EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 12
Issue: 9
Year: 2025

REVIEW ON RECENT ADVANCES AND APPLICATIONS OF MEDICAL AND PHARMACEUTICAL BIOTECHNOLOGY

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Article Received on 16/07/2025 **Article Revised on 06/08/2025** **Article Accepted on 26/08/2025**

ABSTRACT
The field of medical biotechnology is experiencing rapid growth in recent years, leading to the development of several innovative techniques for preventing, diagnosing, and treating diseases. Novel methodologies, including polymerase chain reaction, gene sequencing, fluorescence in situ hybridization, microarrays, cell culture, gene silencing using interference RNA, and genome editing, have significantly contributed towards improving health science, such as the sequencing of the human genome, use of stem cells for regenerative medicine, tissue engineering, development of antibiotics, and the generation of monoclonal antibodies for therapy. This chapter will summarize and update important techniques used and the products generated using these tools in the field of medical biotechnology. If the current growth rate continues, medical biotechnology will soon become a major pillar of health science. Pharmaceutical biotechnology is a branch of biomedical sciences that uses novel technologies for production, formulation, and synthesis of biological substances from the living organisms, which act as drug molecules for the treatment and/or prevention of various diseases and/or syndromes. Pharmaceutical biotechnology has a major role in drug discovery and development for the understanding of many diseases and their novel treatment strategies and therapeutic interventions. In this chapter, we have described in detail the modern concepts of different branches of biotechnology in relation to their role in drug discovery and development. Moreover, we have also discussed the different techniques, including gel electrophoresis, western blotting, polymerase chain reaction, molecular cloning tissue culture, microarrays, deoxyribonucleic acid sequencing, and enzyme-linked immunosorbent assay that are frequently used during the process of drug development. We have also comprehensively described the new emerging drug classes such as monoclonal antibodies, small drug molecules, protein drugs, therapeutic hormones and enzymes, cytokines, and antisense drugs that are biotechnologically derived from the genetically modified organisms.

KEYWORDS: Medical biotechnology: Gene therapy, Vaccines, Stem cell therapy, Diagnostic tools Pharmaceutical biotechnology: Monoclonal antibodies, Recombinant proteins, Biosimilars.

➢ INTRODUCTION

Medical biotechnology is a branch of medicine that uses living cells and cell materials to research and then produce pharmaceutical and diagnosing products. These products help treat and prevent diseases. From the Ebola vaccine to mapping human DNA to agricultural impacts, medical biotechnology is making huge advancements and helping millions of people.

Some of the most recent uses of biological tech is work in genetic testing, drug treatments, and artificial tissue growth. With the many advancements in medical biotechnology, there are new concerns that arise. From funding to ethics, there are many things to determine and regulate when it comes to this fast-paced industry. Learn about the many technical biology advancements and the concerns surrounding them.

An emerging field in pharmaceutical biotechnology is represented by the generation of novel binding molecules based on small globular domains serving as protein frameworks. In this approach, certain amino acid residues of the surface of a single domain are combinatorially mutated to produce a protein library,

which can then be screened for binding specificities of interest. Thus, the concept of a universal binding site from the antibody structure is transferred to alternative protein frameworks with suitable biophysical properties. On one hand these new proteins provide further insights into the processes of molecular recognition, on the other hand they also have commercial applications, as therapeutic agents, diagnostic reagents or affinity ligands. urnal of Medical Reviews.

➢ **MEDICAL BIOTECHNOLOGY**

Medical biotechnology focuses on using biological tools to understand and treat diseases. It combines biology, genetics, and technology to create solutions for health problems.

Medical Biotechnology Types

1. Gene therapy: Treating or preventing disease by fixing or replacing faulty genes.
2. Vaccines: Developing safer and more effective vaccines using modern biotechnology.
3. Stem cell therapy: Using stem cells to repair or replace damaged tissues and organs.
4. Diagnostic tools: Creating advanced tests to detect diseases quickly and accurately.

➢ **Pharmaceutical Biotechnology**

Pharmaceutical biotechnology involves using living organisms to make drugs and other products that help treat diseases. Many modern medicines, especially those for serious conditions, are made using biotechnology.

- **Pharmaceutical Biotechnology Types**

1. **Monoclonal antibodies:** These are lab-made molecules that can target specific parts of the immune system to treat diseases like cancer and autoimmune disorders.
2. **Recombinant proteins:** These are proteins, such as insulin or growth hormones, made using genetically engineered bacteria or yeast.
3. **Biosimilars:** These are versions of biological drugs that are similar to the original but made by different companies after the original patent expires.

➢ **Medical Biotechnology**

1. Gene therapy

Gene therapy is an innovative approach to medicine that uses genetic material to prevent, treat and potentially even cure disease. In gene therapy, genetic material is delivered to your cells and changes how your cells produce proteins. While still in its earliest stages, gene therapy has the promise to be a life-changing medical treatment.

Gene therapy is a medical approach that uses genetic material to prevent and treat disease. The technique allows healthcare providers to treat certain conditions by changing your genetic makeup instead of using traditional treatment methods like medication and surgery. In this way, providers can address the underlying cause of the disease or instruct your own body to mass-produce desirable medication or proteins.

In gene therapy, genetic material is transferred to your cells. This genetic material then changes how your cells produce proteins.

It can

- Reduce levels of certain disease-causing proteins.
- Increase production of working proteins.
- Produce new or modified proteins within a cell.

Your body's genetic information is kept in chromosomes inside the nucleus of your cells. Each chromosome is made up of DNA that stores information to determine your unique traits. Specific sections of DNA are called genes. Genes provide instructions for how to make proteins. Proteins play an important role in how your body functions. A small change to the DNA within your genes can alter how proteins work.

Gene variants (genetic changes) occur as cells age or after exposure to certain chemical or environmental factors. Cells often recognize these genetic changes and repair them. Other times, they can cause a disease or disorder and you'll need treatment. Your biological parents can also pass along these gene variants, causing disease from an early age. By using gene therapy, healthcare providers aim to address the underlying cause of disease. If genes are like the blueprint of your body, gene therapy can fill in missing parts or correct errors in the drawings.

Most gene therapies are still in the clinical trial phase. Clinical trials play an important role in finding treatments that are safe and effective. Clinical trials are investigating gene therapy for the treatment of cancer, macular degeneration and other eye diseases, certain genetic conditions and HIV/AIDS.

The U.S. Food and Drug Administration (FDA) has approved two gene therapies for use in the U.S.

- **Luxturna:** Approved in December 2017, Luxturna is a one-time treatment used to improve vision in people with genetic vision loss due to certain inherited retinal(eye) diseases.
- **Zolgensma:** The FDA approved Zolgensma in May 2019 to treat spinal muscular atrophy in children younger than 2 years old.

Gene therapy works by replacing or inactivating disease-causing genes. In some cases, gene therapy introduces new genes into your body to treat a specific disease.

With gene therapy, healthcare providers deliver a healthy copy of a gene to cells inside your body. This healthy gene may replace a damaged (mutated) gene, inactivate a mutated gene or introduce an entirely new gene.

- **Gene addition:** Gene addition inserts a new copy of a gene into your cells. The working gene has

instructions for the cell to produce more of the specific protein it needs. This method most often uses an adeno-associated virus (AAV) to carry the gene to the cells.

- **Gene silencing:** Gene silencing transfers genetic material that prevents the activity of a gene that's already in a cell. This method decreases the amount of a specific protein the cell is making by targeting messenger RNA (mRNA).
- **Gene editing:** Gene editing modifies parts of your DNA by altering or deleting elements within your gene. Genetic material is delivered to edit or change pieces of DNA located within a cell, which corrects the protein that the DNA is producing.

Gene editing uses technology like CRISPR/cas9.

2. Vaccines

Vaccine is a biological substance which stimulates the immune system by introducing a killed, weakened disease causing organism, or its surface protein in healthy body. Vaccines provide acquired immunity against a particular disease. The mode of action of vaccine is either prophylactic (to prevent the future infection) or it could be threptic specifically many cancer vaccines are under experimental stages. The term vaccine or vaccination derived from Variolae vaccinae (smallpox of the cow) was coined for the first time by an English Physician Edward Jenner to describe cow pox. He used the term in 1798 for his long experiments to establish protective role of cow pox against smallpox. According to World Health Organization so far twenty-five (25) licensed vaccines are available for different infectious diseases. The traditional vaccines are either killed microorganism or attenuated one to generate immune response in body after their inoculation. After emergence of Recombinant DNA Technology is a sub-field of Biotechnology remarkable positive impacts were observed on human health. From production of safe proteins, antibodies and gene therapy RDT revolutionized different aspects of biological studies.

3. Stemcelltherapy

Stem-cell therapy uses stem cells to treat or prevent a disease or condition. As of 2024, the only FDA-approved therapy using stem cells is hematopoietic stem cell transplantation. This usually takes the form of a bone marrow or peripheral blood stem cell transplantation, but the cells can also be derived from umbilical cord blood. Research is underway to develop various sources for stem cells as well as to apply stem-cell treatments for neurodegenerative diseases and conditions such as diabetes and heart disease.

Stem-cell therapy has become controversial following developments such as the ability of scientists to isolate and culture embryonic stem cells, to create stem cells using somatic cell nuclear transfer, and their use of techniques to create induced pluripotent stem cells. This controversy is often related to abortion politics and human cloning. Additionally, efforts to market treatments based on transplant of stored umbilical cord blood have been controversial.

- **Medical uses**

For over 90 years, hematopoietic stem cell transplantation (HSCT) has been used to treat people with conditions such as leukemia and lymphoma; this is the only widely practiced form of stem-cell therapy. During chemotherapy, most growing cells are killed by the cytotoxic agents. These agents, however, cannot discriminate between the leukaemia or neoplastic cells, and the hematopoietic stem cells within the bone marrow. This is the side effect of conventional chemotherapy strategies that the stem-cell transplant attempts to reverse; a donor's healthy bone marrow reintroduces functional stem cells to replace the cells lost in the host's body during treatment. The transplanted cells also generate an immune response that helps to kill off the cancer cells; this process can go too far, however, leading to graft vs host disease, the most serious side effect of this.

4. Diagnostic tool

Diagnostic tools are essential for identifying and characterizing diseases monitoring treatment effectiveness, and guiding patient care. These tools range from simple physical examination techniques like using a stethoscope to sophisticated laboratory and imaging technologies. Advanced molecular diagnostics are also playing an increasingly important role in disease detection and management.

Challenges and Considerations

- **Diagnostic Errors:** Diagnostic tools are not always perfect, and errors can occur due to various factors, including human error, limitations of the technology, and variability in disease presentation.
- **Cost and Accessibility:** Some advanced diagnostic tools can be expensive and may not be readily available in all healthcare settings.

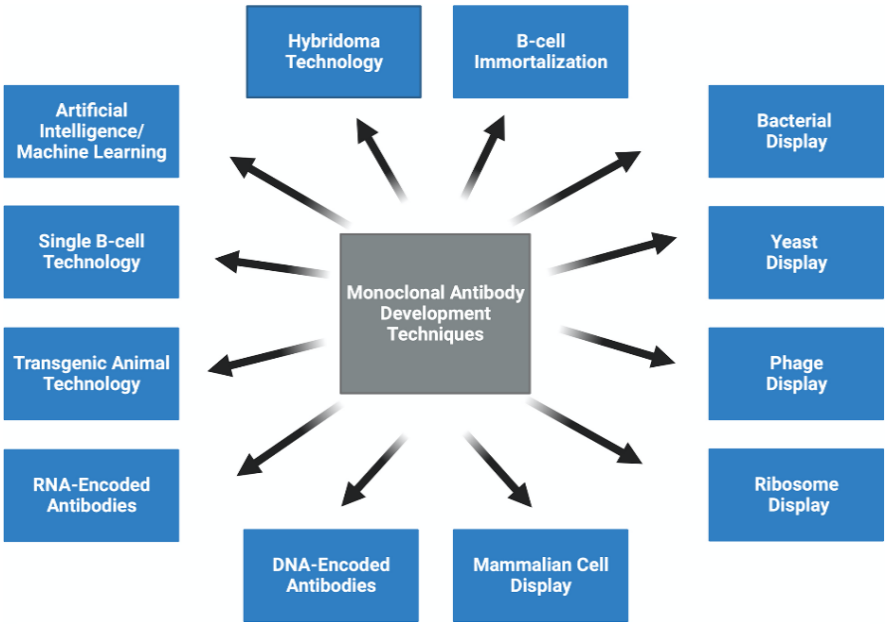
➢ **Pharmaceutical biotechnology**

1. Monoclonal antibodies

Abs are multifunctional components of the immune system produced by differentiated B cells. By exploiting the internal intelligence of the natural host immune response, which involves generation of protective Abs in response to Ag-driven lymphocyte development and subsequent germinal center processes, one can mine and harness a recovered patient's immune response to develop mAbs for use in prophylaxis and therapy.

Until recently, research and use of mAbs as therapeutics have lagged behind antibiotics and drugs. However, in the current scenario of increased emergence of multidrug resistance, interest in developing mAbs for therapeutic applications is rapidly gaining momentum. Currently, mAbs are the fastest-growing category of therapeutics entering clinical studies worldwide and have shown promise against HIV, influenza, malaria, Ebola, and

SARS-CoV-2. Particularly, mAbs have shown remarkable promise in the management of solid tumors and in the use of immunotherapy to treat a broad range of cancers, including lymphomas and breast, cervical, and gastric cancers, among others. Besides being more potent, mAbs (1) exhibit increased specificity, (2) have a longer half-life, and (3) have less adverse effects than conventional drugs. In addition, they are not affected by the emergence of drug resistance.



Schematic representation of various technologies used for mAb generation.

- **Future Directions**

Improved formulations for mAbs, including dosage, delivery methods, and stability, are an ongoing challenge. Moreover, enhancement of the pharmacokinetics and pharmacodynamics of these Abs is required.

There is a need to understand the synergistic effects of mAbs with other drugs or treatment and optimal combinations of ABDs for various diseases.

More investigation is needed into mechanisms of action of mAbs, especially in complex disease environments such as cancer, autoimmune disorders, and infectious diseases.

Very little experimentally verified data exists for the development of AI- and ML-based models, which can be used to further refine the molecular structures of protective Ab molecules. Development of more advanced ML algorithms and models for better prediction is needed.

The manufacture of next-generation mAbs is time-consuming and costly. It demands appropriate, scalable, cost-effective cell line production and procedures, as well as efficient expression and purification platforms.

2. Recombinant proteins

Recent advancements in recombinant protein production focus on enhancing yield, optimizing expression systems, and improving downstream processing. This includes exploring new host organisms, refining bioprocessing strategies, and leveraging technologies like AI for process optimization.

- **Novel Expression Systems and Hosts**

While E. coli remains a popular choice due to its simplicity, there's growing interest in eukaryotic systems like yeast (e.g., Saccharomyces cerevisiae and Pichia pastoris) and mammalian cells (e.g., CHO cells) for producing proteins requiring complex post-translational modifications.

Transgenic plants and animals are also being explored as alternative hosts for recombinant protein production.

Specific examples include engineering yeast for humanized glycosylation patterns and utilizing insect cells for therapeutic proteins.

- **Bioprocessing Optimization**

High-throughput devices are being used for efficient bioprocess optimization.

Continuous upstream and downstream processing, including continuous chromatography, is being adopted to improve efficiency and yield.

Quality by Design (QbD) principles and Process Analytical Technologies (PAT) are being implemented to ensure consistent product quality.

- **Addressing Metabolic Burden in E. coli**

Research continues to investigate the metabolic burden associated with recombinant protein production in E. coli and its impact on host metabolism.

Artificial intelligence tools are being explored to analyze experimental data and gain a better understanding of these complexities.

- **Protein Folding and Solubility**

5. Strategies to improve protein solubility and prevent aggregation are crucial for successful recombinant protein production.

Techniques like optimizing buffer conditions, using chaperones, and employing specific purification methods are being utilized.

- **Functional peptide tags**

Functional peptide tags are being developed and utilized for protein production, modification, and purification.

These tags can enhance translation, facilitate protein purification, and enable specific modifications.

- **AI and Machine Learning**

AI and machine learning are being increasingly used to optimize various aspects of recombinant protein production, from strain selection to process optimization.

- **Applications**

Recombinant proteins are used in various applications, including therapeutics, diagnostics, and research tools.

Examples include recombinant antibodies, enzymes, growth factors, and vaccines.

3. Biosimilars

Biosimilar was born to be an alternative term for "biogeneric" medicinal product whereas it is defined as a similar copy of officially registered reference biological product.

Consequently, the demand to new regulations pushed the global regulatory agencies to put guidance for manufacturing these types of biomolecules with addressing many challenges related to quality, safety and efficacy assessment.

- **Regulatory framework and related aspects**

Biosimilar regulations have been an international issue since 2004 with regard to the evaluation system and identification problem. It meets an important agreement point that biosimilars should have their regulations rather than those of generic small molecule drugs. As such, the approval needs a similarity proof of biosimilars with originator biologics supported by reliable data of quality, nonclinical, and clinical evaluations. The tremendous efforts via the European Medicines Agency (EMA)

Economic prospects and beyond

The availability of biosimilar products in the biological medicine market increases significantly, together with expiring patents and the new implementation of regulatory pathways. This condition is predicted to influence the sustainability of the pharmaceutical business. The Biologic Price Competition and Innovation Act (BPCIA) is responsible for the biologic and biosimilar price controls. Due to this market battle, biosimilars offer a price reduction of about 10% to 40% lower than biologic.

➢ CONCLUSION

Medical and pharmaceutical biotechnology have revolutionized modern healthcare by enabling the development of targeted therapies, personalized medicine, and innovative diagnostic tools. From producing recombinant proteins and vaccines to advancing gene and cell therapies, these technologies continue to transform the way we prevent, diagnose, and treat diseases. As research progresses, the integration of biotechnology with AI, nanotechnology, and synthetic biology holds the promise of even more precise and effective medical interventions. However, ethical considerations, regulatory oversight, and equitable access remain critical challenges. By balancing innovation with responsibility, biotechnology will continue to play a pivotal role in shaping the future of medicine and global health.

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