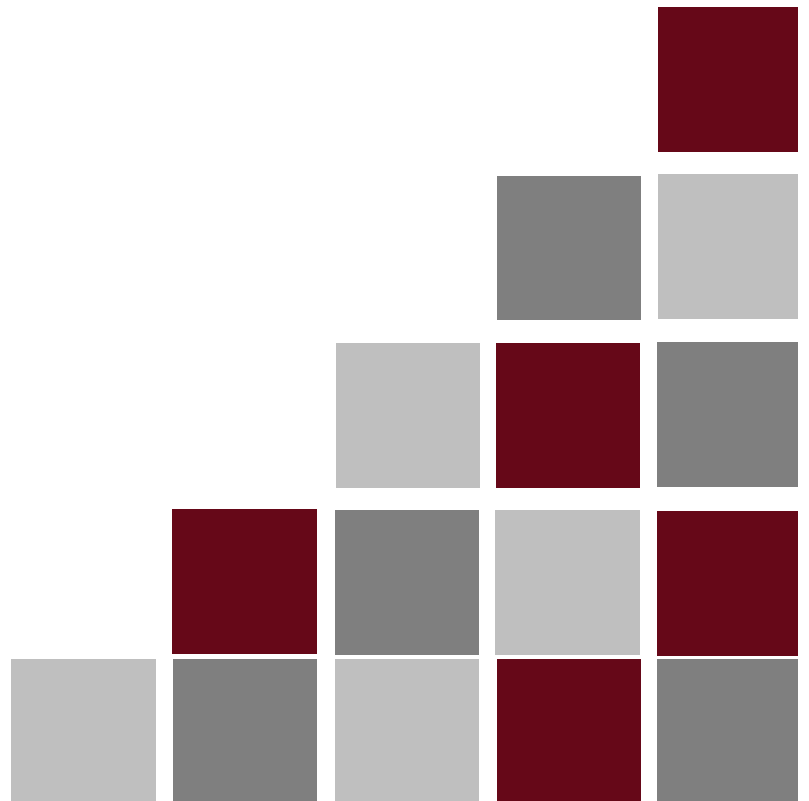


Principles by IUCG:

*Investigating the Biotechnology
Industry*



INDUSTRY OVERVIEW

What is Biotechnology?

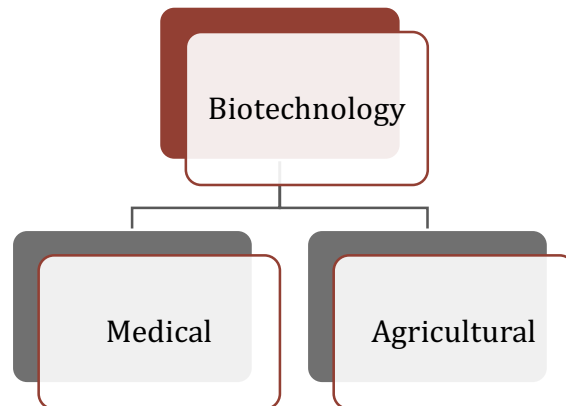
Biotechnology refers to the utilization of biological and biomolecular processes to innovate and develop products and technologies. This includes the manufacturing of drugs, the development of biofuels, and the engineering of agriculture.¹

General Process



Industry Breakdown:

The biotechnology industry is divided into two major sectors:



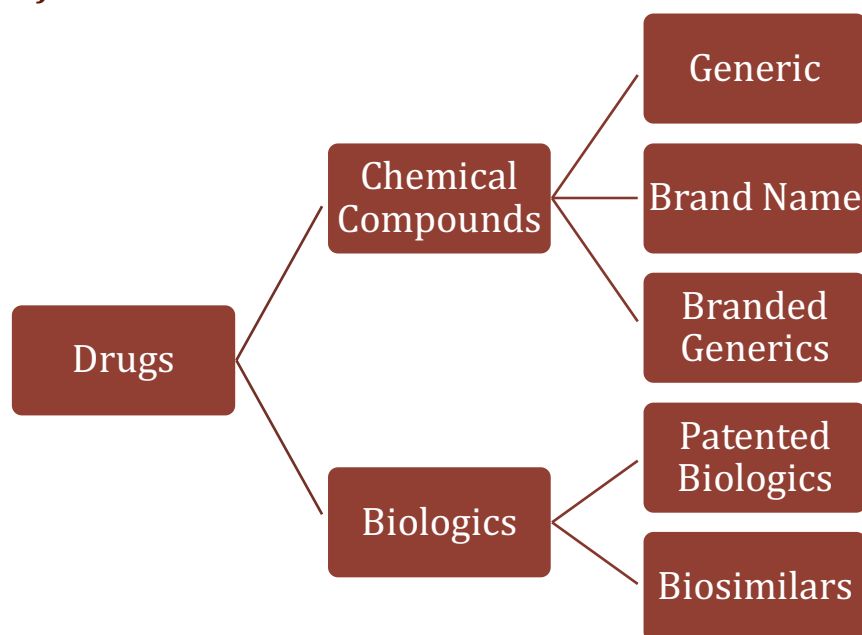
Medical	Agricultural
Medical biotechnology is the use of living cells and its components to research and manufacture drugs and products that help treat existing diseases. It involves creating a drug for a disease that does not have a treatment yet, or making a previously established drug treatment more efficient.	The agricultural sector involves the genetic modification of crops to selectively choose characteristics that appeal more to people. It also relates to the non-food uses of crops and other products to develop new sources of sustainable renewable energy.

THE MEDICAL SECTOR

Statistical Information

Revenues of Established Biotech Centers Worldwide In 2016	139.4bn USD
U.S. Public Biotech Companies Revenues In 2015	112.2bn USD
Number of public biotech companies in the U.S. in 2016	449

Drug Classification:



Biotechnological companies tend to only produce patented biologics and brand name drugs

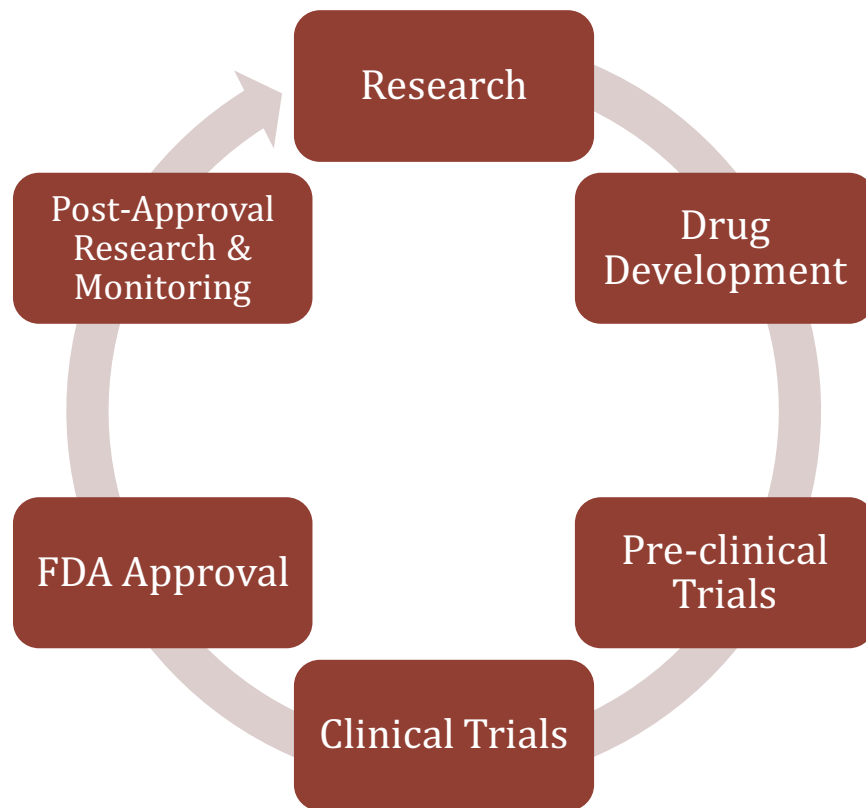
Patented Biologics:

Newly created biologic drugs protected by patents

Brand Name Drugs:

Chemical compounds protected by patents that can only be produced and marketed by patent holders

Drug Development Process



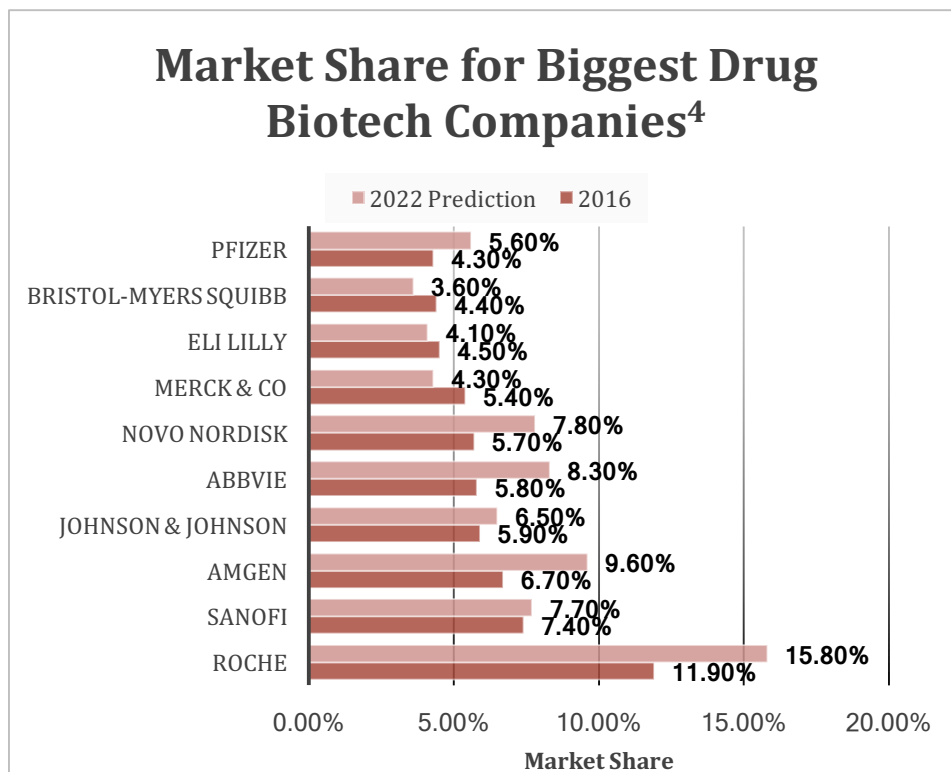
1. The **research phase** includes two periods of research: pre-discovery and drug discovery. Pre-discovery provides an understanding of the illness and drug. Drug discovery subsequently selects a target molecule for the drug.
2. **Drug development** occurs through a process known as *drug screening*. This is an automatic process that uses systems to test compound effectiveness².
3. During **pre-clinical trials**, drugs are tested in labs and on animals to determine whether they are safe to then test on humans.
4. **Clinical trials** are split into three separate phases:
 - a. **Phase I:** The drug is tested on humans and is usually administered to 100 healthy volunteers.
 - b. **Phase II:** Researchers attempt to evaluate the effectiveness of the drug in a group of specified volunteers (between 100 and 500).
 - c. **Phase III:** The drug is tested on volunteers from around the globe. This is the largest and most expensive of the clinical phases. Volunteers range from 1,000 to 5,000 people.
5. Following the end of clinical trials, Biotech companies need to submit a New Drug Application (NDA) or a Biologics License Application (BLA) to gain **FDA approval**. These applications contain data and analysis from the clinical development program and preclinical testing results along with proposals for manufacturing the product.

6. A company must maintain **post-approval research and monitoring** even after large scale production. As long as the drug is being sold, a company must continue monitoring for effectiveness and safety.³

Major Players

(Market Share & Prediction for 2022):

Company Name	2016	2022
Roche	15.8%	11.9%
Sanofi	7.7%	7.4%
Amgen	9.6%	6.7%
Johnson & Johnson	6.5%	5.9%
AbbVie	8.3%	5.8%
Novo Nordisk	7.8%	5.7%
Merck & Co	4.3%	5.4%
Eli Lilly	4.1%	4.5%
Bristol-Myers Squibb	3.6%	4.4%
Pfizer	5.6%	4.3%



Since only a few players concentrate the market, market power is relatively high for individual companies which allows them to charge high prices for each product. This gives rise to ethical issues and poses a threat from pressure groups on the industry. Market concentration of firms is expected to increase for those that are already dominating, increasing their price-setting power and elevating anti-competitive behavior.

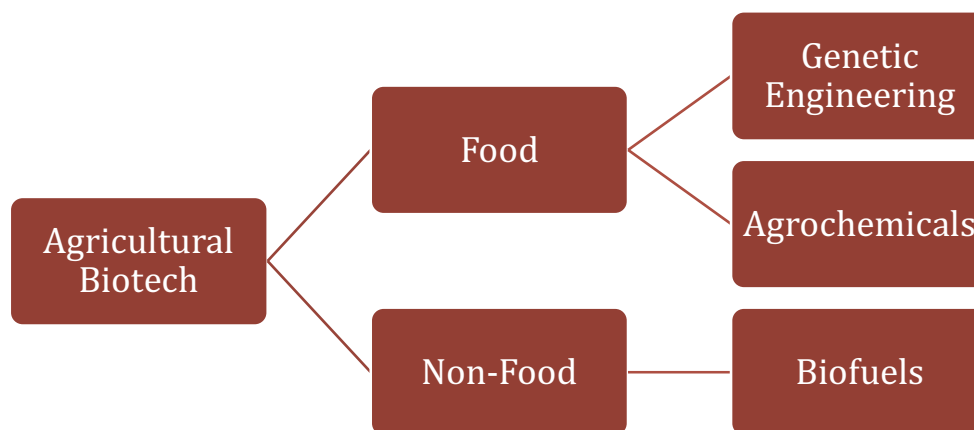
THE AGRICULTURAL SECTOR

Agricultural biotechnology refers to the manipulation of living organisms to accomplish a specific agricultural task. Subjects range from plants to animals to micro-organisms. Agricultural biotechnology is broken down into two subsectors: food and non-food. As shown below, this is a growing, global market that is projected to continue to expand into the future.

*Statistical Information*⁵

Year	Global Market (in billions of U.S. dollars)
2016	29.2
2017	32.1*
2022	53.7*

Sector Breakdown



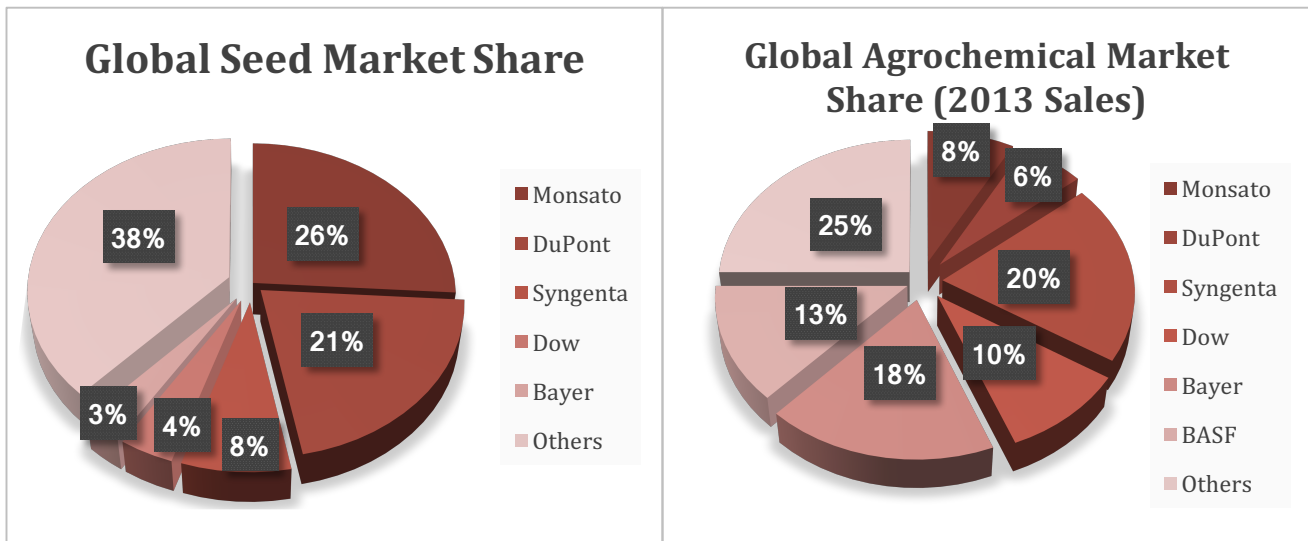
Genetic Engineering: Researchers and developers identify desirable traits in certain crops and transfer these traits to other crops to improve their harvest.

Agrochemicals: Any substance used to help control the organisms in an agricultural environment is considered an agrochemical. They are often used to increase crop yield by targeting ecological inefficiencies such as pests and weeds.

Non-Food Agricultural Biotechnology: This subsector refers to the use of living cells to create industrial products and improve processes. In addition to biofuels, plant-based plastics and less toxic pulp (within the paper industry) are real world examples.⁶

Biofuels: These are the products of research and manufacturing of liquid fuels or energy from biomass. Their purpose is to create alternatives to non-renewable fuels.

Market Share of Food-Related Sector⁷



Six companies own a majority of the global market share of agrochemicals. These companies consist of Bayer, BASF, Syngenta, Dow, Monsanto, and DuPont. Based on sales alone, these corporations control 75% of the global agrochemical market, as well as 63% of the seeds market (which includes crop seeds and genetically modified variations).

Recent merger proposal developments between members of the *Big Six* have altered this dynamic. Both Dow and DuPont as well as Syngenta and ChemChina (a public company) merged this past year for \$130 billion and \$43 billion respectively. A third merge between Bayer and Monsanto for \$66 million is estimated to be complete by January 2018 and would officially downsize the *Big Six* to the *Big Four*⁸

Despite approval from anti-trust organizations, the new presence of increased market power will affect market dominance. There are a number of potential negative consequences to agrochemical firm mergers that need to be addressed. Reducing the number of big corporations in the agricultural sector of biotechnology could limit competition and subsequently cause price increases. Competition decreases have the potential to negatively impact future innovations should surviving firms decide to take a step back from R&D. In an industry that already maintains high barriers to entry allowing large company mergers has the potential to increase predatory pricing and deter new players from entering the vital niche of food-related biotechnology.

Big Six Data⁹

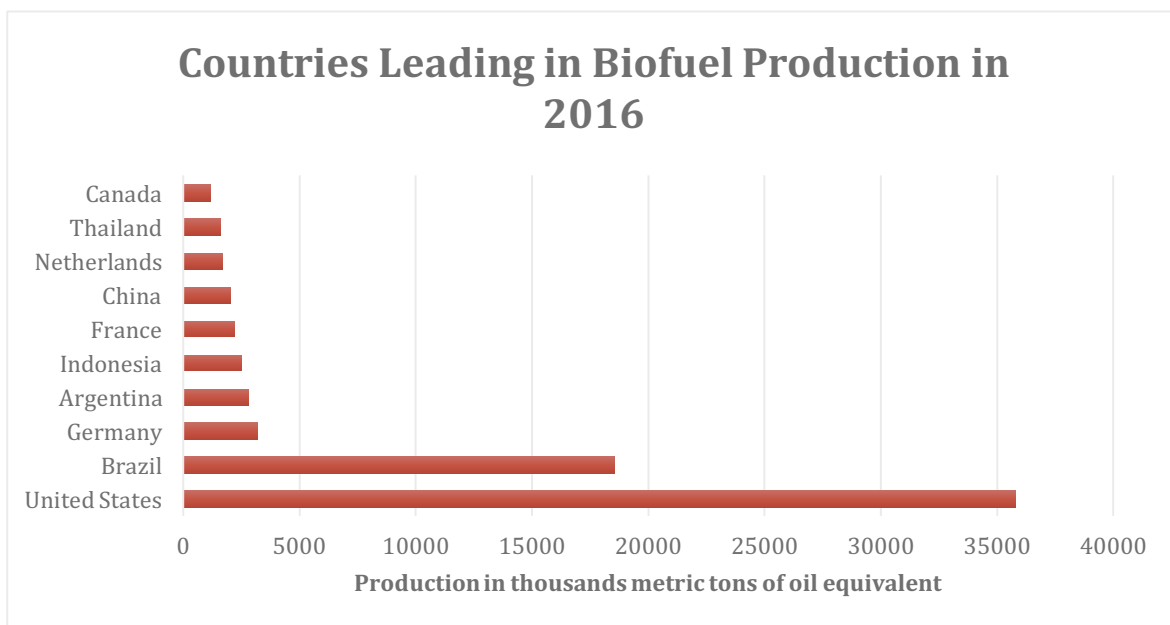
Company	2015 Sales (\$ millions)		Merger Partner
	Seeds	Agrochemicals	
BASF	0*	6,211	None
Bayer	819	9,548	Monsanto
Dow	1,409	4,977	DuPont
DuPont	6,785	3,013	Dow
Monsanto	10,243	4,758	Bayer
Syngenta	2,838	10,005	ChemChina

*BASF does not specifically track their seed sales

Biofuels

Although a subsector of agricultural biotechnology, biofuels are closely related to products like pesticides and vaccines. There is a general assumption that biofuels are better for the environment than fossil fuels, but this is met with criticism. Depending on the feedstock, the creation process can take up to 84 times more water than fossil fuels. Along with this, land that is used in the process is diverted away from the world's food supply.⁹ In addition, the energy put into creating biofuels through land maintenance emits carbon dioxide. Speculation leads one to believe that there is room for innovation in the biofuel industry to make it more sustainable and earth conscious.

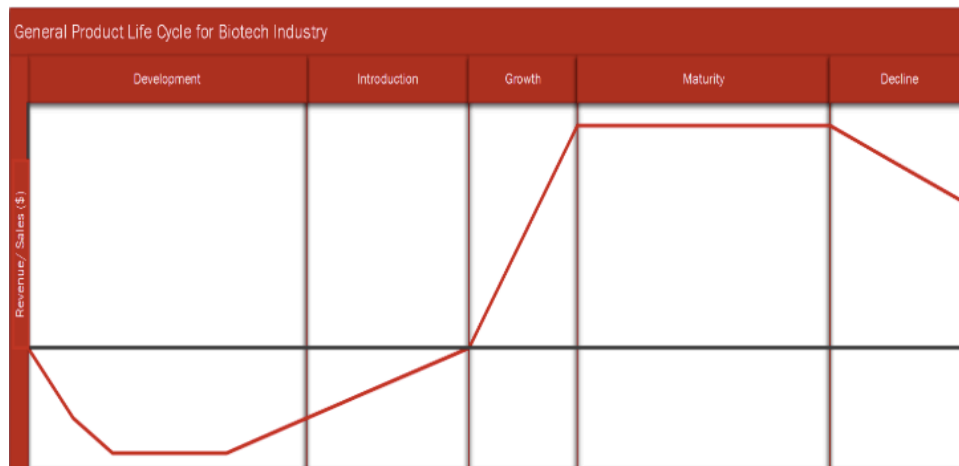
Due to the wide range of sources being used to create biofuels, this market is not as cleanly divided as the other sectors of biotechnology. Though, from a global standpoint, production levels show the United States as a clear front runner in biofuel production.¹⁰



OUTLOOK

Although biotechnology is a rapidly growing industry, startups attempting to enter the market do not necessarily have face guaranteed success. Success rates are low for new entrants. High fixed costs combined with long periods of time before payoff deter smaller businesses from entering the Biotechnology market. Research and development costs comprise a high percent of spending for most companies, regardless of its relation to a new drug or genetically engineered seed or biofuel.

Biotechnology is a broad field, but irrespective of what aspect is being considered, there will be a larger market for companies to fight for in the near future. Barriers to entry are high, but barriers to exit are minimal. Market power of individual firms is also expected to increase, intensifying anti-competitiveness. This makes it a rather risky industry to be involved in. This is due to the volatile nature of the products created in this industry and their life cycle. To illustrate the general process involved in production in Biotechnology, a general product life cycle was created.



It seems that there is much room for growth and innovation in the biotechnology industry, especially with regards to biofuels. Despite benefits in terms of GHG reduction and fossil fuel replacement, concerns have been raised about the overall sustainability of biofuels. Competition with food production, water use, and the destruction of land and biodiversity to clear land are all major concerns regarding biofuels. This may be a potential section of the market for new, innovating players to emerge from and disrupt.

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