Journal of Advances in Drug Research

ISSN: 2230-7761
www.jadr.co.in

Volume 17, Issue 04 | Received 13.09.2026 | Accepted 15.09.2026 | Online 20.09.2026

BIOTECHNOLOGY-BASED APPROACHES FOR THE DEVELOPMENT OF NEXT-GENERATION THERAPEUTIC MOLECULES

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Abstract.

Biotechnology has expanded the therapeutic design space beyond conventional small molecules by enabling the rational construction, expression and delivery of proteins, antibodies, nucleic acids and engineered cellular systems. This structured narrative review evaluates major biotechnology-based approaches that are shaping next-generation therapeutics, with emphasis on recombinant and engineered proteins, monoclonal and multispecific antibodies, antibody-drug conjugates, messenger RNA and RNA interference platforms, genome editing, engineered cells, and advanced biomanufacturing. Peer-reviewed international literature was prioritized to identify enabling technologies, translational advantages, manufacturing requirements and safety constraints. Across therapeutic classes, the strongest trend is convergence: molecular engineering is increasingly combined with precision delivery, advanced analytics, synthetic biology and quality-by-design principles. Engineered proteins benefit from structural and chemical optimization, while antibody formats provide modular targeting and effector control. RNA medicines offer programmable and comparatively rapid redesign, but delivery, innate immune activation and tissue selectivity remain central challenges. CRISPR-based technologies enable durable genetic correction, although off-target activity, delivery and long-term safety require rigorous control. Cell therapies add adaptive biological functions but introduce complex manufacturing, phenotypic variability and logistics. Continuous processing, cell-free systems and molecular farming may improve production flexibility and access. The evidence indicates that future therapeutic innovation will depend less on a single platform than on integrated biotechnology systems that connect design, manufacturability, delivery, safety and clinical translation from the earliest development stages.

Keywords: Biotechnology; therapeutic proteins; monoclonal antibodies; mRNA therapeutics; CRISPR; cell therapy; antibody-drug conjugates; biomanufacturing

1. INTRODUCTION

Modern drug development is undergoing a fundamental transition from predominantly small-molecule chemistry toward a broader landscape that includes biologically produced and biologically active therapeutic entities. Recombinant DNA technology, protein engineering, high-throughput sequencing, synthetic biology, advanced cell culture, genome editing and nanoscale delivery systems have collectively transformed the range of

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ISSN: 2230-7761
www.jadr.co.in
Volume 17, Issue 04 Received 13.09.2026 Accepted 15.09.2026 Online 20.09.2026

druggable mechanisms. Instead of being restricted to enzymatic active sites or conventional receptors, therapeutic design can now manipulate extracellular ligands, intracellular transcripts, genetic sequences, immune-cell programs and even cellular behavior. Protein-based therapeutics already demonstrate how structural and chemical engineering can convert unstable or short-lived natural molecules into clinically useful products with optimized half-life, specificity and functional activity (1,2).

The biotechnology paradigm is especially important for diseases driven by proteins or genetic abnormalities that are difficult to modulate with traditional medicinal chemistry. Recombinant enzymes and replacement proteins can restore deficient biological functions; monoclonal antibodies can recognize targets with high molecular specificity; bispecific antibodies can connect two biological partners; antibody-drug conjugates (ADCs) can deliver potent payloads to selected cells; RNA therapeutics can direct or suppress protein expression; and genome-editing systems can alter disease-causing sequences at their source (3-10). These modalities change the concept of a drug from a static chemical entity to a programmable biological system.

Next-generation therapeutics are also distinguished by modularity. Antibody domains can be rearranged or combined to create multispecific formats, linker-payload combinations can be redesigned in ADCs, coding regions and untranslated elements can be optimized in mRNA medicines, and guide RNAs can redirect CRISPR-associated proteins to new sequences (3-10). This modularity can accelerate optimization and enable platform-based development. However, the same complexity creates additional translational constraints, including immunogenicity, tissue-selective delivery, manufacturing heterogeneity, cold-chain dependence, potency assays, long-term safety assessment and higher production costs (2,6-10).

Biotechnology-based therapeutics therefore require integration of molecular design with manufacturability and delivery from the earliest development stages. The physicochemical and biological attributes that produce therapeutic activity are inseparable from the expression system, purification process, formulation and route of administration. For example, a protein may display excellent potency but fail because of aggregation or unwanted immune responses; an RNA sequence may be pharmacologically compelling but clinically ineffective without appropriate delivery; and a genome editor may be highly active in vitro yet unsuitable if it cannot reach the intended cell population safely (2,6,8-10).

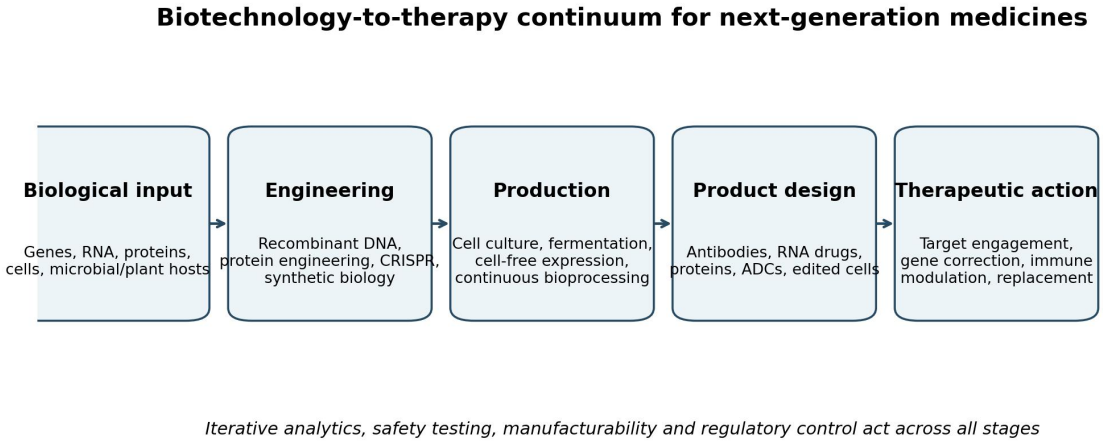
The objective of this article is to synthesize current biotechnology-based strategies for developing next-generation therapeutic molecules and to identify the technological principles that connect these otherwise diverse modalities. Particular attention is given to engineered proteins, antibody-based therapeutics, RNA medicines, genome editing, engineered cells and emerging biomanufacturing approaches. The analysis also considers translational bottlenecks and proposes an integrated development framework in which molecular performance, safety, delivery, quality and scalability are evaluated as mutually dependent criteria.

Figure 1. Biotechnology-to-therapy continuum in the development of next-generation medicines.

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2. MATERIALS AND METHODS

This work was designed as a structured narrative review using an IMRAD organization. International peer-reviewed publications were prioritized from major biomedical and biotechnology journals, including Nature Reviews Drug Discovery, Nature Communications, Nature Reviews Bioengineering, Nature Reviews Clinical Oncology, Drug Discovery Today and Biotechnology Progress. Literature searches emphasized publications from 2023-2025, while selected earlier or platform-defining sources were retained when necessary to explain technological foundations. Search concepts included combinations of “therapeutic protein engineering”, “monoclonal antibody therapeutics”, “bispecific antibodies”, “antibody-drug conjugates”, “mRNA therapeutics”, “RNAi drug design”, “CRISPR therapeutics”, “cell therapy engineering”, “continuous biomanufacturing” and “molecular farming”.

Sources were selected for relevance to one or more of four predefined domains: (i) molecular engineering and mechanism of action; (ii) delivery and pharmacological control; (iii) manufacturing and quality; and (iv) translational safety or clinical applicability. Regulatory news items, commercial forecasts and non-peer-reviewed claims were not used as primary evidence for mechanistic conclusions. Because the aim was integrative rather than meta-analytic, no pooled effect size was calculated and no artificial experimental dataset was generated. Results were synthesized qualitatively across therapeutic platforms and organized into comparative tables and conceptual diagrams.

Table 1. Major biotechnology-derived therapeutic platforms and their development characteristics.

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Platform	Primary therapeutic principle	Main advantages	Key limitations
Engineered proteins	Replacement, receptor modulation, enzymatic activity	High biological specificity; tunable half-life and activity	Stability, aggregation, immunogenicity, parenteral delivery
Monoclonal / bispecific antibodies	Selective recognition and immune/receptor modulation	High affinity; modular Fc and multispecific design	Large-molecule delivery; manufacturing complexity; immunogenicity
Antibody-drug conjugates	Targeted delivery of a linked payload	Combines targeting with potent pharmacology	Linker/payload optimization; heterogeneity; resistance
mRNA / RNAi therapeutics	Programmable expression or gene silencing	Rapid sequence redesign; platform manufacturing	Delivery, innate immune sensing, tissue selectivity
Genome editing	Durable sequence modification	Potential one-time correction of causal defects	Off-target effects, delivery, irreversibility, long-term follow-up
Engineered cells	Living adaptive therapeutic function	Persistence, sensing, amplification and personalized activity	Complex manufacture, logistics, phenotypic variability, safety control

3. RESULTS

The literature synthesis identified six major, partially overlapping biotechnology domains that are currently shaping next-generation therapeutics. Their common feature is the use of programmable biological components or biological production systems to create therapeutic functions that are difficult to achieve with conventional small molecules. The comparative findings are summarized below.

3.1 Engineered and recombinant protein therapeutics

Recombinant proteins remain one of the most mature biotechnology-derived therapeutic classes, but the field has moved well beyond simple replacement of naturally occurring proteins. Structural engineering, sequence optimization, domain fusion, glycoengineering, covalent modification and half-life extension strategies are increasingly used to improve

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Volume 17, Issue 04 Received 13.09.2026 Accepted 15.09.2026 Online 20.09.2026

stability, receptor selectivity, tissue exposure and dosing convenience. Ebrahimi and Samanta described how rational structural and chemical design can transform proteins that are intrinsically susceptible to denaturation, proteolysis or aggregation into therapeutics with substantially improved pharmaceutical behavior (1). This illustrates a central principle of modern biotechnology: biological activity alone is insufficient; developability must be engineered into the molecule.

Protein engineering also introduces immunological risk. Sequence changes, aggregates, impurities, post-translational variants and repeated exposure may contribute to anti-drug antibody formation. Carter and Quarmby emphasized that immunogenicity risk assessment should be integrated across discovery, development and clinical use rather than treated as a late-stage problem (2). Consequently, next-generation protein design increasingly combines in silico sequence assessment, high-resolution analytics, orthogonal aggregation measurements and human immune-risk evaluation. The design goal is not simply maximum potency, but a balanced profile of potency, stability, manufacturability and low immunogenicity.

3.2 Monoclonal, bispecific and conjugated antibody platforms

Monoclonal antibodies are highly adaptable therapeutic scaffolds because antigen recognition, Fc-mediated functions, half-life and molecular architecture can all be engineered. Recent antibody innovation has focused on formats that perform functions unavailable to conventional monospecific IgG molecules. Bispecific antibodies can bind two antigens or epitopes simultaneously, enabling mechanisms such as immune-cell redirection, receptor co-engagement or dual-pathway blockade. A recent review documented rapid expansion of bispecific antibody formats and clinical applications, demonstrating how modular domain engineering has become a major route to new therapeutic mechanisms (3).

ADCs extend the antibody concept by coupling selective target recognition to a cytotoxic or otherwise bioactive payload. Their performance depends on coordinated optimization of target biology, antibody properties, linker stability, conjugation chemistry, drug-to-antibody ratio and payload mechanism. Mature ADC technology has broadened both target space and payload diversity (4). Newer concepts include bispecific ADCs, conditionally active conjugates, immune-stimulating payloads, protein-degrader payloads and dual-payload systems intended to address tumor heterogeneity and resistance (5). These examples show that future biologics are likely to be hybrid constructs in which multiple biochemical technologies are integrated into a single therapeutic architecture.

3.3 RNA therapeutics and programmable expression

RNA therapeutics offer a distinct form of programmability because changing the nucleotide sequence can alter the encoded protein or the transcript targeted for silencing without rebuilding the entire production platform. Therapeutic mRNA is particularly attractive for transient protein expression. Sequence design can be optimized at the level of codons, untranslated regions, nucleoside chemistry, cap structure and poly(A) tail, while

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formulation affects cellular uptake and biodistribution. Metkar, Pepin and Moore emphasized that mRNA medicines are highly designable, but that this design space is multidimensional and must balance translation, stability and immune sensing (6).

The broader RNA field includes siRNA and other regulatory nucleic-acid modalities. RNA interference can achieve potent and durable post-transcriptional silencing, yet extrahepatic delivery remains a major limitation for many applications (7). RNA-based medicine therefore demonstrates the importance of co-developing cargo and delivery system. Lipid nanoparticles, conjugated ligands and tissue-selective formulations are not auxiliary components; they determine whether a programmable sequence can become a clinically usable medicine. Platform thinking is also important because validated chemistry and delivery components can be reused across new sequences, creating opportunities for faster development cycles (6,7,15).

3.4 Genome editing as a therapeutic platform

CRISPR-Cas systems have transformed therapeutic biotechnology by enabling sequence-directed genome modification. Unlike transient pharmacological modulation, genome editing can potentially create durable or permanent changes. The therapeutic toolkit now includes nuclease-mediated editing as well as emerging base-editing, prime-editing and transcriptional-control strategies. However, activity alone does not determine suitability. Stability of editing components, off-target modification, immunogenicity, DNA-damage responses and tissue-selective delivery must all be controlled (8,9).

Delivery is one of the dominant constraints in genome-editing therapeutics. Viral vectors provide efficient gene transfer in selected contexts, whereas lipid nanoparticles and other non-viral systems can support transient delivery of nucleic acids or ribonucleoprotein components. Madigan, Zhang and Dahlman highlighted how delivery architecture directly influences tissue targeting, exposure and immune responses (9). More recent work on chemical engineering of CRISPR-Cas components shows that protein and guide-RNA modification can improve stability, specificity and pharmacological behavior (8). These approaches shift genome editing from a laboratory tool toward a true therapeutic engineering discipline.

3.5 Engineered cells and living therapeutics

Cell therapies occupy the most biologically complex end of the biotechnology spectrum. Instead of administering a molecule that acts on a cell, the therapeutic product is itself a living cell with endogenous or engineered functions. Immune cells, stem cells and other cellular systems can be programmed to recognize disease-associated signals, produce therapeutic molecules or change local tissue behavior. Advances in synthetic receptors, gene circuits and ex vivo engineering have increased the precision of cell-based interventions (11).

The major advantage of engineered cells is functional adaptability, but this is accompanied by manufacturing and quality challenges. Cellular identity, activation state, differentiation,

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exhaustion, viability and potency can vary over time and among manufacturing lots. Drug-delivery technologies are increasingly being used to modulate cell therapy directly, for example by supporting viability, localizing cells, providing stimulatory signals or reducing immunogenicity (12). Thus, cell therapy is converging with biomaterials and drug-delivery engineering rather than developing as an isolated field.

3.6 Emerging production platforms and biomanufacturing

Biotechnology therapeutics are inseparable from the systems used to produce them. Mammalian cell culture remains central for many complex proteins and antibodies, while microbial hosts are valuable for selected recombinant products. Plant molecular farming provides an alternative route for producing proteins and vaccines, with potential advantages in scalability and infrastructure flexibility. Modern plant-based systems use rational genetic circuits and host engineering to improve expression and post-translational quality (13).

At the process level, continuous and integrated biomanufacturing aims to replace disconnected batch operations with more tightly coupled upstream and downstream processing. Potential benefits include higher facility utilization, smaller equipment footprints, improved process control and more flexible production. However, adoption remains limited by integration complexity, legacy infrastructure, data architecture, process analytical technology and regulatory implementation (14). The manufacturing platform must therefore be considered a design variable, particularly for personalized or rapidly updated medicines whose economics differ from traditional high-volume biologics.

Figure 2. Converging biotechnology platforms used to generate next-generation therapeutic products.

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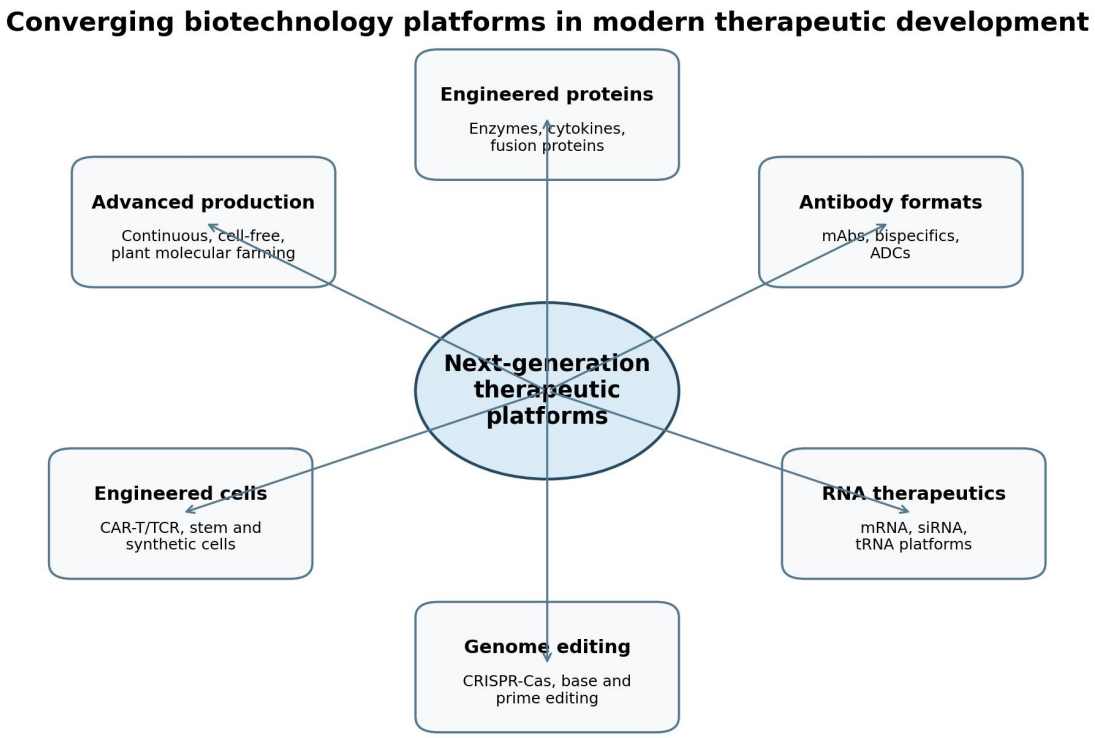


Table 2. Enabling biotechnologies that connect molecular design with therapeutic translation.

Enabling biotechnology	Role in therapeutic development	Typical impact
Recombinant DNA / synthetic biology	Constructs expression cassettes and controllable biological circuits	Faster design cycles and modular product architectures
Protein engineering	Alters sequence, domains, glycosylation and conjugation sites	Improved affinity, stability, half-life and functional selectivity
Lipid nanoparticles / targeted delivery	Protects and directs nucleic-acid cargo	Improves intracellular exposure and tissue distribution
CRISPR and genome engineering	Edits product cells, hosts or therapeutic targets	Enables durable correction and redesigned production systems
High-resolution analytics	Defines sequence, structure, variants, aggregates and potency	Supports comparability and quality-by-design

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Enabling biotechnology	Role in therapeutic development	Typical impact
Continuous / integrated bioprocessing	Links upstream and downstream production with data-rich control	Potentially improves flexibility, consistency and facility utilization

4. DISCUSSION

The reviewed evidence shows that next-generation therapeutics are defined by convergence rather than by any single biotechnology. Protein engineering, antibody modularity, RNA programmability, genome editing, cell engineering and advanced bioprocessing increasingly share the same development logic: define a biological function, construct a controllable molecular or cellular system, deliver it to the correct site, manufacture it reproducibly and continuously measure attributes that predict clinical performance. This systems perspective is essential because improvements in one dimension can create new problems in another. Increasing protein potency can increase aggregation risk; extending exposure can amplify immunogenicity; increasing intracellular editing activity can increase off-target concerns; and adding complex ADC payloads can complicate manufacturing and analytical characterization (1-9).

A second major theme is that delivery has become part of the therapeutic mechanism. For conventional small molecules, formulation can sometimes be optimized after lead selection. For many biotechnology products, by contrast, cargo and delivery are co-dependent. mRNA and siRNA require protection from degradation and cellular entry; genome editors require access to specific cell populations; cell therapies may need biomaterials or local delivery systems to maintain function; and ADCs depend on target-mediated internalization and linker behavior (4-12). This means that delivery science should be incorporated during molecular selection rather than treated as a downstream formulation problem.

A third theme is the growing importance of quality-by-design. Complex biologics are heterogeneous systems, and small changes in sequence, glycosylation, conjugation, culture conditions or purification can influence activity and safety. Development programs therefore benefit from defining critical quality attributes early and linking them to molecular design and process parameters. Advanced analytics, multi-attribute methods, high-throughput biophysical screening and mechanistic potency assays can support this linkage. Continuous manufacturing and data-rich process control may strengthen this approach, but only if upstream, downstream and analytical systems are integrated in a way that preserves product understanding (2,14).

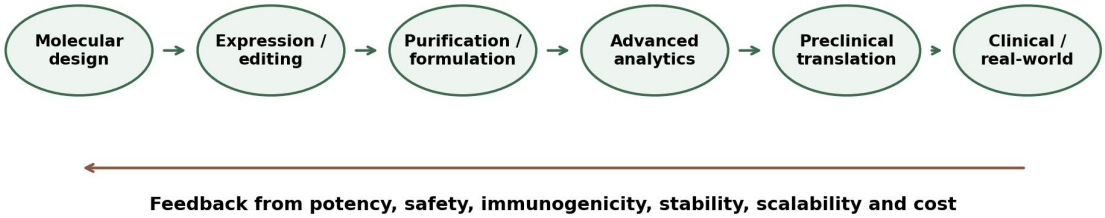
Figure 3. Iterative quality-by-design and translational feedback loop for biotechnology therapeutics.

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www.jadr.co.in

Volume 17, Issue 04 | Received 13.09.2026 | Accepted 15.09.2026 | Online 20.09.2026

Iterative development and quality-by-design loop for biotechnology therapeutics



Data-driven redesign closes the loop and reduces late-stage failure risk

The therapeutic platforms also differ in durability and reversibility. Recombinant proteins and many antibodies are generally titratable and reversible because exposure declines after dosing stops. RNA therapies may provide transient or semi-durable effects depending on chemistry and target biology. Genome editing may produce permanent changes, which can be advantageous for monogenic diseases but raises a higher threshold for precision and long-term safety. Engineered cells may persist, expand or alter function after administration. These differences should influence preclinical models, clinical monitoring and benefit-risk evaluation. A single development framework cannot be applied mechanically across all modalities.

Manufacturability and access are likely to become decisive determinants of clinical impact. A biologically elegant technology may have limited public-health value if it requires complex individualized production, highly specialized infrastructure or prohibitively expensive logistics. Platform standardization, modular manufacturing, automated closed systems, continuous processing and alternative expression hosts may reduce cost and increase geographic flexibility (13,14). At the same time, cost reduction must not compromise characterization or control, particularly for products with long-lasting biological effects.

The next stage of biotechnology development will likely be driven by combinations of modalities. Antibodies can deliver cytotoxic drugs, nucleic acids or immune agonists; RNA can encode therapeutic proteins or genome editors; engineered cells can be equipped with synthetic receptors and controlled by externally administered molecules; and biological production hosts can be redesigned using genome engineering. Such convergence blurs traditional categories of 'drug', 'biologic', 'gene therapy' and 'cell therapy'. Regulatory science and manufacturing standards will need to evolve accordingly.

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www.jadr.co.in
Volume 17, Issue 04 Received 13.09.2026 Accepted 15.09.2026 Online 20.09.2026

Several limitations should be considered when interpreting this review. The evidence base is heterogeneous across platforms, and the maturity of clinical validation differs substantially. Antibodies and recombinant proteins have decades of manufacturing experience, whereas many RNA, gene-editing and synthetic-cell technologies remain comparatively young. In addition, this article is a structured narrative synthesis rather than a quantitative meta-analysis. Its value lies in identifying shared engineering principles and translational constraints rather than estimating comparative clinical efficacy.

Table 3. Major translational bottlenecks and corresponding biotechnology-based mitigation strategies.

Translational bottleneck	Why it matters	Biotechnology-based mitigation strategy
Immunogenicity	Can reduce efficacy or cause adverse immune responses	Humanization/deimmunization, impurity control, aggregate reduction, immune-risk assessment
Tissue-selective delivery	Many biologics and nucleic acids do not cross membranes or distribute uniformly	Ligand targeting, LNP optimization, local delivery, engineered carriers
Product heterogeneity	Variants may affect potency, stability or safety	Process control, site-specific conjugation, advanced analytics, QbD
Scalability and cost	Complex products may limit access and commercial viability	Automation, continuous processing, modular facilities, alternative expression hosts
Durability / reversibility	Long-lived effects can be beneficial but increase safety burden	Dose control, transient delivery, switchable systems, long-term monitoring
Regulatory characterization	Novel modalities may lack mature standards	Mechanistic potency assays, standardized critical quality attributes, platform comparability

5. CONCLUSION

Biotechnology is redefining therapeutic development by making biological function itself engineerable. Recombinant and engineered proteins provide precise replacement and signaling functions; monoclonal, bispecific and conjugated antibodies enable modular targeting; RNA therapeutics provide programmable control of protein expression; CRISPR-based systems offer sequence-directed genetic intervention; and engineered cells introduce living, adaptive therapeutic behavior. These capabilities are being strengthened

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Volume 17, Issue 04 | Received 13.09.2026 | Accepted 15.09.2026 | Online 20.09.2026

by synthetic biology, advanced delivery, high-resolution analytics and new biomanufacturing strategies. The central challenge is no longer simply discovering an active molecule. Successful next-generation therapeutics require simultaneous optimization of biological activity, delivery, stability, immunogenicity, manufacturability, quality and long-term safety. Future development programs should therefore adopt integrated platform strategies in which molecular design and process design evolve together. Such convergence offers the most credible path toward safer, more precise, scalable and clinically transformative biotechnology medicines.

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