‘’Comprehensive Review of Approved Biological Products by The U.S. FDA in 2023 ‘’

A project was submitted to satisfy several requirements for the bachelor of Pharmacy (B. Pharm) Degree

Submitted To

Department of Pharmacy

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Approval

This project has been submitted to the Department of Pharmacy, Faculty of Allied Health Sciences at Daffodil International University. It has been accepted as satisfactory for the partial fulfillment of the requirements for the degree of Bachelor of Pharmacy (B.Pharm). The style and contents of the project have been approved.

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Declaration

I hereby certify that I independently completed this project report to satisfy the requirements for the Bachelor of Pharmacy (B.Pharm) degree under the supervision of Galib Muhammad Abrar Ishtiaque, Lecturer (Senior Scale), Department of Pharmacy, Faculty of Allied Health Sciences, Daffodil International University. By signing this, I certify that I am the only author of this work. In addition, I swear that neither this project nor its components have ever been submitted to another university to receive a Bachelor's degree or any other degree.

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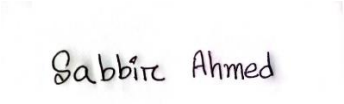

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Acknowledgment

I'm grateful to God for providing me with the health and stamina I need to finish this work. I'm extremely grateful to Professor Dr. Muniruddin Ahamed for giving me access to all the materials I needed for the research. He is a professor and the program director at Daffodil International University. I'd also like to thank Galib Muhammad Abrar Ishtiaque, Lecturer (Senior Scale) in the pharmacy program at Daffodil International University. He imparted her knowledge to me and provided me with genuine, precious advice and assistance; for these things, I am grateful and owe a debt of appreciation. I want to take this time to thank every one of the department's faculty for their encouragement and support. In addition, I want to thank my parents for their constant support, love, and wisdom. I'm also appreciative of my partner's help in this endeavor. I also want to express my gratitude to everyone who has contributed to this effort in any way, whether directly or indirectly.

Sabbir Ahmed

Author

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Dedication

I dedicate this work to my parents and my teachers. The person who always encouraged me in every sphere of my life and guided me in this process kept me on track.

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Abstract:

The United States Food and Drug Administration (US.FDA) approved numerous innovative pharmaceuticals in 2023. These pharmaceuticals have been subjected to a rigorous evaluation to guarantee their safety and efficacy, and they represent substantial improvements in the treatment of a variety of medical conditions. A diverse array of analytical techniques has been implemented to facilitate their development and subsequent quality control. The analytical methodologies utilized for the evaluation and quality control of FDA-approved drugs are the primary focus of this review. These methodologies comprise a variety of methods that facilitate the characterization, quantification, and quality assessment of pharmaceutical compounds. Frequently implemented chromatographic methods, including high-performance liquid chromatography (HPLC) and liquid chromatography-mass spectrometry, are among the analytical techniques. Spectrometry (LC-MS), Ultra-Performance Liquid Chromatography (UPLC), Ultra-high-performance liquid chromatography (UHPLC), and Ultraperformance liquid chromatography-Mass Spectrometry (UPLC-MS). The drugs that have been approved are bexagliflozin (Sodium-glucose cotransporter 2). Daprodustat (Hypoxia-inducible factor prolyl hydroxylase inhibitor), Valmanasealfa-tycv (Recombinant human lysosomal alpha-mannosidase), Rezafungin (Echinocandin antifungal drug), Sparsentan (Dual endothelin and angiotensin II receptor antagonist), and Nirmatrelvir (Antiviral), Ritonavir (Protease Inhibitors). In general, the FDA's approval of pharmaceuticals in 2023 was contingent upon the implementation of a variety of robust analytical methods. These methods enabled the comprehensive evaluation of drug quality, safety, and efficacy, thereby guaranteeing that patients receive reliable and effective treatment. The development and evaluation of innovative technologies will be further facilitated by the ongoing advancement of analytical techniques pharmaceuticals in the future.

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"Comprehensive Review of Approved Biological Products by The U.S. FDA in 2023"

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Chapter 1
INTRODUCTION

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1.1 Introduction

The United States Food and Drug Administration (US.FDA) is a federal agency that is part of the United States Department of Health and Human Services. Its primary obligation is to guarantee the safety, efficacy, and security of a variety of products that are utilized by the public, with a particular emphasis on food, pharmaceuticals, medical devices, cosmetics, and other items. For more than a century, the FDA has been dedicated to the promotion and protection of public health, which includes your health. [1] In the United States, the U.S. Food and Drug Administration ensures that the foods and medications we consume are safe daily. [2] The FDA employs over 18,000 individuals in all 50 states and on an international scale to guarantee the safety and efficacy of medical devices, biologics, and human and veterinary medicines. Additionally, we oversee the safety of tobacco products, cosmetics, radiation-emitting devices, and food. [3]

1.2 Regulatory Oversight of the US.FDA

The US.FDA regulates many products that affect public health. This covers prescription and over-the-counter medications, vaccines, biologics, medical devices, food and drinks (for both humans and animals), dietary supplements, cosmetics, and tobacco items. [4] The U.S. Food and Drug Administration (FDA) has a detailed system in place to make sure that food, drugs, medical devices, and other health-related products are safe, effective, and secure. The FDA operates under important laws such as the Food, Drug, and Cosmetic Act. It is structured into specialized centers, like the Center for Drug Evaluation and Research (CDER) and the Center for Food Safety and Applied Nutrition (CFSAN), which each concentrate on different types of products. Before products can be sold, they go through thorough evaluations before hitting the market, which includes clinical trials for drugs and detailed reviews for medical devices. [4] Once approved, the FDA keeps an eye on product safety by doing post-market surveillance, which involves reporting any bad events and inspecting facilities. [5] The agency uses different ways to enforce rules, like sending warning letters, requiring recalls, and imposing fines for not following the regulations. The FDA plays a crucial role, but it has to deal with challenges in finding the right balance between safety and innovation, especially when it comes to the complexities of new technologies. The FDA's regulatory oversight is really important for keeping public health safe and making sure that people can use products that are both safe and effective. [6]

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1.3 Drug Approval and Safety of the US.FDA

The US.FDA looks over and gives the green light to new drugs and therapies before they can be sold to the public. This means looking at how safe and effective the products are by conducting thorough clinical trials and scientific studies. The agency keeps an eye on drug safety and steps in if any negative effects come up after they've been approved. [7]

Ensuring food safety

The US.FDA makes sure that the food supply in the U.S. is safe. This includes managing how food is produced, distributed, labeled, and packaged. The agency establishes guidelines for food additives and contaminants, keeps track of foodborne illnesses, and carries out recalls when needed. [8]

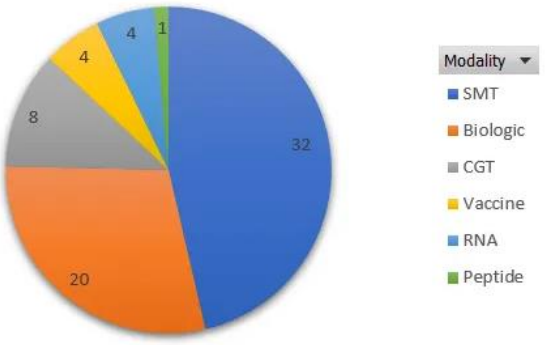

Chart 01: Percentages of approved drugs categories by the US.FDA

1.4 Regulations & Responsibilities of the US.FDA

Regulation of Medical Devices

The US.FDA is in charge of overseeing medical devices to make sure they are safe and work well. This covers things like pacemakers, imaging devices, and diagnostic tests. Devices are sorted into various categories depending on their potential risks, and the rules that apply change accordingly. [9]

Biological products and vaccines

The agency is responsible for making sure that biological products, like vaccines, blood products, and gene therapies, are approved and safe for use. [10] The US.FDA checks that these products are safe and work well before they can be sold to people. Such as:

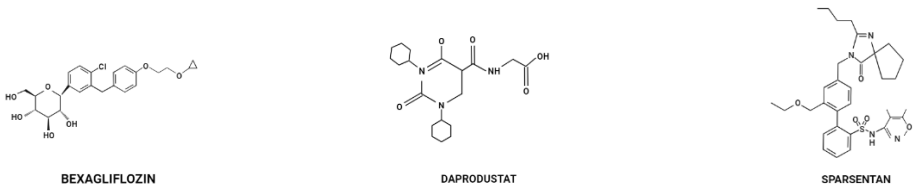

Fig 01: Structure of some biological products approved by US.FDA

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Beauty and Self-Care Items
The US.FDA is in charge of overseeing cosmetics to make sure they are safe for people to use. Cosmetics go through less strict testing and regulation than drugs and medical devices do. [11]
Tobacco Regulation
The US.FDA regulates tobacco products, which include cigarettes, smokeless tobacco, and e-cigarettes. The agency is working to cut down on illnesses and deaths caused by tobacco by using regulations, education, and enforcement. [12]
Emergency Response
The US.FDA is really important when it comes to dealing with public health emergencies like disease outbreaks, natural disasters, and threats from bioterrorism. It brings together efforts to make sure that the food and medical product supply chains are safe during these kinds of crises. [13]
Exploration and Creativity
The US.FDA does research to make its regulatory processes better and keep up with new scientific developments. It works together with schools, businesses, and other regulatory bodies to improve its knowledge of different products and how they impact public health. [14]

Public Education
The US.FDA shares information with the public regarding health and safety concerns related to the products it oversees. This involves teaching consumers how to make informed decisions and comprehend product labels. The US.FDA's main goal is to keep people healthy by making sure that the products we use daily are safe, effective, and of good quality. It uses a mix of rules, scientific studies, enforcement actions, and communication with the public to achieve its goals. [15]

1.5 Biotechnology:

Biotechnology is the use of cells, biological systems, and live things to make things or do things that are useful. It incorporates ideas from computer science, engineering, physics, chemistry, and biology. Károly Ereky used the term "biotechnology" in 1919 to describe the process of creating things from raw materials using live organisms as a help. Utilizing biological systems and organisms such as bacteria, yeast, and plants to carry out particular functions or generate useful materials is the fundamental idea of biotechnology. [16]

Biotechnology has had a big impact on a lot of societal fields, such environmental science, agriculture, and medicine. Genetic engineering is one of the most important tools in science because it lets scientists change the genes of living things to get the results they want. This may entail introducing genes from one organism into another in order to either produce new features or alter already existing ones. Biotechnology can be used in many different ways. [17] It has led to the creation of important things like biofuels, genetically modified foods, life-saving drugs, and

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new materials. Some examples of how it has been used to help the environment are to make biodegradable plastics and use microbes to clean up polluted areas. Biotechnology includes many different methods for changing live things for human use. This includes raising animals as pets, growing plants, and making "improvements" to these things through breeding programs that use artificial selection and hybridization. [18] Today, genetic engineering and cell and tissue culture tools are also used. Biotechnology, according to the American Chemical Society, is the use of living things, systems, or processes in different fields to learn more about the science of life and make things and living things, like medicines, crops, and animals, more valuable. The European Federation of Biotechnology says that biotechnology is the use of natural science and organisms, cells, parts of organisms, and molecular equivalents to make goods and provide services. Biotechnology builds on the basic biological sciences, like molecular biology, biochemistry, cell biology, embryology, genetics, and microbiology. On the other hand, it gives biologists new ways to do basic study. [19]

With the potential to address some of the most important issues in agriculture, health, and environmental sustainability, biotechnology is a sector that is poised for revolutionary change. It is crucial to strike a balance between innovation, ethical issues, and public involvement as the area develops. [20]

1.6 Classification of biotechnology:

1. Biopharmaceuticals

The word "biopharmaceutical" is used a lot these days, but what does it really mean? There is no mention for the term in pharmaceutical dictionaries, and many books on the subject (Lubiniecki and Vargo, 1994; Zito, 1997; Walsh, 1998; Grindley and Ogden, 1999) also don't give short or clear definitions or descriptions. Many scientists agree that biopharmaceuticals are a type of medicine made using modern biotechnology, such as recombinant DNA technology or hybridoma technology for goods based on murine monoclonal antibodies. This view was formed in the 1980s and hasn't changed since. [21] Basically, this meant that the word "biopharmaceutical" meant healing proteins made in lab-grown living systems. Biopharmaceuticals, on the other hand, are not healing proteins that are directly extracted from a source that makes them naturally. Insulin taken from the pancreatic tissue of animals raised for food and clotting factors taken straight from blood are examples of the second type. These are drugs that are manufactured using biotechnology. Based on what is actually thought to be a biopharmaceutical, it seems hard to come up with a definition based on just one factor, like source, method of production, use, or structure. To meet all of these requirements, we suggest the following set of words: "A biopharmaceutical is a pharmaceutical

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substance based on protein or nucleic acid that is used for therapeutic or in vivo diagnostic purposes and is made by other means." [22]

Examples:

o Monoclonal antibodies are used in cancer therapies, such as Rituximab for non-Hodgkin lymphoma.
o Recombinant proteins, such as insulin, are used to manage diabetes.
o Gene Therapies: Treatments for genetic disorders, such as Luxturna for inherited retinal disease. [23]

2. Biotechnology in agriculture

Innovations in biotechnologies have been used more in agriculture and forests over the past 20 years (Plomion et al., 2016; Tester and Langridge, 2010). Still, the forest sector is still pretty new to biotechnologies compared to agriculture (Lelu-Walter et al., 2013). Unlike things grown for farming, forest trees don't need to be cared for much, live a long time, and take a long time to reach reproductive maturity. Because of these traits, trees are harder to study genetically than crops, which is one reason why we know less about trees' genes than about crops' genes (Aitken and Bemmels, 2016). [24] There is, however, a growing movement to use biotechnologies more in forests. Biotechnological changes that make trees less vulnerable to insects are being thought of more and more as a way to improve forest health (National Academies of Sciences, Engineering, and Medicine, 2019) and make forests more resistant to the effects of climate change, like extreme droughts and forest fires (Hagerman and Pelai, 2018). [25] Additionally, biotechnology could make the process of making wood more efficient (Porth et al., 2015). Genetically modified (GM) tree trials are becoming more common around the world, though they are still less common than trials on crops (James, 2014; Lu and Hu, 2011). In the 1980s and 1990s, there were only 15 tree-based biotechnology trials. From 2000 to 2009, there were 41, and since 2010, there have been 50. 2018 had the most trials of any year (National Academies of Sciences, Engineering, and Medicine, 2019). The utilization of biotechnological instruments to enhance livestock and crops. [26]

Examples:
o Genetically Modified Organisms (GMOs): Plants that have been changed to fight pests and herbicides, like but corn and Roundup Ready soybeans.
o Biofortified Crops: For example, Golden Rice is high in Vitamin A to help fight hunger.
o Biopesticides and biofertilizers: Natural ways to get rid of pests and add nutrients to the soil that require less chemical input. [27]

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3. Biotechnology in Industry

When it comes to the big new technologies that have come out since the 1970s, biotechnology might be the most talked-about. Biotechnology has shown that it can make a lot of money and have an effect on every important part of the business. Already, biotechnology has had a big impact on healthcare, food production and processing, forestry and farmland, protecting the environment, and making materials and chemicals. [28] This review is mostly about what biotechnology has done well and what it could do in the future when it comes to making goods and services that last, especially ones that are mostly made by the standard chemical industry right now. Biotechnology is being used in many different industries, and it has always led to economic and environmental benefits. For example, processing is cheaper, product quality is better, completely new products are made, and processing is better for the environment than traditional methods. Bioprocessing and bioproducts are becoming more popular because they are good for the economy, but ecology is also becoming more important. Making use of biological processes to produce materials and chemicals. [29]

Examples:

o Biofuels: Made from biomass, biodiesel and ethanol are created.
o Bioplastics: Natural ingredients, such as corn starch, are used to make biodegradable plastics.
o Enzymes: Provide more environmentally friendly and efficient processes in the production of textiles, food processing, and detergents.

4. Biotechnology in the Environment

Environmental biotechnology is a broad field that uses living things and biological systems to solve important environmental problems and improve the health of the environment. Microorganisms, plants, and natural processes are used in this new field to clean up polluted areas, restore ecosystems, and get rid of garbage properly. One important use for it is bioremediation, which uses certain microbes to break down dangerous chemicals like heavy metals, petroleum hydrocarbons, and pesticides in polluted water and soil. [30] Environmental biotechnology not only helps clean up toxic areas by speeding up natural degradation processes, but it also cuts down on the need for expensive chemical treatments. Bioaugmentation is another important factor. This is the process of adding certain types of bacteria or fungi to an area to help break down pollutants more quickly. Phytoremediation also uses plants to remove and detoxify pollutants from water and soil, making it a greener and more visually pleasing option than traditional methods of cleanup. The field also includes methods for managing waste, such as anaerobic digestion and composting, which turn organic waste into biogas and fertilizers full of nutrients, supporting the ideas of a cycle economy. Environmental biotechnology is also very important for the creation of biofuels, which are renewable energy sources that cut down on the use of fossil fuels and greenhouse gas emissions. By combining engineering, scientific study, and environmental management, environmental biotechnology not only solves today's environmental problems but also makes way for new ideas that will make the world a healthier place for future generations. [31] Genetic engineering and synthetic biology are always getting better, which increases the field's potential even more. This makes it possible to create customized microbial strains and bioprocesses that can successfully

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target specific pollutants or make ecosystems more resilient. In the end, environmental biotechnology is a forward-thinking method that combines new technology with caring for the environment. This makes sure that natural resources are used in a responsible way while reducing the damage that humans do to the environment. Biological processes used for environmental remediation and protection. [32]

Examples:

o Bioremediation: Using microorganisms to purify contaminated water and soil (bacteria, for example, can break down oil spills).

o Water Waste Treatment: Pollutants are broken down by microorganisms in wastewater treatment facilities. [33]

5. Artificial Biotechnology

Artificial biotechnology, also called synthetic biology, is a new area that is growing quickly. It combines biology, engineering, and computer science to create and design new biological devices, parts, and systems. Artificial biotechnology tries to make new biological functions and abilities. This is different from traditional biotechnology, which mostly involves changing living things and biological processes that are already in place. This is done using methods like genetic engineering, in which scientists change organisms' DNA to give them desired traits or functions, and metabolic engineering, in which cells' processes are improved so that more valuable compounds like drugs, biofuels, and specialty chemicals can be made. [34] Bio bricks are standard biological parts that can be put together in different ways to make complicated biological systems that behave in predictable ways. They are one of the most important parts of artificial biotechnology. This modular method not only speeds up the creation and testing of new biotechnological uses, but it also makes it easier to come up with new ways to deal with global problems like climate change, food security, and disease. For example, synthetic biology has made it possible to engineer microorganisms to make biofuels from waste, make crops that are resistant to pests and environmental stressors, and make bacteria that can make high-value drugs more quickly and efficiently than before. Also, artificial biotechnology is a big part of personalized medicine, which creates medicines that are specifically made for each person based on their genes. This makes treatments more effective while reducing side effects. But the fast development of artificial biotechnology also brings up safety and ethics concerns, such as the chance of ecosystems having unintended effects, biosecurity problems, and the moral implications of designing and changing living things. So, for scientists, policymakers, and the public to be able to handle the challenges and possibilities this field brings, they need to keep talking to each other. In the end, artificial biotechnology is the cutting edge of scientific progress. It has the potential to change many fields by offering long-lasting and effective solutions. It has also sparked important conversations about the future of biotechnology and how it affects society. An interdisciplinary field within biotechnology that works with the creation of novel biological components, apparatus, and systems. [35]

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Examples:

o Gene editing: techniques that enable precise DNA alterations, such as CRISPR-Cas9.

o Metabolic engineering: modifying microbes' metabolic pathways to create useful materials (like medicines or biofuels).

6. Medical diagnostics and customized treatment

Biotechnology advances have made it easier to understand and meet the health needs of each person. This has led to new areas in healthcare like medical testing and personalized treatment. At the heart of this innovation are the creation of very sensitive diagnostic tools, like next-generation sequencing, which lets scientists quickly and accurately look at a person's genes. These technologies help doctors find specific DNA changes or biomarkers that are linked to diseases. This makes it easier to find diseases early and make more accurate diagnoses. Also, biotechnology has made it possible for personalized medicine, in which each patient's genetic and molecular profile is used to make their care. [36] For example, in oncology, targeted therapies are made to fight cancer based on the genetic changes found in a patient's tumor. This makes treatment plans more successful while causing fewer side effects compared to traditional chemotherapy. Biopharmaceutical advances, such as monoclonal antibodies and gene therapies, have also changed the way diseases are treated by letting doctors target the causes of illnesses instead of just treating their symptoms. [37] When artificial intelligence and big data analytics are used in medical diagnostics, it makes it easier to understand complicated biological data. This helps doctors make better choices about how to customize treatment plans. Not only does this personalized method improve patient outcomes, it also makes the healthcare system more efficient by cutting down on trial-and-error prescribing and bad reactions. Biotechnology is also leading to the creation of companion diagnostics, which are tests that can predict how well a patient will react to a certain treatment. This makes healthcare even more personalized. As we continue to look into how biotechnology could be used in medical diagnosis and treatment, patient consent and ethical concerns are still very important. This is to make sure that the benefits of personalized medicine are matched with protecting people's rights and keeping them safe. Overall, combining biotechnology with medical diagnostics and personalized treatment is not only making it easier to treat diseases, but it is also changing the way patients feel by encouraging a more proactive, informed, and personalized approach to healthcare that gives people more power and makes public health better as a whole. Biotech products that improve patient-specific therapy planning and disease diagnostics. [38]

Examples:

o Genetic Testing: BRCA testing to determine a person's risk of breast cancer.

o Point-of-Care Diagnostics: Quick testing (like COVID-19 tests) for infectious disorders.

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7. Bioengineering

Bioengineering is a dynamic and multidisciplinary area that uses biology, engineering, and technology ideas to come up with new ways to solve many biological and medical problems. This field includes many uses, such as tissue engineering, genetic engineering, biomaterials, and medical gadget design. All of these are meant to improve health and quality of life. In tissue engineering, bioengineers make fake organs and tissues by combining cells with biocompatible scaffolds. [39] This could help with the severe lack of donor organs and make it easier for harmed tissues to heal. Another important part of bioengineering is genetic engineering, which changes organisms' DNA to make them more attractive, make therapeutic proteins, or make genetically modified organisms (GMOs) that can increase crop yields and make them less vulnerable to pests. Biomaterials, which are materials made to work with living things, have led to big steps forward in technologies for internal devices, drug delivery systems, and wound healing. These technologies make medical solutions safer and more effective. [40] Bioengineering is also very important for the progress of biotechnology and synthetic biology. In these fields, living systems are modified to make useful things like biofuels, medicines, and enzymes using environmentally friendly methods. Bioengineers can predict and improve biological processes by using simulations and computer modeling together. This makes bioproducts better in both design and effectiveness. There are also big steps forward in fields like regenerative medicine, where bioengineers work on stem cell treatments and gene editing tools like CRISPR to treat genetic diseases and injuries at the cellular level. However, the fast progress in bioengineering also raises ethical questions, especially when it comes to genetic changes and how they might affect biodiversity and human health. As bioengineering develops, it holds the promise of big steps forward that could change healthcare, farming, and the long-term health of the environment, eventually making people healthier and better their quality of life around the world. The area of study concentrated on replacing or mending damaged organs and tissues. [41]

Examples:

o Stem Cell Therapy: This technique uses stem cells to repair injured tissues, such as spinal cord injuries.

o Tissue engineering: Using biocompatible materials and cells, artificial organs or tissues are created.

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1.7 Importance of biotechnology:

Biotechnology is an important and rapidly changing area that is helping to solve some of the most important problems people are facing right now. It's important in many areas, like agriculture, healthcare, managing the environment, and industry processes. These are all necessary for long-term growth and bettering people's lives. In healthcare, biotechnology has changed the way diagnostic tools, vaccines, and medicines are made. This has made it possible to treat illnesses like cancer, diabetes, and infectious diseases more effectively. [42] Changing biological systems at the molecular level makes personalized medicine possible. In this type of medicine, treatments are made to fit each person's genes, which leads to better results and fewer side effects. Biotechnology improves crop resilience and productivity by creating genetically modified organisms (GMOs) that are resistant to pests, diseases, and environmental stresses. This helps ensure food security in a world where climate change is happening and the population is rising. Biotechnology is also very important for protecting the environment. Bioremediation methods are used to clean up polluted areas, and biofuels made from renewable resources cut down on greenhouse gas emissions. Biotechnology makes it easier to make chemicals and materials from living things. This encourages environmentally friendly methods that use less fossil fuels and make less trash. Furthermore, progress in synthetic biology and genetic engineering has opened up new ways to be creative, making it possible to create new biological systems that can make useful substances like medicines and biofuels more effectively. Biotechnology has a bigger effect when scientists, politicians, and businesses work together. This encourages a more complete way of dealing with tough global problems. However, as the field moves forward, it needs ethical concerns and rules to make sure that biotechnological advances are used in a responsible way. In the end, biotechnology is important because it can drive progress and sustainability. It can provide solutions that not only improve health and agricultural productivity, but also encourage responsible environmental management and economic growth. This makes it an essential part of a strong and long-lasting future. [43] Biotechnology is an important area that uses both biology and technology to make products and processes that help people in many ways. Here are some important facts that show how important bioengineering is:

1. Progress in Healthcare Drug Development:

Biotechnology has made biologics, like monoclonal antibodies and gene therapies, possible. These are targeted treatments for conditions like cancer and genetic disorders.

- Vaccines: Biotech innovations have made it much easier to make vaccines, which lets us respond quickly to new diseases (like COVID-19 vaccines).
- Diagnostics: Biotechnological tools, such as PCR and CRISPR, make it easier to find diseases, which lets doctors make quick and correct evaluations. [44]

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2. **Improvements to farming**
   - Food Security: Genetically modified organisms (GMOs) and other biotech crops are designed to produce more food, be resistant to pests, and survive drought. This helps make sure that there is enough food for everyone as the world's population grows.
   - Sustainable Practices: Biotechnology helps make farming more sustainable by creating biofertilizers and biopesticides that use bacteria instead of chemicals. [45]

3. **Good for the environment**
   - Bioremediation: Microorganisms are used to clean up dirt and water that have been polluted. This is an effective way to deal with pollution.
   - Waste Treatment: Biotechnological processes make recycling and waste handling better, which makes business practices more environmentally friendly.

4. **Applications in Industry**

As a result of biotechnology, green energy sources like bioethanol and biodiesel can be made from biomass. This cuts down on our use of fossil fuels and our carbon emissions.

   - Bioprocessing: Microorganisms and enzymes are used in industry to make processes more efficient and less harmful to the environment. [46]

5. **Growth of the economy**
   - Job Creation: The biotech business helps the economy grow by creating jobs in research, manufacturing, and regulatory areas.
   - Innovative ideas and investments: Biotechnology encourages new ideas, brings in investments, and helps both new and old businesses grow.

6. **How to Make Food and Keep It Safe**
   - Nutritional Improvement: Biotechnology makes it possible to add important nutrients to foods, which helps weak groups that aren't getting enough food.
   - Food Safety: Biotechnology has made food safer by making it possible to test quickly for germs and contaminants. [47]

Some of the most important problems our society is facing right now, like health care, food security, and protecting the environment, can't be solved without biotechnology. It is a key area in shaping a healthier, more sustainable future because it can use biological processes to come up with new ideas. As technology keeps getting better, biotechnology will be able to be used in more areas, making it even more important in many areas.

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1.8 Biotech products:

Biotech products are new items made using biotechnological methods that take advantage of the power of live things and biological systems. These goods can be used in many areas, such as agriculture, pharmaceuticals, industrial settings, and environmental issues. Biotech has helped the pharmaceutical industry create biologics, like monoclonal antibodies and vaccines, which have changed the way diseases are treated and prevented in a big way. Genetically modified organisms (GMOs) help solve problems with food security by giving crops better qualities like tolerance to pests and higher nutritional value. Biotech goods used in industry include biodegradable plastics and biofuels made from renewable sources, which help with efforts to be more environmentally friendly. There are also important environmental uses for biotechnology, like bioremediation, which uses bacteria to clean up polluted areas. Overall, biotech goods show how biotechnology can be used to spur innovation, improve health, and support sustainability in many areas. Many new products have been made possible by biotechnology. [48] These products are changing many areas, such as healthcare, agriculture, food production, and environmental management. Biotech products in healthcare include medicines, vaccines, and diagnostic tools that are made from living things or parts of living things to stop, identify, and treat diseases. Biopharmaceuticals, which include gene therapies, monoclonal antibodies, and recombinant proteins, are some of the most important advances because they allow for targeted treatments for illnesses like cancer, autoimmune diseases, and genetic disorders. For example, trastuzumab (Herceptin) and other monoclonal antibodies are specially made to target cancer cells, which makes treatment more effective while minimizing side effects. Also, biotechnology has changed the way vaccines are made, allowing scientists to make very effective ones like the mRNA vaccines for COVID-19. These use messenger RNA to tell cells to make a virus-free piece of protein, which causes a strong immune response without actually spreading disease. In agriculture, biotech goods like genetically modified organisms (GMOs) have made crops much more productive, resistant to disease, and healthy. [49] Crops like Roundup and Bt cotton Ready soybeans are genetically modified to resist both pests and herbicides. This means that chemical pesticides are not needed as much, and farming methods are more environmentally friendly. Biotechnology also makes it possible to add important vitamins and minerals to staple foods. This helps fight malnutrition in poor countries, as shown by Vitamin A-enriched Golden Rice. Biotechnology has also helped the food business by creating enzyme-based products that make processing food better. For example, rennet is used to make cheese, and amylases are used in baking. These products make the process more efficient and improve the quality of the food. Biotechnology is also very important for managing the environment. For example, bioremediation products use microorganisms to break down pollutants in polluted soil and water, which helps environments recover. Making biofuels from biomass, like ethanol and biodiesel, is a sustainable way to replace fossil fuels and help lower greenhouse gas pollution. In the area of synthetic biology, scientists are pushing the limits even further by engineering microbes to make valuable compounds like bio-based plastics, pharmaceuticals, and specialty chemicals in a way that is better for the environment. As the need for long-lasting answers grows, biotechnology keeps coming up with new products that improve health, make farming more productive, and protect the environment. These products are very important for solving world problems. But the use of biotech goods also needs thorough safety checks, close attention from

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regulators, and input from the public to make sure that their benefits are gained in an honest and responsible way. [50]

1.9 Classifications of biotech products

Biotech goods can be put into different groups based on what they are used for, where they come from, and how they are made. Here is a full list of all the different types of biotech products:

1. Pharmaceutical products:

Biotech pharmaceutical products are a huge step forward in medicine because they use live things, cells, and biological systems to make new medicines and vaccines that treat a wide range of illnesses. In contrast to traditional drugs, which are often made using chemicals, biotech drugs usually come from biological sources like nucleic acids, proteins, and antibodies. Monoclonal antibodies are one of the most important types of biotech drugs because they are designed to target specific antigens on disease-causing cells, especially cancer cells. For example, trastuzumab (Herceptin), a monoclonal antibody, is used to treat HER2-positive breast cancer. It stops the growth of tumors while leaving healthy cells alone, so it has fewer side effects than traditional treatment. [51] Recombinant proteins, like insulin and clotting factors, are another important type of biotech drugs. They are made using recombinant DNA technology. These products have changed the way diabetes and hemophilia are treated by giving patients safe, highly effective treatments that are easy to handle. Genetic therapies are another type of biotech pharmaceutical goods. These involve changing a patient's DNA to fix or replace bad genes that cause disease. For instance, CAR-T cell therapy changes the genes of a patient's T cells so that they express chimeric antigen receptors that can find and attack cancer cells. This treatment works very well for some types of leukemia and lymphoma. Besides medicines, biopharmaceuticals also include therapeutic vaccines, like those made to treat cancer, which make the immune system find and kill tumor cells. Advanced bioprocessing methods, such as cell culture, fermentation, and purification, are used to make these goods. These methods ensure the production of high-quality therapies that work. The popularity of biosimilars, which are biotech drugs that are very close to biological products that have already been approved, has also made these new treatments easier for more people to get. They are more affordable for patients while still being effective. Before agencies like the FDA and EMA approve biotech pharmaceutical goods, they have to go through a strict regulatory process that includes long clinical trials to test their safety and effectiveness. Next-generation biopharmaceuticals are coming out as research keeps going strong. These include RNA-based

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therapies and personalized medicine methods that make treatments fit each person's genetic profile. However, the complexity of biotech pharmaceutical goods makes it harder to make, store, and ship them, which means they need to be handled and managed in a special way. Overall, biotech pharmaceutical goods are the cutting edge of modern medicine. They provide new ways to treat complicated illnesses and make patients' lives better. They also solve important problems with healthcare access and cost. As the field develops, it will be important for researchers, clinicians, and regulatory bodies to keep coming up with new ideas and working together so that biotechnology can fully change the pharmaceutical environment. [52] Biologics are things that come from live things and include:

Monoclonal antibodies: Used to treat diseases like cancer and autoimmune disorders (for example, trastuzumab is used to treat breast cancer).

Vaccines: These are shots made from biotechnology that help keep people from getting sick (for example, mRNA vaccines for COVID-19).

Hormones: These are things like insulin and growth hormones that are made with recombinant DNA technology.

Gene therapy products: These are medicines that change genes to treat or stop illnesses, usually with the help of viruses. [53]

2. Products for agriculture:

Biotech agricultural products, which use biotechnological approaches to improve crop yield, resilience, and sustainability while addressing global food security challenges, constitute a significant achievement in agricultural science. Genetically modified organisms (GMOs) are one of the most well-known ways that biotechnology is used in agriculture. These are plants and animals that have had certain genes added to their DNA to give them desired traits. For instance, Bt cotton and Bt corn have been modified to produce a protein from the bacteria Bacillus thuringiensis. This protein makes the plants resistant to many insect pests, which lowers the need for chemical pesticides and helps the environment. These GMOs not only boost crop growth but also help farmers lower their costs of production, which can make food more accessible and less expensive. Biotechnology is also very important for making crops that can handle abiotic stresses like drought, saltiness, and high temperatures, in addition to making them resistant to pests. Some strains of maize that were made through genetic engineering are drought-resistant, which lets farmers grow crops in dry areas and helps protect food sources in the face of climate change. Biotech crops can also be modified to have better nutritional profiles. For example, Golden Rice has been genetically modified to have higher amounts of provitamin A (beta-carotene), which helps people who eat a lot of rice avoid vitamin A deficiency. [54] Biotechnology also includes making biofertilizers and biopesticides from natural sources, which can improve the health of the land and cut down on the use of chemicals. This includes microbial products that help plants grow or take in nutrients better, as these can increase crop production in a way that doesn't harm the environment. The use of CRISPR-Cas9 technology is another important area. This technology lets

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plant genomes be precisely edited to get desired traits without adding foreign DNA. This makes goods that are better for consumers and regulators. Biotech goods used in agriculture are regulated in a complicated way that often requires thorough safety checks to protect both human and environmental health. More and more people are learning about and accepting biotechnology. This means that people want clear labels and a full understanding of the pros and cons of biotech foods. Biotechnology has the potential to completely change agriculture, and study is still being done to improve crop traits even more, make plants more resistant to climate change, and encourage environmentally friendly practices. Overall, biotech products for agriculture have the potential to change the way food is produced, make food more secure, and encourage environmentally friendly growing methods that are good for farmers, consumers, and the environment. [55]

Genetically Modified Organisms (GMOs): Crops that have been changed to have certain features, such as

Pest Resistance: Plants that have been modified to make their own poisons, like Bt cotton.

Herbicide Tolerance: Plants that can survive being sprayed with certain pesticides (for example, Roundup Ready soybeans).

Nutritional Enhancement: Crops that have better nutritional values, like Golden Rice, which has extra vitamin A.

Biofertilizers and biopesticides: are natural substances made from microorganisms that make land more fertile or get rid of pests.

3. Biotechnology Products Used in Industry

Industrial biotechnology products are utilized in a wide range of applications that use living things and biological processes to provide novel solutions for a variety of industries, such as food production, agriculture, pharmaceuticals, and environmental management. Biotechnology has transformed medication development in the pharmaceutical sector by producing biopharmaceuticals, such as gene treatments, recombinant proteins, and monoclonal antibodies. These goods are made with specific ailments in mind, maximizing therapeutic effectiveness while reducing adverse effects. Monoclonal antibodies for the treatment of cancer and insulin for the control of diabetes, for example, are two prominent examples of biotech-derived medicines that have greatly improved patient outcomes. [56]

Biofuels: are clean fuels made from biological sources, like

Bioethanol: is made by fermenting sugars that come from plants like sugarcane or maize.

Biodiesel: is made by converting to food oils or animal fats.

Biodegradable plastics: are made from natural materials that can be used again and again. They break down more quickly than regular plastics, like polylactic acid. Bioprocessing products are enzymes and microorganisms that are used in industry, like cellulases for making biofuel. [57]

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4. Biotechnology Products for Food

Food biotechnology products are a broad category of technological advancements that address global issues like food security and sustainability while increasing agricultural output, refining food processing, and enhancing nutritional quality. Developing genetically modified organisms (GMOs), where crops are altered to display desired features like pest resistance, herbicide tolerance, and higher nutritional content, is a significant application. In order to reduce the need for chemical pesticides and promote environmental sustainability, Bt corn, for example, is genetically engineered to express proteins that provide insect pest resistance. Apart from genetically modified organisms, biotechnology is also essential to food fermentation. [58] It uses microorganisms such as yeast and bacteria to make bread, cheese, and yogurt, among other staple foods. This technique improves these foods' nutritional profile and digestibility in addition to their flavor and texture. The food industry makes considerable use of enzyme-based products obtained from biological sources, like amylase and proteases, to maximize processing efficiency and improve product quality, resulting in lighter baked items and creamier cheeses. Additionally, biotechnology aids in the process of biofortification, which raises the nutrient content of staple crops to help communities that depend on these foods fight micronutrient shortages. Technological developments in molecular biology also make it easier to quickly identify foodborne bacteria, improving food safety and safeguarding public health. All things considered, food biotechnology products greatly improve food systems' sustainability and efficiency while enhancing nutritional quality and safety. They also play a critical role in meeting the changing needs of the world's expanding population. [59]

Fermented foods: are things that are made by fermenting other things, like

Cheese and yoghurt made with certain types of bacteria are examples of dairy products.

Alcoholic drinks: Beer and wine are made when yeast ferments sugars.

Food additives: enzymes and other biotechnology-made ingredients that help process or store food better.

5. Biotechnology products for the environment

Biotechnology products for the environment, which use biological processes and creatures to address ecological concerns and enhance environmental health, constitute an important convergence of science and sustainability. In this field, bioremediation—a technique that uses microbes, plants, or fungi to detoxify contaminated soil and water—is one of the most important uses of biotechnology. For instance, certain bacteria are capable of decomposing dangerous chemicals including pesticides, heavy metals, and petroleum hydrocarbons, effectively cleaning up oil spills and polluted areas. Another cutting-edge strategy is phytoremediation, which uses plants to absorb and immobilize pollutants from the soil. Certain plants, including hyperaccumulators and sunflowers, are especially chosen for their capacity to absorb harmful compounds and promote their breakdown. [60]

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Bioremediation agents: are microorganisms that are used to clean up places that are polluted, like after an oil spill or heavy metal pollution.

Solutions for treating wastewater: that use biological processes to clean it up and lower the amount of toxins it contains before it is released.

6. Tools for research and diagnosis

Diagnostic kits: are biotechnology-based tests that can find diseases and viruses. For example, PCR tests can identify pathogens by amplifying specific DNA sequences.

Lateral Flow Assays: are quick diagnostic tests that can be used for things like pregnancy checks.

You can use plasmids, primers, and enzymes, among other things, as study reagents in genetics and molecular biology.

7. Items for personal care

Personal care biotechnology products are a growing industry that uses biological technologies and processes to improve the efficacy and composition of hygiene and beauty products. These goods frequently contain both biotechnologically created components that provide enhanced performance and safety and substances that come from natural sources. Creating active substances from microorganisms, plants, and algae is one of the main uses of biotechnology in personal care. For example, probiotics like Bifidobacterium and Lactobacillus are being utilized more often in skincare products to improve the function of the skin barrier, lower inflammation, and support a healthy skin microbiota. These probiotics are useful in treating eczema and acne since they can help balance the skin's natural flora. [61]

Cosmetics: are beauty and skin care products that use biotechnological ingredients, like probiotics and peptides, to keep the face healthy.

Nutritional supplements: are made from food and have health benefits. They are usually made using biotechnology.

The different types of biotech goods show how biotechnology can be used and how it might help many different areas. Biotech products are very important for solving world problems because they help make healthcare better through new drugs and therapies and for protecting the environment and increasing crop yields. The way biotech goods are organized may change over time as technology improves, creating new categories and uses. [62]

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1.10 Recombinant DNA technology:

Recombinant DNA technology is a strong and flexible way for scientists to make new DNA sequences by combining genetic material from different sources. A lot of different areas, like medicine, farming, and research, use this technology. Here's a quick rundown of the main ideas, methods, uses, and effects of recombinant DNA technology:

Concepts:

Recombinant DNA, or rDNA: This is DNA that was made in a lab by mixing DNA from different living things. Usually, a gene of interest is put into a vector, which is a DNA molecule used to get genetic material into cells. [63]

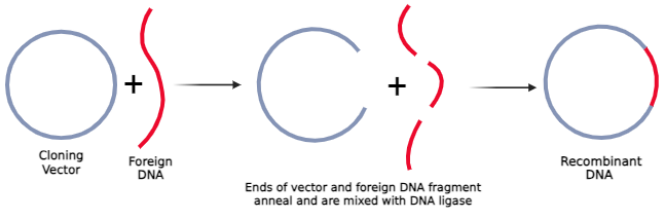

Fig: 02: The process of Recombinant DNA.

Gene cloning: This is the process of making many copies of a certain piece of DNA. It lets scientists learn more about the gene, make proteins, or create GMOs, or genetically edited organisms.

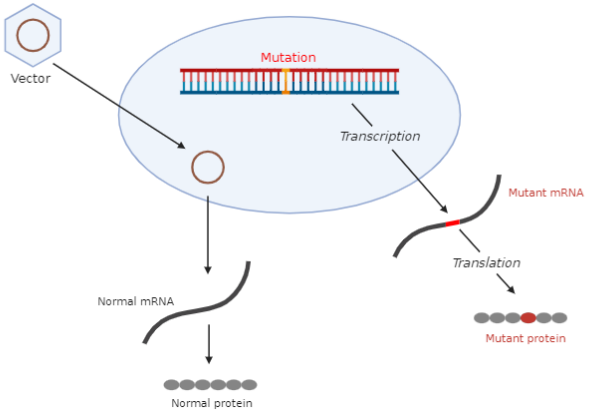

Fig: 03: the process of gene cloning.

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Techniques Used:

Restriction Enzymes: Enzymes That Cut DNA at Specific Sequences: These enzymes, which are also called restriction endonucleases, make DNA pieces with blunt or sticky ends. This makes it possible for DNA pieces to join together.

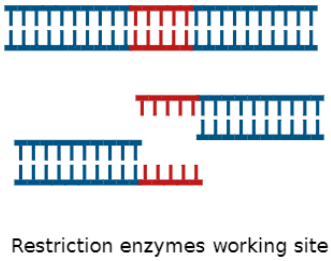

Fig: 04: Restriction enzyme working site on DNA.

DNA Ligase: This enzyme seals the sugar-phosphate backbone and joins DNA pieces together to make stable recombinant DNA molecules.

Vectors: These are the tools that are used to get rDNA into target cells. Some common routes are:

Plasmids: These are circular DNA units discovered by Laderburg and it is contained by bacteria. Plasmids can copy themselves on their own.

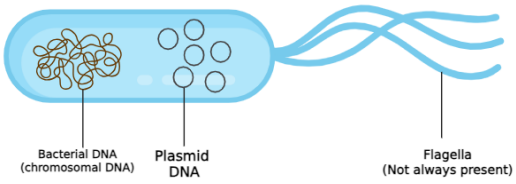

Fig: 05: The location of Plasmid in Bacteria body.

Bacteriophages: These are viruses that attack bacteria and are often used to deliver genes.

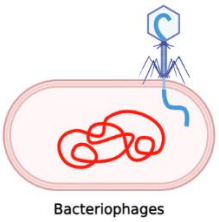

Fig: 06: Virus inserting its DNA in Bacteria to increase its number

Artificial Chromosomes: These are bigger carriers, like yeast artificial chromosomes (YACs) or bacterial artificial chromosomes (BACs), that are used to copy larger pieces of DNA.

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Transformation: Putting recombinant DNA into host cells, which are usually bacterial cells, so that those cells can produce and copy the gene that was added.

Selection and Screening: Once the cells have been transformed, researchers use markers for antibiotic resistance or other ways to pick out the ones that have taken up the recombinant DNA. [64]

1.11 Pharmaceutical products:

Pharmaceutical biotech products, which use the concepts of biotechnology to create novel cures and treatments, are a ground-breaking development in medicine. Biologics, which are generated from living things and provide tailored treatments for a variety of ailments, including cancer, autoimmune disorders, and infectious diseases, are among these items. Examples of these include monoclonal antibodies and vaccinations. Recombinant DNA technology is one prominent example of how it has greatly improved diabetes care by producing human insulin. Furthermore, gene therapy products seek to replace or repair defective genes in order to address genetic abnormalities, providing hope for conditions that were previously thought to be incurable. These products' efficacy and safety are guaranteed by the stringent research and development procedures that went into their creation, and this has a revolutionary effect on patient care. Pharmaceutical biotechnology has a lot of potential for solving new health issues and creating personalised medicine solutions as it develops further. [65]

1.12 Monoclonal Antibodies:

The term "monoclonal antibodies" has come to mean innovative therapeutics and very important medical advancements in recent years. Has it ever occurred to you why these antibodies are so unique? These small but potent molecules are becoming more and more important in the fight against anything from autoimmune diseases to cancer as research advances. This article will discuss what monoclonals are, how they are manufactured, how they are used in healthcare, and their potential uses in the future. [66]

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Monoclonal antibodies: **What Are They?**

Lab-produced molecules known as monoclonal antibodies (mAbs) have the capacity to imitate the immune system's defence against dangerous pathogens such as bacteria and viruses. They are made to attach themselves to particular targets in the body, called antigens, which are usually proteins present on the surface of cells. [67]

The Mechanisms of Action of Monoclonal Antibodies:

What is the cellular mechanism of action of these antibodies? Here's a condensed explanation:

• Production: To make monoclonal antibodies, a cancer cell and a certain kind of immune cell called a B cell are fused. The resulting hybrid cell, known as a hybridoma, may reproduce indefinitely and only produce one kind of antibody.

• Selection: Following the generation of hybridomas, researchers look for those that produce the appropriate antibody that specifically targets an antigen.

• Amplification: After the hybridoma of choice is cloned, identical antibodies can be produced on a massive scale.

Because of this customised method, monoclonal antibodies may be produced to specifically target diseases, making them extremely accurate medical instruments. [68]

Uses for Monoclonal Antibodies

One of the main benefits of monoclonal antibodies is their adaptability, which allows for a variety of uses, including therapeutic treatments and diagnostics.

1. Treatment for Cancer

In oncology, monoclonal antibodies are causing quite a stir. They can be employed for:

• Directly target cancer cells: Certain mAbs are made to attach to particular proteins on the outside of cancer cells, designating them so that the immune system can destroy them.

• Drug delivery: In order to minimise harm to healthy cells, additional antibodies can serve as vehicles for the direct delivery of chemotherapeutic medications to cancer cells.

Consider **Trastuzumab**.

HER2-positive breast cancer is treated with the well-known monoclonal antibody trastuzumab (Herceptin), which binds to the HER2 receptor on cancer cells to stop them from growing.

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2. Autoimmune Diseases

The immune response that wrongly targets the body's own tissues can be suppressed by monoclonal antibodies for illnesses such as multiple sclerosis and rheumatoid arthritis.

Rituximab, for instance

Rituximab targets B-cells' CD20 protein, which causes these rogue immune cells—which are linked to autoimmune disorders—to become less numerous.

3. Infection Diseases

Monoclonal antibodies became known as a potential therapy for neutralising the virus during the COVID-19 pandemic, offering a vital instrument in the fight against outbreaks.

For instance, **Bamlanivimab**

One of the first monoclonal antibodies approved for use in an emergency setting to treat COVID-19 was Bamlanivimab, which demonstrated potential in lowering viral load in individuals receiving treatment. [69]

Prospects for Monoclonal Antibodies in the Future:

The field of monoclonal antibodies is developing quickly, offering new opportunities for therapy as well as improvements in precision medicine.

Horizontal Innovations:

• Bispecific Antibodies: These can be used for more intricate therapeutic applications because they are designed to bind two distinct antigens.

• Combination Therapies: To increase the effectiveness of monoclonal antibodies, researchers are exploring the possibility of mixing them with other medications, such as vaccinations. [70]

1.13 Vaccines:

Vaccines are an essential tool for maintaining public health because they help the immune system identify and fight particular invaders, such bacteria and viruses, protecting the body from infectious diseases. They function by delivering a pathogen's innocuous part into the body, which could be a protein generated from the pathogen, a fragment of its genetic material, or an inactivated or attenuated form of the virus. This exposure sets off an immunological response that includes the production of antibodies, allowing the body to identify and eliminate the infection should it resurface. Immunizations have been essential in managing and even completely eliminating illnesses like smallpox and polio that formerly caused high rates of morbidity and mortality. The recent creation and use of mRNA vaccines, such as those for COVID-19, shows how quickly vaccine technology is developing and how it might be used to counter new disease threats. Vaccination reduces the overall occurrence of diseases in the community and protects vulnerable populations that may not be able to acquire vaccines for themselves. Vaccination also helps to

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create herd immunity. Public education and outreach are crucial to ensuring universal vaccine uptake and safeguarding global health since, despite the vaccines' established efficacy and safety, reluctance and false information still hinder vaccination efforts globally. Biological preparations known as vaccines are intended to produce immunity against particular infectious illnesses. They aid in the immune system's recognition and protection against the pathogen in subsequent exposures because they contain elements that mimic a germ that causes disease. This is a thorough explanation of vaccines, covering their various forms, working principles, stages of development, and significance. [71]

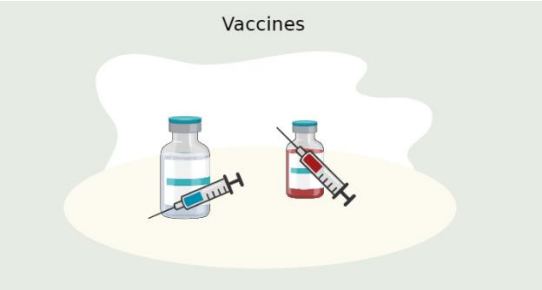

Fig: 07: vaccines

Vaccine Types:

1. Vaccines with live attenuation

Synopsis: The pathogen included in these vaccinations is weakened so that it cannot infect healthy people. Vaccinations against varicella (chickenpox), yellow fever, measles, mumps, and rubella (MMR).

Benefits: They frequently only need one or two doses to produce robust and long-lasting immune responses.

2. Vaccines that are inactivated or killed

Synopsis: These vaccinations are derived from microorganisms that have been rendered inactive or destroyed, rendering them incapable of causing illness. Hepatitis A, influenza, and the polio vaccine (inactivated poliovirus vaccine) are a few examples.

Benefits: Although they are safe and stable, adequate immunity may need to be achieved by several doses or booster shots.

3. Vaccines that are Subunit, Recombinant, and Conjugate

Description: Rather fighting the entire germ, these vaccines only include particular components of the disease, such as proteins or carbohydrates.

Subunit: Hepatitis B vaccine subunit (which includes surface proteins).

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Recombinant: The HPV vaccination, which includes recombinant L1 protein.

Conjugate: Polysaccharide linked to a protein; pneumococcal conjugate vaccination.

Benefits: They may be customized for certain immune responses and are safer because they don't contain live viruses.

4. Vaccines with messenger RNA (mRNA)

Description: Synthetic mRNA is used in these vaccines to direct cells to create a safe portion of the pathogen, typically a protein, in order to initiate an immune response.

Examples: Pfizer-BioNTech and Moderna COVID-19 vaccines are two examples.

Benefits: Strong immune responses and quick development and production because they don't need the virus itself.

5. Viral Vector Vaccines:

Description: The genetic material from the pathogen is delivered into the body by these vaccinations using a harmless virus (not the one that causes the sickness).

Examples: Ebola vaccine and the Janssen COVID-19 vaccine from Johnson & Johnson.

Benefits: They often only need one dosage and boost the cellular and humoral arms of the immune system. [72]

Method of Action:

Vaccines function by simulating an illness. The immune system mounts an immunological response in response to a vaccination because it perceives the pathogen's components as foreign. This reply consists of:

- Antibody Production: Certain antibodies that neutralize the infection are produced by the immune system.
- Formation of Memory Cells: The pathogen's “memory” is retained by the development of specialized immune cells, such as memory T and B cells. These cells can identify and react to the virus fast, allowing the body to develop immunity in the event that it comes into contact with it again. [73]

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Method of Development

1. Research and Discovery: Researchers pinpoint the pathogen's identity and ascertain which components of it trigger an immune reaction. Animal testing and laboratory investigations are frequently a part of this step.

2. Preclinical Testing: To evaluate the vaccine candidate's safety and immunological response, tests are conducted on animals and in laboratories.

3. Clinical Trials: Three stages of clinical trials involving human subjects are conducted for the vaccine:

- Phase 1: To test dose and safety, small groups of healthy volunteers participate.
- Phase 2: Evaluation of adverse effects and efficacy in larger populations.
- Phase 3: Thousands of participants to monitor adverse effects in a varied group and validate efficacy.

4. Regulatory Approval: Data is submitted for evaluation and approval to regulatory bodies (such as the EMA in Europe or the FDA in the United States) following successful trials.

5. Manufacturing and Distribution: Following approval, the vaccine is mass produced and supplied to medical professionals.

6. Post-Market Surveillance: After the vaccination is administered, continued safety and efficacy monitoring is conducted. [74]

The importance of vaccines

Disease Prevention: By drastically lowering rates of morbidity and death, vaccinations are one of the most powerful public health instruments for preventing infectious diseases.

Herd Immunity: By lowering the overall prevalence of the disease, widespread vaccination might result in herd immunity, protecting those who cannot receive vaccinations (such as infants and those with impaired immune systems).

Eradication of illnesses: Immunization campaigns have greatly decreased the prevalence of measles and polio while also effectively eliminating illnesses like smallpox.

Economic Benefits: By lowering hospital stays and medical treatments for diseases that are vaccine-preventable, vaccination can result in significant cost savings in healthcare. [75]

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In summary, as a secure and reliable method of preventing infectious diseases, vaccines are a fundamental component of contemporary medicine. The continuous investigation and progress in vaccine science, encompassing innovations such as mRNA vaccines, keeps improving our capacity to counter new disease hazards. Worldwide immunization campaigns are still essential for maintaining public health since they shield people from potentially fatal illnesses.

1.14 Hormones

Pharmaceutically produced hormones are either naturally or synthetically derived hormones that are utilized in medical therapies to control different bodily physiological processes. They are essential for treating hormonal imbalances or illnesses, hormone replacement treatment, and contraception. This is a comprehensive guide on hormones produced by pharmaceutical companies, covering their types, mechanisms, production methods, uses, and safety concerns. Bioactive substances generated using biotechnological techniques, pharmaceutically manufactured hormones play a crucial role in the treatment of various hormonal diseases and ailments. These hormones, which can be synthesized or obtained from natural sources, include growth hormones, sex hormones, insulin, and others. For example, because it controls blood glucose levels, insulin is essential for controlling diabetes. In the past, human insulin was produced using genetically engineered bacteria or yeast, but recombinant DNA technology has made it possible to produce human insulin from animal pancreases. This ensures a safer, more effective product devoid of impurities obtained from animals. Similarly, adult medical issues such growth hormone insufficiency and muscle atrophy linked to chronic diseases are treated with recombinant human growth hormone (rhGH). [76] It is also used to treat growth disorders in children. It is made on a big scale with excellent purity and bioactivity utilizing genetically modified E. Coli or mammalian cells. Sex hormones like testosterone and estrogen are also created artificially and are crucial components of hormone replacement treatment for menopausal women and those with hormone deficiency. To successfully restore hormonal balance, these hormones can be produced synthetically or taken from plant sources and prepared into a variety of administration methods, such as pills, patches, and injections. Biotechnology has also made it easier to synthesize peptide hormones, such glucagon-like peptide-1 (GLP-1), which is used to treat type 2 diabetes and obesity by improving insulin sensitivity and encouraging weight reduction. Strict regulatory guidelines are applied throughout the manufacture of these hormones to guarantee their efficacy, safety, and uniformity. Furthermore, the capacity of biotechnology to generate hormones permits customization in formulations and dosages, more efficiently meeting the demands of individual patients. All things considered, pharmaceutically manufactured hormones are a huge step forward in medical care, offering patients more effective ways to address their hormonal imbalances and enhance their quality of life. [77]

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Types of Hormones Manufactured by Pharmaceuticals:

1. Sex hormones

- **Estrogens:** Found in some contraceptive formulations and in hormone replacement treatment (HRT) for menopausal women.
  Examples: Ethyl estradiol and estradiol.

- **Progesterones:** Frequently seen in combination with estrogens in oral contraceptives and HRT.
  Examples: Norethindrone and medroxyprogesterone acetate.

- **Androgens:** Used to treat certain forms of breast cancer and disorders associated with low testosterone levels.
  Examples: Methyltestosterone and testosterone are two examples.

2. Thyroid Hormones

- Levothyroxine (T4): Hypothyroidism is treated with this synthetic version of thyroxine.

- Liothyronine (T3): A synthetic version of triiodothyronine that is sometimes prescribed for thyroid cancer and hypothyroidism.

3. Peptide Hormones

- Insulin: Comes in a variety of forms and is necessary for controlling glucose levels in the treatment of diabetes.
  Example: Insulin glargine, insulin aspart, and regular insulin.

- Growth hormones: Used to treat adult hormone deficiencies and growth problems in youngsters.
  Example: Somatropin, a human growth hormone recombinant.

- Gonadotropins: Used to induce ovulation in fertility treatments.
  Example: Follicle-stimulating hormone (FSH) and luteinizing hormone (LH).

4. Steroids

- Hydrocortisone: Used to treat inflammatory diseases and adrenal insufficiency.

- Prednisone: Used to treat certain malignancies, autoimmune conditions, and inflammatory diseases.

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5. Adrenal Hormones

- Aldosterone: Synthetic variants are utilized in certain adrenal diseases. This hormone regulates blood pressure and electrolyte balance.

- Dexamethasone: A synthetic glucocorticoid used to treat autoimmune and inflammatory disorders, among other ailments. [78]

Method of Action

Hormones produced in pharmaceuticals either replicate or intensify the body's natural hormonal balance. They cause physiological reactions by acting on certain receptors in the target tissues. As an illustration:

- Estrogens and Progesterones: These hormones bind to receptors for estrogen and progesterone, which affects functions such as bone density, pregnancy, and menstruation.

- Insulin: Helps control blood sugar levels by facilitating cells' absorption of glucose.

- Thyroid Hormones: Control target tissue gene expression to govern growth, development, and metabolism. [79]

Production Procedures:

1. Techniques in Biotechnology

- Recombinant DNA technology: This method is used to make additional peptide hormones, insulin, and growth hormone. This entails introducing the hormone's gene into yeast or bacterial cells, causing them to manufacture the hormone.

- Cell Culture: Mammalian cell cultures are used in the production of hormones such as monoclonal antibodies and some recombinant proteins to ensure correct folding and post-translational modifications.

2. Chemical Synthesis

- A number of steroid hormones, including progesterone and testosterone, are produced chemically, frequently beginning with sterols taken from plants.

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3. Refinement

- Hormones are thoroughly purified to get rid of contaminants and byproducts once they are produced. Filtration, crystallization, and chromatography are typical methods.

4. Synthesis

- To ensure appropriate distribution and absorption, hormones are packaged into a variety of dose forms, such as tablets, injections, creams, and patches. [80]

Safety Information Adverse Reactions:

The adverse consequences of hormonal therapy can include mood swings, weight gain, an increased risk of some cancers (including breast cancer and estrogen therapy), as well as cardiovascular problems. [81]

Restrictions:

Certain medical problems, such as a history of hormone-sensitive malignancies, liver disease, or blood clot disorders, may make the usage of particular hormones contraindicated. [82]

Observing:

To guarantee effectiveness and reduce hazards, regular monitoring of hormone levels and physiological responses is crucial throughout hormone therapy. Individual needs should be taken into account while designing hormonal therapy, taking into account things like age, sex, health, and particular medical issues. [83]

In summary, pharmaceutically produced hormones are essential to modern medicine because they can treat a wide range of hormonal diseases and abnormalities. Many patients' quality of life is greatly enhanced by these artificial and biologically derived hormones, which are used in hormone replacement therapy, reproductive treatments, and the management of chronic diseases. The efficiency and security of hormone treatments are being improved by ongoing research and developments in hormone production and administration methods.

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1.15 Gene and Cell Therapy:

The Gene therapy is a modern medical strategy that modifies a patient's cell genetic makeup in order to treat or prevent disease. This approach has the potential to offer long-term treatments for cancer, a number of genetic disorders, and other illnesses caused by anomalies in the DNA. [84]

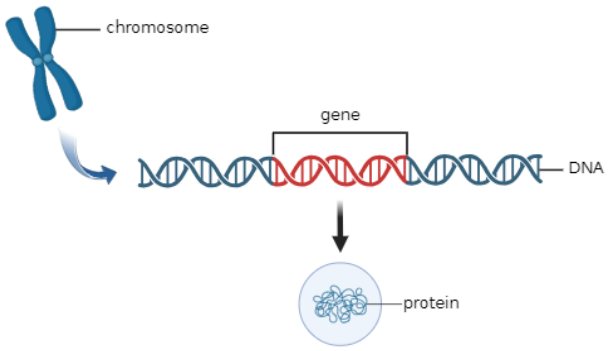

Fig: 08: Protein from genetic information.

Essential Ideas in Gene Therapy

1. Action Mechanism

Gene therapy corrects faulty genes that cause disease development by adding, deleting, or changing genetic material in the patient's cells. The main tactics consist of:

Gene addition: Adding a functional copy of a gene to make up for a mutated or non-functioning one. When the CFTR gene is faulty, as in the case of cystic fibrosis, this method is frequently employed. Gene editing is the process of precisely altering the DNA at particular sites throughout the genome using tools like CRISPR-Cas9. This makes it possible to directly fix mutations in the patient's DNA, which may provide treatments for hereditary illnesses. Targeting hyperactive genes to lower their expression is known as gene silencing. When treating some tumors where specific genes play a role in tumor growth, this approach is especially helpful. [85]

2. Modes of Delivery

The therapeutic genes must be effectively inserted into the target cells for gene therapy to work. The principal techniques of delivery consist of:

Viral Vectors: Viruses that have been altered are frequently employed as carriers. Viruses that are often utilized include:

Adenoviruses: Non-integrating vectors that are efficient at delivering genes, particularly for transient therapeutic effects.

Integrating vectors capable of stably inserting genes into the host genome and enabling long-term expression are known as lentiviruses.

Adeno-Associated Viruses (AAV): Smaller viruses that can integrate into the host genome at low

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risk and are less likely to elicit an immune response.
Non-Viral Techniques: These consist of chemical and physical techniques like:
Liposomes: Tiny vesicles that can carry DNA and make it easier for cells to absorb it.
Applying an electrical field to a cell membrane to improve its permeability and permit DNA entry is known as electroporation.
Microinjection: The process of directly injecting DNA with tiny needles into the target cell's nucleus. [86]

3. Utilization
There are several uses for gene therapy, such as:
Genetic conditions: Focusing on conditions caused by a single gene, like:
The goal of gene therapy for cystic fibrosis is to replace the defective CFTR gene with a functioning one.
Duchenne Muscular Dystrophy: Restoring dystrophin production using gene editing is one method.

Treatment for Cancer:
Oncogene Targeting: Introducing genes through gene therapy that can stop tumor growth or strengthen the body's defenses against cancerous cells.
CAR-T Cell Therapy: Creating chimeric antigen receptors on a patient's T cells that specifically target and kill cancer cells.
Infectious Diseases: By focusing on and altering the viral genome or by boosting the immune system to manage the infection, research is investigating the use of gene therapy to treat diseases like HIV.
Rare Diseases: Treatments such as Luxturna, which gives retinal cells a copy of the RPE65 gene to cure specific forms of inherited blindness, have demonstrated efficacy. [87]

4. Difficulties and Considerations
Gene therapy presents a number of obstacles despite its potential:
Safety: Immune reactions against the vector, insertional mutagenesis is a process in which the insertion of a new gene breaks an existing gene and possible off-target consequences from gene editing technologies are among the hazards connected to gene therapy.
Efficacy: Depending on the target tissue, the type of disease, and the delivery mechanism, the outcome of gene therapy can differ significantly.
Cost and Manufacturing: Patients' affordability and accessibility are concerns due to the expensive development and treatment costs, as well as the difficulty of manufacturing gene treatments on a large scale.
Regulatory Obstacles: Before obtaining regulatory approval, gene therapy products must pass stringent testing to guarantee their safety and effectiveness. This can be a time-consuming and

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complicated procedure. [88]

5. Prospective Paths

Gene therapy is a rapidly developing field where current research is concentrated on:

Enhancing Delivery Systems: To increase the accuracy and potency of gene treatments, more effective and focused delivery techniques must be developed.

Progressing with Gene Editing Technologies: New developments in gene editing, such prime and base editing, hold promise for more accurate alterations with fewer unintended consequences.

Expanding Applications: Ongoing research on gene therapy to treat a wider variety of illnesses, such as metabolic and neurological conditions.

Customizing gene therapies for each patient according to their genetic composition has the potential to improve treatment outcomes. This is known as personalized medicine.

In summary

By targeting the underlying genetic causes of diseases, gene therapy holds the promise of treating or curing them. It is a revolutionary development in the world of medicine. Even though there are a lot of obstacles to overcome, the continued study and advancement in this field have the potential to drastically alter the way we manage a variety of hereditary illnesses and disorders. Gene therapy has the potential to significantly enhance personalized treatment and improve health outcomes for a vast number of individuals globally as the science develops. [89]

1.16 Global response of biotech products

The global response to biotechnology products has been characterized by significant investments, rapid advancements, and increasing acceptance, which have been motivated by the necessity to address urgent challenges in environmental sustainability, agriculture, and healthcare. Biotechnology products including gene treatments, recombinant proteins, and monoclonal antibodies have transformed therapy possibilities for a wide range of ailments in the healthcare sector, including cancer, genetic disorders, and infectious diseases like COVID-19. Millions of lives have been saved by international vaccination efforts thanks to the quick invention and implementation of mRNA vaccines during the epidemic, which demonstrated the promise of biotechnological advancements. [90] Consequently, nations all over the world have turned their attention to biotechnology research and development, encouraging public-private partnerships and academic cooperation to speed up the regulatory approval and product development processes. Biotechnology products in agriculture, such genetically modified (GM) crops, have drawn interest because they offer the potential to improve food security through higher crop yields, better nutritional value, and less need on chemical pesticides. [91] The acceptance of genetically modified agriculture, however, differs greatly throughout geographical areas due to differences in legal frameworks, public opinion, and cultural perspectives on biotechnology. While many European countries maintain severe laws and labeling requirements that hinder the use of GM crops, other countries, like the United States and Brazil, have welcomed the technology. The growing awareness of climate change and the need for sustainable farming practices has led to a surge in interest in biotechnological solutions, such biopesticides and biofertilizers, that help reduce environmental consequences. Environmental applications, where bioremediation and waste management solutions are being created to combat pollution and promote sustainability, are another area where the worldwide response to biotechnology goods is visible. In line with global

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sustainability goals, biotechnological technologies including biodegradable plastics and biofuels are being investigated to lessen dependency on fossil fuels and plastic waste. [92]
However, there are obstacles to the regulation and acceptance of biotechnology products, such as false information, safety concerns, and ethical dilemmas. Therefore, fostering trust and guaranteeing the responsible application of biotechnology requires stakeholder participation, public education, and open regulatory procedures. It is clear from the global response to biotechnology products that governments, corporations, and communities must collaborate in order to fully realize the potential of these innovations to transform industries and address some of the most critical global issues. This will allow for the harnessing of the benefits of biotechnological innovations while addressing societal concerns.

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Chapter 2

PURPOSE of THE STUDY

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2 Purpose of The Study:

During my high school studies, my special interest in Biology, especially the Biotechnology chapter, worked on how humans got so far in science. Humans currently select DNA from within cells to alter it between human life and natural and other substances. The study of biotechnology products serves several critical purposes across diverse fields, including healthcare, agriculture, environmental science, and industrial applications. In healthcare, it aims to develop innovative therapies and vaccines to improve health outcomes, enabling targeted treatments for diseases such as cancer and genetic disorders. The study of biotech products in agriculture focuses on enhancing crop resilience, nutritional value, and yield, which are essential for ensuring food security in a growing global population. Moreover, biotechnology research contributes to sustainable practices by developing biopesticides and biofertilizers that minimize environmental impact. In environmental science, the study of biotech products is pivotal for creating bioremediation strategies to clean up contaminated sites and address pollution, while also fostering the production of biodegradable materials and biofuels. Additionally, in industrial applications, biotechnology enhances manufacturing processes through bioprocessing techniques that improve efficiency and reduce reliance on non-renewable resources. Overall, the study of biotechnology products is crucial for driving innovation, addressing global challenges, and promoting economic growth, ultimately contributing to a healthier and more sustainable world.

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Chapter 3

METHODOLOGY

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3 Methodology

I conducted a thorough search on several research databases, such as Google, Google Scholar, and PubMed, and retrieved about 20 documents comprising research and review papers. After reading the articles and relevant sources, I produced a paper. To ensure the accuracy of my essay, I only cited works published between 2010 and 2023. PubMed is a widely used biomedical literature resource that provides access to publications on comprehensive review of biotechnology products. I have also used the governmental site of US FDA to collect the approval information of biotech products of 2023. Obtaining trustworthy information regarding biotechnology products is crucial for research and development in a multitude of industries. Important sources include governmental and regulatory organizations that offer guidelines on biotechnology rules and licensed products, such as the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA). The Biotechnology Innovation Organization (BIO) and other industry associations provide information about market trends and lobbying initiatives in the biotechnology space. Furthermore, universities and research organizations disseminate important materials via magazines like Nature Biotechnology and Journal of Biotechnology, which include reviews and cutting-edge research. Market research companies that offer reports that evaluate the biotechnology sector, along with product trends and projections, include MarketResearch.com and Research and Markets. Moreover, commercial biotech firms like as Genentech and Amgen provide comprehensive details on their innovations and products. A wealth of information about clinical trials and biotechnology technologies can be found in online databases like ClinicalTrials.gov and the Biotechnology Resource Database (BRD). When combined, these tools offer a thorough environment for obtaining important data about biotechnology products, enabling both academic and industrial decision-making.

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Chapter 4

RESULT

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4. Results

FDA Novel Drug Therapy Approvals for 2023

In 2023, CDER approved 55 new drugs never before approved or marketed in the U.S., known as "novel" drugs. They also made other important approval decisions, such as expanding the use or patient population of previously approved drugs. Details of some of them mentioned below:

Monoclonal Antibodies:

Monoclonal antibodies are a major class of therapeutic biological molecules and have had many breakthroughs in modern medicine.

1.Epcoritamab

In May 2023, the FDA granted accelerated approval for epcorab, intended for patients with relapsed or refractory DLBCL. Its ongoing approval for this use may depend on the confirmation and documentation of clinical benefits from further trials. In September 2023, epcoritamab received approval in the EU for the same condition.

Mechanism of action:

Epcoritamab is a humanized bispecific IgG1 antibody designed to target CD20 on B-cells and CD3 on T-cells. Unlike typical monoclonal antibodies that focus on a single receptor on lymphocytes, epcoritamab is capable of identifying and attaching to two distinct targets: the CD3 receptor found on T-cells and CD20 present on both lymphoma cells and normal B-lineage cells. By engaging with these two receptors, epcoritamab enhances the release of proinflammatory cytokines and facilitates the destruction of CD20+ malignant B-cells through targeted T-cell-mediated cytotoxicity.

Brand name: Epkinly

Indication: For the treatment of adults with relapsed or refractory B-cell malignancies, including large B-cell lymphoma.

Manufacturer: AbbVie and Genmab

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Biologic Classification: Protein Based Therapies

2.lecanemab

Lecanemab is a recombinant humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta (Aβ), which are implicated in the pathophysiology of Alzheimer's disease. Lecanemab works to reduce Aβ plaques and prevent Aβ deposition in the brain with high selectivity to Aβ protofibrils. In clinical trials, it significantly reduced brain Aβ plaques compared to placebo.

On January 6, 2023, lecanemab was granted accelerated approval by the FDA for the treatment of Alzheimer's Disease. It was granted full FDA approval on July 6, 2023.

Mechanism of action:

Extracellular amyloid-β (Aβ) plaques are a hallmark pathology of Alzheimer's disease (AD), making them a desirable therapeutic target for potential drugs for treating AD. The production and accumulation of Aβ plaques in the brain are commonly observed in AD, and distinct characteristics of Aβ plaques - such as the solubility, quantity, and composition of Aβ pools - may affect the disease state. Aβ causes synaptic impairment, neuronal death, and progressive neurodegeneration, which leads to dementia and cognitive impairment associated with AD.

Aβ peptides exist in various conformational states, including soluble monomers, soluble aggregates of increasing size, and insoluble fibrils and plaque. Soluble Aβ aggregates such as Aβ protofibrils are more neurotoxic than monomers or insoluble fibrils. Lecanemab is an antibody that lowers Aβ plaques in the brain. It preferentially targets soluble aggregated Aβ and works on Aβ oligomers, protofibrils, and insoluble fibrils.

Brand name: Leqembi

Indication: Lecanemab is indicated for the treatment of Alzheimer's disease. Treatment with lecanemab should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

Manufacturer: Eisai Co., Ltd. and Biogen

Biologic Classification: Protein based therapies

3.Glofitamab

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Glofitamab is a full-length bispecific monoclonal antibody with affinity for both CD20 and CD3 surface antigens found on B- and T-cells, respectively. In June 2023, the FDA approved the use of glofitamab for the treatment of patients with relapsed or refractory DLBCL not otherwise specified or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy under accelerated approval based on response rate and durability of response.

Mechanism of action:

Glofitamab is a bispecific monoclonal antibody targeted towards CD20 surface antigens - found on B-cells - and CD3 protein complexes found on the surface of T-cells. It binds bivalently to CD20 and monovalently to CD3, thereby creating an immunological synapse that serves to recruit T-cells to CD20-expressing B-cells. This simultaneous binding allows for potent T-cell activation and proliferation which ultimately results in the lysis of the target B-cells.

Brand name: Columvi

Indication: To treat adult patients with relapsed or refractory diffuse large B-cell lymphoma after two or more lines of systemic therapy.

Manufacturer: Roche

Biologic Classification: Protein based therapies

4.Talquetamab

Talquetamab is a bispecific antibody used to treat adults with relapsed or refractory multiple myeloma. On August 9, 2023, talquetamab was granted FDA accelerated approval.

Mechanism of action:

Talquetamab is a bispecific T-cell-engaging antibody that binds to the CD3 receptor expressed on the surface of T-cells and GPRC5D expressed on the surface of MM cells. It works to recruit CD3-expressing T cells to GPRC5D-expressing MM cells to induce T-cell–mediated cytotoxicity, prevent tumour growth, and promote tumour regression. When activated, T cells cause the release of proinflammatory cytokines, promoting the lysis of MM cells.

Brand name: Talvey

Indication: To treat multiple myeloma cancer and stop the growth of cancer cells. In the US, talquetamab is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

Manufacturer: Janssen Biotech

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Biologic Classification: Protein based therapies

5.Elranatamab

Elranatamab is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager. It is a humanized immunoglobulin 2-alanine kappa antibody derived from two monoclonal antibodies (mAbs), an anti-BCMA mAb and an anti-CD3 mAb, each of which contributes one heavy chain and one light chain to drug structure. The resulting 4-chain bispecific antibody is covalently linked via five inter-chain disulfide bonds. On August 14, 2023, the FDA granted accelerated approval to elranatamab for the treatment of multiple myeloma.

Mechanism of action:

Elranatamab is a bispecific B-cell maturation antigen (BCMA)-directed T-cell engaging antibody. It binds BCMA on plasma cells, plasmablasts, and multiple myeloma cells and CD3 on T-cells leading to cytolysis of the BCMA-expressing cells. Elranatamab activated T-cells, caused pro-inflammatory cytokine release, and resulted in multiple myeloma cell lysis.

Brand name: Elrexio

Indications: To treat multiple myeloma.

Manufacturer: Pizer

Biologic Classification: Protein based therapies

6.Bexagliflozin

Bexagliflozin is a sodium-glucose co-transporter 2 inhibitor that is employed to enhance glycemic control in patients with type 2 diabetes mellitus. Bexagliflozin is a sodium-glucose co-transporter 2 (SGLT2) inhibitor that is both highly specific and potent. Bexagliflozin, like other SGLT2 inhibitors, comprises three fundamental moieties: glucose, two benzene rings, and a methylene bridge. The FDA approved bexagliflozin for the treatment of adults with type 2 diabetes in January 2023. It is not advised for patients with type 1 diabetes to consume it, as it may elevate their susceptibility to diabetic ketoacidosis.

Mechanism of action

Bexagliflozin is a sodium–glucose co-transporter 2 (SGLT2) inhibitor that is highly selective. SGLT2 is situated in the proximal renal tubule, a region of the kidney where the majority of reabsorption occurs. It is responsible for the transportation of glucose and sodium from the tubular lumen to the epithelium. Bexagliflozin reduces glucose reabsorption in the kidney and promotes its excretion in urine by inhibiting SGLT2. Consequently, bexagliflozin reduces blood glucose levels in patients with type 2 diabetes mellitus (T2DM) regardless of insulin sensitivity.

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Brand name: Brenzavvy

Indication: Bexagliflozin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

7.Pirtobrutinib

Pirtobrutinib is a kinase inhibitor that is used to treat relapsed or refractory mantle cell lymphoma (MCL) following the completion of at least two lines of systemic therapy. Pirtobrutinib is a highly selective non-covalent inhibitor of Bruton's tyrosine kinase (BTK) and a small molecule. Its high selectivity has been linked to a lower incidence of atrial fibrillation and lower discontinuation rates as a result of adverse events. The FDA's Accelerated Approval pathway approved the use of pirtobrutinib for the treatment of relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy in January 2023.

Mechanism of action

Bruton's tyrosine kinase (BTK) is a tyrosine kinase that is recruited to the cytoplasm upon activation. BTK is involved in the activation of the B-cell antigen receptor (BCR) signaling and cytokine receptor pathways in B-cells, which are essential for the development, function, adhesion, and migration of B-cells. Consequently, the inhibition of BTK is a beneficial target for the treatment of B-cell cancers. Pirtobrutinib inhibits the activity of Bruton's tyrosine kinase (BTK) by binding to it in a non-covalent manner. Pirtobrutinib's inhibitory activity is sustained in the presence of mutations in the active site of BTK, such as the presence of Cys481, in contrast to other BTK inhibitors that bind covalently to the active site. Pirtobrutinib inhibited the expression of CD69 on B-cells and the proliferation of malignant B-cells in nonclinical studies that were mediated by BTK.

Brand name: Jaypirca

Indication: The treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor, is indicated with pirtobrutinib.

8.Zavegepant

Zavegepant is a calcitonin gene-related peptide receptor antagonist that is prescribed for the acute treatment of migraine with or without aura. Zavegepant (BHV-3500) is an antagonist of the calcitonin gene-related peptide (CGRP) receptor. CGRP is a potent vasodilator and is released from sensory nerves. As a result, it is implicated in pain pathways. The central and peripheral nervous systems express CGRP receptors. zavegepant nasal spray was approved by the FDA in March 2023 for the acute treatment of migraine with or without aura in adults.

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Mechanism of action

Zavegepant is an antagonist of the calcitonin gene-related peptide (CGRP) receptor that is employed to treat migraines in an acute setting. The pathophysiology of migraine has not been thoroughly investigated; however, the neurovascular and cortical spreading depression mechanisms may be influenced by specific vasoactive substances and neurotransmitters, including CGRP, neurokinin A, nitric oxide, and substance P. In acute migraine, the release of CGRP enhances vasodilation and regulates neuronal excitability, thereby facilitating pain responses in structures that facilitate migraine pain transmission, such as the trigeminal system. Consequently, CGRP receptor antagonists, including zavegepant, desensitize neuronal circuits and inhibit vasodilation mechanisms.

Brand name: Zavzpret

Indication: Zavegepant in a nasal spray form is indicated for the acute treatment of migraine with or without aura in adults. It is not indicated for the preventive treatment of migraine.

9.Trofinetide

Trofinetide is a medication that is administered to individuals with Rett syndrome, including children and adults. Trofinetide is a novel synthetic analog of glypromate, also referred to as glycine–proline–glutamate (GPE), a naturally occurring protein in the brain and the N-terminal tripeptide of insulin-like growth factor 1 (IGF-1). On March 10, 2023, the FDA authorized trofinetide for the treatment of Rett syndrome.

Mechanism of action

The majority of Rett syndrome cases are the result of loss-of-function mutations in a gene that encodes methyl CpG binding protein 2 (MECP2), a DNA binding protein that plays a role in the epigenetic regulation of gene expression. In the cortex, these mutations are suspected to result in synaptic immaturation, anomalous neuronal development, and abnormal neuronal signaling, as well as aberrant metabolism of brain cholesterol. Rett syndrome is more prevalent in females than in males.

Brand name: Daybue

Indication: Trofinetide is prescribed for the treatment of Rett syndrome in adults and pediatric patients aged two years and older.

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10.Motixafortide

Motixafortide is a peptide inhibitor of CXCR4 that is employed to mobilize hematopoietic stem cells in multiple myeloma patients before they are collected and autologously transplanted. Motixafortide is a cyclic peptide hematopoietic stem cell mobilizer that is employed to enhance the collection of stem cells prior to autologous transplantation. Hematopoietic stem cell transplantation (HSCT) is a treatment that is frequently implemented in the treatment of hematologic malignancies. High-dose chemotherapy regimens are used to eliminate cancerous blood cells, which are subsequently replaced by infusing the patient's own stem cells. Motixafortide was approved by the FDA in September 2023 for the purpose of mobilizing stem cells in patients with multiple myeloma before an autologous stem cell transplant. It was used in conjunction with filgrastim.

Mechanism of action

Motixafortide is a C-X-C Motif Chemokine Receptor 4 (CXCR4) inhibitor that prevents the binding of its ligand, stromal-derived factor-1α (SDF-1α)/C-X-C Motif Chemokine Ligand 12 (CXCL12). The trafficking of hematopoietic stem cells to the bone marrow compartment is influenced by both CXCR4 and SDF-1α. CXCR4 is responsible for anchoring stem cells to the marrow matrix through the induction of other adhesion molecules or SDF-1α. Therefore, the inhibition of CXCR4 leads to an increase in the concentration of circulating hematopoietic stem and progenitor cells in the peripheral circulation, which facilitates their collection for the purpose of autologous transplantation.

Brand name: Aphexda

Indication: Motixafortide is recommended for use in conjunction with filgrastim to facilitate the mobilization of hematopoietic stem cells to the peripheral circulation for collection and subsequent autologous transplantation in patients with multiple myeloma. [93]

Vaccines:

Vaccination is a crucial public health measure aimed at preventing infectious diseases and reducing morbidity and mortality rates globally. Vaccines work by stimulating the immune system to recognize and combat pathogens such as viruses and bacteria without causing the disease itself.

The development and deployment of vaccines have led to the eradication or significant reduction of harmful diseases, such as smallpox and polio. Routine immunization programs target various

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populations, particularly children, to ensure widespread immunity against diseases like measles, mumps, and rubella.

In the wake of global health crises, such as the COVID-19 pandemic, vaccination has showcased its paramount importance. Vaccines were rapidly developed, tested, and distributed, demonstrating the efficacy of science in protecting public health. Comprehensive vaccination campaigns have been essential in achieving herd immunity, which protects vulnerable populations who may not be able to receive vaccines due to medical contraindications.

Public trust and education about vaccines are vital for overcoming vaccine hesitancy. Misinformation can undermine vaccine uptake, thereby threatening community health. It is essential for healthcare professionals and public health organizations to communicate transparent, evidence-based information to the public.

Moreover, ongoing research and innovation in vaccine technology, including mRNA vaccines and recombinant vaccines, hold promise for the future, potentially paving the way for more effective and targeted immunizations.

In conclusion, vaccines play an indispensable role in safeguarding public health. Their continued development, equitable distribution, and effective communication are crucial for combating infectious diseases and promoting community well-being.

1.Paxlovid (nirmatrelvir/ritonavir)

Indication: Treatment of COVID-19 in certain populations, though primarily used as an antiviral rather than a vaccine, it is closely related to COVID-19 prevention strategies.

2.Bivalent COVID-19 Vaccines:

- Moderna's Updated Bivalent COVID-19 Vaccine:

Indication: For COVID-19 prevention, targeting both the original strain and newer variants (e.g., Omicron subvariants).

Manufacturer: Moderna

- Pfizer-BioNTech's Updated Bivalent COVID-19 Vaccine:

Indication: For COVID-19 prevention, covering both the original strain and newer variants.

Manufacturer: Pfizer and BioNTech

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3.MenQuadfi (meningococcal quadrivalent vaccine)

Indication: Prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y.

Manufacturer: Sanofi Pasteur

4.Nirsevimab (Beyfortus)

Indication: For the prevention of respiratory syncytial virus (RSV) in infants and young children.

Manufacturer: Sanofi and AstraZeneca

5.Tetraxim (DTPaVIPV)

Indication: Combination vaccine for the prevention of diphtheria, tetanus, whooping cough, and polio.

Manufacturer: Sanofi Pasteur. [94]

Gene and cell therapies:

1.ABECMA (idecabtagene vicleucel)

Indication: Treatment for adult patients with relapsed or refractory multiple myeloma.

Manufacturer: Bristol-Myers Squibb and Bluebird Bio

2.TECLISTAMAB (Tecartus)

Indication: For the treatment of adults with relapsed or refractory multiple myeloma.

Manufacturer: Janssen Biotech

3.Zynteglo (betibeglogene autotemcel)

Indication: For the treatment of beta-thalassemia in patients who require regular red blood cell transfusions.

Manufacturer: Bluebird Bio

4.Beyfortus (nirsevimab)

Indication: For the prevention of respiratory syncytial virus (RSV) in infants and young children.

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Manufacturer: Sanofi and AstraZeneca

5.Exagamglogene autotemcel & **6.Lovotibeglogene autotemcel** for sickle cell disease.

7.Beremagenegeperpavec for dystrophic epidermolysis bullosa.

8.Lantidra for type 1 diabetes.

9.Delandistrogene moxeparvovec for Duchenne muscular dystrophy.

10.valoctocogene roxaparvovec for severe hemophilia A. [95]

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No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date*
1.	Leqembi	lecanemab-irmb	1/6/2023	To treat Alzheimer's disease
2.	Brenzavvy	bexagliflozin	1/20/2023	To improve glycemic control in adults with type 2 diabetes mellitus
3.	Jaypirca	pirtobrutinib	1/27/2023	To treat relapsed or refractory mantle cell lymphoma in adults
4.	Orserdu	elacestrant	1/27/2023	To treat estrogen receptor-positive, human epidermal growth factor receptor 2-negative
5.	Jesduvroq	daprodustat	2/1/2023	To treat anemia caused by chronic kidney disease for adults on dialysis for at least four
6.	Lamzede	velmanase alfa-tycv	2/16/2023	To treat non-central nervous system manifestations of alpha-mannosidosis
7.	Filspari	sparsentan	2/17/2023	To reduce proteinuria in adults with primary immunoglobulin A nephropathy
8.	Skyclarys	omaveloxolone	2/28/2023	To treat Friedrich's ataxia
9.	Zavzpret	zavegepant	3/9/2023	To treat migraine
10.	Daybue	trofinetide	3/10/2023	To treat Rett syndrome
11.	Zynyz	retifanlimab-dlwr	3/22/2023	To treat metastatic or recurrent locally advanced Merkel cell carcinoma
12.	Rezzayo	rezafungin	3/22/2023	To treat candidemia and invasive candidiasis
13.	Joenja	leniolisib	3/24/2023	To treat activated phosphoinositide 3-kinase delta syndrome
14.	Qalsody	tofersen	4/25/2023	To treat amyotrophic lateral sclerosis in adults who have a SOD1 gene mutation
15.	Elfabrio	pegunigalsidase alfa-iwxj	5/9/2023	To treat confirmed Fabry disease
16.	Veozah	fezolinetant	5/12/2023	To treat moderate to severe hot flashes caused by menopause
17.	Miebo	perfluorhexyloctane	5/18/2023	To treat signs and symptoms of dry eye disease
18.	Epkinly	epcoritamab-bysp	5/19/2023	Treat relapsed/refractory diffuse large B-cell lymphoma and high-grade B-cell lymphon
19.	Xacduro	sulbactam, durlobactam	5/23/2023	To treat hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneu
20.	Paxlovid	nirmatrelvir, ritonavir	5/25/2023	To treat mild-to-moderate COVID-19 in adults at high risk for progression to severe CO
21.	Posluma	flotufolastat F 18	5/25/2023	To use with positron emission tomography imaging in certain patients with prostate can
22.	Inpefa	sotagliflozin	5/26/2023	To treat heart failure
23.	Columvi	glofitamab-gxbm	6/15/2023	To treat diffuse large B-cell lymphoma
24.	Litfulo	ritlecitinib	6/23/2023	To treat severely patchy hair loss
25.	Rystiggo	rozanolixizumab-noli	6/26/2023	To treat generalized myasthenia gravis in adults
26.	Ngenla	somatrogon-ghla	6/27/2023	To treat growth failure due to inadequate secretion of endogenous growth hormone
27.	Beyfortus	nirsevimab-alip	7/17/2023	To prevent respiratory syncytial virus (RSV) lower respiratory tract disease
28.	Vanflyta	quizartinib	7/20/2023	To use as part of a treatment regimen for newly diagnosed acute myeloid leukemia

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No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date*
29.	Xdemvy	lotilaner	7/25/2023	To treat Demodex blepharitis
30.	Zurzuvae	zuranolone	8/4/2023	To treat postpartum depression
31.	Izervay	avacincaptad pegol	8/4/2023	To treat geographic atrophy secondary to age-related macular degeneration
32.	Talvey	talquetamab-tgvs	8/9/2023	To treat adults with relapsed or refractory multiple myeloma
33.	Elrexfio	elranatamab-bcmm	8/14/2023	To treat adults with relapsed or refractory multiple myeloma
34.	Sohonos	palovarotene	8/16/2023	To reduce the volume of new heterotopic ossification in adults
35.	Veopoz	pozelimab-bbfg	8/18/2023	To treat patients 1 year old and older with CD55-deficient protein-losing enteropathy (P
36.	Aphexda	motixafortide	9/8/2023	To use with filgrastim (G-CSF)
37.	Ojjaara	momelotinib	9/15/2023	To treat intermediate or high-risk myelofibrosis in adults with anemia
38.	Exxua	gepirone	9/22/2023	To treat major depressive disorder
39.	Pombiliti	cipaglucosidase alfa-atga	9/28/2023	To treat late-onset Pompe disease
40.	Rivfloza	nedosiran	9/29/2023	To lower urinary oxalate levels in patients 9 years and older with primary hyperoxaluria
41.	Velsipity	etrasimod	10/12/2023	To treat moderately to severely active ulcerative colitis in adults
42.	Zilbrysq	zilucoplan	10/17/2023	To treat generalized myasthenia gravis in adults
43.	Bimzelx	bimekizumab	10/17/2023	To treat moderate to severe plaque psoriasis in adults
44.	Agamree	vamorolone	10/26/2023	To treat Duchenne muscular dystrophy
45.	Omvoh	mirikizumab-mrkz	10/26/2023	To treat ulcerative colitis
46.	Loqtorzi	toripalimab-tpzi	10/27/2023	To treat recurrent or metastatic nasopharyngeal carcinoma
47.	Fruzaqla	fruquintinib	11/8/2023	To treat refractory, metastatic colorectal cancer
48.	Defencath	taurolidine, heparin	11/15/2023	To reduce the incidence of catheter-related bloodstream infections
49.	Augtyro	repotrectinib	11/15/2023	To treat ROS1-positive non-small cell lung cancer
50.	Ryzneuta	efbemalenograstim alfa-vuxw	11/16/2023	To treat neutropenia
51.	Truqap	capivasertib	11/16/2023	To treat breast cancer that meets certain disease criteria
52.	Ogsiveo	nirogacestat	11/27/2023	Treat adults with progressing desmoid tumors who require systemic treatment
53.	Fabhalta	iptacopan	12/5/2023	To treat paroxysmal nocturnal hemoglobinuria

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No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date*
54.	Filsuvez	birch triterpenes	12/18/2023	To treat wounds associated with dystrophic and junctional epidermolysis bullosa
55.	Wainua	eplontersen	12/21/2023	To treat polyneuropathy of hereditary transthyretin-mediated amyloidosis

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Chapter 5

CONCLUSION

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5. Conclusion

To conclude, a thorough examination of biotechnology products demonstrates their transformative potential in a variety of sectors, such as healthcare, agriculture, environmental sustainability, and industrial applications. These products—which are the result of cutting-edge scientific study and technical innovation—have shown a number of noteworthy advantages, including better medical care, increased crop yields, and environmentally friendly solutions. However, strict governmental control, public acceptability, and ethical concerns are also necessary for the effective development and implementation of biotechnology goods. To fully realize the potential of these products while addressing safety, efficacy, and sustainability concerns, continued collaboration among researchers, industry stakeholders, and regulatory agencies will be crucial as the biotechnology environment continues to change. In the end, biotechnology's continuous development looks set to be crucial in solving some of the world's most important problems, such as environmental degradation, public health, and food security, and it will open the door to a more sustainable and healthy future.

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Chapter 6

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