

Genetic Engineering Pharmaceutical Technology: A Brief Review

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Abstract. Genetic engineering has emerged as a transformative technology in the pharmaceutical industry, offering unprecedented control over the manipulation of genetic material. This technology enables the precise editing, combining, and expression of target genes in various organisms, leading to the production of specific proteins, enzymes, and biologics essential for therapeutic applications. This review provides an overview of the basic principles and strategies of gene therapy, the development of genetic engineering pharmaceuticals, and their applications in producing physiologically active substances, antibodies, and vaccines. The review also highlights the significant advancements in the field, and explores the future potential of genetic engineering in advancing medical science and improving human health.

Keywords: genetic engineering, pharmaceuticals, DNA.

1. Introduction

Genetic engineering, a cornerstone of modern molecular biology, operates primarily at the genetic level, offering unprecedented control over the manipulation of genetic material [1]. This advanced technology involves the precise cutting, combining, and splicing of target genes with vectors in vitro, which are subsequently introduced into receptor cells of various organisms, including microorganisms, plants, animals, and their respective cells [2,3]. Once inside these cells, the target genes can be expressed, enabling the production of specific proteins, enzymes, or other biological products that are either beneficial to humans or contribute to the creation of new biological entities.

Since its inception in the late 20th century, genetic engineering has revolutionized numerous fields, with its impact on medicine being particularly profound [4]. The ability to manipulate genetic material with such precision has not only accelerated the pace of drug discovery and development but has also opened new avenues for personalized medicine, gene therapy, and the production of biologics. This technology has become indispensable in the pharmaceutical industry, where it is leveraged to produce therapeutic proteins, vaccines, and other innovative treatments that were previously unattainable through conventional methods.

The application of genetic engineering in pharmaceutical technology represents one of the most dynamic and rapidly evolving areas of research and development. Its contributions are not limited to the creation of new drugs but extend to improving existing therapies, reducing production costs, and enhancing the efficacy and safety of pharmaceutical products. This brief review aims to provide an overview of the key developments in genetic engineering as it pertains to pharmaceutical technology,

highlighting the transformative impact this technology has had on the field and exploring the future potential it holds for advancing medical science.

2. Basic Principles and Methods of Genetic Engineering Pharmaceutical

2.1. Basic Principles of Gene Therapy

Gene therapy is an innovative medical technology that involves introducing functional exogenous genes into the target cells of patients to correct or compensate for genetic defects and abnormalities, ultimately aiming to treat or manage diseases [5,6]. This approach focuses on addressing the root cause of genetic disorders by supplementing or replacing defective genes with normal ones, allowing for the restoration of normal cellular function. The core of gene therapy lies in the application of transgenesis, where exogenous genes are inserted into appropriate target cells through advanced gene transfer technologies. Once inside the cells, these exogenous genes are expressed, producing therapeutic substances that can combat specific diseases.

Beyond the insertion of corrective genes, gene therapy encompasses a wide range of techniques at the DNA level, broadening its potential applications. It is not limited to a single type of disease but can be used to treat a variety of genetic disorders, rare diseases, and certain types of cancers. The versatility and potential of gene therapy make it a groundbreaking treatment method, offering the medical community new tools to improve patient outcomes and quality of life.

2.2. Strategies of Gene Therapy

Gene therapy strategies can be broadly categorized into direct and indirect approaches, each with its distinct applications and characteristics.

Direct strategies in gene therapy focus on targeting pathogenic genes themselves. The two primary methods within this category are gene correction and gene intervention. Gene correction is also known as gene editing, this technique involves correcting mutated bases within pathogenic genes to restore their normal function. By precisely altering the DNA sequence of the affected gene, gene correction aims to rectify the underlying genetic defect and achieve therapeutic outcomes. This strategy directly addresses the faulty gene, ensuring that its normal sequence and function are reinstated [7,8,9]. Gene intervention: This strategy involves the introduction of exogenous genes to interfere with, inhibit, or block the expression of harmful genes at the DNA, RNA, or protein levels. Unlike gene correction, gene intervention does not alter the sequence of the pathogenic gene itself. Instead, it modulates the gene's expression or the activity of its products to mitigate the disease's effects. By intervening in the gene expression process, gene intervention provides a way to control the harmful effects of defective genes without directly modifying their structure [9,10].

Indirect strategies in gene therapy do not directly target the pathogenic genes but instead focus on introducing therapeutic genes that can aid in disease treatment through alternative mechanisms. These strategies include immune gene therapy, molecular chemotherapy, and specific cell-killing approaches. Immune gene therapy aims to enhance or restore the body's immune function to fight diseases. By introducing genes that boost immune responses, this approach helps the body better recognize and combat disease-causing agents [11]. Molecular chemotherapy strategy involves using specific chemical drugs that target molecules related to the disease. The therapeutic genes introduced in this approach work in conjunction with these drugs to enhance their effectiveness in treating the disease [7,9]. In specific cell killing therapeutic genes are used to target and eliminate specific cells associated with the disease. This approach is particularly useful in treating cancers, where the goal is to selectively kill cancerous cells while sparing healthy ones [10].

3. Genetic Engineering Pharmaceutical and Development

Genetic engineering pharmaceuticals are produced through a series of precise and sophisticated procedures that involve the extraction of genes responsible for producing proteins with therapeutic effects, followed by their introduction into receptor cells capable of large-scale production [12]. The

process begins with identifying the target protein, extracting the corresponding gene, and then manipulating the gene to optimize its function. This modified gene is introduced into receptor cells, which, through continuous reproduction, mass-produce the desired pharmaceutical protein.

The application of genetic engineering technology in drug production offers several significant advantages. Firstly, it allows for the mass production of physiologically active substances and peptides that were previously difficult to obtain in large quantities, thereby providing a reliable source of these crucial compounds for clinical applications. Secondly, genetic engineering has facilitated the discovery and exploration of new endogenous physiologically active substances, opening up new avenues for drug research and development. Furthermore, genetic engineering enables the modification and enhancement of endogenous physiological substances, improving the efficacy of drugs. Finally, this technology expands the pool of new compounds available for drug screening, thereby broadening the scope of drug research and development.

Biological engineering is a multidisciplinary field that includes genetic engineering, cell engineering, enzyme engineering, protein engineering, and fermentation engineering [2]. Among these, genetic engineering stands out as the core of modern biotechnology, having achieved remarkable milestones since its inception. For example, the use of *Escherichia coli* to produce growth hormone-releasing inhibitory factor marked a significant breakthrough, followed by the development of numerous genetic engineering products such as human insulin, thymosin, urokinase, and human growth hormone. These products have been widely adopted in the prevention and treatment of diseases, yielding significant therapeutic outcomes and substantial economic benefits.

The continuous advancements in genetic engineering have deepened our understanding of life processes and expanded the possibilities for medical innovation. China, for instance, has made significant strides in this field. The Ministry of Health has approved the country's first genetic engineering drug, granting it a new drug certificate [14]. Moreover, Chinese scientists have made important breakthroughs in mapping the human genome, contributing to global efforts in genetic research.

In summary, the development and application of genetic engineering pharmaceuticals represent one of the most significant achievements of modern biotechnology. The unique advantages and vast potential of genetic engineering technology have established it as a critical tool in drug research and development. Looking ahead, as science and technology continue to evolve, genetic engineering is expected to play an increasingly vital role in various fields, making even greater contributions to human health and scientific progress.

4. Application of Genetic Engineering Pharmaceutical Technology

In the contemporary pharmaceutical industry, genetic engineering technology has become a cornerstone, particularly in the research, development, and production of new drugs, as well as in the transformation of traditional drugs. This cutting-edge technology addresses significant challenges associated with the sourcing of traditional drug materials and the limitations of existing manufacturing techniques. Moreover, it has enabled the successful synthesis of drugs that were previously unattainable. These genetically engineered drugs primarily fall into three categories: physiologically active substances, antibodies, and vaccines [14,15].

4.1. Application in Production of Physiologically Active Substances

Advanced genetic engineering techniques have revolutionized the production of a wide range of effective drugs, including but not limited to hormonal and cytokine-based therapies. Notable examples include biologically derived drugs such as insulin, recombinant human growth hormone, follicle-stimulating hormone, and interferon. Additionally, genetic engineering has facilitated the development of recombinant thrombolytic agents like streptokinase and tissue-type plasminogen activator. The research and application of these drugs have opened new avenues for treating various diseases, underscoring the significant role and vast potential of genetic engineering technology in medicine.

4.2. Application in Production of Antibodies

Genetically engineered antibodies, particularly recombinant antibodies, are produced by manipulating and modifying antibody genes using protein engineering and recombinant DNA technology. These genes are then reassembled and transfected into appropriate receptor cells to express the desired antibody molecules. This technology is extensively utilized in the prevention, diagnosis, and treatment of clinical diseases, offering broad application prospects and substantial theoretical value. The ability to produce customized antibodies through genetic engineering has led to significant advancements in targeted therapies and personalized medicine.

4.3. Application in Production of Vaccines

The production of genetic engineering vaccines involves cloning protective antigen gene fragments of pathogens into expression vectors, followed by transfection into cells or microorganisms. Alternatively, the deletion of pathogen virulence-related genes can be employed to create gene-deleted vaccines. These vaccines come in various forms, including subunit vaccines, live vaccines, live vector vaccines, nucleic acid vaccines, and transgenic plant vaccines. Genetic engineering vaccines offer several advantages, such as enhanced safety, effectiveness, cost-efficiency, and the capability for large-scale production. These benefits have made genetically engineered vaccines a vital tool in the prevention and control of infectious diseases, as well as in addressing emerging global health challenges.

5. Conclusions

Genetic engineering has established itself as a cornerstone of modern pharmaceutical technology, enabling the production of innovative drugs and therapies that address previously insurmountable challenges in medicine. From gene therapy and the mass production of physiologically active substances to the development of customized antibodies and advanced vaccines, genetic engineering has demonstrated its vast potential and critical importance in the pharmaceutical industry. As science and technology continue to evolve, the applications of genetic engineering are expected to expand further, driving significant advancements in medical research, treatment, and global health. The continued progress in this field promises to unlock new possibilities for improving patient outcomes and enhancing the quality of life worldwide.

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