses of Biotechnology

- Industrial manufacturing

- Textile industry

- Biotechnology has helped to improve efficiency, increase yields, and reduce environmental impacts from manufacturing industries
      - Laundry detergent has enzymes derived from cold water microorganisms that work at cold temperatures
      - Stone washing of jeans is now done with enzymes and greatly decreases the time and effort required to stone wash jeans

- Plastics

- Plant-based plastics take fewer resources to produce and are biodegradable



Tide Coldwater laundry detergent

# Uses of Biotechnology

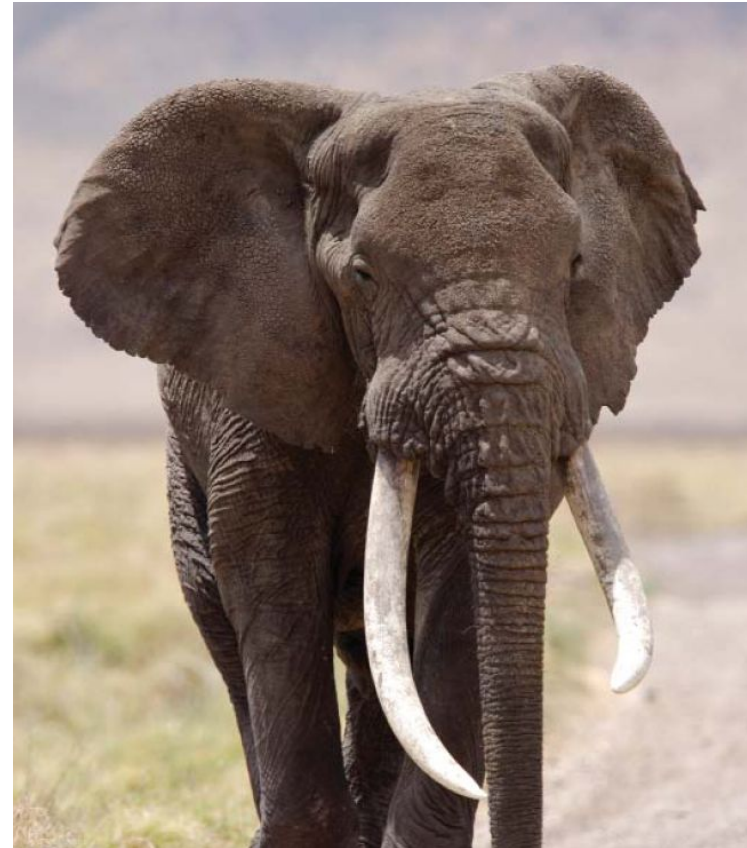
- **Biofuels**
  - **Used to develop alternative energy sources**
    - Conversion of left over plant stover (stalks and parts of plants left over after harvest) to ethanol
    - U.S. Energy Independence and Security Act provides billions of dollars to biofuel development
- **Mining**
  - **Use of microorganisms to leach minerals out of mine waste piles (tailings). This bioprocessing can reduce pollution and increase yield from a pre-existing source**

# Uses of Biotechnology

- Pollution monitoring and waste management
  - **Biosensors**
    - Biotechnological instruments that convert the action of a biological molecule or organism into an electrical signal. These can use many different mechanisms such as antibodies, enzymes, and PCR
  - **Bioremediation**
    - Use of microorganisms to convert hazardous waste into a less hazardous form
      - Oil-eating bacteria were used to help clean up the BP oil spill in the Gulf of Mexico

# Uses of Biotechnology

- Conservation
  - **Wildlife protection**
    - DNA profiling is used map endangered species and is used to track the origins of contraband ivory and identify elephant populations that are being poached
  - **Consortium for the Barcode of Life (CBOL)**
    - Catalog every living organism by generating a genetic barcode



# Uses of Biotechnology

- Biodefense
  - Protection from attack using biological weapons.
    - Biosensors
    - Vaccine production
    - Remediation to attack
    - Epidemiology for tracing back to source
- Forensics
  - Criminal evidence
    - The Innocence Project



Front row are inmates exonerated by DNA evidence. Photo courtesy of Greg Hampikian



# Uses of Biotechnology

- Human origins
  - Genetic analysis is used to map the movement and origins of human populations on the earth
    - The National Geographic Society has funded the Genographic Project to create detailed map of human migration

# Biotechnology Industry and Research

- Began in the 1970s
  - Categorized as either pharmaceutical companies (big pharma) or biotechnology companies
    - Biotechnology
      - Genentech was founded in 1976 and the first drug produced was Humulin, a recombinant human insulin
    - Pharmaceutical
      - Pfizer produces many drugs and products and has annual revenues around \$50 billion dollars

# Biotechnology Industry and Research

- Differences between biotech and big pharma

	<b>Pharmaceutical</b>	<b>Biotechnology</b>
Size	Medium to large	Start-up to medium
Development process	Formal	Innovative
Expertise	Chemical	Biological
Focus	Drug development, manufacture, and marketing	Drug discovery and development or novel technologies
Industry served	Health care	Health care and/or many other industries
Financing	Shareholders, revenues	Private investors, shareholders
Business approach	Low risk	High risk

# Biotechnology Industry and Research

- How different organizations fund biotech research

Type of Organization	Funding Sources
Large biotechnology and pharmaceutical companies	Profits from the sales of existing products
Small biotechnology companies and start-ups	Venture capital and government grants
Academic institutions, research institutes, hospitals, government laboratories	Government grants and other funding, foundations, endowments, and charities

# Sharing of Scientific Information

- Peer-reviewed publications
  - Most traditional method used by scientists to share their work
    - Reviewed by other scientists in the same field to determine if the research is of sufficient quality for publication
  - Conferences, meetings, seminars, and posters
    - Less formal ways to share information
    - Often posters are where junior scientists get to stand by their posters to explain their findings
- Patents
  - Allows inventors a set time period (often 20 years) to make back the money they invested in developing invention
    - In exchange, the invention must be disclosed to the scientific community
    - If others wish to use the process they have to negotiate with the patent holder for permission to use or license the invention

# Governmental Regulation of Biotechnology

- Main U.S. agencies involved:
  - FDA or Food and Drug Administration
    - Responsible for ensuring that food and beverages are safe for human consumption
  - EPA or Environmental Protection Agency
    - Responsible to protect human health and the environment
  - OSHA or Occupational Safety and Health Administration
    - Responsible for regulating the safety of workers in the workplace

# Industry Practices

- Companies often adhere to a set of industry rules and standards
  - Organisation for Economic Co-operation and Development (OECD) or International Organization for Standardization (ISO)
    - Ensures products are researched, developed, and manufactured correctly and consistently
    - Certifies that business processes, practices, and products adhere to a specific set of standards called a quality system or quality management system
    - Companies choose to which standards they will adhere to
    - Requires records be maintained such as laboratory notebooks

# Industry Practices

- Standard operating procedures (SOP)
  - A single way to perform a common task or process
    - For example, the task may be a lab procedure or method used to calibrate lab equipment. They are often referred to as SOPs
- Good laboratory practice (GLP)
  - Governmental organizations may require the preclinical trials and products be produced under certain standards
    - GLP is a quality system used for non-clinical health and environmental safety studies
    - Basic principles of GLP are the basis for sound lab work and require a quality assurance (QA) program be in place
    - Used to develop test data on the properties and safety of chemicals, biological molecules, or organisms so they can be relied upon with confidence among countries



- **GLP Requirements**
  - The responsibilities of all individuals involved in the study, from management to laboratory workers, need to be stated and the qualifications and training required for personnel to conduct the study need to be recorded
  - SOPs are required to state how samples, materials, and controls will be received, labeled, and stored; how apparatus will be maintained and calibrated; and how computer systems will be validated and backed up
  - A detailed plan needs to be written prior to the start of the study outlining the purpose of the study, detailed test methods and how the results will be reported. Laboratory notebooks are an integral part of how results are reported
  - The results and data generated by the study need to be properly stored and archived in case follow-up experiments are required

# Industry Practices

- Good manufacturing practices (GMP)
  - Is similar to GLP, but is a set of principles for ensuring the quality and safety of manufactured products used in health care, such as therapeutic drugs and diagnostic and medical devices
- GLP and GMP should be followed only when the health or environmental effects of the product are important. It is costly and results in a more expensive product
- Often biotech companies follow the ISO9001 standards. They are close to the GLP standards

# Careers in Biotechnology

- Employment base of the bioscience industry in 2008

<b>Bioscience Subsector</b>	<b>Establishments</b>	<b>Employment</b>
Agricultural feedstock and chemicals	2,440	114,793
Drugs and pharmaceuticals	2,771	311,882
Medical devices and equipment	15,227	435,509
Research, testing and medical laboratories	27,154	558,140
<b>Total Biosciences</b>	<b>47,593</b>	<b>1,420,324</b>

Source: Battelle/BIO State Biosciences Initiatives 2010

# Careers in Biotechnology

- The effect of education on earnings

<b>Level of Education</b>	<b>Years in Post-Secondary Education</b>	<b>Average Weekly Earnings in 2009*</b>
No high school diploma	0	\$454
High school diploma	0	\$626
Associate degree	2	\$761
Bachelor degree	4	\$1,025
Master's degree	6	\$1,257
Doctoral degree	8–12	\$1,532

Source: U.S. Bureau of Labor Statistics, Current Population Survey. Data are 2009 annual averages for persons age 25 and over. Earnings are for full-time wage and salary workers.

# Careers in Biotechnology

- **Laboratory technician**
  - Associate's or bachelor's degree
    - Works under the supervision of a scientist and is responsible for carrying out the hands-on work involved in laboratory work
      - Setting up assays
      - Using instruments
      - Recording data
- **Research associate**
  - Bachelor's or master's degree
    - Similar to a technician, however research associates have more responsibility and have a larger role in experimental design and data analysis

# Careers in Biotechnology

- Research and development scientist
  - Generally a doctoral degree (Ph.D.) is required, but often a master's degree with experience can be sufficient
    - Study how biological processes work
    - Develop methods to investigate biological processes
    - Use knowledge to develop products and processes for industry
    - Design experiments, analyze data, and draw conclusions
    - Train and supervise technicians and research associates

# Careers in Biotechnology

- Clinical scientist
  - Bachelor's degree, graduate degree, or a specialized certification
    - Perform all levels of work from analyzing blood samples to overseeing clinical trials for a pharmaceutical company
    - Responsible for proper handling of medical samples ensuring the proper testing of the samples
    - Train and supervise clinical technologists and technicians

# Careers in Biotechnology

- Engineer
  - Bachelor's degree required, but often graduate degrees are desired
    - Biological engineers are often called biomedical or bioengineers
    - Use science and math to solve biological problems
    - Have formal training in life science and engineering
    - Biotechnology industry employs biological, agricultural, chemical, mechanical, electrical and computer engineers



# Careers in Biotechnology

- Non-laboratory careers

- The majority of jobs in biotechnology are not in a lab
- Bachelor's, master's, MBA, Ph.D. could all be appropriate for these positions

- Administrators
- Technical writers
- Graphic designers
- Sales representatives
- Marketing specialists
- Public relations specialists
- Lawyers
- Logistics experts
- Quality assurance
- Buyers
- Accountants
- Biostatisticians
- Project managers

# Chapter 1 Summary

- Background
  - What Is Biotechnology
  - Historical Uses
  - Systems Approach
- Uses of Biotechnology
  - Health and Pharma
  - Agriculture
  - Food
  - Forensics, etc.
- Biotech Industry
  - Biotechnology vs. Pharma
  - Sharing Information
  - Regulations
- Careers
  - Laboratory Technicians
  - Research Associates
  - Scientists
  - Non-Laboratory Careers