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Original Article

Recent Advances In Nanotechnology For Drug Delivery: A Comprehensive Review

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ABSTRACT

Nanotechnology has emerged as a transformative force in the field of drug delivery, offering innovative solutions to longstanding challenges, including poor bioavailability, off-target effects, and multidrug resistance. By enabling the design of nanoscale carriers that can encapsulate, protect, and precisely release therapeutic agents, this technology has the potential to revolutionise how drugs are administered and function within the human body. This review explores the diverse array of nanocarriers currently under investigation or in clinical use, including liposomes, polymeric nanoparticles, dendrimers, solid lipid nanoparticles, and inorganic nanostructures such as gold nanoparticles and quantum dots. Each of these platforms possesses unique physicochemical properties that can be tailored for specific therapeutic applications, ranging from oncology and infectious diseases to neurological and autoimmune disorders. Recent breakthroughs in targeted drug delivery, including stimuli-responsive nanocarriers and surface functionalisation with ligands for active targeting, have significantly enhanced the precision and efficacy of treatments. Several nanotechnology-based formulations have advanced to clinical trials or received regulatory approval, underscoring the growing clinical relevance of this field. Despite these advances, key challenges remain, including issues of large-scale manufacturing, long-term biocompatibility, and regulatory hurdles. Addressing these barriers is crucial for the broader translation of nanotechnology-based drug delivery systems from the bench to the bedside. Future directions point toward the integration of artificial intelligence and personalised medicine with nanotechnology to create more innovative, adaptive delivery platforms tailored to individual patient profiles

Keywords: Nanoparticle-based drug delivery, Lipid-based nanocarriers, Polymeric nanoparticles, Targeted nanomedicine, Stimuli-responsive nanocarriers, Blood-brain barrier delivery, FDA-approved nanodrugs.

INTRODUCTION

Nanotechnology, the science of manipulating matter at dimensions typically below 100 nanometres, has dramatically expanded the frontiers of biomedical research. In medicine, nanotechnology enables precise control over the composition, distribution, and function of drugs at the molecular and cellular levels. Since its conceptual inception in the late 20th century, the field has undergone rapid evolution, transitioning from theoretical constructs to tangible clinical applications.[1] The advent of nanomedicine has ushered in a new era wherein therapeutic interventions are increasingly sophisticated, leveraging nanoscale engineering to address the limitations of conventional treatment modalities.[2]

Traditional drug delivery systems, such as oral tablets or intravenous injections, often suffer from significant drawbacks, including nonspecific biodistribution, poor solubility, rapid systemic clearance, and limited capacity to cross biological barriers. These limitations compromise drug efficacy and increase the risk of adverse effects, particularly in diseases requiring site-specific treatment such as cancer, neurodegenerative disorders, and chronic infections. Moreover, systemic toxicity and multidrug resistance continue to challenge clinicians and pharmacologists alike, highlighting the urgent need for more effective and safer delivery strategies.[3]

Nanotechnology offers a compelling solution to these unmet needs. The key goals of nanotechnology-based drug delivery systems include: (1) targeted delivery to

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specific tissues or cells, minimising off-target effects and enhancing therapeutic efficacy; (2) controlled and sustained drug release, maintaining optimal drug concentrations over time; and (3) the ability to traverse biological barriers such as the blood-brain barrier, gastrointestinal lining, and tumour microenvironment. By achieving these objectives, nanocarriers can significantly enhance pharmacokinetics and pharmacodynamics, ultimately leading to improved clinical outcomes.[4]

Various types of nanocarriers have been developed to achieve these goals. Liposomes, among the earliest and most extensively studied, offer biocompatibility and versatility in drug encapsulation. Polymeric nanoparticles allow for tunable degradation rates and controlled release profiles. Dendrimers, with their highly branched architecture, facilitate multivalent interactions and offer a high payload capacity. Solid lipid nanoparticles combine the advantages of lipids and polymers for enhanced stability and drug protection. Inorganic nanocarriers, such as gold nanoparticles and quantum dots, possess unique optical and electronic properties that enable the integration of diagnostic and therapeutic applications in modern oncology.[5,6]

The scope of this review encompasses the design principles, functional attributes, and clinical applications of the most prominent nanocarriers in drug delivery. We will begin by examining the physicochemical characteristics and synthesis methods of various nanocarriers. The subsequent sections will delve into the mechanisms of drug loading and release, strategies for targeting and crossing biological barriers, and recent advances in stimuli-responsive systems. We will also highlight key translational milestones, including approved nanomedicine products and ongoing clinical trials. Finally, we will discuss prevailing challenges and potential future directions, particularly the integration of nanotechnology with emerging fields like artificial intelligence and personalised medicine.

Through this comprehensive analysis, we aim to provide an in-depth understanding of how nanotechnology is reshaping the landscape of drug delivery, bridging the gap between bench-side innovation and bedside application.

1. Classification of Nanocarriers

Nanocarriers are the cornerstone of nanotechnology-enabled drug delivery systems, enabling the transport of therapeutic agents with enhanced precision, efficacy, and safety.[7] They can be broadly categorised based on their structural composition and physicochemical properties into lipid-based systems, polymeric nanoparticles, inorganic nanoparticles, dendrimers, micelles/nanospheres, and emerging biomimetic carriers such as exosomes. Each category brings distinct advantages and design considerations tailored to specific biomedical applications.[8]

1) Lipid-Based Systems

Liposomes: These spherical vesicles consist of one or more phospholipid bilayers surrounding an aqueous core. Their biocompatibility, ability to encapsulate both hydrophilic and lipophilic drugs, and ease of surface modification make them highly versatile. Liposomal formulations, such as Doxil (doxorubicin liposomes), are already clinically approved, demonstrating their potential for effective and safe drug delivery.[9]

***Solid Lipid Nanoparticles (SLNs)*:** Composed of solid lipids stabilised by surfactants, SLNs offer excellent physical stability, controlled drug release, and protection of labile drugs. They overcome some limitations of liposomes, such as drug leakage and fusion.[10]

***Nanostructured Lipid Carriers (NLCs)*:** NLCs are second-generation lipid nanoparticles comprising a blend of solid and liquid lipids. This composition results in improved drug loading capacity and reduced drug expulsion during storage. NLCs are particularly promising in dermal and transdermal delivery systems.[11]

2) Polymeric Nanoparticles

***Natural Polymers*:** Chitosan and gelatin are widely used due to their biodegradability, mucoadhesive properties, and minimal toxicity. Chitosan nanoparticles exhibit a strong interaction with negatively charged biological membranes, thereby enhancing cellular uptake and facilitating the opening of tight junctions for the transport of drugs.[12]

***Synthetic Polymers*:** Polymers like PLGA (poly(lactic-co-glycolic acid)) and PEG (polyethene

glycol) offer controlled degradation rates and enhanced circulation times. PLGA is FDA-approved and widely used due to its tunable mechanical and chemical properties. PEGylation of nanoparticles enhances systemic stability and evades immune recognition.[13]

3) Inorganic Nanoparticles

Inorganic nanoparticles bring unique physical and optical properties that are advantageous in drug delivery and imaging.

***Gold Nanoparticles*:** Known for their tunable size, ease of functionalisation, and photothermal capabilities, gold nanoparticles are functional in targeted drug delivery and cancer therapy.[14]

***Silica Nanoparticles*:** Mesoporous silica nanoparticles (MSNs) offer a high surface area and tunable pore sizes, facilitating efficient drug loading and controlled release.[15]

***Iron Oxide Nanoparticles*:** Their superparamagnetic properties are exploited in magnetic resonance imaging (MRI) and magnetically guided drug delivery.[16]

Quantum Dots: These semiconductor nanocrystals possess unique fluorescent properties, making them ideal for real-time tracking of drug distribution; however, their heavy metal content raises concerns about biocompatibility.[17]

4) Dendrimers

Dendrimers are highly branched, monodisperse macromolecules characterised by a central core, interior branches (or generations), and multiple surface functional groups.[18] Poly(amidoamine) (PAMAM) dendrimers are the most extensively studied of all dendrimers. Their multivalency allows high drug loading through encapsulation or covalent conjugation. Surface modification enables targeting and reduces toxicity. The architectural precision of dendrimers enables the design of structures tailored to specific therapeutic needs, including gene delivery and antimicrobial applications.[19]

5) Micelles and Nanospheres

Micelles are formed by the self-assembly of amphiphilic block copolymers in aqueous solutions. Their core-shell structure enables solubilisation of hydrophobic drugs within the core, while the hydrophilic shell provides steric stability in biological fluids. Polymeric micelles are ideal for solubilising poorly water-soluble drugs and prolonging circulation time.[20]

Nanospheres are solid matrix systems in which drugs are uniformly dispersed. They offer controlled release and stability advantages, and their synthesis can be adapted to various drug types and therapeutic targets.[21]

6) Exosomes and Biomimetic Carriers

Exosomes are naturally occurring extracellular vesicles derived from cells, playing a crucial role in intercellular communication. Their intrinsic ability to carry proteins, lipids, and RNA, combined with biocompatibility and low immunogenicity, makes them promising drug delivery vehicles. Exosome engineering allows for targeted delivery of therapeutic cargos, and they can be harvested from autologous sources to minimise immune response.[22]

Biomimetic carriers, including cell membrane-coated nanoparticles, are designed to mimic natural biological entities. They can evade immune detection, prolong circulation, and achieve specific targeting through surface markers derived from source cells such as red blood cells, platelets, or cancer cells.[23]

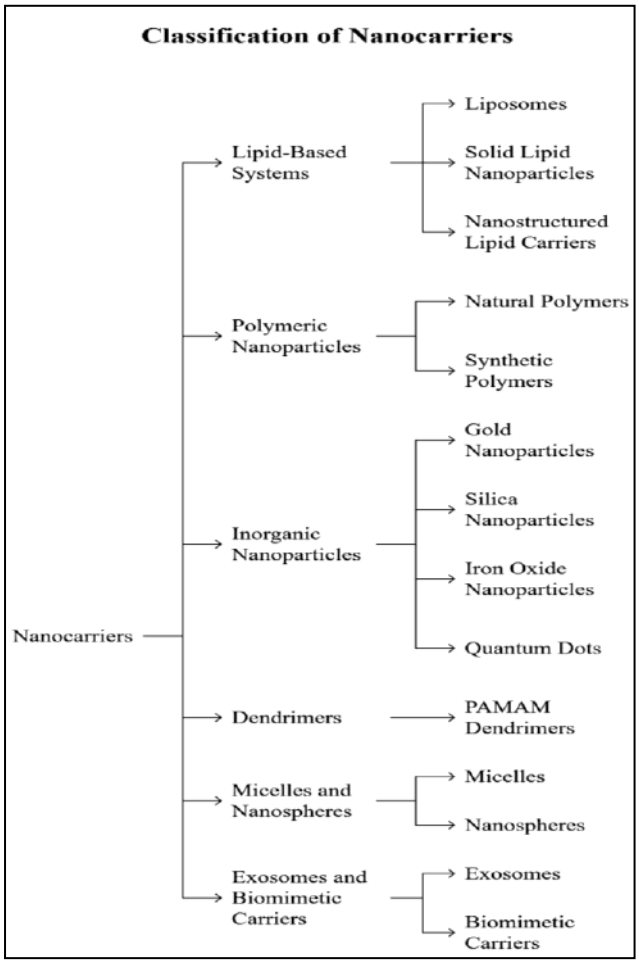

Figure 1. Classification of Nanocarriers

In conclusion, the classification of nanocarriers reveals a versatile toolkit for overcoming the limitations of traditional drug delivery systems. The continued refinement and hybridisation of these systems promise even more targeted, effective, and safe therapeutic interventions in the future.

Table 1. Comparison of Major Nanocarriers for Drug Delivery

Nanocarrier Type	Composition	Typical Size (nm)	Key Features	Example Drugs / Uses
Liposomes	Phospholipid bilayers	50–300	Vesicle structure, aqueous core	Doxil (doxorubicin), cancer therapy
Solid Lipid Nanoparticles (SLNs)	Solid lipids stabilised by surfactants	50–1000	Solid lipid core	SLN-based antifungal and anticancer delivery
Polymeric Nanoparticles	PLGA, PEG, PCL, chitosan	10–1000	Matrix or reservoir systems	Lupron Depot (leuprolide), hormonal therapy
Dendrimers	Branched polymers (PAMAM, PPI)	<10	Highly branched 3D structure	Anti-HIV, anticancer agents in preclinical trials
Micelles	Amphiphilic block copolymers	10–100	Self-assembled core-shell	Paclitaxel micelles (Genexol-PM)
Inorganic Nanoparticles	Gold, silica, iron oxide, QDs	1–100	Rigid, easily functionalised	Theranostic agents, MRI contrast carriers
Exosomes / Biomimetic Carriers	Cell-derived vesicles	30–150	Natural vesicles, membrane proteins	mRNA, miRNA, immunotherapy (early stage)

1. Mechanisms of Drug Delivery

Nanocarriers leverage a range of biological and physicochemical mechanisms to enhance the precision, efficiency, and therapeutic index of drug delivery. Understanding these mechanisms is critical for optimising nanoparticle design and function for specific clinical applications. The principal strategies include passive and active targeting, stimulus-responsive delivery, controlled and sustained drug release, and mechanisms facilitating intracellular trafficking.[24]

Passive Targeting via the Enhanced Permeability and Retention (EPR) Effect

Passive targeting capitalises on the pathophysiological characteristics of diseased tissues, notably tumours and inflamed sites. The Enhanced Permeability and Retention (EPR) effect is caused by the leaky vasculature and impaired lymphatic drainage in these tissues, allowing nanoparticles (typically 10–200 nm in size) to accumulate preferentially. This effect is non-specific, but it provides a foundational mechanism for increasing drug concentration at target sites without requiring molecular recognition.[25]

Active Targeting through Ligand–Receptor Interactions

Active targeting enhances specificity by decorating the surface of nanocarriers with ligands, such as antibodies, peptides, aptamers, or small molecules, that bind selectively to receptors overexpressed on target cells. Examples include folate receptors on cancer cells, transferrin receptors on the blood-brain barrier, and integrins on angiogenic endothelium. Binding to these receptors facilitates receptor-mediated endocytosis, enabling intracellular drug delivery and reducing off-target effects.[26]

Stimuli-Responsive Delivery Systems

Stimuli-responsive or "smart" nanocarriers are designed to release their payload in response to specific internal or external cues:

- **pH-Responsive**: Tumour microenvironments and intracellular compartments (e.g., endosomes, lysosomes) have a lower pH than normal tissues or blood. Nanocarriers with acid-labile linkages (e.g., hydrazone bonds) degrade in acidic environments to release drugs selectively.
- **Temperature-Responsive**: Certain polymers exhibit phase transitions at physiological or hyperthermic temperatures, enabling drug release in response to localised heating.
- **Redox-Responsive**: Tumour and intracellular environments exhibit elevated levels of reducing agents, such as glutathione (GSH). Nanocarriers containing disulfide linkages break apart in high-GSH environments, triggering release.
- **Light-Responsive**: Incorporating photosensitive moieties allows on-demand release upon exposure to light of specific wavelengths (e.g., UV or NIR), offering spatial and temporal control.

These stimuli-responsive strategies significantly enhance on-site activation of drug release, minimising systemic toxicity.[27,28]

Controlled and Sustained Release

Controlled release refers to the regulated release of therapeutic agents over an extended period, maintaining drug concentrations within the therapeutic window. Polymeric nanoparticles and liposomes are often engineered to degrade or erode slowly, or to respond to environmental changes, ensuring prolonged exposure at the target site. Such systems reduce the frequency of dosing and improve patient compliance, particularly for chronic conditions.[29]

Endocytosis and Intracellular Trafficking

Once at the target site, nanocarriers must enter cells and release their cargo in the appropriate subcellular compartment. Common endocytic pathways include clathrin-mediated endocytosis, caveolae-mediated endocytosis, macropinocytosis, and phagocytosis. The uptake pathway influences intracellular trafficking and the final destination of the nanocarrier. For instance, clathrin-mediated endocytosis often results in lysosomal degradation unless the nanocarrier can escape the endosome before fusion.[30]

To enhance intracellular delivery, nanoparticles can be modified with endosomal escape mechanisms such as pH-buffering "proton sponge" effects or membrane-disrupting peptides. Once in the cytoplasm, carriers can further direct drugs to specific organelles, such as the nucleus or mitochondria, depending on the therapeutic objective.[31]

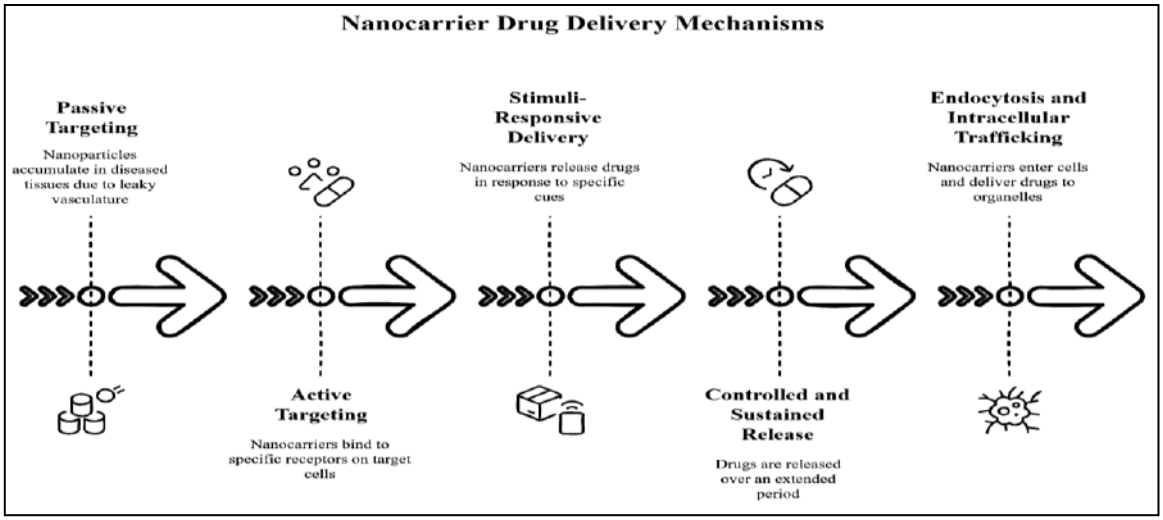

Figure 2. Mechanisms of Drug Targeting & Release

In conclusion, the multifaceted mechanisms of drug delivery employed by nanocarriers not only enhance targeting and efficacy but also enable dynamic interaction with complex biological environments. A deeper understanding of these processes informs the rational design of next-generation nanomedicines with improved clinical performance.

2. Routes of Administration and Applications

The clinical utility of nanocarriers hinges not only on their physicochemical design but also on the route of administration, which influences biodistribution, pharmacokinetics, therapeutic efficacy, and patient compliance. Nanocarriers are being adapted for a wide range of administration routes, each with unique biological challenges and technological solutions.[32]

1) Oral Delivery

Oral administration remains the most preferred route due to its convenience and patient compliance. However, it presents significant obstacles for nanocarrier-based drug delivery. These include harsh gastric pH, digestive enzymes, mucus barriers, and variable intestinal permeability.[33]

Nano strategies addressing these challenges include:

- **Mucoadhesive Nanoparticles**: Chitosan-coated nanoparticles can adhere to mucosal surfaces, prolonging residence time and improving drug absorption.
- **Enzyme Shielding**: Polymeric coatings and encapsulation within protective Nano matrices shield the active drug from enzymatic degradation.
- **Permeation Enhancers**: Some nanocarriers incorporate functional groups or surfactants to open tight junctions, thereby enhancing transient paracellular transport.

These strategies have shown promise in enhancing the oral bioavailability of peptides, proteins, and hydrophobic drugs.[34–36]

2) Parenteral Delivery (Intravenous, Subcutaneous, Intramuscular)

Parenteral administration allows direct entry into systemic circulation, bypassing first-pass metabolism. Among parenteral routes, intravenous (IV) injection is the most common for nanomedicines.[37]

Key considerations include:

- **Circulation Time**: Nanocarriers are often modified with hydrophilic polymers (e.g., PEGylation) to prevent opsonisation and prolong circulation.

- **RES Evasion**: Surface modifications reduce recognition by the reticuloendothelial system (RES), thereby enhancing bioavailability and tumour accumulation.
- **Clinical Success**: Several nanodrugs, such as Doxil (liposomal doxorubicin) and Abraxane (albumin-bound paclitaxel), are administered intravenously and have demonstrated superior pharmacokinetics and reduced toxicity.

Subcutaneous (SC) and intramuscular (IM) routes are explored for vaccines and depot formulations, benefiting from slow, sustained drug release enabled by nanocarriers.[38,39]

3) Transdermal Delivery

The skin acts as a formidable barrier, but nanocarriers offer innovative solutions for non-invasive transdermal drug delivery:

- **Microneedles**: Arrays of nanoscale needles painlessly penetrate the stratum corneum, facilitating the delivery of nanoparticles or nanoparticle-loaded patches.
- **Nanoemulsions and Lipid Carriers**: These enhance the dermal penetration of lipophilic drugs, providing hydration and making them suitable for treating chronic skin conditions and cosmetic applications.

Transdermal nanocarrier systems are under active investigation for hormone therapy, pain management, and vaccine delivery.[40,41]

4) Pulmonary and Nasal Delivery

Pulmonary and intranasal routes provide rapid systemic absorption and direct access to local tissues or the central nervous system (CNS), bypassing the blood-brain barrier.

- **Pulmonary Delivery**: Nanoparticles delivered via aerosols or dry powders can effectively target lung tissues, offering treatment options for asthma, COPD, and lung cancer.
- **Nasal Delivery**: Exploits the olfactory and trigeminal nerve pathways to deliver drugs directly to the brain. Nanocarriers, such as mucoadhesive nanoparticles and lipid-based systems, enhance mucosal retention and uptake.

These strategies are gaining traction for neurodegenerative diseases, psychiatric disorders, and nasal vaccines.[42,43]

5) Ocular and Targeted Brain Delivery

Ocular drug delivery faces challenges such as blinking, tear drainage, and corneal barriers. Nanocarriers, such as liposomes, micelles, and dendrimers, can penetrate ocular tissues and provide sustained release profiles.[44]

In the context of brain delivery, the blood-brain barrier remains a significant hurdle. Targeted nanocarriers functionalised with ligands (e.g., transferrin or lactoferrin) facilitate receptor-mediated transcytosis, enhancing brain uptake. Lipid nanoparticles and PEGylated systems have shown promise in treating central nervous system (CNS) tumours, infections, and neurodegenerative conditions.[45]

Table 2. Summary of Nanocarriers and Their Applicable Routes of Administration

Nanocarrier Type	Routes of Administration	Key Applications
Liposomes	IV, SC, ocular, nasal	Cancer, infections, ocular diseases
Polymeric nanoparticles	Oral, IV, transdermal, nasal	CNS, cardiovascular, and gastrointestinal diseases
Solid lipid nanoparticles	Oral, IV, transdermal, ocular	Skin disorders, neuroprotection
Dendrimers	IV, ocular, nasal	Gene therapy, ophthalmology, and brain disorders
Micelles	IV, oral, ocular	Hydrophobic drug solubilisation, cancer therapy
Exosomes/biomimetics	IV, nasal	Personalised therapy, regenerative medicine

In summary, the choice of route of administration for nanocarriers depends on the properties of the drug, the target site, and the clinical goals. Advances in nanotechnology continue to expand the boundaries of what is achievable across all delivery routes, bringing forth a new era of precision therapeutics.

3. Clinical Applications of Nanotechnology in Drug Delivery

Nanotechnology has transitioned from a promising concept to a powerful clinical tool in modern medicine. Its application in drug delivery is now realised across a spectrum of diseases, offering improvements in specificity, efficacy, and patient safety. Several FDA-approved nanomedicines validate their translational success, including Doxil (liposomal doxorubicin), Abraxane (albumin-bound paclitaxel), and Onpattro (patisiran lipid complex).[46]

1) Cancer

Cancer therapy remains the most advanced field in nanomedicine. Nanocarriers address significant challenges in oncology, such as non-specific toxicity, chemoresistance, and the need for combination therapies.

- Passive targeting via the EPR effect enables nanoparticle accumulation in tumour tissues, while active targeting enhances cell-specific uptake through ligands binding to receptors such as HER2, EGFR, or folate.
- Nanocarriers can bypass drug efflux pumps, addressing multidrug resistance.
- Co-delivery systems enable the simultaneous transport of chemotherapeutics with synergistic agents, such as siRNA or immunomodulators.

Doxil reduces cardiotoxicity associated with doxorubicin therapy, while Abraxane enhances the solubility of paclitaxel without relying on toxic solvents. These clinical successes exemplify the promise of nanomedicine in the treatment of cancer.[47,48]

2) Neurological Diseases

Neurological disorders are challenging to treat due to the blood-brain barrier (BBB), which limits CNS drug delivery. Nanocarriers, such as liposomes, polymeric nanoparticles, and lipid-based systems, are engineered to cross the blood-brain barrier (BBB) using receptor-mediated transcytosis (e.g., via transferrin or lactoferrin ligands).

- In **Alzheimer's disease**, nanoparticles have been used to deliver acetylcholinesterase inhibitors and beta-amyloid-targeting agents.
- In **Parkinson's disease**, dopamine or gene therapy agents delivered via nanocarriers bypass systemic metabolism and reach brain regions more effectively.
- For **stroke**, nanocarriers can encapsulate neuroprotective agents or thrombolytics, delivering them to ischemic regions while minimising systemic effects.[49–51]

3) Infectious Diseases

The global burden of infectious diseases demands novel delivery methods to improve drug efficacy and minimise resistance.

- Nanocarriers protect **antimicrobials** from degradation, enhance absorption, and enable targeted delivery to infected tissues.
- In **tuberculosis (TB)**, long-acting injectable nanocarriers reduce dosing frequency, improving patient adherence.
- For **HIV**, nanotechnology has been applied in antiretroviral therapy to improve intracellular uptake and reach latent reservoirs.

Liposomal amphotericin B is a classic example, reducing nephrotoxicity in fungal infections compared to conventional formulations.[52,53]

4) Inflammatory and Autoimmune Diseases

Nanocarriers improve the pharmacokinetics of immunomodulatory drugs while reducing systemic toxicity.

- In **rheumatoid arthritis**, nanoparticles deliver methotrexate or TNF-alpha inhibitors selectively to inflamed joints, enhancing efficacy.

- In **inflammatory bowel disease (IBD)**, pH-sensitive or microbiota-responsive nanocarriers ensure the release of drugs in the colon, thereby bypassing degradation in the upper gastrointestinal tract.
- Surface-modified nanoparticles reduce off-target immune activation, a significant concern with chronic immunosuppressive therapy.

These systems show promise in modulating immune responses without compromising systemic immunity.[54,55]

5) Gene Therapy and RNA Delivery

Recent breakthroughs in gene editing and RNA therapeutics rely heavily on nanocarrier technology.

- **siRNA and miRNA delivery** via lipid nanoparticles allows gene silencing in cancer, viral infections, and genetic disorders.
- **mRNA vaccines** against COVID-19, using lipid nanoparticles (e.g., Pfizer-BioNTech and Moderna), have demonstrated the scalability and efficacy of this platform.
- **CRISPR-Cas9** gene-editing systems require nanocarriers for safe and targeted in vivo delivery, thereby avoiding risks associated with viral vectors.

Onpattro, the first FDA-approved RNAi therapeutic, uses a lipid nanoparticle to deliver siRNA for hereditary transthyretin-mediated amyloidosis, representing a landmark in RNA nanomedicine.[56,57]

In summary, nanotechnology-based drug delivery is reshaping clinical paradigms across multiple disciplines, offering tailored therapies that were previously unattainable through conventional means.

4. Safety, Toxicity & Regulatory Issues

As nanotechnology-based drug delivery systems progress from bench to bedside, addressing their safety, toxicity, and regulatory compliance becomes paramount. Despite their therapeutic promise, concerns regarding long-term effects, immune responses, and translation scalability persist and must be rigorously evaluated.[58]

Biocompatibility and Biodegradability

Nanocarriers must be biocompatible to prevent adverse biological reactions. Materials such as phospholipids, PLGA, PEG, and chitosan are generally recognised as safe and have a long history of medical use. Biodegradable carriers are especially favoured as they break down into non-toxic by-products that are easily eliminated from the body. Non-degradable inorganic carriers, such as some metal oxides or quantum dots, require extensive evaluation due to their potential for bioaccumulation and chronic toxicity.[59]

Long-Term Toxicity

Chronic exposure to nanoparticles can lead to tissue accumulation, organ dysfunction, or cytotoxicity. Factors influencing toxicity include size, shape, surface charge, and degradation kinetics. For instance, positively charged nanoparticles may disrupt cell membranes and induce oxidative stress. Longitudinal animal studies and advanced in vitro models are needed to simulate long-term human exposure and provide predictive toxicological data.[60]

Immune Responses

Nanocarriers can elicit immunogenicity or hypersensitivity, potentially leading to adverse effects such as complement activation-related pseudoallergy (CARPA). PEGylation, although widely used to reduce immunogenicity, has been associated with the formation of anti-PEG antibodies in some individuals. Strategies like biomimetic coating or the use of autologous exosomes may mitigate these responses. Immune profiling of patients and preclinical immunotoxicology assessments are crucial to minimise risks.[61]

Regulatory Pathways

The regulatory landscape for nanomedicines is evolving. Agencies such as the FDA (U.S.), EMA (Europe), and ICH (International Council for Harmonisation) have issued guidelines emphasising quality, safety, and efficacy.[62]

- **FDA** evaluates nanomedicines under existing drug and biologic frameworks, with additional scrutiny for nanospecific issues.

- **EMA** requires a stepwise approach for nanocarrier characterisation, including physicochemical properties, biodistribution, and safety profiles.
- **ICH** guidelines, such as Q8–Q10, provide frameworks for pharmaceutical development, risk management, and quality systems that apply to nanomedicines.

Despite these frameworks, a lack of harmonised global standards and validated models for nanotoxicity assessment remains a barrier.[63,64]

Challenges in Translation and Scalability

Manufacturing nanomedicines at a clinical or commercial scale while maintaining consistency, stability, and efficacy poses significant hurdles. Batch-to-batch reproducibility, sterilisation, and storage stability are critical factors. Regulatory approval demands comprehensive documentation of manufacturing protocols under Good Manufacturing Practices (GMP).[65]

Moreover, the high costs associated with nanomedicine development and unclear reimbursement policies may hinder commercialisation. Collaborative efforts between academia, industry, and regulatory bodies are essential to bridge these gaps and accelerate clinical translation.[66]

In conclusion, while nanocarriers hold substantial clinical potential, ensuring their safety and meeting regulatory requirements is crucial for their successful integration into healthcare. Continued investment in safety science, standardisation, and regulatory innovation will pave the way for broader acceptance and deployment of nanotechnology in medicine.

5. Current Challenges and Future Prospects

Despite the remarkable progress in nanotechnology-based drug delivery, several critical challenges continue to impede its full-scale translation and integration into mainstream healthcare. These obstacles span technical, regulatory, and systemic domains, but ongoing innovations and interdisciplinary approaches hold promise for overcoming them.[67]

Scale-Up and Reproducibility Issues

One of the most significant barriers to clinical adoption is the difficulty in scaling up laboratory-developed nanocarriers to industrial production levels while maintaining batch-to-batch reproducibility. The complex synthesis and functionalisation processes required for many nanocarriers introduce variability in size, surface charge, drug loading, and stability. Minor inconsistencies can drastically impact therapeutic performance and safety.[68]

To address this, there is a growing emphasis on developing standardised, automated, and modular manufacturing platforms. Microfluidic technologies and continuous-flow synthesis offer promising avenues for precision and reproducibility. Moreover, advanced analytical tools like dynamic light scattering (DLS), nanoparticle tracking analysis (NTA), and high-resolution electron microscopy are essential for rigorous quality control during scale-up.[69]

Regulatory Bottlenecks

The regulatory environment for nanomedicines is still maturing. Existing frameworks, initially designed for conventional small-molecule drugs or biologics, often fall short in addressing the unique properties of nanocarriers. Regulatory ambiguity creates delays in approval and increases the cost of bringing nanodrugs to market.[70]

Harmonisation of international standards, development of validated toxicity assays, and early engagement with regulatory bodies are critical to navigating these challenges. Regulatory science must evolve in parallel with nanotechnology to ensure both innovation and patient safety.[71]

Personalised and AI-Driven Nanomedicine

Precision medicine calls for therapies tailored to individual genetic, phenotypic, and environmental profiles. Nanotechnology, with its capacity for functional customisation, is ideally suited to fulfil this vision. Personalised nanocarriers can be engineered based on patient-specific biomarkers, enhancing targeting and reducing adverse effects.[72]

Artificial Intelligence (AI) and machine learning (ML) are being increasingly integrated into

nanomedicine for the predictive modelling of drug release, biodistribution, and therapeutic outcomes. AI can also optimise formulation parameters, identify lead candidates, and accelerate preclinical development by analysing complex datasets.[73,74]

Green Nanotechnology and Sustainable Development

As the environmental impact of nanomaterial production becomes more apparent, green nanotechnology has emerged as a vital area of focus. It involves the design and synthesis of nanocarriers using eco-friendly materials and energy-efficient processes. Biogenic synthesis using plant extracts or microorganisms, solvent-free processing, and biodegradable polymers contribute to reduced ecological footprints.[75]

Sustainable development in nanomedicine encompasses not only waste management and lifecycle analysis but also equitable access. Ensuring that advanced therapeutics do not exacerbate health disparities or environmental degradation is essential for long-term viability.[76]

Integration with Bioinformatics and Predictive Modelling

The convergence of nanotechnology with bioinformatics offers powerful tools for drug development and therapeutic optimisation. Predictive modelling platforms can simulate nanoparticle interactions with biological systems, forecast pharmacokinetic behaviour, and identify optimal design parameters. Omics technologies (genomics, proteomics, metabolomics) feed data into these models, enabling rational design of nanocarriers for complex diseases. This integrative approach minimises trial-and-error experimentation, reduces development costs, and enhances translational success rates.[77]

The future of nanotechnology in drug delivery lies at the intersection of multidisciplinary innovation, regulatory reform, and sustainability. Addressing current challenges in manufacturing, regulation, and personalisation through emerging technologies and systems biology will unlock the full potential of nanomedicine. As the field advances, its impact on patient-specific, environmentally responsible, and clinically transformative therapies will continue to grow.[78]

CONCLUSION

Nanotechnology has revolutionised the landscape of drug delivery by addressing the critical shortcomings of conventional therapeutic modalities. Through the design of advanced nanocarriers, ranging from liposomes and polymeric nanoparticles to exosomes and dendrimers, researchers have developed systems capable of targeted delivery, controlled release, and traversal of biological barriers. These technologies have demonstrated profound clinical potential, particularly in the management of cancer, neurological disorders, infectious diseases, and genetic conditions.

A key strength of nanotechnology lies in its capacity for customisation. Functionalisation strategies enable selective targeting of pathological sites, while stimuli-responsive mechanisms provide controlled and site-specific drug release. The translation of these concepts into real-world therapeutics is evidenced by several FDA-approved nanodrugs, such as Doxil, Abraxane, and Onpattro, which have improved treatment outcomes and minimised toxicity.

However, the full potential of nanomedicine will only be realised through robust interdisciplinary collaboration. Advances in materials science, bioengineering, pharmacology, and computational modelling must be harmonised to overcome challenges in scale-up, regulatory approval, and long-term safety evaluation. Furthermore, the integration of artificial intelligence, bioinformatics, and green chemistry will be pivotal in driving the next generation of sustainable and personalised nanomedicines.

Looking ahead, nanotechnology is poised to redefine how drugs are developed, delivered, and optimised. Its convergence with emerging technologies and its adaptability to patient-specific profiles position it as a cornerstone of future precision healthcare. As research matures and regulatory pathways evolve, nanomedicine holds the promise of more effective, safer, and accessible therapies that will significantly impact global health outcomes.

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