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Review Article

Comprehensive Review of Novel Drug Delivery Systems: Current Status and Future Directions (2025)

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Abstract

The pharmaceutical industry is experiencing a paradigm shift with the emergence of novel drug delivery systems that address fundamental limitations of conventional therapies. This comprehensive review examines recent advances in drug delivery technologies from 2020 to 2025, focusing on nanoparticle-based systems, smart stimuli-responsive platforms, personalized medicine approaches, and advanced biomaterials. Key innovations include lipid-based nanocarriers, polymeric nanoparticles, intelligent drug delivery systems responding to endogenous and exogenous stimuli, and AI-driven formulation optimization. These technologies demonstrate significant improvements in drug bioavailability, targeted delivery, controlled release kinetics, and reduced systemic toxicity. Current challenges include scalability, regulatory approval pathways, biocompatibility concerns, and translation from bench to bedside. This review provides critical insights into the current state of drug delivery science, highlighting transformative technologies poised to revolutionize therapeutic outcomes while addressing patient compliance and personalized treatment needs.

Keywords: Novel drug delivery systems, nanoparticles, smart delivery, stimuli-responsive, personalised medicine, bioavailability, targeted therapy

1. Introduction

Drug delivery systems have evolved dramatically from simple oral tablets and injections to sophisticated nanotechnology-based platforms capable of targeted, controlled, and responsive drug release. The escalating demand for enhanced therapeutic efficacy while minimizing adverse effects has catalysed innovation in pharmaceutical sciences, leading to the development of novel drug delivery systems (NDDS) that address fundamental limitations of conventional drug administration, including abbreviated half-life, inadequate targeting, low solubility, and poor bioavailability. [1,2]

The convergence of pharmacy, materials science, and biomedicine has enabled the design of efficient and safe drug delivery systems with unprecedented precision.[3]. Modern drug delivery platforms leverage nanoscale materials, smart polymers, and biological vectors to achieve site-specific delivery, protect drugs from premature degradation, cross biological barriers, and release therapeutics in a controlled manner.[4] These innovations are particularly crucial for treating life-threatening diseases such as cancer, where accurate tissue targeting minimizes systemic exposure and maximizes therapeutic efficacy.[5]

Recent advances have introduced stimuli-responsive systems that release drugs in response to specific triggers, including pH variations, temperature changes, enzymatic activity, or external stimuli such as magnetic fields, ultrasound, and light.[6,7] Furthermore, the integration of artificial intelligence and machine learning has revolutionized drug

formulation optimization, enabling predictive modelling for enhanced bioavailability, stability, and targeting accuracy.[8] This review comprehensively examines the current status of novel drug delivery systems, categorizing them into carrier-based platforms, smart responsive systems, and advanced device-driven technologies while discussing future directions and translational challenges.

2. NANOPARTICLE-BASED DRUG DELIVERY SYSTEMS

2.1 Lipid-Based Nanocarriers

Lipid-based nanocarriers, including liposomes, solid lipid nanoparticles, and lipid nanoparticles, represent the most clinically advanced drug delivery platforms. Liposomes, composed of lipid bilayers, can encapsulate both hydrophilic and hydrophobic drugs, mimicking cell membrane structure to facilitate cellular uptake.[9] The FDA approval of several liposomal formulations, including Doxil for cancer therapy, validates their clinical potential. [10] Recent innovations focus on surface modifications with polyethylene glycol (PEGylation) to prolong circulation time and active targeting ligands to enhance tumor specificity. [11]

Solid lipid nanoparticles offer advantages in stability and controlled release compared to conventional liposomes. These systems protect encapsulated drugs from degradation while providing sustained release profiles beneficial for chronic disease management.[12] Lipid nanoparticles gained prominence with mRNA vaccine delivery during the COVID-19 pandemic, demonstrating their versatility in delivering nucleic acid therapeutics beyond traditional small molecules.[13]

2.2 Polymeric Nanoparticles

Polymeric nanoparticles fabricated from biocompatible and biodegradable polymers such as poly(lactic-co-glycolic acid) (PLGA), chitosan, and polyethylene glycol provide versatile platforms for drug encapsulation and controlled release.[14] PLGA nanoparticles are particularly attractive due to FDA approval for several biomedical applications, excellent biocompatibility, and tunable degradation kinetics.[15] Surface functionalization with targeting moieties enables active targeting to specific cells or tissues, significantly improving therapeutic indices.[16]

Polymeric micelles formed by amphiphilic block copolymers self-assemble in aqueous environments, creating core-shell structures ideal for hydrophobic drug delivery. These systems demonstrate enhanced stability, prolonged circulation times, and passive tumor targeting through the enhanced permeability and retention effect.[17] Recent developments focus on stimuli-responsive polymeric systems that release drugs in response to tumor microenvironment characteristics, including acidic pH and elevated reactive oxygen species.[18]

2.3 Inorganic Nanoparticles

Inorganic nanoparticles, including gold nanoparticles, mesoporous silica nanoparticles, and quantum dots, offer unique optical, magnetic, and electronic properties beneficial for theranostic applications.[19] Gold nanoparticles exhibit surface plasmon resonance enabling photothermal therapy combined with drug delivery.[20] Mesoporous silica nanoparticles provide large surface areas and tunable pore sizes for high drug loading capacity with controlled release characteristics.[21] These systems can be functionalized with targeting ligands and stimuli-responsive gatekeepers for on-demand drug release.[22]

3. SMART STIMULI-RESPONSIVE DRUG DELIVERY SYSTEMS

3.1 pH-Responsive Systems

pH-responsive drug delivery systems exploit pH gradients between different tissues and cellular compartments to trigger drug release at target sites.[23] The acidic tumour microenvironment (pH 6.5-6.8) compared to normal physiological pH [7.4] provides an attractive trigger for cancer therapy. pH-sensitive polymers containing ionizable groups undergo conformational changes or degradation in acidic conditions, releasing encapsulated drugs specifically at tumour sites while minimising systemic toxicity.[24]
Recent developments include pH-responsive micelles, hydrogels, and polymer-drug conjugates that demonstrate enhanced therapeutic efficacy in preclinical models. [25] These systems protect drugs during systemic circulation and rapidly release payloads upon exposure to acidic environments, improving therapeutic indices while reducing off-target effects.[26]

3.2 Temperature-Responsive Systems

Thermoresponsive polymers undergo phase transitions at specific temperatures, enabling controlled drug release triggered by body temperature or externally applied heat. Poly(N-isopropylacrylamide) represents the most studied thermoresponsive polymer with a lower critical solution temperature near body temperature.[27] These systems can be designed to release drugs upon local hyperthermia, combining photothermal or magnetic hyperthermia with chemotherapy for synergistic cancer treatment.[28]

3.3 Redox-Responsive and Enzyme-Responsive Systems

Redox-responsive systems exploit elevated glutathione concentrations in tumour cells and diseased tissues to trigger drug release through disulfide bond cleavage.[29] Enzyme-responsive systems utilize disease-specific enzymes, such as matrix metalloproteinases overexpressed in cancer, to cleave peptide linkers and release drugs. [30] These endogenous triggers provide high specificity and minimal off-target effects, representing promising strategies for precision medicine.[31]

Table 1: Classification of Nanoparticle-Based Drug Delivery Systems

Nanoparticle Type	Key Characteristics	Clinical Applications
Liposomes	Lipid bilayer vesicles; biocompatible; encapsulate hydrophilic and hydrophobic drugs	Cancer therapy (Doxil); fungal infections; pain management
Polymeric Nanoparticles	PLGA, chitosan-based; biodegradable; controlled release; surface modifiable	Sustained drug release; vaccine delivery; cancer therapeutics
Solid Lipid Nanoparticles	Solid lipid matrix; enhanced stability; high drug loading; scalable production	Oral and topical formulations; chronic disease management
Mesoporous Silica	Large surface area; tunable pore size; high loading capacity; functional surfaces	Controlled drug release; theranostic applications; gene delivery
Gold Nanoparticles	Surface plasmon resonance; biocompatible; easy functionalization; photothermal properties	Photothermal therapy; diagnostics; targeted drug delivery; imaging

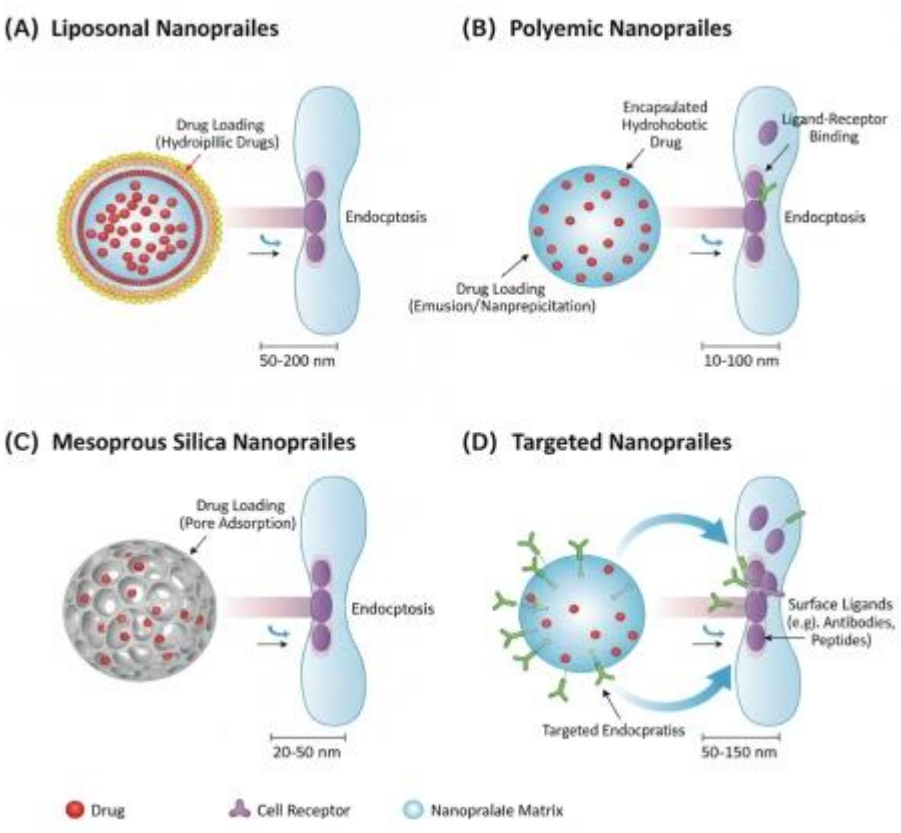
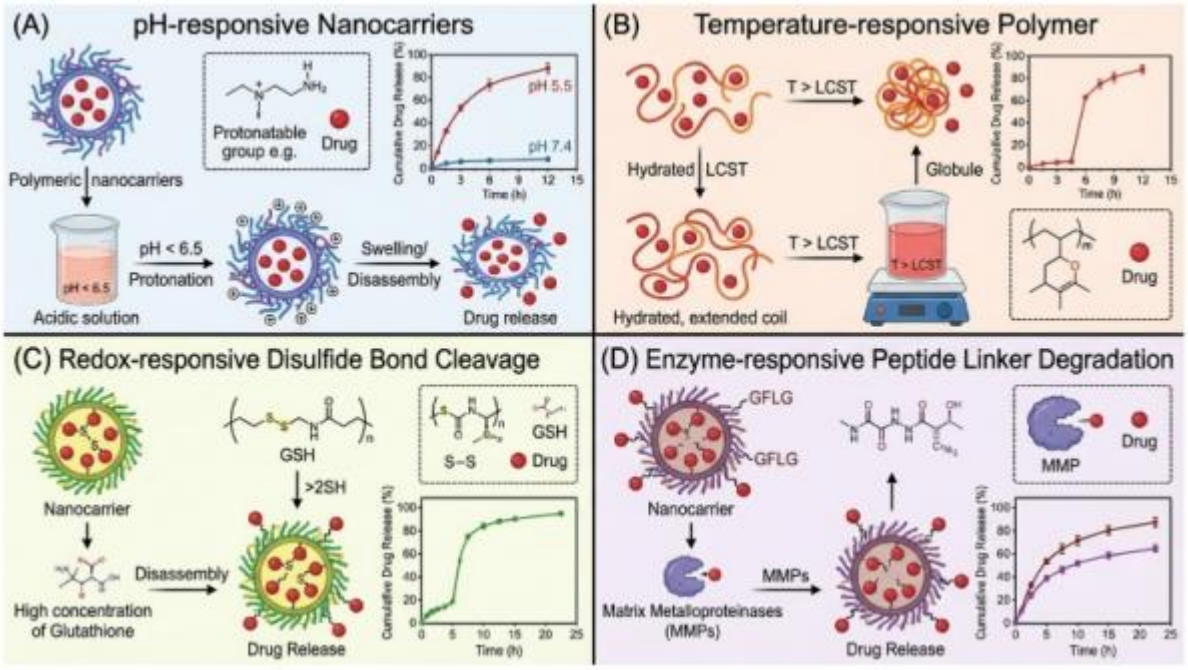


Figure 1: Schematic illustration of different nanoparticle-based drug delivery systems
Source: Adapted from References [9,14,19]

Table 2: Stimuli-Responsive Drug Delivery Platforms and Their Mechanisms

Stimulus Type	Trigger Mechanism	Release Strategy	Examples
pH-Responsive	Protonation/deprotonation; polymer swelling; bond cleavage	Tumor acidic microenvironment (pH 6.5-6.8); endosomal escape	pH-sensitive micelles; hydrazone linkers; acid-cleavable polymers
Temperature-Responsive	Phase transition at LCST; polymer collapse/expansion	Local hyperthermia (40-42°C); body temperature trigger	PNIPAM-based systems; thermosensitive liposomes
Redox-Responsive	Disulfide bond reduction by glutathione	High GSH concentration in tumor cells (2-10 mM)	Disulfide-crosslinked nanoparticles; prodrugs with SS linkers
Enzyme-Responsive	Peptide bond cleavage by specific enzymes	Overexpressed MMPs, esterases in diseased tissue	MMP-cleavable peptide linkers; ester-based prodrugs
Light-Responsive	Photoisomerization; photocleavage; photothermal heating	UV, visible, or NIR light irradiation at specific sites	Photocaged compounds; azobenzene switches; gold nanoparticles
Magnetic-Responsive	Magnetic targeting; magnetically-induced heating	External magnetic field application for targeting and heating	Iron oxide nanoparticles; magnetic hyperthermia systems



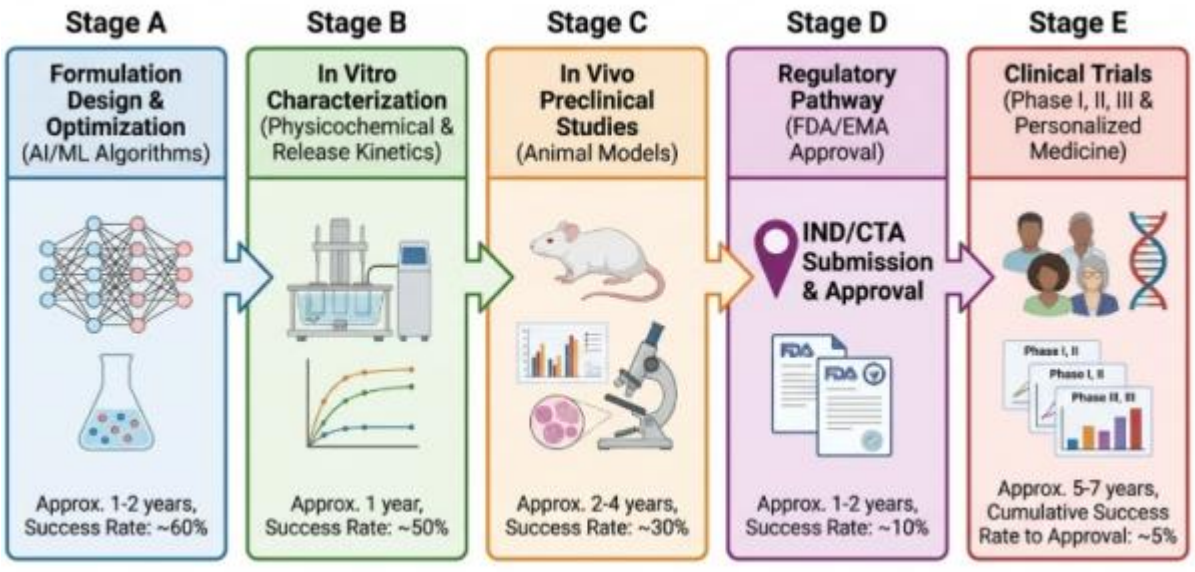
[FIGURE 2 PLACEHOLDER]

Figure 2: Mechanisms of stimuli-responsive drug delivery systems. The illustration should depict (A) pH-responsive nanocarriers showing protonation-triggered drug release in acidic tumour microenvironment, (B) temperature-responsive polymer phase transition above critical temperature, (C) redox-responsive disulfide bond cleavage by glutathione, and (D) enzyme-responsive peptide linker degradation by matrix metalloproteinases. Include molecular structures, environmental triggers, and drug release kinetics for each mechanism.

Source: Adapted from [23,27,29]

Table 3: Clinical Translation and Regulatory Considerations for Novel Drug Delivery Systems

Challenge Category	Key Issues	Potential Solutions/Strategies
Manufacturing and Scalability	Batch-to-batch variability; complex production processes; high costs; scale-up challenges	Continuous manufacturing; microfluidics; automated systems; process analytical technology
Regulatory Approval	Lack of standardised guidelines; complex characterisation requirements; long approval timelines	FDA/EMA guidance documents; industry-regulatory collaboration; accelerated pathways for breakthrough therapies
Safety and Toxicity	Long-term bioaccumulation; immunogenicity; off-target effects; organ toxicity	Biodegradable materials; comprehensive toxicity studies; biocompatibility testing; long-term monitoring
Clinical Translation	In vitro-in vivo correlation gaps; species differences; limited biomarkers; patient heterogeneity	Advanced animal models; human organoids; biomarker development; personalized medicine approaches
Cost and Accessibility	High development costs; expensive materials; limited insurance coverage; healthcare disparities	Generic formulations; biosimilars; government subsidies; value-based pricing models
Intellectual Property	Patent complexities; freedom to operate; licensing challenges; technology transfer issues	Clear IP strategies; academic-industry partnerships; patent pools; open innovation models



[FIGURE 3 PLACEHOLDER]

Figure 3: Timeline of drug delivery system development from concept to clinic. The flowchart should illustrate stages including (A) formulation design and optimization using AI/ML algorithms, (B) in vitro characterization of physicochemical properties and drug release kinetics, (C) in vivo preclinical studies in animal models, (D) regulatory pathway considerations for FDA/EMA approval, and (E) clinical trial phases with emphasis on personalized medicine

integration. Include approximate timeframes and success rates for each stage with key regulatory milestones.
Source: Adapted from [32,42,43]

4. ADVANCED DELIVERY TECHNOLOGIES AND PERSONALIZED MEDICINE

4.1 Artificial Intelligence in Drug Delivery

Artificial intelligence and machine learning are revolutionizing drug delivery system design through predictive modelling, formulation optimization, and personalized medicine approaches.[32] AI algorithms analyse extensive datasets to predict drug-excipient compatibility, optimise nanoparticle characteristics, and forecast patient responses.[33] Machine learning models trained on molecular descriptors predict skin permeability for transdermal delivery and brain penetration for central nervous system therapeutics.[34]

Recent applications include AI-driven design of lipid nanoparticles for mRNA delivery, optimisation of 3D-printed drug formulations, and real-time monitoring of drug release kinetics. [35] These technologies accelerate development timelines, reduce costs, and enable precision medicine by tailoring formulations to individual patient characteristics.[36]

4.2 Transdermal and Oral Delivery Innovations

Transdermal drug delivery systems offer non-invasive administration, bypassing first-pass metabolism and improving bioavailability.[37] Recent innovations include microneedle arrays, iontophoresis, and nanoparticle-enhanced penetration for delivering both small molecules and biologics.[38] Smart wearable patches incorporating biosensors enable real-time monitoring and on-demand drug release based on physiological parameters.[39]

Oral drug delivery remains the preferred route for patient compliance, with recent advances focusing on overcoming gastrointestinal barriers.[40] Strategies include mucoadhesive systems, gastric retention devices, and nanoparticle formulations that enhance permeability across the intestinal epithelium. Three-dimensional printing technology enables personalised oral dosage forms with controlled release profiles tailored to individual patient needs.[41]

5. CHALLENGES AND FUTURE DIRECTIONS

Despite remarkable advances, several challenges impede clinical translation of novel drug delivery systems. Scalability remains a critical bottleneck, as many promising nanotechnology-based platforms demonstrate excellent preclinical results but face manufacturing challenges at commercial scales.[44] Standardisation of characterisation methods and quality control parameters is essential for reproducible production and regulatory approval.[45]
Biocompatibility and long-term safety concerns require comprehensive toxicity assessments beyond acute studies. Accumulation of nanoparticles in organs, potential immunogenicity, and environmental impacts necessitate thorough evaluation.[46] Regulatory frameworks continue evolving to address unique aspects of nanomedicine, with agencies developing specific guidelines for nanoparticle-based therapeutics, implantable devices, and AI-driven formulations.[47]

Future directions include the development of multi-functional theranostic platforms combining diagnosis and therapy, integration of real-time monitoring capabilities, and personalized formulations based on patient-specific pharmacogenomics.[48] Advances in biomaterials science, synthetic biology, and digital health integration promise to address current limitations while expanding therapeutic possibilities.[49] Collaboration between academia, industry, and regulatory agencies will be crucial for translating innovative delivery technologies into clinical practice, ultimately improving patient outcomes and healthcare delivery.[50]

6. CONCLUSION

Novel drug delivery systems represent a transformative paradigm in pharmaceutical sciences, offering unprecedented opportunities to enhance therapeutic efficacy while minimizing adverse effects. The convergence of nanotechnology, smart materials, artificial intelligence, and personalized medicine has yielded sophisticated platforms capable of targeted, controlled, and responsive drug delivery. Lipid-based nanocarriers, polymeric systems, and inorganic nanoparticles demonstrate significant clinical potential, with several formulations already FDA-approved and many others in various stages of clinical development.
Stimuli-responsive systems responding to endogenous triggers such as pH, redox potential, and enzymes, or exogenous stimuli including temperature, magnetic fields, and light, enable precise spatiotemporal control of drug release. Integration of artificial intelligence accelerates development timelines and enables predictive optimization of formulations, paving the way for truly personalized medicine. However, challenges in scalability, standardization, biocompatibility assessment, and regulatory approval require concerted efforts from researchers, clinicians, industry partners, and regulatory agencies.
Looking forward, the field is poised for continued innovation with emerging technologies including cell-based delivery systems, exosome-mediated therapeutics, and multi-functional theranostic platforms. Success in translating these technologies from bench to bedside will require interdisciplinary collaboration, robust preclinical validation, and adaptive regulatory frameworks. As these systems mature and overcome current challenges, novel drug delivery technologies promise to revolutionize treatment paradigms

across numerous therapeutic areas, ultimately improving patient outcomes and advancing precision medicine.

Author Contributions

The author has significantly contributed to the study's conception, design, data collection, analysis, and interpretation. All authors were involved in writing the manuscript or critically reviewing it for its intellectual value. They have reviewed and approved the final version for submission and publication and accept full responsibility for the content and integrity of the work.

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Conflicts of Interest

The authors state that there are no financial, personal, or professional conflicts of interest associated with this research.

Ethical Approvals

This research did not involve the use of human participants or animal subjects and therefore did not require ethical clearance

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