

# Biotechnology regulations assignment

[Technology](#)



**ASSIGN  
BUSTER**

Products of biotechnology include medications, human insulin, enzymes used in laundry detergents and cheese-making, and even more recently, the use of biotechnology has led to new pesticide reduces that control a variety of pests. When Biotechnology products have unique biological properties, they also pose unique regulatory challenges. It is not surprising that from conception to market most compounds face an uphill battle to become an approved drug.

For approximately every 5,000 to 10,000 compounds that enter preclinical testing, only one is approved for marketing. A 1993 report by the Congressional Office of Technology Assessment estimated the cost of developing a new drug to be \$359 million. Newer figures place the cost at more than \$500 million. Today, roughly 90 percent of corn, cotton and soybeans grown in the US. have been improved through biotechnology, and farmers are choosing biotech traits when growing other crops such as alfalfa, sugar-beets and canola. 5% of investigation human medicines fail to be both effective and safe. In 2012, the average cost for a large pharmaceutical company to develop a new medicine was 5 billion dollars. Regulation Since 1986, the Coordinated Framework for Regulation of Biotechnology has successfully governed how the Department of Agriculture (USDA the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA) work together to regulate new biotech products.

In recent years, however, the process has become unpredictable and the timeline for reviewing new products has increased dramatically. This is due to overlapping regulatory responsibilities, a lack of inter-agency coordination, the looming threat of activist lawsuits that drain agency

<https://assignbuster.com/biotechnology-regulations-assignment/>

resources, and efforts to introduce socioeconomic criteria into regulatory decisions. Food and Drug Administration (safe to consume) Purpose: It is an Agency of the United States Department of Health and Human Services. Known as one of the Federal Executive Department.

The FDA is responsible for protecting and promoting public health through the regulation and supervision of the following: Food safety, tobacco products, dietary supplements, prescription and blood transfusions, medical devices, electromagnetic radiation emitting devices (RED), and veterinary products. The FDA has regulations that govern both animal studies (Gulps), and human studies (Gaps). The Center for Biologic Evaluation and Research is the branch of the FDA responsible for ensuring the safety of biological therapeutic agents.

These include cell and tissue based products, vaccines, gene therapy products, and allergens. Getting Approval? Before use, all biologics are required to go through a premarket approval process called a Biologic License Application (BLA), similar to that for drugs. There are two types of approval: FDA Cleared: requests are for medical devices that prove they are "substantially equivalent" to the predicate devices already on the market. FDA Approved: items that are new or substantially different and need to demonstrate "safety and efficacy."

FDA Regulation in Drug Development Three Phases Preclinical Phase Takes on average 3-4 years to complete. Upon completion IND (Investigational New Drug) Application Upon approval Clinical Phases 1-3 Takes on average 2-3 years to complete Upon successful completion AND (New Drug Application)

<https://assignbuster.com/biotechnology-regulations-assignment/>

The FDA can approve, reject, or require additional research to be done before making a decision. If accepted, the FDA can also request that the manufacturer conduct additional post-marketing studies. Overall, this entire process, on average, takes between 8 to 12 years.

**Phase 1: To test the safety and pharmacology of compound.** 0-100 volunteers are used. Low doses of investigation compounds are administered to a small group of healthy volunteers who are closely supervised. In cases of severe or life-threatening illnesses, volunteers with the disease may be used. These studies usually start with very low doses, which are gradually increased. Roughly 2/3 are deemed safe enough to go to Phase 2.

**Trials Phase 2: Examine effectiveness of a compound.** 100-300 volunteers used. Analysis of the fewest volunteers needed to provide sufficient statistical power to determine efficacy.

Determine the effective dose, the method of delivery (e.g., oral or intravenous), and the dosing interval, and also to reconfirm product safety. A substantial number are discontinued.

**Phase 3: Confirm previous findings in larger population.** Final step before seeking FDA approval. Last from 2 to 10 years and involve thousands of patients across multiple sites. 10% fail. The application contains information on the chemical makeup and manufacturing process, pharmacology and toxicity of the compound, human pharmaceuticals, results of the clinical trials, and proposed labeling.

The FDA will then complete an independent review and make its recommendation. Environmental Protection Agency (Safe for the environment). In 1970, President Richard Nixon proposed an executive reorganization that would insulate many of the federal government's environmental responsibilities under one agency: Environmental Protection Agency.

<https://assignbuster.com/biotechnology-regulations-assignment/>

Agency Purpose: Protection of human and the environmental health by writing and enforcing regulations based on laws passed by Congress.

Water, Air, Land, Endangered Species, and pollution management are all governed by this agency. U. S. Department of Agriculture (Safe to grow)

Purpose: The development of policy on farming, agriculture, forestry, and food. Why? To promote agricultural trade and production, work to assure food safety, protect natural resources, foster rural communities and end hunger in the United States and abroad.

Problems with Regulation Despite rapid adoption by farmers and a strong scientific consensus that biotechnology does not pose health and environmental risks, regulatory burdens are slowing research and innovation of new biotech traits and are starting to reduce U. S. Farmers' international competitive advantage. Activist groups have repeatedly threatened new traits by blocking science-based regulatory decisions, filing spurious lawsuits and advocating for labeling mandates.