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## Biopharmaceutical breakthroughs in modern therapeutics

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### Abstract

Biopharmaceutical innovations have redefined treatment strategies across diverse diseases. From monoclonal antibodies and mRNA vaccines to gene and CAR-T cell therapies, these biologically derived agents offer unprecedented specificity and effectiveness. Biosimilars are making advanced treatments more accessible, while cutting-edge delivery systems are enhancing patient compliance. Personalized medicine is ushering in a new era of tailored care, optimizing outcomes based on individual profiles. Alongside scientific progress, improvements in manufacturing and quality control are ensuring scalability and safety. Despite regulatory challenges, ongoing research continues to expand the therapeutic frontier, promising a future of more effective and personalized disease management.

**Keywords:** Biopharmaceutical; Monoclonal Antibodies; Ribonucleic Acids (RNA); Gene-Based Vectors; Therapeutics Enzymes

### 1. Introduction

Biopharmaceuticals—also known as biological medicinal products—represent a transformative category of therapeutic agents derived through advanced cellular and molecular biotechnology. Unlike traditional small-molecule drugs synthesized via chemical routes, biopharmaceuticals comprise complex macromolecules such as recombinant proteins, monoclonal antibodies, ribonucleic acids, therapeutic enzymes, and gene-based vectors. These agents harness biological mechanisms to deliver precision medicine that aligns more closely with human physiological processes.

The emergence of biopharmaceuticals can be traced back to the 1980s with the advent of recombinant DNA technology. This milestone enabled the industrial-scale synthesis of insulin and growth hormones, setting a precedent for large-scale bioproduction of intricate proteins. Over the ensuing decades, technological advancements have expanded the biopharmaceutical portfolio to encompass treatments for oncological, immunological, metabolic, and rare genetic conditions [1], [3].

One of the defining advantages of biopharmaceuticals is their highly targeted mode of action. Monoclonal antibodies (mAbs), for example, mimic endogenous immune mechanisms by binding specifically to disease-associated antigens, thereby disrupting pathological pathways or flagging targets for immune-mediated clearance [10]. Similarly, mRNA-based vaccines, such as those rapidly deployed during the COVID19 pandemic, exemplify next-generation prophylactic interventions that program host cells to transiently express immunogenic proteins, stimulating robust immune responses without introducing live pathogens [2], [11].

Despite their promise, biopharmaceutical development is fraught with challenges. Production involves living systems—often mammalian cell cultures—that are sensitive to environmental fluctuations, necessitating stringent control of temperature, pH, and nutrient supply. Downstream processing requires precision purification steps to remove host-cell proteins, endotoxins, and other impurities, ensuring safety and consistency. Additionally, storage and transportation

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demand cold chain logistics to preserve molecular stability [5], [7]. To navigate these complexities, regulatory authorities such as the FDA and EMA have developed comprehensive frameworks focusing on quality assurance, pharmacovigilance, and adaptive approval pathways. These regulatory evolutions aim to safeguard public health while accommodating the dynamic nature of innovation in biopharmaceutical sciences [5], [9].

In parallel, the field has witnessed the rise of biosimilars—post-patent equivalents of reference biologics. Rigorous comparative studies affirm that biosimilars maintain efficacy, safety, and structural fidelity, thus enabling broader patient access and reducing healthcare costs [5], [14]. Furthermore, delivery system innovation—such as microneedle patches, implantable depots, and nanoparticle vectors—has improved patient compliance and broadened the applicability of biologics [15].

The momentum of biopharmaceutical progress is sustained by interdisciplinary research that integrates systems biology, pharmacogenomics, and AI-enabled drug discovery. These efforts support the growing paradigm of personalized medicine, where therapeutic regimens are tailored based on individual genomic, proteomic, and metabolic profiles. This precision approach not only enhances therapeutic outcomes but also minimizes adverse effects, ushering in a new era of individualized healthcare.

As the landscape of global medicine continues to evolve, biopharmaceuticals are poised to play an increasingly central role. Their ability to target complex diseases with precision, coupled with advances in manufacturing scalability and data driven personalization, marks them as the cornerstone of 21st century therapeutics [20]. Future trajectories are expected to explore solid tumor immunotherapies, cross-species genetic interventions, and integrative platforms combining diagnostics and therapeutics into unified systems.

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## 2. Monoclonal antibodies

Monoclonal antibodies (mAbs) are laboratory-engineered immunoglobulin analogs that have become pivotal in modern therapeutic paradigms. These antibodies are designed to bind selectively to specific antigens, including proteins expressed on cancer cells, inflammatory mediators, or viral components. This binding not only blocks pathological signaling cascades but also flags the target for immune destruction via mechanisms such as antibody-dependent cellular cytotoxicity (ADCC) or complement activation [10].

Therapeutically, mAbs have shown remarkable success across oncology, autoimmune diseases, and infectious diseases. In oncology, agents like trastuzumab and rituximab target HER2 and CD20, respectively, improving survival outcomes in breast cancer and lymphomas. In autoimmune conditions, adalimumab and infliximab neutralize TNF-alpha, curbing inflammation in rheumatoid arthritis and Crohn's disease [19]. Additionally, during the COVID-19 pandemic, neutralizing monoclonal antibodies such as casirivimab and imdevimab provided passive immunity to high-risk individuals [21].

Their high specificity translates to lower systemic toxicity compared to traditional chemotherapeutics or small molecules. However, their complex structure demands intricate production processes involving mammalian cell cultures and rigorous purification protocols to maintain efficacy and safety. The potential for immunogenicity, although minimized through humanization strategies, remains a regulatory concern [6].

Ongoing research explores bispecific antibodies, antibody drug conjugates (ADCs), and subcutaneous long-acting formulations to expand clinical efficacy and improve patient compliance. As a class, mAbs continue to lead biopharmaceutical pipelines, especially in precision oncology and immunotherapy.

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## 3. mRNA-based immunization

Messenger RNA (mRNA) vaccines have revolutionized the field of immunization, offering a rapid, adaptable, and safe alternative to traditional vaccine platforms. Instead of introducing attenuated or inactivated pathogens, mRNA vaccines deliver a nucleotide sequence encoding a pathogen-specific antigen. Once administered, host cells uptake the mRNA, synthesize the antigenic protein, and present it via major histocompatibility complex (MHC) molecules, priming the immune system for future encounters [2], [11].

The success of mRNA vaccines was exemplified during the COVID-19 pandemic, with products like BNT162b2 (PfizerBioNTech) and mRNA-1273 (Moderna) demonstrating high efficacy, safety, and rapid scalability. These vaccines

encoded the SARS-CoV-2 spike protein and were formulated with lipid nanoparticles (LNPs) to ensure cellular delivery and mRNA stability [5].

Beyond COVID-19, the mRNA platform holds promise for combating diseases such as Zika, rabies, HIV, and even cancer. Therapeutic mRNA vaccines are under investigation for generating immune responses against tumor-associated antigens in melanoma and glioblastoma [3]. Moreover, self-amplifying RNA (saRNA) and thermostable mRNA formulations are being explored to enhance efficacy and broaden global applicability, especially in resource-limited settings [2].

The advantages of mRNA-based vaccines include accelerated development timelines, the absence of pathogen handling, high precision in antigen design, and favorable safety profiles due to transient protein expression. Challenges such as cold-chain logistics, innate immune activation, and long-term durability of immunity are active areas of research and development.

Overall, mRNA vaccines represent a paradigm shift not only for infectious disease prevention but also for personalized therapeutic vaccines tailored to individual genetic and tumor profiles.

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#### 4. Genetic therapeutics

Gene-based therapeutics represent a transformative leap in the treatment of hereditary and acquired disorders by addressing disease mechanisms at the genomic level. These interventions aim to correct or compensate for faulty genes through strategies such as gene insertion, editing, or silencing. By intervening at the root cause, genetic therapies offer the potential for long-lasting or even curative outcomes, unlike conventional treatments that typically manage symptoms [3].

One of the most revolutionary techniques enabling gene-based therapeutics is CRISPR-Cas9, a programmable endonuclease system that facilitates precise DNA editing. This technology has been successfully used in clinical trials to correct mutations associated with sickle cell disease, beta-thalassemia, and Leber congenital amaurosis. In these contexts, targeted editing of hematopoietic stem cells or retinal cells has demonstrated sustained therapeutic benefits [12].

Beyond monogenic disorders, gene therapy is also being explored in oncology, where it is used to enhance tumor suppressor activity or silence oncogenes. Viral and non-viral vectors are employed to deliver therapeutic genes into tumor sites, either directly (in vivo) or into isolated cells ex vivo. Examples include adenoviral-mediated p53 gene therapy for head and neck cancers and antisense oligonucleotide therapies for glioblastoma [13].

Despite its promise, gene therapy faces substantial challenges, including immunogenicity, delivery specificity, and off-target effects. Additionally, ethical concerns regarding germline modifications and equitable access must be carefully addressed. Nevertheless, the convergence of synthetic biology, bioinformatics, and advanced delivery platforms continues to improve the precision, safety, and scalability of gene-based interventions [8].

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#### 5. Car-T Cell Platforms

Chimeric Antigen Receptor T-cell (CAR-T) therapy is an advanced form of adoptive cell transfer that reprograms a patient's immune cells to target and destroy cancer cells. In this approach, autologous T lymphocytes are genetically engineered to express synthetic receptors that combine an antigen-recognition domain with T-cell activation signals. This enables the modified cells to recognize specific tumor antigens independently of major histocompatibility complex (MHC) presentation [63].

CAR-T therapy has demonstrated significant clinical success in hematological malignancies. Notably, therapies such as tisagenlecleucel (for B-cell acute lymphoblastic leukemia) and axicabtagene ciloleucel (for large B-cell lymphoma) have achieved high remission rates in patients with relapsed or refractory cancers. These therapies have been approved by regulatory agencies and represent a paradigm shift in personalized oncology care [17].

Upon reinfusion, CAR-T cells undergo in vivo expansion, enabling them to mount a sustained cytotoxic response against malignant cells. However, this potent activity can result in severe side effects, including cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). These toxicities necessitate specialized clinical monitoring and the development of safety switches in CAR designs to mitigate risk [6].

Next-generation CAR-T research focuses on extending efficacy to solid tumors, improving persistence in the tumor microenvironment, and developing allogeneic “off-the-shelf” CAR-T products using gene-editing technologies. Innovations such as dual-antigen targeting, suicide switches, and armored CAR-T cells aim to overcome limitations and broaden applicability to a wider range of cancers [13].

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## 6. Biosimilar biologics

Biosimilars are biologic medical products that are highly similar to already approved reference biologics in terms of structure, function, efficacy, and safety, though they may exhibit minor differences in clinically inactive components. They arise once the patent protection of originator biologics expires, providing cost-effective alternatives without compromising therapeutic impact [5].

Unlike generic drugs, which are chemically synthesized and identical to their brand-name counterparts, biosimilars are derived from living systems and cannot be precisely replicated. Consequently, demonstrating bio similarity involves rigorous comparative studies that evaluate pharmacokinetics, pharmacodynamics, immunogenicity, and clinical efficacy across multiple endpoints. Regulatory agencies like the EMA and FDA have established distinct approval pathways for biosimilars, emphasizing analytical and clinical comparability [14].

The rise of biosimilars is reshaping global healthcare by improving access to advanced biologics—particularly in oncology, rheumatology, and endocrinology—while reducing treatment costs and increasing market competition. For example, biosimilar versions of infliximab, trastuzumab, and bevacizumab have been widely adopted across Europe, with growing acceptance in the United States and Asia-Pacific regions [22].

Nevertheless, challenges remain. Prescriber hesitancy, limited public awareness, and concerns over switching from originators to biosimilars necessitate educational campaigns and real-world evidence studies. Future directions include interchangeable biosimilars, global regulatory harmonization, and development of biosimilars for next-generation biologics, including monoclonal antibodies and fusion proteins [6].

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## 7. Advanced drug delivery systems

The effectiveness of biopharmaceuticals heavily depends not only on molecular design but also on the mode of delivery. Traditional intravenous or subcutaneous routes often pose limitations regarding patient compliance, stability, and pharmacokinetics. Advanced drug delivery systems (DDS) have emerged to address these limitations by enhancing bioavailability, ensuring targeted release, and minimizing adverse effects [5].

Innovative platforms such as microneedle arrays, nanoparticle carriers, inhalable powders, and implantable reservoirs are being developed to facilitate non-invasive, site-specific, and sustained delivery. Microneedles, for instance, enable painless transdermal administration of vaccines or biologics by penetrating the stratum corneum without reaching pain receptors. These platforms offer improved adherence and self-administration potential [15].

Lipid nanoparticles (LNPs) have been pivotal in the success of mRNA vaccines, ensuring cellular uptake and endosomal escape. Similarly, PEGylation techniques are used to prolong the half-life of proteins by enhancing solubility and reducing immunogenicity. Biodegradable polymers and hydrogels also enable controlled release of therapeutic proteins in chronic conditions, offering sustained plasma concentrations and fewer dosing intervals [5], [23].

Despite advances, delivery of large, unstable biomolecules remains a challenge. Future research is focusing on stimuli responsive carriers, real-time monitoring of drug distribution, and AI-assisted optimization of DDS for individualized pharmacological profiles. The integration of delivery technologies with wearable sensors and microelectronic control units may further personalize and automate drug administration.

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## 8. Tailored therapeutics

Personalized or tailored therapeutics aims to match the right treatment to the right patient at the right time, guided by individual genetic, molecular, and environmental profiles. This approach diverges from the one-size-fits-all model and leverages tools such as pharmacogenomics, transcriptomics, and biomarker analysis to inform treatment decisions [16]. In oncology, personalized medicine has already altered treatment landscapes through companion diagnostics that identify patients likely to respond to specific targeted therapies. For example, EGFR mutation testing in non-small cell lung cancer or HER2 overexpression in breast cancer helps clinicians select the most appropriate biologic agent. In the

case of immunotherapy, PD-L1 expression and tumor mutational burden (TMB) are being evaluated as predictive biomarkers [17].

Beyond cancer, pharmacogenomic testing has found application in tailoring antidepressant prescriptions, anticoagulant dosing, and statin safety profiles. Commercial platforms now offer patient-specific drug-gene interaction panels that guide clinicians toward optimal therapy choices while minimizing adverse effects [7].

Tailored therapeutics is expected to gain momentum with the integration of AI and big data analytics. Machine learning models trained on multi-omics datasets can predict drug responses, stratify disease subtypes, and suggest combinatorial therapies. The convergence of digital health technologies, wearable biosensors, and genomic sequencing is laying the foundation for real-time, personalized disease management systems [6].

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## 9. Applications in oncology

Biopharmaceuticals have significantly expanded the therapeutic arsenal in oncology, enabling targeted, immune modulating, and cell-based approaches that improve survival outcomes and quality of life for cancer patients. Traditional chemotherapeutics, though effective, often lack selectivity and result in systemic toxicity. Biopharmaceuticals offer precision by acting on specific oncogenic pathways or by mobilizing the patient's immune system against tumors [13].

Monoclonal antibodies like bevacizumab and cetuximab inhibit angiogenesis and receptor signaling, while antibody drug conjugates (ADCs) deliver cytotoxic payloads directly to tumor cells, sparing normal tissues. Immune checkpoint inhibitors such as nivolumab and pembrolizumab restore immune activity by blocking inhibitory signals (e.g., PD-1/PDL1) that allow cancer cells to evade immune surveillance [17].

CAR-T cell therapies have shown exceptional efficacy in hematologic cancers and are being adapted for solid tumors using enhanced homing mechanisms, dual antigen specificity, and resistance to immunosuppressive microenvironments. Additionally, bispecific T-cell engagers (BiTEs) are being explored for bridging immune cells with cancer cells, offering another route of targeted immunotherapy [4].

Challenges such as tumor heterogeneity, resistance mechanisms, and cost of advanced biologics continue to hinder broad implementation. However, integration of biopharmaceuticals with precision diagnostics, next-generation sequencing, and real-time treatment monitoring holds promise for more effective and durable cancer management strategies.

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## 10. Manufacturing innovation and quality assurance

The manufacturing of biopharmaceuticals demands a high degree of precision due to the inherent complexity and sensitivity of biologic molecules. Traditional batch processes have given way to advanced bioproduction methodologies that emphasize scalability, consistency, and responsiveness to dynamic production needs. Central to this evolution is the adoption of automation, continuous flow systems, and digital bioprocessing technologies [8].

Single-use systems, such as disposable bioreactors, have revolutionized upstream processing by reducing cleaning requirements, minimizing cross-contamination, and enabling faster turnaround between production cycles. These systems are particularly advantageous for multiproduct facilities and clinical-scale operations. In downstream processing, innovations like membrane chromatography and process analytical technology (PAT) have enhanced purification efficiency and real-time quality control [18].

Digital transformation in biomanufacturing includes the integration of supervisory control and data acquisition (SCADA) systems, machine learning algorithms for process optimization, and digital twins for virtual testing. These tools support predictive maintenance, error mitigation, and scalability from pilot to commercial production. Continuous bioprocessing, enabled by perfusion culture and real-time feedback systems, is gaining momentum for its potential to improve yields and reduce production costs [7].

Quality assurance remains a cornerstone of biopharmaceutical manufacturing. Regulatory expectations mandate extensive validation protocols, in-process testing, and traceability across the product lifecycle. The integration of Quality by Design (QbD) principles allows manufacturers to anticipate variability and design robust processes from the outset.

Overall, innovation in manufacturing is pivotal for meeting the rising global demand for biologics while maintaining safety and efficacy standards.

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## 11. Regulatory landscape and prospects

As biopharmaceutical modalities continue to diversify, regulatory frameworks are under increasing pressure to evolve accordingly. Traditional regulatory paradigms designed for small molecules are often ill-suited for complex biologics, necessitating adaptive and forward-looking governance models. Central to this transformation is the concept of risk-based, lifecycle-focused regulation that aligns scientific innovation with patient safety [6].

One major regulatory challenge is the harmonization of biosimilar approval standards across jurisdictions. While the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) have established robust pathways, differences in requirements for clinical trials, immunogenicity testing, and interchangeability assessments can delay global market entry. Ongoing efforts by the International Council for Harmonization (ICH) aim to bridge these regulatory gaps [9].

For gene and cell therapies, regulatory agencies have developed specialized programs such as the FDA's Breakthrough Therapy and RMAT (Regenerative Medicine Advanced Therapy) designations. These initiatives facilitate expedited reviews and iterative communication between developers and regulators. However, ensuring long-term safety, manufacturing consistency, and equitable access remains a complex task due to the individualized and high-risk nature of these therapies [3].

Looking forward, the integration of real-world evidence (RWE), digital biomarkers, and artificial intelligence in regulatory decision-making represents a paradigm shift. These tools enable continuous post-market surveillance and adaptive regulation. Collaborative networks between academia, industry, and regulators are essential to align safety oversight with the pace of biotechnological progress, ensuring that innovation translates into broad and equitable health outcomes.

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## 12. Conclusion

The field of biopharmaceuticals has emerged as a cornerstone of modern medicine, offering highly targeted, potent, and often curative options for a wide array of diseases. From monoclonal antibodies and mRNA vaccines to gene editing and CAR-T cell therapies, biopharmaceuticals have redefined the therapeutic landscape. These advances are rooted in decades of molecular biology, genetic engineering, and bioinformatics research that continue to yield transformative innovations.

Equally significant are developments in manufacturing and regulatory science that have enabled safe, scalable, and cost-effective production of biologics. The adoption of continuous manufacturing, single-use bioreactors, and real-time process control ensures not only efficiency but also consistency in product quality. Meanwhile, adaptive regulatory frameworks are paving the way for timely market access while maintaining high safety standards [18], [8].

Despite remarkable progress, the journey of biopharmaceuticals is far from complete. Challenges such as high treatment costs, complex logistics, regulatory disparities, and variable patient responses must be addressed to ensure global and equitable access. Moreover, ethical considerations surrounding gene editing, data privacy in personalized medicine, and long-term safety require ongoing societal and policy engagement [20].

In conclusion, biopharmaceuticals are poised to play a defining role in the future of healthcare. Their integration with personalized medicine, AI, and next-generation delivery platforms holds promise for truly individualized, effective, and accessible therapies. As innovation continues to accelerate, a concerted focus on collaboration, regulation, and equity will be key to realizing the full potential of biopharmaceutical science.

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